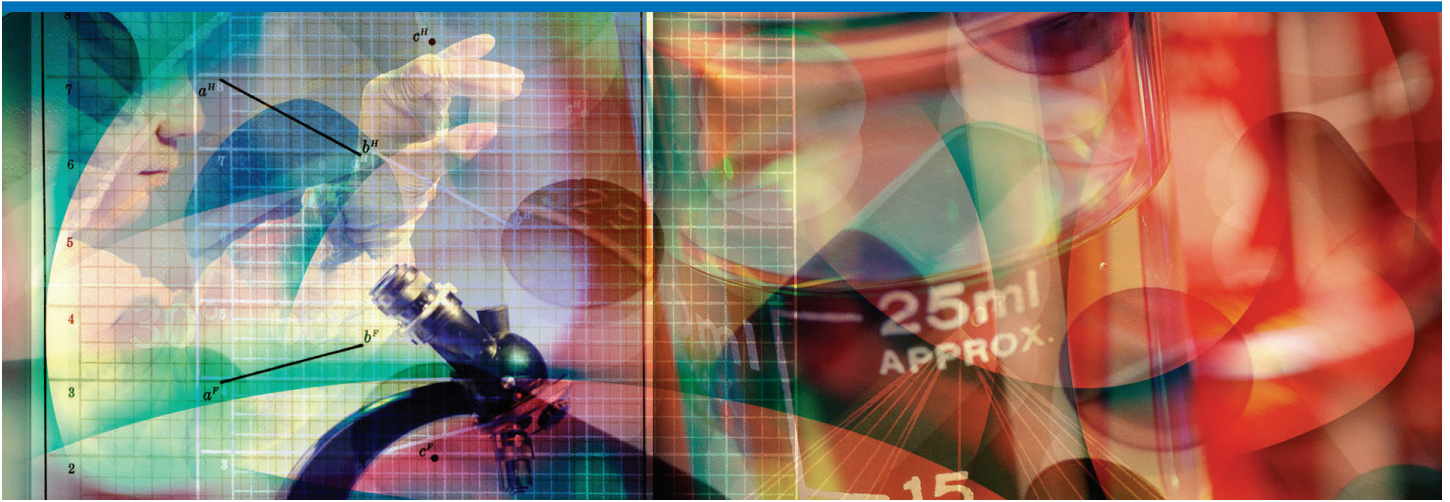


# CONTEMPORARY LEGAL NOTES



## ONLINE PHARMA MARKETING: LACK OF CLEAR RULES COMPELS CAUTION ON THE WEB

by **Joseph P. McMnamin**  
McGuireWoods LLP

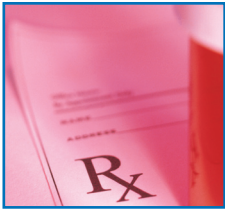
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**Washington Legal Foundation**  
Contemporary Legal Note Series  
Number 59  
June 2008

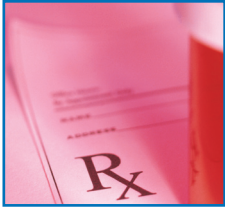
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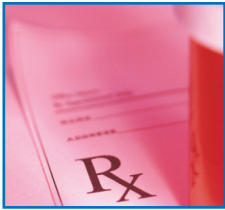
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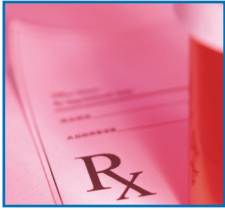
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Joseph P. McMenamain is a partner based in the Richmond office of the law firm McGuireWoods LLP. He was a university-trained internist and a practicing emergency physician before being admitted to the bar. He holds medical (1978) and law (1985) degrees from the University of Pennsylvania, and served a straight medicine residency (1978-1981) at Emory University and Grady Memorial Hospital in Atlanta before joining McGuireWoods in 1985.

A member of the firm's Life Sciences Industry team, Mr. McMenamain focuses on health-related litigation, including products liability and toxic torts, risk management and claims avoidance, and health law. His practice places particular emphasis upon identification and development of the science informing the defense of claims against the manufacturers of medicines, vaccines and medical devices. Part of that service includes identifying and diminishing risks associated with corporate communications on the Internet. More recently, he has been assisting clients in the preparation of pandemic and emergency plans. He is a Fellow of the College of Legal Medicine, and an associate professor of legal medicine at the Medical College of Virginia.



## ONLINE PHARMA MARKETING: LACK OF CLEAR RULES COMPELS CAUTION ON THE WEB

by Joseph P. McMenamain McGuireWoods LLP

### INTRODUCTION

Internet pharmaceutical marketing has grown dramatically. Of 213 million Internet users in the United States, 116 million use the Internet to search for health information. According to Manhattan Research, this represents an increase of 75 million over five years. According to the American Council on Science and Health, seven of ten consumers (41 million) use the Internet yearly to find information about prescription drugs specifically. Users, wishing to play a larger role in their own health care, seek potential safety risks and side effects of their treatments. Pharma and health care on-line ad spending is up by 9% this year to \$975 million. Seventy-one percent of pharma marketers, more than for direct-to-consumer advertising, see the Internet as an effective channel to provide information and services on demand.

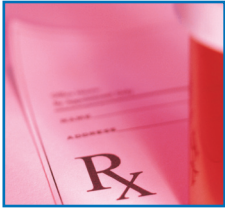
By several measures, Internet advertising is effective. According to an April, 2006 Accenture survey, for example, 61% of respondents trusted physicians more than any other source for medication information, followed by pharmacists (16%) and by on-line medical sites (13%). Twenty-two percent reported learning about medications from pharma-sponsored sites. Fifty-Nine percent asked their physicians about medications they had learned about on-line or elsewhere. Of patients initiating these discussions, one-third said that their physicians prescribed those same medications. Sites thought to be particularly effective in driving prescription requests are those for Ambien, Allegra, Wellbutrin, Lunesta, and Nexium.

### I. WEB 2.0

A recent development has been pharma's adoption of Web 2.0 technology in response to physician and consumer demand for interactive media. In 2007, one in three Americans used some form of social media online to procure health information. iCrossing, "How America Searches: Health & Wellness" (Jan. 2008). The technology takes many forms: social networking, blogs, wikis, podcasts, RSS ("really simple syndication") feeds, interactive quizzes and polls, BMI calculators, e-newsletters, compliance reminders, virtual nurseries, clinical wizards, microsites, flash videos, coupons and so forth. Wyeth's knowmenopause.com provides Web T.V. and interactive tools that simulate real-world interactions. Merck offers RSS feeds and podcasts. Pfizer webcasts its annual shareholder meeting. APS Healthcare provides emergency alert messages to patients via email, text messaging, pagers and the Internet. GlaxoSmithKline has appointed its own social media manager.

A striking example of this trend is the FluFix video contest sponsored by Novartis. There, young adults are invited to submit videos to YouTube showing how they "feel about ... flu, and how it can affect [their] every day [lives]." Under the arrangement, Novartis will own the rights to the videos submitted. Entrants must participate in an interview with the sponsor, and permit the sponsor to use the entrant's name, likeness, voice, hometown, biographical information, interview, and, of course, his winning entry.

Nexium is a proton pump inhibitor used in management of gastroesophageal reflux disease. Its manufacturer, AstraZeneca, provides podcasts at about.com, educating patients about its product. Late in 2006, about.com and AstraZeneca launched a 6-part podcast series as a part of AstraZeneca's Web destination "Living with Heartburn." The program was designed to educate consumers on how to cope with their medical problems. Each podcast was three to five minutes long, hosted by a physician, using content written specifically for the series.



Roche manufactures Pegasys, used for management of hepatitis C. This is a remarkably prevalent problem; around the world, more than 170 million people have the disease. Potentially, hepatitis C can be fatal. For all its risks, however, the condition generally remains asymptomatic for decades. In collaboration with Google, Roche developed an “at risk” unbranded awareness campaign for hepatitis C patients. Surfers go to [haveyouever.com](http://haveyouever.com) to gain information about risky behaviors and other related topics. Visitors can take advantage of a free hepatitis C risk profile, a newsletter, and downloadable patient brochures.

Certain third-party sites not sponsored by pharma shed additional light on this trend. Uptodate.com supplies answers to doctors’ queries for a fee. With growing pharma support, WebMD.com provides free information across 30 medical specialties at its Medscape site. WebMD facilitates free appointment services, personal health records, interactive symptom checkers, and conditionspecific message boards. At [oncologySTAT.com](http://oncologySTAT.com), Reed Elsevier offers oncologists immediate access to current cancer-related articles from 100 Elsevier journals, including *Lancet* and *Surgical Oncology*, among others. On registering their personal information, oncologists can obtain current information on chemotherapy, drug interactions, and the like. To a limited extent, Reed Elsevier is providing access to other publishers’ journals, too. Experts write free summaries, and update them weekly, on cancer-related articles from 25 other leading journals, including *The Journal of the American Medical Association* and *The New England Journal of Medical*. Until they become publicly available six to twelve months after publication, however, the reader must still buy the journals to get the full texts. Reed Elsevier has announced plans to sell ads and its subscription list information. In the future, it may offer analogous services in neurology, psychiatry, cardiology, and infectious disease.

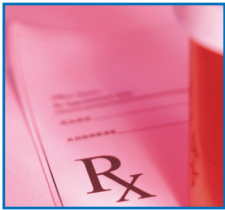
## II. DIRECT-TO-PHYSICIAN ADVERTISING

Much has been written, of course, about direct-to-consumer advertising. Direct-to-physician (DTP) communication remains important as well, but it is increasingly being done electronically. Pharmaceutical houses now own their own full service physician portals. DTP sites synthesize disease education information and tailor the messages to the visitor’s specialty and sophistication. Doctors can link to the sites at their convenience; from those sites they can order journal articles, product samples, and email updates. Electronic detailing enables physicians to speak with a sales representative, and to complete on-line surveys. Some pharmaceutical houses have concluded that physicians may be more willing to spend time with electronic detailing than they are with in-person calls. The expense to pharma sponsors is lower than it is for detailers, yet the return on investment is thought to be similar.

## III. THE INTERNET v. PRINT MEDIA

FDA has still not issued regulations on Internet advertising as such. On the Internet, there are no space limitations, images are easy to use, the text can be updated quickly and easily, links can be provided, and, increasingly, interactivity is possible. On the other hand, under the Prescription Drug User Fee Act IV, companies can get FDA’s input on whether their DTC ads intended for television are deemed accurate, balanced, and adequately supported before public dissemination. There is no analogous provision for Internet advertising.

FDA has long advised inquiring parties to apply to the Web the existing rules developed for marketing via print and broadcast media. The problem is that the Web is neither, though it has characteristics of each. Until FDA acts, however, the standing admonition is all the guidance available. To the extent that pharma wish to employ videos on the Web, the analogy to broadcast marketing is easier both to see and to apply. See DDMAC’s April 16, 2008 warning letter to Jeffrey B. Kindler, CEO and Chairman, Pfizer, available at [http://www.fda.gov/foi/warning\\_letters/s6749c.htm](http://www.fda.gov/foi/warning_letters/s6749c.htm), respecting a Viagra (sildenafil) video that, owing to a technical error,



ran without intended safety information on [www.cnn.com](http://www.cnn.com). The Agency took the position that, since risk information called for under 21 C.F.R. 202.1(e) was omitted, the video misbranded the drug under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. 352(a) and (n).

#### **IV. BLOGS**

Pharmas should ask whether the risks of blogs outweigh the benefits. The credibility of blogs is debatable and the role of ads is unclear. Keeping tabs on what it said about your product, or any given topic, is difficult if not impossible. Employee blogs are particularly concerning. State and federal statutes and constitutional protections do not give employees carte blanche to publish, even anonymously, content that is anti-employer or in violation of established company policy. A company can impose discipline against employees for content they post on the Net. On the other hand, employees do enjoy protections under the National Labor Relations Act, anti-discrimination statutes, whistle-blowing statutes, and the like. Wrongful termination suits could potentially arise if aggressive discipline is imposed after an employee makes a blog post. It is not at all clear that employers can do anything about blogging by an off-duty employee at his own personal computer. State and local statutes prohibit discipline for lawful off-duty conduct.

The question arises whether liability to a third party could result from Internet activity. Employee Internet activity could lead to release of private data, trade secrets and other sensitive material. The best approach is to put in place a strong, clear company policy on the subject and to disseminate it widely among employees.

#### **V. CHAT ROOMS**

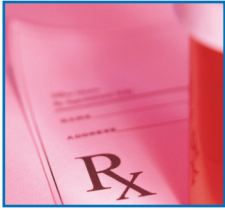
Like blogs, chat rooms are risky. A company electing to create one as a forum to discuss its products may wish to consider whether to establish parameters for its participation. It should decide whether content should be monitored. If it is, then the company needs to decide whether any misinformation has to be corrected. It should also decide whether to correct erroneous statements. Is there a duty to report adverse events described there? What is the appropriate response when a user posts information about off-label uses?

#### **VI. THIRD PARTY POSTS**

If your site allows third parties to post content, you should give serious thought to the control mechanisms you have in place. What policies have you adopted to limit liability for third-party intellectual property liability and to discourage posting of infringing, illegal, obscene, pornographic or other unwanted content? Does your site comply with the Digital Millennium Copyright Act, Public Law No. 105-304, 112 Stat. 2860 (Oct. 12, 1998)? Compliance requires that the site owner register with the Copyright Office, discourage copyright infringement, and identify an agent responsible for taking down content violative of copyright on notice from the copyright owner. Taking these steps affords broad immunity from liability.

As interactive sites become more prevalent, *Fair Housing Council of San Fernando Valley v. Roommates.com, LLC*, 489 F.3d 921 (9th Cir. 2007) gives cause to stop and consider the risks of users' posts. The Communications Decency Act, 47 U.S.C. § 230 ("CDA"), provides immunity to "interactive computer service providers" against claims arising from third-party or user content: "[No] provider ... of an interactive computer server shall be treated as the publisher or speaker of any information provided by another information content provider." A content provider is defined to mean "any person or entity that is responsible, in whole or in part, for the creation or development of information provided through the Internet."

On the other hand, under the Fair Housing Act and under state law, discrimination against tenants is prohibited. At *roommates.com*, applicants were invited to complete on-line questionnaires



so they could be matched with potential housemates. They were asked to reveal, among other things, their sexual orientations and whether they had children. The court declared that by asking questions such as these, and providing potential answers for subscribers, roommates.com was a content provider, responsible for the information provided, and therefore not entitled to immunity. The court also noted that a user could ask to see a list of others seeking roommates, but limit that list to heterosexuals, for example, or to “females without children.” Permitting searches with “non-neutral tools” such as these, said the court, was content development and so not protected. *Fair Housing Council of San Fernando Valley v. Roommates.com, LLC*, No. 04-56916 (9th Cir., Apr. 3, 2008).

Contrast Roommates.com with *Chicago Lawyers’ Comm. For Civil Rights Under Law, Inc. v. Craigslist, Inc.*, No. 07-1101 (7th Cir., Mar. 14, 2008). Craigslist provides a site designed to help homeowners find potential buyers, and landlords, potential tenants. The plaintiff alleged that by allowing users to post discriminatory ads, Craigslist violated the federal Fair Housing Act. Just as Roommates.com did, Craigslist invoked the CDA, but unlike Roommates.com, Craigslist prevailed. The Seventh Circuit wrote that Craigslist did not “induce anyone to post any particular listing or express a preference for discrimination.” Craigslist was under no duty to police users’ postings, and in furnishing a neutral forum for others to use was not responsible for the content of the statements made there.

There may be good business reasons for pharmas to enable site visitors to post their own material, but given the pervasive regulation to which they are subject, and the complexity of this evolving area of the law, they should do so only cautiously and with a weather eye out for potential liability exposure.

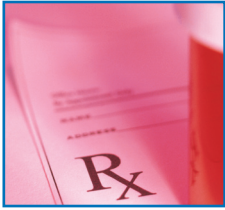
## VII. CONTRACTS

Statements made on the Web may create enforceable contracts. Disclaimers and terms and conditions are examples. Merchants have long offered agreements relating to payment mechanisms for their merchandise. Material posted on the site may be subject to content and software licenses. There may be agreements to promote the site through co-branding or linking agreements, key word purchases, banner arrangements, or contracts relating to the use of unsolicited email to promote the site.

In *Feldman v. Google, Inc.*, No. 06-2540 (E.D. Pa. 2007) the plaintiff had to scroll through the defendant’s 13-page AdWords Agreement and then click on a button saying “Yes, I agree to the above terms and conditions” before he could open his account. According to the Agreement, all disputes relating thereto had to be brought in state court in Santa Clara County, California. Plaintiff sued the defendant, disputing the defendant’s fees. Pursuant to the Agreement, the defendant moved to transfer to the court specified there. The plaintiff argued that he was not bound by the agreement because he had not read it. The court ruled, however, that the terms of the defendant’s click wrap agreement were enforceable. By clicking the button, the plaintiff had agreed to them. The plaintiff had been given reasonable notice. Accord, *Krause v. Chippas*, 2007 WL 4563471 (N.D. Tex. 2007); *Doe v. Network Solutions*, No. 07-5115, 2008 WL 19149 (N.D. Cal. 2008).

## VIII. PRIVACY

Violation of privacy is a potential source of liability. What does the site say with respect to its collection, use, or dissemination of personal identifying information about consumers? Does the site collect information from children? If so, does it comply with the Children’s On-Line Privacy Protection Act, 15 U.S.C. § 6501, et seq., and the Federal Trade Commission’s accompanying regulations, 16 C.F.R. Part 312? In *Douglas v. U.S. District Court*, 495 F.3d 1062 (9th Cir. 2007),



the court held that a site owner could not unilaterally change the terms of its service contract by posting a revised contract on-line without notice to consumers. The company had posted clauses governing service charges, class action waivers, arbitration, and choice-of-law, among other things. A notice that identifies the applicable contract accompanied by a summary of the modifications, however, may well be sufficient. See *Bischoff v. DirecTV, Inc.*, 180 F. Supp. 2d 1097 (C.D. Cal. 2002). The wisest course is probably to require a customer to affirmatively “accept” the revised contract before he sees any other material.

After *Douglas*, privacy policies, in and of themselves, may not be construed as binding contracts. A privacy policy can be part of a binding customer agreement, however. FTC already requires notice and acceptance to “material changes.” *Douglas* may extend a duty of notice to non-material changes where the privacy policy is structured so that it is considered an on-line contract. Check to see whether your mechanisms to notify customers of changes to customer agreements and privacy policies are sufficient to bind them.

#### **IX. LINKS**

Links are part of what make the Internet such a remarkably effective way to gain information quickly about virtually any topic. Pharmaceutical sites may wish to provide links and they are certainly legally entitled to do so. The question arises, however, whether links to non-medical sites should be regulated. Do links or frames create a false impression about the content origin or about the sponsorship or affiliation of the site or the owner or the product? Do the links or frames refer the users to infringing material? The solution to these problems is a well-drafted disclaimer.

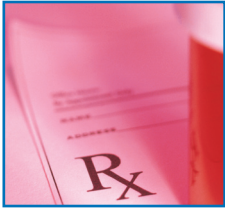
#### **X. METATAGS**

Metatags consist of information inserted into the “head” area of a Web page. A metatag may affect how the Web page is described by some search engines. Metatags raise the question whether there are any third-party trademarks in the metatags. Are the Website owner’s marks included in third-party metatags?

#### **XI. LEARNED INTERMEDIARY**

In general, pharmaceutical manufacturers are under a duty to warn not the patients who take their drugs, but rather the physicians prescribing them. Direct-to-consumer advertising, however, has been invoked by at least one court as a justification to limit application of the rule. *Perez v. Wyeth Labs*, 734 A.2d 1245 (N.J. 1999). There, the court held that the rule was inapplicable to DTC ads for Norplant. *Love v. Wolf*, 38 Cal. Rptr. 183 (Cal. App. 1964) held that overpromotion gutted the protection. The most extreme position is West Virginia’s, where the Supreme Court of Appeals held, in part because of the rise of direct-to-consumer advertising, that the doctrine does not apply there. *State of W. Va. ex rel. Johnson & Johnson Corp. v. Hon. Mark A. Karl*, No. 33211, slip op. (W.Va. 2007). On the other hand, in *In re Norplant Contraceptive Products Litigation* ADD, 4 F.2d 1064 (8th Cir. 1989), the court held that the rule did apply so long as the physician had to prescribe the product before the consumer could use it.

*Perez* has had few progeny. Companies may wish to consider, however, whether an enterprising plaintiffs’ lawyer might invoke *Perez* and argue that the use of the Internet to promote pharmaceuticals guts the rule.



## **XII. OTHER RISKS**

A company should check to be sure that it has properly acquired both its domain name and any obvious variations of recognized marks or domain names. The company should consider what countries its site is directed to. Should residents of particular countries be blocked from gaining access or engaging in transactions because of the content or of the nature of the goods or services offered?

## **XIII. ENFORCEMENT**

In 2000, FDA issued 21 warning letters relevant to pharmaceutical-related websites. In 2006, the number had risen to 33. Cyberletters addressed press releases for unapproved use of a screen panel test, promotion of a cellular imaging system for an unintended use, and promotion of unapproved cosmetic procedures. Any product that is promoted without clearance, or promoting approved products for unapproved uses, or employing claims that FDA deems to be misleading or unsupported may trigger enforcement action.

## **XIV. JURISDICTION**

At least one court has held that jurisdiction lies where a foreign citizen can access the site. *Maritz, Inc. v. CyberGold, Inc.*, 947 F. Supp. 1328 (E.D. Mo. 1996). On the other hand, in *Zippo Mfg. Co. v. Zippo.com*, 952 F. Supp. 1119 (W.D. Pa. 1997), the court applied a sliding scale. Jurisdiction may depend upon whether the site was passive, inactive, or commercial. For all the virtues of interactivity, companies may want to consider the potential jurisdictional implications of two-way communication.

## **CONCLUSION**

Pharmas will undoubtedly expand their Internet activities, to the benefit not only of themselves, but also of health care professionals and the patients they serve. In doing so, however, they should continually bear in mind the legal issues implicated by use of this rapidly evolving technology, so that its benefits can be fully realized. At minimum, this will require attention to developing case law, regulations, and statutes. Companies may also want to consider whether to seek to influence the law, so that the price they pay for the benefits of Internet communications does not become unacceptably high.