

# Legal Issues Concerning the Promotion of Pharmaceutical Products on the Internet to Consumers

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## I. INTRODUCTION

The promotion of pharmaceutical products on the internet, an unforeseen event only a few years ago, has begun. While some companies only have registered domain sites with Internic,<sup>1</sup> others have set up home pages that deal with pharmaceutical products such as Rogaine® (minoxidil), a drug product approved to promote the growth of hair;<sup>2</sup> Claritin® (loratidine), a prescription nonsedating antihistamine product;<sup>3</sup> and Nicorette®, a nicotine-based gum used to aid in the cessation of smoking.<sup>4</sup>

In general, most pharmaceutical companies that have set up internet home pages do not provide product-specific information, but instead provide information and news about the company, financial status, and job listings.<sup>5</sup> Others also may provide information about diseases without mention of their products. There are relatively few home pages that focus on specific pharmaceutical products.<sup>6</sup> This is probably because of the legal concerns that arise from such sites being considered consumer promotion.

The promotion of pharmaceutical products on the internet and through other emerging technologies, such as e-mail and other forms of electronic communication, is in its infancy. As such, there is little, if any, specific guidance as to the restrictions under law regarding how such advertising and promotion can and cannot be done. The government agencies that are involved in the regulation of pharmaceutical product promotion have been silent as to how the internet and other such novel means of promotion should be handled; they, however, have stated that they will take an active role in regulating internet promotions. There are only a limited number of decisions dealing with legal issues involving the internet, and none involve pharmaceutical products. Nevertheless, by the very nature of the internet, information on it largely is directed to consumers.

Except for current laws, regulations, and regulatory guidance, there is a dearth of specific guidance for companies who are contemplating marketing over the internet and

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<sup>1</sup> Procter & Gamble has registered more than 100 domain names, one-half of which are product names and one-half of which are generic names, such as "cough," "diarrhea," "flu," "pimples," "dandruff," "toothpaste," and "dental care." *P&G's More Than 100 Internet Sites Include Generic Words Like Headache*, F-D-C REP. ("The Pink Sheet"), Sept. 18, 1995, at 13-14.

<sup>2</sup> See <http://www.igroup.com/rogaïne>.

<sup>3</sup> See <http://www.allergy-relief.com>.

<sup>4</sup> See <http://www.nicorette.com>.

<sup>5</sup> See, e.g., <http://www.bms.com/squibb/news/news1128.html> (Bristol-Myers Squibb); <http://www.pnu.com> (Pharmacopia & Upjohn); <http://www.glaxowellcome.co.uk> (Glaxo Wellcome); <http://www.colgate.com> (Colgate); <http://merck.com/websearch.html> (Merck); <http://www.luitpold.com> (Luitpold/American Regent).

<sup>6</sup> See, e.g., <http://www.2igroup.com/rogaïne/index.html>; <http://www.2impotent.com/caverject/welcome.html> (Caverject); <http://www.colgate.com/SMILES/PRODUCTS/index.html> (Colgate toothpastes, toothbrushes); <http://ns.gamewood.net/abbott/abbott.html> (Calcijex); <http://www.bms.com/squibb/customer/customer.html> (Excedrin); <http://www.durex.com> (Durex condoms); <http://www.linkmag.com/trojan> (Trojan condoms).

by other new methods of electronic communication. Due to the unique nature of the internet, how it is accessed, and what it can contain, many unresolved issues undoubtedly will arise in the coming years, as advertising and promotion of pharmaceutical products on the internet increases. Much of what regulatory agencies develop with regard to regulation of information on the internet is likely to be influenced by its availability to consumers.

This article attempts to address how current laws, regulations, and guidance may be used to regulate the promotion of pharmaceutical products on the internet and through other emerging electronic communication technologies. Next, it will consider how proposed legislative changes may affect future laws. Lastly, it will discuss other legal issues, such as product liability concerns, that can arise from promotion of pharmaceutical products over the internet.

## II. REGULATION OF CONTENT BY ADMINISTRATIVE AGENCIES

The content of pharmaceutical product promotions is regulated by two federal agencies — the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). In general, the FDA has jurisdiction over advertising and promotion of prescription pharmaceutical products, both drugs and biologics; the FTC has jurisdiction over the promotion of over-the-counter (OTC) drug products (there are no OTC biologics). While there is some dispute as to whether the agencies share concurrent jurisdiction over the advertising of the prescription drug products, the agencies have entered into a Memorandum of Understanding that grants the FDA primary responsibility over advertising of prescription products and the FTC primary responsibility over advertising of OTC drug products.<sup>7</sup>

## III. REGULATION BY THE FDA

For prescription pharmaceutical products, the FDA has issued some general rules that regulate the content of prescription drug advertising and labeling.<sup>8</sup> In addition, the FDA has issued a number of guidance documents and letters to industry as to how it interprets its statutory authority over the content of prescription drug promotions.<sup>9</sup> An understanding of the rules is necessary to surmise how the FDA will regulate content of pharmaceutical promotion on the internet and other new forms of electronic communication.

Under section 502(n) of the Federal Food, Drug, and Cosmetic Act (FDCA), the advertising of a prescription drug must contain a brief summary of the indications, warnings, and contraindications for use of the product.<sup>10</sup> The FDA has devised a comprehensive scheme for the regulation of prescription drug promotions based on this grant of statutory authority. While some parties recently have questioned whether the agency has exceeded its statutory mandate,<sup>11</sup> these rules currently govern prescription drug promotion through all media, including the internet and other emerging forms of

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<sup>7</sup>Memorandum of Understanding, 36 Fed. Reg. 18,538 (Sept. 9, 1971).

<sup>8</sup>See 21 C.F.R. §§ 201 (labeling), 202 (advertising) (1996).

<sup>9</sup>These can be found, for example, in the *FDA Advertising and Promotion Manual* (published by Thompson Publishing Group, Inc., Washington, D.C.).

<sup>10</sup>21 U.S.C. § 352(n) (1994).

<sup>11</sup>See, e.g., AMERICAN ASSOCIATION OF ADVERTISING AGENCIES, LEGISLATIVE PROPOSAL TO REFORM FDA MARKETING REGULATION (1995); Citizen Petition of Washington Legal Foundation, Dkt. No. 95P-0224 (July 20, 1995).

electronic technologies.

It must be noted that the FDA distinguishes between advertising and labeling. The FDA defines an "advertisement" to include "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."<sup>12</sup> "Labeling", on the other hand, is defined to include "brochures, booklets, mailing pieces, detail pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, filmstrips, lantern slides, sound recordings, exhibits, literature, and prints and similar types of printed, audio or visual matter."<sup>13</sup> The reason for the distinction is based on the FDCA.

While labeling of prescription drugs must contain "full disclosure" (requiring a copy of the approved package insert to accompany all labeling), advertisements for prescription drugs need only contain a brief summary of the information in the package insert.<sup>14</sup>

The FDA has yet to decide whether promotion of a product over the internet is advertising or labeling. For example, in a *Federal Register* notice announcing a public hearing on the regulation of direct-to-consumer advertisements of prescription drugs, the agency requested comments on the type of disclosure that should be required of promotions made by new computer-based promotional vehicles such as the internet, and questioned whether the promotions are print (labeling) or broadcast (advertising).<sup>15</sup> More recently, Melissa Montcavage of the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) in the Center for Drug Evaluation and Research (CDER), stated the following:

We have no idea when a ruling or regulations might be forthcoming. . . . For now, we're letting drug companies choose whatever category of current regulations they think best fits their presence on the [i]nternet.

This is a new area and requires a concerted effort to develop an agency-wide policy. . . . The problem doesn't apply just to prescription drugs. We also have to look at devices and food supplements [as well as implications for over-the-counter products].<sup>16</sup>

Thus, at this point, manufacturers must decide themselves how to comply with FDA rules.

The FDA is likely to consider promotional material on the internet as advertising, in much the same way that it regulates telephone communications — including interactive telephone communications — as advertising. Note, however, that Byron Tart, the director of the Center for Devices and Radiological Health's promotions and advertising policy staff, stated at a July 11, 1996 Health Industry Manufacturers Association meeting that device information on internet home pages "likely" constitutes labeling.<sup>17</sup>

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<sup>12</sup> See 21 C.F.R. § 202.1(l)(1).

<sup>13</sup> See *id.* § 202.1(l)(2).

<sup>14</sup> See *id.* § 202.1(e).

<sup>15</sup> See Direct-to-Consumer Promotion Public Hearing, Notice of Public Hearing, Request for Comments, 60 Fed. Reg. 42,581 (Aug. 16, 1995).

<sup>16</sup> *Drug Ads Casting Wider Net, Finding a New Home on the Web*, AM. MED. NEWS, Nov. 20, 1995, at 3.

<sup>17</sup> *Device Information on Internet Home Pages Likely Constitutes Labeling*, M-D-D-I REP. ("The Gray Sheet"), July 15, 1996, at I&W 5-6.

Until the FDA issues a ruling or guidance on this issue, however, companies probably will include full disclosure on their internet home pages. Indeed, all of the product specific internet sites discussed in this article contain full disclosure, and not a brief summary. Because it is no more difficult to add the full disclosure, companies may choose to adopt the more conservative route until the FDA makes a decision.

Regardless, however, of whether full disclosure or a brief summary is required, there are a host of other issues that will arise. For example, how will companies that supply product specific information on an internet home page comply with disclosure requirements? Because the brief summary or full disclosure cannot be put on every page of a domain site, will it be sufficient, for example, to state something such as "see full prescribing information at the end of this page"? Will the FDA require that the companies with internet domain sites get the name and address of visitors to their home page, and mail or fax a copy of the prescribing information to any visitor to the home page as is required, for example, for certain promotions made by telephone?<sup>18</sup>

Second, the FDA requires that a prescription drug advertisement or any other promotional material contain "fair balance."<sup>19</sup> "Fair balance" means that any claim relating to the safety and/or effectiveness of a drug must be balanced by a presentation of information relating to side effects, contraindications, and warnings. The fair balance must be provided along with, and must be reasonably prominent to, the claim of safety and/or effectiveness. Does the fair balance requirement mean that every page on the internet site where a safety or effectiveness claim is made has to provide fair balance? This is an issue that the FDA has yet to address, but that has raised concern in the pharmaceutical industry as to how companies can comply with current FDA rules on advertising and labeling in setting up home pages on the internet.

Third, most internet home pages are available to any consumer. Under current regulations, the FDA does not distinguish between the content of prescription drug advertising directed to consumers and that directed to physicians. The agency uses the same rules to regulate both. The FDA, however, is and always has been concerned about whether advertising of prescription drugs to consumers is appropriate, and whether consumers can understand and accurately assess claims made regarding the safety and effectiveness of prescription drugs and biologics.<sup>20</sup> For this reason, among others, the FDA held a public hearing on October 18 and 19, 1995, on direct-to-consumer advertising of prescription drugs. The FDA seems concerned that internet advertising will be directed to consumers. In February 1996, Melissa Montcavage of DDMAC stated:

Because we will regulate the information that drug companies put on the Internet, consumers will have some kind of assurance that what they read on company home pages is well-balanced, accurate information about those drugs. The FDA will be able to provide some kind of assurance that there are places consumers can go for good information.<sup>21</sup>

Because of the FDA's concern about direct-to-consumer advertising of prescription

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<sup>18</sup> See Clarifying Letter from Janet L. Ruso, Acting Director, Div. of Drug Marketing, Advertising, & Communications, CDER, FDA, to the Pharmaceutical Industry Regarding Telephone Advertisements (Aug. 1993), reprinted in FDA ADVERTISING AND PROMOTION MANUAL, app. II, at A99-101.

<sup>19</sup> See, e.g., 21 C.F.R. § 202.1(e)(5)(ii).

<sup>20</sup> Minnie Baylor-Henry, Acting Director, Div. of Drug Marketing, Advertising, and Communications, CDER, FDA, Speech at The Food and Drug Law Institute's seminar, Marketing and Advertising of Drugs, Medical Devices, and Biologics in a New Environment (Sept. 7, 1995).

<sup>21</sup> Hema N. Nair, *On-line Regulation*, 2(1) PHARMACEUTICAL MGMT. 34 (1996).

drugs, the agency has requested that companies submit all such advertising to it prior to dissemination. Companies considering product-specific domain sites should keep this policy in mind before activating any such home page.

Finally, and perhaps most important, an internet home page for a prescription drug product cannot contain information about an unapproved use of a pharmaceutical product. Sections 301 and 505 of the FDCA prohibit the promotion of a pharmaceutical product for an unapproved claim.<sup>22</sup> Any home page sponsored by a manufacturer/ distributor of a prescription pharmaceutical product therefore may not promote any information on an unapproved use. The FDA, however, announced a new policy in December 1995 that will permit distribution of certain published data that contains reference to unapproved uses.<sup>23</sup> The FDA will permit studies to be distributed if:

- the article reports on an investigation that served as the basis of approval of the product,
- the principal subject of the article is the uses or indications approved by the FDA,
- The reprint is from a bona fide peer-reviewed journal,
- a sticker attached to the reprint indicates what information in the reprint is unapproved or contradictory to approved labeling, and
- all material facts are disclosed and the reprint is not false or misleading.

Obviously a “sticker” could not be placed on an internet page, but some notice satisfying the condition could be added.

It seems clear that discussion or reference to unapproved uses will be one of the FDA’s major concerns. A February 1996 article reported that:

FDA regulation of device advertising and marketing might extend soon into the growing use of the Internet to distribute drug information. An FDA source said the agency is looking at industry use of the Internet and *is most concerned with dissemination of information on unapproved uses of drugs.*

One concern is the World Wide Web, a powerful part of the Internet, that allows creation of “home pages” or “Web sites” which can link to other sites as well as chat rooms where live free-wheeling discussions on product can take place.

*The links between Web sites are a major FDA concern, and FDAer said.* Even when a company’s Web site provides only information on an approved use, the site also might provide access to other sites, not under the firm’s control. These sites could well be used to provide information on off-label uses.

For example, a company’s Web page can link to a Web page of a publication such as the Journal of the American Medical Association [sic] (JAMA), with articles on off-label uses. As FDA restricts industry distribution of these articles, it is likely the agency will try to limit these types of links.

FDA likely will be able to monitor only links from regulated companies. The agency has no authority over what an organization like JAMA puts on its

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<sup>22</sup> 21 U.S.C. §§ 331, 355.

<sup>23</sup> Advertising and Promotion, Draft Guidance, 60 Fed. Reg. 62,471, 62,472 (Dec. 6, 1995).

home page. Picking a policy direction will be hard, the FDAer said. "There is so much going on out there," she said. "Right now, the staff is just looking at what is going on out there, what the [i]nternet's capabilities are, and what we should be doing."<sup>24</sup>

More recently, the following was reported about the agency's concern with links:

FDA also is evaluating the practice of providing links from a manufacturer home page to other sites on which off-label uses are discussed. The agency has received inquiries about home page links to sites such as the National Library of Medicine or the *Journal of the American Medical Association*, in which there may be discussion of unapproved uses. "Probably for these general areas, we wouldn't have any problem," [Byron] Tart said. However, "if you link to a specific site where all they do is talk about the off-label use of a product, then we would think that you would be responsible for that," he added. Company sponsored sites which mainly address off-label device use also would be "a problem" for the agency.<sup>25</sup>

In addition to these concerns, there are a number of other unresolved issues. For example, disseminated advertising and labeling of prescription pharmaceuticals have to be submitted to the FDA on a routine basis. How is a home page to be submitted? Does it have to be submitted any time an update is made? What about communications and other interactive features of a home page? Do they have to be submitted and what kinds of disclosure need be made?

Another interesting issue arises from the international nature of the internet. What if a multinational company that has approval of a product in Europe has an internet home page — set up in Europe but available in the United States — for a product not yet approved in the United States? Is this unlawful promotion of an unapproved new drug? It should be noted that Schering-Plough added a statement at the end of its home page that "[t]his information is intended for U.S. consumers."<sup>26</sup> Would a similar disclaimer, stating that the information was "not intended for U.S. consumers," resolve any concerns the FDA might have? An agency staffer recently was reported to have stated the following about disclaimers: "'We have not looked too favorably on the use of country flags' on disclaimers, . . . [t]he 'bottom line' is 'try not to promote your device for an unapproved use if you control that home page.'"<sup>27</sup>

How the FDA will regulate promotions of prescription drugs on the internet raises many currently unresolved questions. At the public hearing on direct-to-consumer advertising of prescription drugs in October 1995, former FDA Commissioner Arthur Hull Hayes urged the FDA to consult with internet experts before deciding how to regulate promotions of pharmaceutical products on the internet.<sup>28</sup> Dr. Robert Temple, Associate Director for Medical Policy of CDER, and supervisor of the DDMAC, however, believes that the "content aspects of [the internet] are more traditional than one might imagine," concluding that "there is a message and someone has written it."<sup>29</sup> This

<sup>24</sup> *Will FDA Cops be Surfing the Net?*, WASH. DRUG LETTER, Feb. 19, 1996, at 2 (emphasis added).

<sup>25</sup> *Device Information on Internet Home Pages Likely Constitutes Labeling*, *supra* note 17, at I&W 6.

<sup>26</sup> See <http://www.allergy-relief.com/bbar/spcdi.htm>.

<sup>27</sup> *Device Information on Internet Home Pages Likely Constitutes Labeling*, *supra* note 17, at I&W 5.

<sup>28</sup> See *FDA Must Address Internet Advertising, Former Agency Commissioner Hayes Suggests*; *Agency's Temple Sees Internet Ad "Fitting" Traditional Mode*, F-D-C REP. ("The Pink Sheet"), Oct. 23, 1995, at 10.

<sup>29</sup> *Id.*



seems to imply that the FDA does not believe any new rules need to be issued for internet promotions and other new forms of electronic communication.

Until the FDA issues a guidance document on promotion on the internet, there will be uncertainty as to how to comply with current FDA rules on advertising and labeling of prescription drugs and biologics. Companies may be reluctant to provide product-specific information on the internet, except for "relatively" safe type drug products such as Rogaine®, Claritin®, and Nicorette®, choosing instead to set up domain sites on medical conditions, such as headaches, migraine headaches, diabetes, and depression. For example, the manufacturer of Excedrin has set up a home page on the internet to allow for question and answer sessions between physicians, researchers, counselors, and other healthcare professionals.<sup>30</sup> Provided that such home pages do not discuss specific pharmaceutical products but only disease conditions, they should not be considered advertising or labeling subject to FDA regulations. If, however, such home pages are set up to deliver messages similar to those "help seeking" advertisements currently seen on television or in print, the FDA is likely to require compliance with the guidelines for the content and disclosure of information in such promotions.

How the FDA will enforce its current authority thus remains unclear. An unnamed FDA staffer has stated:

"that a lack of resources and training likely will inhibit the agencies' enforcement efforts in this arena."

"The FDA already is 'playing catch-up' with the drug and device industry when it comes to on-line capabilities," the staffer noted. "Ultimately, the FDA likely will rely heavily on competitors' reports of improper promotional activity on the [i]nternet," the staffer predicted.<sup>31</sup>

More recently, however, Melissa Montcavage has stated that "[t]he regulatory agency is planning to take a more active role in regulating pharmaceutical promotion on the internet."<sup>32</sup> Indeed, at the beginning of March 1996, the Center for Devices and Radiological Health sent a warning letter concerning a promotion of an unapproved use of a device on the internet.<sup>33</sup> The agency has indicated that it has sent at least one other warning letter to a company that had aggressively promoted the effectiveness of its device on the internet.<sup>34</sup> According to agency statements and other reports, the FDA is developing a compliance policy on the internet.<sup>35</sup>

Pending issuance of any FDA guidance on the issue, there will be a degree of uncertainty on how to promote pharmaceutical products over the internet and other similar forms of electronic communication. For the present, companies only can be guided by analogy to current laws, rules, and guidelines.

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<sup>30</sup> See *Bristol-Myers Establishes Excedrin Headache Information Center*, F-D-C REP. ("The Tan Sheet"), Sept. 25, 1995, at 18-19.

<sup>31</sup> FDA ADVERTISING & PROMOTION MANUAL MONTHLY BULL., NOV. 1995, at 4.

<sup>32</sup> Nair, *supra* note 20, at 4.

<sup>33</sup> Warning letter issued to U.S. Medical Products (Mar. 7, 1996).

<sup>34</sup> *Device Information on Internet Home Pages Likely Constitutes Labeling*, *supra* note 17, at I&W 5.

<sup>35</sup> *Internet Device Promotion: FDA Compliance Policy Under Development*, M-D-D-I REP. ("The Gray Sheet"), Apr. 8, 1996, at I&W 10. See also *FDA Targets Internet Drug Ads for Possible Regulation*, WASH. DRUG LETTER, Apr. 22, 1996, at 1; Melissa M. Montcavage, *Surf's Up at Cyber Beach, DDMAC Surveillance Begins on Web*, 2(2) CDER'S NEWS ALONG THE PIKE, Mar. 21, 1996, at 1-2; FDA ADVERTISING AND PROMOTION MANUAL MONTHLY BULL., June 1996, at 1, 3.

## IV. REGULATION BY THE FTC

As previously indicated, the FTC has the authority to regulate advertising of OTC drug products — those products sold without a prescription. While it presently is unclear whether the FDA and the FTC will regard promotion of OTC drugs as labeling within the FDA's primary jurisdiction under the FDA-FTC Memorandum of Understanding or advertising subject to regulation by the FTC under its primary jurisdiction, it is likely that the FTC will assume responsibility for regulation of such promotions of OTC drugs, and possibly for consumer promotions of prescription drugs.

The FTC also has said little about regulation of advertising on the internet, but it has taken a number of regulatory actions with regard to internet advertising. None of these actions, however, have dealt with a drug product.

The FTC's authority to regulate advertising is derived from section 5 of the Federal Trade Commission Act,<sup>36</sup> which prohibits the dissemination of any false or misleading advertising, among other things.<sup>37</sup> Unlike the FDA, the FTC does not have extensive content requirement rules for OTC drug advertising; there are no format, disclosure, or fair balance requirements.<sup>38</sup>

FTC regulation of the content of product specific home pages on the internet is likely to follow current FTC enforcement policy. A recent speech by FTC Commissioner Varney suggests this will be the Commission's approach.<sup>39</sup> Indeed, the FTC, in commenting to the FDA on direct-to-consumer advertising of pharmaceutical products, recommended application of existing standards to prevent deception. The Commission stated that "[a]lthough new media such as the [i]nternet clearly present new challenges with respect to monitoring and enforcing laws against deception, we believe that the core principles underlying the FTC's deception policy apply as well to these developing technologies as to the more traditional advertising media."<sup>40</sup>

The FTC requires that product claims be substantiated, that the substantiation exist at the time the claim is made, and that all product claims be based on competent and reliable scientific evidence. The FTC has acknowledged that it is conducting investigations of on-line promotions to consumers, although it is unclear what products they are focusing on.<sup>41</sup>

Thus, in devising home pages for OTC drugs, companies should follow the same procedures and the same guidance that they currently do in preparing and substantiating other OTC drug advertising. It should be noted that while the FTC has no authority to enforce the FDCA, the prohibition against making unapproved claims on an internet home page for an OTC drug also would apply and would be subject to enforcement by the FDA.

Nevertheless, there are some questions that could arise in the FTC's regulation of internet advertising. For example, similar to infomercials, will the FTC require companies sponsoring home pages to provide some disclosure that the home page is an adver-

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<sup>36</sup> Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914) (codified at 15 U.S.C. § 45 (1994)).

<sup>37</sup> See also *id.* §§ 12-15 (codified at 15 U.S.C. §§ 52-57) (specific provisions on advertising of drugs, devices, cosmetics, and foods).

<sup>38</sup> Many states have laws similar to the Federal Trade Commission Act. State attorneys general also may have authority to regulate the content of internet home pages for drug products.

<sup>39</sup> Christine A. Varney, Commissioner, FTC, Antitrust and Technology: What's on the Horizon?, Address Before the ASAE Legal Symposium, Washington, D.C. (Oct. 6, 1995).

<sup>40</sup> See Comments of the Staff of the Bureau of Consumer Protection and Bureau of Economics, Federal Trade Commission, FDA Dkt. No. 95N-0227 (Jan. 11, 1996).

<sup>41</sup> FDA ADVERTISING & PROMOTION MANUAL MONTHLY BULL., *supra* note 28, at 4.



tisement and specify the sponsor? Will the FTC require disclaimers or warnings as to proper use of products? Failure to include such information could be considered an omission of a material fact, making a home page misleading, if not false. There also are a number of issues that could arise if the home page provides for the direct sale of products.<sup>42</sup>

Unlike the FDA, the FTC generally does not rely on the issuance of rules and/or guidances to provide an interpretation of its statutory authority. Instead, the Commission relies on enforcement on a case-by-case basis. Companies that decide to market OTC drugs on the internet will need to familiarize themselves with such decisions and to keep abreast of any FTC enforcement developments. For the time being, however, companies marketing OTC drug products on the internet generally can rely on the policies and procedures currently in place for advertising of OTC drugs.

#### V. PROPOSED LEGISLATIVE CHANGES TO THE FDA'S REGULATORY AUTHORITY

It should be noted that changes in the FDA's statutory authority over the regulation of the content of prescription drug promotions are possible. A number of bills and other legislative proposals that would limit the FDA's authority over prescription drug promotions have been introduced or discussed by Congress.<sup>43</sup> For example, proposals that would permit the distribution of reprints of published articles from medical journals on prescription drugs, regardless of whether they discuss unapproved uses, are being debated.<sup>44</sup> If the FDCA is amended to include such a provision, this would change dramatically the type of information that could be included on an internet home page for a prescription drug product. Most of these bills, however, would limit the distribution of such articles to physicians and not allow direct dissemination to consumers. Furthermore, proposals are being discussed to amend the FDA's authority over advertisements of prescription drugs directed to consumers. Some of these proposals would transfer regulatory authority to the FTC; others would eliminate the brief summary and fair balance requirements. To the extent that these restrictions are eliminated, or made less onerous, the ability to market prescription drug and biologic products on the internet and by other means could be enhanced.

#### VI. REGULATION BY THE NATIONAL ADVERTISING DIVISION OF THE COUNCIL OF BETTER BUSINESS BUREAUS

In addition to regulation by the FDA and the FTC, another concern for manufacturers of pharmaceutical and device products being promoted on the internet is the authority of the National Advertising Division (NAD) of the Council of Better Business Bureaus. NAD is a nongovernmental organization that, in response to complaints, can review advertising and request substantiation for advertising. The organization has be-

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<sup>42</sup> See *How Do You Police Cyberspace*, BUS. WK., Feb. 5, 1996, at 97.

<sup>43</sup> See, e.g., FDA Modernization Act of 1995, H.R. 1742, 104 Cong., 1st Sess. (1995); see also American Association of Advertising Agencies Inc. legislative proposal submitted to the Honorable Thomas J. Bliley, Chairman, House Commerce Committee (May 30, 1995); H.R. 2932, 104 Cong., 2d Sess. (1996); S. 1744, 104 Cong., 2d Sess. (1996); S. 1197, 104 Cong., 1st Sess. (1995).

<sup>44</sup> It is unclear at this point whether the FDA's December 6, 1995 policy guidances will resolve congressional and industry concerns. See 60 Fed. Reg. at 62,471. It does not appear that it has, in light of ongoing legislative proposals.

gun a regular monitoring review program of the internet.

In December 1995, for example, NAD reviewed an internet advertisement for a weightlifting product called Proteabolic Mass Building (marketed by the Infinity Distribution company). Infinity had used the internet to make claims for Proteabolic Mass Building saying, among the milder claims, that the product was "far superior to any product or system ever developed" and that it was "an all-natural process for keeping the body in an anabolic (growth) state." NAD found that the claims could not be substantiated and that they should cease to be used. The organization forced a settlement with Infinity whereby the company agreed to modify future ads on the internet based on NAD recommendations. More recently, NAD referred advertisements on the internet to the FTC, after the company declined to provide substantiation.<sup>45</sup>

#### VII. OTHER LEGAL CONCERNS REGARDING PROMOTIONS OF PHARMACEUTICALS VIA INTERNET AND ELECTRONIC FORMS OF COMMUNICATION TO CONSUMERS

Product liability is an extremely important concern for pharmaceutical companies. Because of the inherently dangerous nature of drugs, and of prescription drugs in particular, promotions made for drugs must be scrutinized carefully to avoid increasing liability for claims such as a failure to warn. Because promotion of a pharmaceutical product (unless restricted) on the internet is a promotion made directly to consumers, the mere presence of a promotion on a pharmaceutical company's internet home page may increase the potential liability of the company.

The learned intermediary rule is a particular source of difficulty for pharmaceutical companies seeking to advertise on the internet. Under traditional product liability law, prescription drug manufacturers have not had to provide warnings directly to consumers. Instead, they have been permitted to direct their warnings to physicians who act as a learned intermediary, and provide the necessary warnings to consumers. The learned intermediary rule has relieved pharmaceutical companies of the difficult task of creating warnings about prescription drugs that would be meaningful to the average consumer.

While there have been almost no cases that have addressed the issue, commentators have suggested that promotion of prescription drug products directly to consumers may increase liability because such promotion circumvents the logic of the learned intermediary rule.<sup>46</sup> This is partly the reason that some pharmaceutical companies have been reluctant to advertise directly to consumers, and is why the types of products advertised directly to consumers tend to be those that are relatively safe or for relatively uncomplicated conditions, such as antihistamines and analgesics. This may be one reason why only generally safe products end up being promoted over the internet or through other forms of electronic communication.

Thus, a primary concern in creating a home page or other electronic communication regarding a pharmaceutical product should be the effect, if any, that the dissemination of the contents to consumers will have on potential product liability.<sup>47</sup>

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<sup>45</sup> *Life Plus' Ads for ShapePlus and Endogen Referred to FTC*, F-D-C REP. ("The Tan Sheet"), July 22, 1996, at 6-7.

<sup>46</sup> See, e.g., Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829 (1991).

<sup>47</sup> A number of cases have held the learned intermediary rule should not apply in the case of oral contraceptive drugs, because information on the drug products — although required to be disseminated by

Another concern relates to the type of product involved. If the product is a controlled drug, is it appropriate to promote it to consumers? While there is no specific statutory or regulatory prohibition, the Drug Enforcement Administration (DEA) has taken a position against direct-to-consumer advertising of controlled drugs, arguing that such advertising could increase demand and therefore abuse. According to the DEA, such ads would encourage "narcotic addicts to obtain controlled substances by conning physicians into prescribing drugs for phony symptoms."<sup>48</sup> The DEA has urged the FDA to allow only nonproduct specific and disease-oriented information to be disseminated to consumers.

### VIII. CONCLUSION

The promotion of pharmaceutical products on the internet to consumers raises a variety of legal issues, most of which are unresolved but evolving. The FDA should issue some form of draft guidance by the end of 1996. In the interim, however, companies should treat internet home pages and other emerging forms of electronic communication as subject to the same types of restrictions and other legal concerns that currently apply to promotion of pharmaceutical products under existing laws and regulations.

It is unlikely that the FDA will issue new regulations to deal with advertising of pharmaceutical products on the internet; the agency has made it clear that its current legislative authority is sufficient. As noted above, however, many companies may be reluctant to advertise on the internet because of product liability concerns. For the foreseeable future, there are bound to be a number of unresolved issues concerning this form of pharmaceutical promotion.

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FDA regulations — was provided directly to patients. *See, e.g.,* *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 960 (E.D. Wis.), *modified*, 532 F. Supp. 211 (E.D. Wis. 1981).

<sup>48</sup> FDA ADVERTISING & PROMOTION MANUAL MONTHLY BULL., May 1996, at 1.