Committees Host Brown Bag on Recent Developments in Pharmaceutical Marketing Enforcement & Litigation"

By Danielle M. Garten, Esq.[1]
Arnold & Porter LLP

On September 14, 2009, the Private Advertising Litigation, Health Care and Pharmaceuticals, and Consumer Protection Regulation Committees co-sponsored a program on current trends in enforcement activities related to the marketing of pharmaceutical products. This piece provides a brief summary of the topics discussed during the program.

Amy Mudge, Counsel in Arnold & Porter LLP's Antitrust and Consumer Protection practice group and Chair of the Private Advertising Litigation Committee, as well as Randy Shaheen, Counsel in Arnold & Porter LLP's Antitrust and Consumer Protection practice group, moderated the panel of speakers. Mr. Shaheen explained that the goal of the program was to provide updates in those areas that are of particular interest to pharmaceutical manufacturers, marketers, and attorneys, including an overview of the updates to the Pharmaceutical Research and Manufacturers of America's (PhRMA) self-regulatory direct-to-consumer Guiding Principles, as well as some recent litigation developments and trends. The program also included a detailed discussion of the FDA's requirements for pharmaceutical promotions and recent enforcement activities, particularly in the area of Internet marketing.

Jeffrey K. Francer

Assistant General Counsel, Pharmaceutical Research and Manufacturers of America

Jeffrey K. Francer, Assistant General Counsel of PhRMA, began the presentation by providing an overview of the revised PhRMA Guiding Principles on direct-to-consumer advertisements about prescription medicines ("Principles").[2] PhRMA is the leading trade association for the pharmaceutical research and biotechnology industry and has recently undertaken a review of the value of direct-to-consumer ("DTC") communications, in addition to the potential for improved consumer education through this medium. Mr. Francer began by emphasizing the impact of DTC advertising, noting that in a recent poll 91 percent of adults reported having seen or heard advertisements for prescription drugs, 32 percent of adults recalled speaking with their doctor about a drug they saw advertised, and 42 percent of doctors stated that specific patient inquiries had a positive impact on their interactions with those patients.

PhRMA's Principles, which were approved unanimously by the PhRMA Board of Directors and took effect March 2, 2009, were updated, in part, to respond to certain stakeholder concerns, while acknowledging the potential educational value of DTC advertising. Among the Principles' highlights, Mr. Francer pointed out that they are premised on the idea that DTC advertising can benefit the public health by increasing awareness of certain diseases, educating and motivating patients to inquire about specific treatment options, and encouraging patients to comply with prescription drug treatment plans. Mr. Francer stated that the revised Principles are designed to promote education and that they encourage companies to seek and consider appropriate feedback on educational impact when developing DTC advertising. The Principles contemplate that such feedback could come from both patients, as well as healthcare professionals.

In a similar vein, Mr. Francer emphasized that the Principles are designed, in part, to foster and encourage communication within the healthcare provider community. As such, the Principles recommend that companies spend some time educating professionals about new drugs or indications, as well as new advertising campaigns that may highlight new products.[3] The Principles further encourage companies to set specific timeframes within which education of healthcare professionals should occur prior to the launch of television or print DTC advertising.[4] The Principles contemplate that this effort to educate should continue as more information about a given product becomes available.[5]

The revised Principles require that all DTC advertising be accurate, substantiated, reflect the proper balance between risks and benefits, and remain consistent with FDA-approved labeling.[6] In addition, Mr. Francer noted that the Principles are drafted so as to ensure that companies base promotional claims only on approved labeling, rather than promoting medicines for off-label uses. The revised Principles direct companies to alter or discontinue any DTC advertising should new information become available indicating a serious safety risk.[7] Moreover, prior to broadcasting any television DTC advertising, the Principles instruct companies to submit the advertisements to the FDA earlier than the current law requires (reasonable time in advance of first use) in order to allow the Agency to provide comments and be made aware of the earliest air date of the advertisement.[8] Similarly, Mr. Francer noted that the Principles suggest that all DTC television advertisements direct consumers to print advertisements that contain FDA's toll-free MedWatch telephone number and website. The MedWatch program provides consumers with the ability to report and review potential adverse events associated with a given prescription drug.

Mr. Francer emphasized that the revised Principles stress the need for a balanced presentation to consumers. As such, the Principles require that the health conditions

1 Danielle Garten is an associate in the Antitrust/Competition and Consumer Protection and Advertising practice groups at Arnold & Porter LLP.

2 PHARM. RESEARCH & MFRS. OF AM., PHRMA GUIDING PRINCIPLES DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES (2008), *available at* http://www.phrma.org/files/PhRMA%20Guiding%20Principles_Dec%2008_FINAL.pdf.

3 *Id.* at 4 (Guiding Principle 6).

4 *Id.*

5 *Id.*

6 *Id.* at 4 (Guiding Principle 2).

7 *Id.* at 4 (Guiding Principle 7).

8 *Id.* at 5 (Guiding Principle 8).

for which a given medication is approved are clearly presented to consumers, along with any known risks.[9] In order to provide consumers with the proper balance of risks versus benefits, Mr. Francer noted that the Principles suggest that DTC advertisements include the substance of relevant boxed warnings and that safety information be presented with reasonably comparable prominence to benefit information in a clear and conspicuous way that does not distract from its content. Moreover, the Principles advise that any advertisements containing adult-only content should be placed in publications or on programs that are reasonably expected to draw an audience of 80 percent adults.[10]

In terms of the content of DTC advertisements, Mr. Francer highlighted the fact that the Principles contain a good deal of guidance on what information should be disclosed to consumers. For example, Mr. Francer noted that if an actor plays the role of a healthcare professional in a DTC advertisement, such information should be contained in the advertisement itself. Likewise, Mr. Francer explained that if an advertisement features an actual healthcare professional, the advertisement should be clear on whether that professional was compensated for his or her appearance. Similarly, if a celebrity is featured in a DTC advertisement, Mr. Francer stated that companies should maintain verification of the basis of the actual or implied endorsement of the product, including whether or not the celebrity is an actual user of the product. Finally, the Principles advise that DTC advertisements should include information about assistance available for the uninsured and underinsured, and should promote health and disease awareness generally, along with any specific information about the product being promoted.[11]

In closing, Mr. Francer noted that the PhRMA Office of Accountability will continue to accept and pass along comments to companies, as well as issue periodic reports summarizing comments received, along with any company responses. The companies that choose to sign on to the revised Principles will certify annually that they have policies and procedures in place to foster compliance. PhRMA will publicly identify signatory companies, and will provide information about companies' compliance with the Principles periodically.

Ellen Chung

Associate, Hogan & Hartson, LLP

Ellen Chung, an Associate in Hogan & Hartson LLP's Food, Drug, Medical Device and Agriculture practice group, spoke next about FDA enforcement trends in the area of advertising and promotion of prescription drugs.

Ms. Chung began by discussing the enforcement trends of the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"). In 2009, there has been a notable increase in the number of DDMAC warning letters and Notice of Violation ("NOV") letters, up from 19 in 2007 and 21 in 2008, to 31 by September of 2009.[12] DDMAC also has significantly increased its number of staff by hiring additional reviewers, adding a new DTC review group, a new project management team, additional lawyers, and a new Special Assistant to the DDMAC Director.

In terms of enforcement, Ms. Chung noted that Commissioner Hamburg has indicated some enforcement policy changes, including a new policy streamlining the review of warning letters.[13] Similarly, there has been an increase in Change of Opinion requests with a significant variation in the relevant language (from "listing all violative promotional materials . . . that are the same as or similar to those described above", to "listing all promotional materials in use . . . as of the date of this letter, identifying which of these materials contain violations such as those described above"). Ms. Chung observed that in 2009, common alleged violations by DDMAC included the omission or minimization or risk information, overstatement of efficacy and broadening of an indication, and unsubstantiated superiority or comparative claims. In the area of healthcare provider-directed promotion, DDMAC has focused on professional journal advertisements, oral statements made at conferences, and sales aids distributed directly to providers. Product testimonials and web-based promotions rounded out the list of trends in recent DDMAC enforcement activities.

Ms. Chung highlighted FDA's recent focus on Internet marketing in the area of pharmaceuticals. To date in 2009, fourteen separate NOV letters have been issued to major pharmaceutical companies related to sponsored links on the Internet. Sponsored links pop up at the top of Internet search engine results lists when consumers perform searches of related drug products, diseases, or conditions. FDA has cited violations stemming from these sponsored links that have included the omission of risk information, an inadequate communication of indication, and failure to use established names. In addition to sponsored links, Ms. Chung noted FDA's recent interest in online banner advertisements. In an NOV letter issued earlier this year, FDA called into question the apparent minimization of risks versus the claims made on Internet banner advertisements. Of particular concern to the Agency was the presence of attention-grabbing visual images, the font size of warning information, and the lack of any prominent signals directing consumers to relevant risk information.

In terms of Congressional review of DTC advertisements, Ms. Chung summarized a few key pieces of proposed legislation, including the "Informed Health Care Decision Making Act."[14] This Act requires the disclosure of comparative clinical effectiveness information in labeling and advertisements. Additionally, Ms. Chung mentioned the proposed "Say No to Drug Ads Act,"[15] which seeks to amend the current tax code to prevent pharmaceutical companies from deducting DTC advertising spending as a business expense.

Finally, Ms. Chung provided a brief summary of some key state and federal litigation in the area of pharmaceutical marketing. In the

---

9 *Id.* at 5 (Guiding Principle 11).

10 *Id.* at 11 (Q&A).

11 *Id.* at 5 (Guiding Principle 15).

12 For a full list of warning letters and NOV letters issued to date in 2009, *see* U.S. Food & Drug Admin., *Warning Letters 2009: 2009 Warning Letters and Untitled Letters to Pharmaceutical* Companies, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm055773.htm.

13 *See* Margaret Hamburg, M.D., Comm'r of Food and Drugs, Effective Enforcement and Benefits to Public Health, Remarks at Food and Drug Law Institute (Aug. 6, 2009), *available at* http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm.

14 S. 1142, 111th Cong. (2009).

15 H.R. 2966, 111th Cong. (2009).

area of state enforcement, Ms. Chung summarized the aggressiveness with which states have been pursuing off-label promotions using state consumer protection laws and unfair trade practices laws.[16] Additionally, it appears that State Attorneys General are utilizing DDMAC letters as the starting point for investigations into questionable DTC practices. By way of example, Ms. Chung pointed to the matter involving Bayer's promotion of the drug Yaz®. After an FDA warning letter was issued,[17] Bayer spent $20 million to clarify misinformation in its television advertisements for Yaz® and is required to obtain FDA approval for future advertisements of the drug. This case marked a notable collaboration between federal and state officials in preventing unlawful DTC marketing.

In terms of federal enforcement, Ms. Chung concluded her presentation by discussing the widely publicized case involving the Department of Justice's enforcement action against Pfizer for improper marketing of several of its drugs.[18] In the largest single healthcare fraud settlement in history, Pfizer settled allegations involving the promotion of the sale of the drug Bextra® for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company agreed to pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. In addition, Pfizer agreed to pay $1 billion to resolve allegations that the company illegally promoted four other drugs and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications.

Randall K. Miller

Partner, Arnold & Porter LLP

Finally, Randall Miller, a partner in the Litigation and Consumer Protection and Advertising practice groups at Arnold & Porter LLP presented a brief summary of recent competitor false advertising cases involving pharmaceutical companies. Mr. Miller discussed the various avenues for bringing competitor false advertising cases, including the Lanham Act, the NAD, the FDA and state law avenues. Please refer to Mr. Miller's piece, entitled "False Advertising Litigation Under Lanham Act for Pharmaceutical Companies," featured in the October 2009 edition of the Antitrust Health Care and Pharmaceuticals Chronicle for a more detailed review of these issues.[19]

Conclusion

The Brown Bag presentation offered unique insight into recent developments related specifically to pharmaceutical marketing. In the wake of several recent landmark results relating to the advertising of prescription drugs, the speakers provided interesting commentary on apparent increases in enforcement activity, along with the industry's self-regulatory response. While the industry strongly supports the notion that direct-to-consumer advertising of pharmaceuticals plays a crucial role in patient awareness and education, it is clear that both governmental agencies and private litigants are poised to respond should any such advertising run afoul of current standards.

---

16 Among the examples cited were cases against Merck in 2008, Eli Lily in 2008, Bayer in 2009 and Eli Lily in 2009.

17 Letter from Thomas Abrams, R.Ph., MBA, Director, Division of Drug Marketing, Advertising & Communications, FDA, to Reinhard Franzen, President & CEO, Bayer HealthCare Pharmaceuticals, Inc. (Oct. 3, 2008) *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm053993.pdf.

18 *See* Press Release, Dep't of Justice, Justice Department Announces Largest Health Care Fraud Settlement in its History, Pfizer to Pay $2.3 Billion for Fraudulent Marketing (Sept. 2, 2009) *available at* http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Sept2009/Pfizer.html.

19 Randall K. Miller, *False Advertising Litigation Under the Lanham Act for Pharmaceutical Companies*, HEALTH CARE ANTITRUST CHRONICLE 13 (Oct. 2009), *available at* http://www.abanet.org/abanet/common/login/securedarea.cfm?CFID=175533179&CFTOKEN=287e91be544aacb6-25A3AEF7-0D1C-E040-B09D6080B26F38B7&jsessionid=1a306ac65bfb532ba90e65606dc4a3f23112TR&URL=%2Fantitrust%2Fmo%2Fpremium%2Dat%2Fat%2Dhcic%2Fhc%2Dchronicle%2Dvol23%2Dissue1%2Epdf&REDIRECT_LOCATION=%2Fabanet%2Fcommon%2Flogin%2Fsecuredarea%2Ecfm%3FareaType%3Dpremium%26role%3Dat%26url%3D%2Fantitrust%2Fmo%2Fpremium%2Dat%2Fat%2Dhcic%2Fhc%2Dchronicle%2Dvol23%2Dissue1%2Epdf&AREATYPE=premium&ROLE=at