

# Regulating Drug Promotion on the Internet

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## I. INTRODUCTION

“There is some frank quackery going on out there,” stated a panelist at a 1996 Food and Drug Administration (FDA) conference regarding drug promotion on the Internet.<sup>1</sup> Other commentators have likened the lawlessness of drug promotion on the Internet to the “wild west.”<sup>2</sup> In the past, food and drug law in the United States often has developed in response to fraudulent and dangerous medical claims.<sup>3</sup> Thus, with wild drug claims proliferating on the Internet, FDA’s intention to develop regulation for Internet drug promotion was unsurprising.<sup>4</sup>

Uncontrolled drug promotion on the Internet is a problem of relatively recent vintage.<sup>5</sup> Although the Internet was designed in the 1960s, initially the system was not open to private commercial use.<sup>6</sup> Then, following a series of technological changes, the National Science Foundation lifted its ban on commercial traffic on the Internet in 1991.<sup>7</sup> In the next few years, the user-friendly graphical interface of the World Wide Web (Web) grew quickly to cover much of the Internet. And drug manufacturers, both reliable and unscrupulous, joined other commercial enterprises in marketing their products over the new medium.<sup>8</sup>

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<sup>1</sup> Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), *FDA and the Internet: Advertising and Promotion of Medical Products*, Oct. 16-17, 1996, (last modified Nov. 20, 1996) <[www.fda.gov/opacom/morechoices/transcript1096/fdaint.html](http://www.fda.gov/opacom/morechoices/transcript1096/fdaint.html)> [hereinafter Internet Conference], at Discussion Group 2, Comments of Dr. Grebenau.

<sup>2</sup> *Id.* at Discussion Group 3, Comments of Dr. Allen Douma, Medical Director and CEO of Health Response Ability Systems (“[I]t is the wild frontier.”). See also *id.*, Comments of Lee Peeler, Associate Director for the Division of Advertising Practices, Federal Trade Commission (FTC) (“It is like the wild, wild west out there.”). Typical promotions on the Internet today include those for unapproved devices, dangerous herbal remedies and counterfeit drugs. See, e.g., Carl T. Hall, *HIV Do-It-Yourself Test Kits Worry U.S. Health Experts*, S.F. CHRON., Jan. 13, 1999, at A1; Amy Smith, *Medical Advice From Internet May Be Unsafe*, KNOXVILLE NEWS-SENTINEL, Jan. 26, 1998 (describing a consumer’s acute kidney failure after he ingested wormwood oil purchased over the Internet from a site promoting the toxic product as an herbal remedy); Russell Watson, *The Globe is Gaga for Viagra*, (last visited on Nov. 6, 1999) <[www.newsweek.com/nw-srv/issue/25\\_98a/printed/us/in0325.htm](http://www.newsweek.com/nw-srv/issue/25_98a/printed/us/in0325.htm)> (describing a lucrative Internet-based black market in products — including flour and corn starch — falsely promoted as “Viagra”).

<sup>3</sup> See, e.g., FOOD & DRUG LAW: CASES & MATERIALS (Peter B. Hutt & Richard A. Merrill, eds., 1991), at 1, 8; James C. Munch, *A Half-Century of Drug Control*, 11 FOOD DRUG COSM. L.J. 305 (1956), reprinted in FOOD & DRUG LAW, at 379.

<sup>4</sup> See F-D-C REP., Internet Advertising. See also *Promotion of FDA-Regulated Medical Products on the Internet*, Notice of Public Meeting, 61 Fed. Reg. 48,707 (Sept. 16, 1996).

<sup>5</sup> This article will use the term “drug” throughout, however, the analysis is intended to apply not only to drugs, but also to medical devices and other products currently regulated by FDA.

<sup>6</sup> The system was not designed for commercial purposes; its architects aimed to construct an information infrastructure capable of surviving a nuclear attack. For a concise history of the development and transformation of the Internet, see David W. Opperbeck, *How Should FDA Regulate Prescription Drug Promotion on the Internet?*, 53 FOOD & DRUG L.J. 47 (1998).

<sup>7</sup> See *id.*

<sup>8</sup> One typical unscrupulous site promoted home abortion kits capable of causing heavy internal bleeding, damage to reproductive organs, and death. See FDA Talk Paper, *FDA Warns Consumers on Dangerous Products Promoted on the Internet* (June 17, 1997). Although no longer available on the Web, the site stated that its product was a “[c]omplete kit for early pregnancy termination without surgery. Scientifically proven safe and unriskey [sic] . . . [t]he kit combines two common FDA approved medicines for treatment of rheumatoid arthritis, cancer and to prevent [sic] gastric ulcer produced by AINES.” Resolve Easy Website <[www.resolveeasy.com](http://www.resolveeasy.com)> (last updated Mar. 26, 1997).

Although FDA took action against some of the most egregiously misleading Internet promotions that began appearing, consumer groups, medical associations, and even some drug producers called on the agency to adopt a more comprehensive regulatory approach.<sup>9</sup> Doing so, however, has proven to be an exceedingly difficult task. Nearly three years after the 1996 conference, FDA still has not issued its promised guidance regarding drug promotion on the Internet.<sup>10</sup>

This paper addresses the challenges that FDA faces in developing comprehensive guidance for Internet drug promotion. It does so first by examining the agency's mandate and its efforts to date. Next, it considers the primary challenges the agency faces in developing guidance, including questions of jurisdiction, problems in developing content regulations, and unique enforcement challenges presented by the Internet itself. Finally, this paper concludes by sketching an outline for proposed FDA regulation of drug promotion on the Internet.

### A. Background

Regulating the promotion of pharmaceutical products is an important part of the FDA's statutory mandate.<sup>11</sup> Under the Federal Food, Drug, and Cosmetics Act (FDCA)<sup>12</sup> the term "promotion" includes both advertising and labeling.<sup>13</sup> If promotion is found to be false or misleading, the product being advanced will be considered "misbranded" and, hence, prohibited.<sup>14</sup>

Regulation of drug promotion is important for two reasons.<sup>15</sup> First, government intervention is needed to increase the quantity of product information available because, if left to free market forces, manufacturers tend to under-provide information.<sup>16</sup> Second, regulation plays an important role in monitoring the quality of information that consumers often are unable to verify for themselves.<sup>17</sup> Moreover, even where

<sup>9</sup> See, e.g., Peter S. Reichertz, *Legal Issues Concerning the Promotion of Pharmaceutical Products on the Internet to Consumers*, 51 FOOD & DRUG L.J. 355 (1996) [hereinafter Reichertz, *Legal Issues*].

<sup>10</sup> See, e.g., Peter S. Reichertz, *Understanding Government Regulation of the Marketing and Advertising of Medical Devices, Drugs, and Biologics: The Challenges of the Internet*, 52 FOOD & DRUG L.J. 303 (1997) [hereinafter Reichertz, *Challenges of the Internet*] (reiterating the initial call for guidance). Guidance had not been issued as of November 4, 1999. Telephone Interview with Melissa Moncavage, CDER (Nov. 4, 1999).

<sup>11</sup> FDA's recently enacted mission statement provides explicitly that the agency is to promote public health by taking appropriate and timely action on the marketing of regulated products. See Food and Drug Administration Modernization Act, Pub. L. No. 105-115, § 903(b), 111 Stat. 2296 (1997).

<sup>12</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301 et seq. (1994)).

<sup>13</sup> See 21 U.S.C. § 321(n).

<sup>14</sup> See *id.* § 331(b).

<sup>15</sup> Short of regulation, the threat of product liability may provide some incentive for manufacturers to provide information. See, e.g., Marilyn A. Moberg, James W. Wood & Howard L. Dorfman, *Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet*, 53 FOOD & DRUG L.J. 213, 219 (1998) (arguing that providing information might actually increase liability by undermining the "learned intermediary doctrine" which obligates prescribing physicians, rather than manufacturers, to provide additional information). See also Opperbeck, *supra* note 6, at 63 (arguing that on the Internet liability is unlikely to affect small operators who, if threatened by a lawsuit, "might disappear into cyberspace without a trace and without collectible assets.").

<sup>16</sup> Because information is not depleted when used, consumers often will be able to "free ride," or use information they value without paying for it, and difficulty in charging consumers will lead manufacturers to under-provide information. See, e.g., Federal Trade Commission, Comments of the Staff of the Bureau of Consumer Protection & the Bureau of Economics of the Federal Trade Commission, In the Matter of Direct-to-Consumer Promotion: Public Hearing (Jan. 11, 1996).

<sup>17</sup> See J. Howard Beales, III, *FDA Regulation of Pharmaceutical Advertising: An Economic Analysis*, 24 SETON HALL L. REV. 1370 (1994). Manufacturers may exploit this fact by providing false information. See, e.g., Internet Conference, *supra* note 1, at Presentations, Comments of Lee Peeler, Associate Director for the Division of Advertising Practices at the FTC ("[C]heap, user-friendly software now enables even computer novices to create professional-looking homepages. The potential for deception, with its attendant risks to public health in the case of prescription drugs, is too great simply to allow the Internet to police itself in this area.").

information technically is accurate, regulation of quality is important to ensure that pharmaceutical information is presented in a format accessible to consumers.<sup>18</sup>

### B. Regulatory Actions to Date

FDA first began gathering information about product promotion on the Internet in 1995, when it held a series of meetings with regulated companies.<sup>19</sup> Based on these private meetings, FDA held an Internet Conference in October 1996 to gather information about issues implicated by potential regulation of drug promotion on the Internet.<sup>20</sup> The Internet Conference included panels addressing: 1) the promotion of unapproved uses of approved products; 2) communications in Internet chat rooms; 3) general regulatory issues; 4) the linking of sites; and 5) international issues.<sup>21</sup>

Following the 1996 Internet Conference, FDA continues to initiate enforcement actions against specific Internet promotions it considers false and misleading.<sup>22</sup> These enforcement proceedings typically target websites promoting products without clearance, promoting approved products for unapproved uses, or otherwise employing misleading or unsupported claims.<sup>23</sup> In general, this approach by FDA has proven effective at least in deterring the specific parties against whom actions are brought.<sup>24</sup> Also, FDA supplemented its case-by-case approach in 1997 by joining other public and private agencies to “sweep” the Internet in search of deceptive health claims.<sup>25</sup> In October 1998, FDA participated in a second and expanded sweep.<sup>26</sup>

Critics argue that FDA’s enforcement actions and annual sweeps constitute a sporadic and insufficient approach. As one commentator noted, “most of the formal objections made by [the] FDA are fairly obvious promotional violations — promotion of unapproved uses and investigational products. To a large extent, some of the more

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<sup>18</sup> In a survey of medical sites on the Web, FDA found that most product information used technical language suited to health care professionals, not patients. See Notice of Public Meeting, *supra* note 4, at 48,709.

<sup>19</sup> See Internet Conference, *supra* note 1, at Opening Remarks of William B. Schultz.

<sup>20</sup> *Id.*

<sup>21</sup> For a description of the issues addressed in the 1996 FDA Internet Conference, see generally Marc J. Scheineson, *Legal Overview of Likely FDA Regulation of Internet Promotion*, 51 FOOD & DRUG L.J. 697 (1996).

<sup>22</sup> The agency issued its first warning letter prior to the Internet Conference. See SPOTLIGHT ON FOREIGN COMPANIES, U.S. MEDICAL WEB PAGE PROMO, WARNING LETTER BULLETIN (July 1, 1996). FDA has continued to initiate enforcement actions, targeting large corporations, small companies, and individuals. For example, the large pharmaceutical manufacturer, Merck, received a warning in response to a misleading news report on its website. See, e.g., F-D-C REP. (“The Pink Sheet”), Jan. 4, 1999, at 61(1). A small mail order company, Medications Express, received a letter challenging its practice of helping customers illegally import prescription drugs from Mexico. See Mike Schwartz, *Sun City Firm Closes Web Site After Getting Letter From FDA*, PRESS ENTERPRISE, Nov. 29, 1998, A-section. An individual physician received a warning for his website promoting an unapproved muscular dystrophy treatment as safe and effective. See *Dateline NBC, Profile: One Step at a Time: Experimental Treatment for Muscular Dystrophy*, (NBC television broadcast, Dec. 28, 1998).

<sup>23</sup> See Kristen Green, Note, *Marketing Health Care Products on the Internet: A Proposal for Updated Federal Regulations*, 24 AM. J.L. & MED. 365, 373-74 (1998).

<sup>24</sup> Merck, for example responded to the FDA warning by stating that its violation had been “inadvertent,” and removed the offending promotion from its site. See F-D-C REP., Jan. 4, 1999, *supra* note 22, at 29. The physician warned about promoting his unapproved muscular dystrophy treatment, likewise, apologized for the transgression and corrected his website. See *Dateline NBC, One Step at a Time*, *supra* note 22. Occasionally, however, promoters have proven less compliant with FDA demands. See, e.g., Schwartz, *Firm Closes Web Site*, *supra* note 22 (quoting the president of challenged company as stating that, although he had taken down his website, “I’m just servicing it. . . . It will be back up in a few weeks.”).

<sup>25</sup> See, e.g., *Herbal Dietary Supplement Internet Disease Claims Get Scrutiny*, FOOD LABELING NEWS Nov. 11, 1998, at 7(5).

<sup>26</sup> The sweep reviewed 1200 Internet sites for deceptive claims regarding the treatment, cure, or prevention of six specific diseases: arthritis, cancer, diabetes, heart disease, HIV/AIDS, and multiple sclerosis. See *id.*

complex issues — links, chat rooms, international issues, format — have not been addressed formally, although there has been much discussion.<sup>27</sup> These critics assert that comprehensive FDA guidance is needed not only to protect consumers, but also to protect drug producers, many of whom are awaiting a green light from FDA before going online.<sup>28</sup> The critics argue that guidance will lower social costs by informing parties of FDA expectations in an *ex ante* fashion, rather than requiring producers to invest in developing expensive Internet promotions only to find themselves subject to FDA challenge in an *ex post* enforcement proceeding.

Despite these critiques, however, FDA has yet to produce comprehensive guidance regarding drug promotion on the Internet. If the agency persists in its silence, problems of Internet drug promotion likely will expand in the years to come.<sup>29</sup> Surveys indicate that disease information already is the most sought-out category of information on the Internet, and market researchers predict that the Internet will become the single greatest source of health care information within the next five years.<sup>30</sup> Even FDA admitted that a more comprehensive approach is necessary.<sup>31</sup>

## II. CONSIDERATIONS IN DEVELOPING GUIDANCE

### A. Jurisdiction

The threshold question in analyzing FDA's role in regulating drug promotion on the Internet is one of jurisdiction. While FDA has the authority to regulate drug "labeling," Congress assigned the authority to regulate drug "advertising" to the Federal Trade Commission (FTC).<sup>32</sup> Congress later transferred responsibility for prescription drug advertising to FDA, but the FTC retains the authority to regulate advertising of nonprescription drugs.<sup>33</sup> Thus, in determining jurisdiction in regulating drug promotion on the Internet, the two agencies must determine whether Internet drug promotion constitutes drug advertising or drug labeling. Most commentators have concluded that Internet promotions, quite easily, could qualify as either.<sup>34</sup> Further complicating matters, FDA has offered conflicting clues about which categorization it considers more appropriate for regulation of drug promotion on the Internet.<sup>35</sup>

<sup>27</sup> See Reichertz, *Challenges of the Internet*, *supra* note 10, at 307.

<sup>28</sup> See, Green *supra* note 23, at 1 ("[M]any drug and medical device makers remain inactive waiting for the FDA and FTC to establish guidelines for Internet marketing."). *But see* Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary?* 42 ST. LOUIS. U. L.J. 89, 104 (1998) (noting that most drug and device manufacturers already have moved online).

<sup>29</sup> Worldwide use of the Internet is expected to grow to 233,000,000 by the year 2000. See Hall, *supra* note 2, at A1.

<sup>30</sup> See *DTC Internet Ads Tied to Medical Institutions Can "Jump Start" Campaign*, F-D-C REP. ("The Pink Sheet"), Dec. 21, 1998, at 60(51).

<sup>31</sup> See, e.g., Notice of Public Meeting, *supra* note 4 (stating possible need for guidance); *Peer-Reviewed Studies Presumed "Sound" For Off-Label Dissemination*, F-D-C REP. ("The Pink Sheet"), Nov. 23, 1998, at 60(47) (stating that the agency is preparing a guidance document regarding Internet promotions).

<sup>32</sup> See FOOD & DRUG LAW, *supra* note 3, at 599. See also Memorandum of Understanding, 36 Fed. Reg. 18,538 (Sept. 9, 1971). Under the 1976 Medical Device Amendments, FDA also regulates promotion of restricted medical devices. Pub. L. No. 94-295, 90 Stat. 539.

<sup>33</sup> See 21 U.S.C. § 502(n) (Drug Amendments of 1962). Later, in the Vitamin-Mineral Amendments of 1976, Congress transferred to FDA responsibility for advertising of vitamins and minerals. See *id.* § 403(a)(2) and § 707 (Vitamin-Mineral Amendments of 1976).

<sup>34</sup> See, e.g., Moberg, Wood & Dorfman, *supra* note 15, at 217 ("As a hybrid of print and electronic communication, Internet-provided information about a pharmaceutical or medical device on the Internet is likely to be subject to regulations that apply to either. . ."); Opderbeck, *supra* note 6, at 56-57; Scheineson, *supra* note 21, at 705-06.

<sup>35</sup> For example, Melissa Moncavage of the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) stated, "For now, we're letting drug companies choose whatever category of current regulations

## 1. Advertising

FDA defines "advertising" as including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems."<sup>36</sup> Some commentators have argued that, because the Internet depends on "telephone communications systems," FDA has little choice but to classify all information broadcast across it as "advertisements."<sup>37</sup> If FDA adopts this reasoning, the FTC will gain jurisdiction to regulate all material on the Internet relating to over-the-counter (OTC) drugs. The OTC drug industry, in particular, seems to support this approach.<sup>38</sup>

The main problem with the "advertising" approach is its failure to present any normative justification for so dividing jurisdiction between FDA and the FTC. Although the original split in jurisdiction between the agencies may have been a political compromise, in dividing their workload today, it seems preferable for the agencies to do so in a manner that takes advantage of their relative expertise.<sup>39</sup> Also, because many of the rationales driving the rules for traditional advertising simply are not present in the context of the Internet, problems might arise if defining all Internet promotions as "advertising" led such promotions to be regulated in the same manner as traditional advertising.<sup>40</sup>

## 2. Labeling

Under the FDCA, labeling is defined as "written, printed, or graphic matter (1) upon or (2) accompanying" the product.<sup>41</sup> In practice, the range of material that can be defined as "labeling" for purposes of regulation by FDA is quite broad.<sup>42</sup> In *Kordel v. United States*,<sup>43</sup> the Supreme Court admitted that, "[e]very labeling is in a sense an advertisement."<sup>44</sup> The Court went on to create a broad definition of the term "labeling." It held that the term "accompanying" in the definition of "labeling," "is not restricted to labels that are on or in the article or package that is transported."<sup>45</sup> Instead, information might "accompany" a product, and hence qualify as labeling, as long as it "supplements or explains [the product]. . . . No physical attachment one to the other is necessary. It is the textual relationship that is significant. . . ." <sup>46</sup>

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they think best fits their presence on the Internet." *Drug Ads Casting Wider Net, Finding a New Home on the Web*, AM. MED. NEWS, Nov. 20, 1995, at 3, cited in Reichertz, *Legal Issues*, *supra* note 9, at 357. But see *Device Information on the Internet Likely Constitutes Labeling*, M-D-D-I REP. ("The Gray Sheet"), July 15, 1996, at I&W5-6 (statement of Byron Tart that device information on the Internet "likely" constitutes labeling). See also FDA ADVERTISING & PROMOTION MANUAL § 637 (1997) (indicating that company homepages are "more like labeling" and information found elsewhere is more likely to be treated as "advertising").

<sup>36</sup> 21 C.F.R. § 201(1)(1) (1996).

<sup>37</sup> See Internet Conference, *supra* note 1, at Discussion Group 3, Comments of Jim Czaban, attorney at Venable, Baetjer, Howard, and Civiletti ("The FDA has a regulation . . . 21 C.F.R. § 202(1)(1), that I thought would have resolved the question. . . . [T]he Internet is a telephone communication system. . . .").

<sup>38</sup> See *id.* at Discussion Group 3, Comments of Mark Boulding ("There are a lot of companies, I think, that would prefer to be regulated by the FTC in their advertising.").

<sup>39</sup> See FDA-FTC Memorandum of Understanding, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

<sup>40</sup> For example, FDA's "brief summary" requirements obliging manufacturers to print a short statement describing warnings and contraindications in conjunction with an ad was developed in the context of space constraints that do not exist on the Internet. See 21 C.F.R. §§ 202.1(d)(3)-(4).

<sup>41</sup> *Id.* § 321(m).

<sup>42</sup> See generally FOOD & DRUG LAW, *supra* note 3, at 36-83.

<sup>43</sup> 335 U.S. 345 (1948).

<sup>44</sup> *Kordel v. United States*, 335 U.S. 345, 351 (1948).

<sup>45</sup> *Id.* at 349.

<sup>46</sup> *Id.* at 350.

Following *Kordel*, FDA expanded its interpretation of labeling to include written and oral information supplementing or explaining products.<sup>47</sup> Under this broad definition, information published on the Internet might be seen as “supplementing or explaining a product,” and, hence, qualify as labeling for purposes of FDA regulation. But the all-labeling approach appears to be just as flawed as the all-advertising one; the labeling approach would split authority between FDA and the FTC without any consideration of the relative expertise of the two agencies. Likewise, if the classification triggered application of traditional labeling rules, it would subject all electronic promotion of regulated products to disclosure requirements developed in another context and not necessarily appropriate for promotion on the Internet.

### 3. *Third Party Approach*

A third approach to the advertising/labeling issue is to define information on a manufacturer’s website as labeling and information placed by the manufacturer elsewhere on the Internet as advertising.<sup>48</sup> If FDA and the FTC formally adopt this “third party approach,” FDA would regulate manufacturers’ websites and the FTC would retain jurisdiction to regulate most drug information placed with third parties.

The third party approach has several advantages. First, it utilizes FDA expertise by allowing the agency to monitor technical medical disclosures by manufacturers on their websites. In doing so, FDA can ensure that consumers have access to full and accurate information in at least one location on the Internet.<sup>49</sup> In addition, by assigning primary responsibility for regulating drug information on third party sites to the FTC, the Commission can apply skills it has developed in other arenas in regulating general disclosures. For example, outside of the food and drug context, the FTC often has dealt with disclosure issues such as when information placed with a third party must be acknowledged as a paid advertisement and when payments for endorsements must be disclosed.

## B. *Content Regulation*

After defining the scope of its jurisdiction, FDA must offer guidance regarding the content of promotions falling within that range. Guidance should shed light on what promotional content will and will not be considered misleading.<sup>50</sup> Traditionally, the agency has defined misleading with reference to the most easily-misled segment of the audience.<sup>51</sup> In developing guidance for the Internet, however, many parties

<sup>47</sup> See, e.g., Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52,800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52,800 (Oct. 8, 1996).

<sup>48</sup> This approach is used by CDRH within FDA. FDA ADVERTISING & PROMOTION MANUAL, *supra* note 35, § 637.

<sup>49</sup> At least one court found clear support for an informational floor. *Alberty Food Prods. Co. v. United States*, 185 F.2d 321 (9th Cir. 1950) (holding that consumers “are at least entitled to a chance to somewhere find and examine a ‘label’ which is complete enough to give them information which would lead them to purchase a drug for that purpose.”). Commentators, too, have argued that full information should be available in at least one place on the Internet. See Internet Conference, *supra* note 1, at Discussion Group 3, Comments of Tim Fallon, Director for Medscape (“If you go to a [search engine] and run a couple of searches and look at the sources for the information that are currently driving the information to consumers, it can almost make an argument that it is more irresponsible not to have an official presence with full disclosure information on the Internet.”).

<sup>50</sup> As noted above, if promotions are misleading, the product so promoted will be found to be “misbranded” and, hence, prohibited under the FDCA. See 21 U.S.C. §§ 331(b), 321(n).

<sup>51</sup> See, e.g., *United States v. Article Consisting of 216 Cartoned Bottles . . . “Sudden Change”*, 409 F.2d 734 (2d Cir. 1969) (Law should protect “the ignorant, the unthinking and the credulous.”). *But see United States v. 88 Cases . . . Bireley’s Orange Beverage*, 187 F.2d 967 (3d Cir. 1951) (“The correct standard was the reaction of the ordinary consumer . . . who is neither savant nor dolt.”).

have urged FDA to apply a "reasonable user" standard instead.<sup>52</sup>

If FDA adopts a "reasonable user" standard for the Internet, that decision would produce less stringent regulatory requirements.<sup>53</sup> Many commentators have argued that this is an appropriate outcome because, unlike targets of traditional promotional campaigns, Internet users who come into contact with drug promotions often do so because they have sought out such information.<sup>54</sup> Moreover, commentators claim Internet users' searches are likely to turn up additional information on the same topic, thereby contributing to the overall "balance" of information they receive.<sup>55</sup> Finally, as the FTC noted in comments to FDA, Internet advertising is unlike television advertising where brevity "makes it very difficult to include lengthy or complex disclosures or do so in a comprehensible manner. . . . [By contrast,] Internet advertising can be read at one's own pace and can be saved or printed for the future."<sup>56</sup>

### 1. *Mandatory Content Requirements*

Once FDA determines how it will approach the question of what is misleading, it must apply that baseline to develop more specific guidelines for drug promotion on the Internet. Typically, FDA employs both affirmative and negative content regulations. Focusing first on the former, affirmative content requirements generally consist of both general and specific mandated disclosures.

General disclosure requirements may be necessary to signal to consumers that they are looking at promotional material.<sup>57</sup> Disclosures of funding or sponsorship are important, particularly where consumers are least likely to suspect that they are viewing paid promotions.<sup>58</sup> Also, given that outdated information may be misleading,

<sup>52</sup> See Internet Conference, *supra* note 1, at Comments of Al Rusch, Special Counsel, Division of Enforcement, Securities and Exchange Commission (SEC) (noting that the SEC requires only such disclosures as "a reasonable investor would consider important in whether to buy or sell a particular security. Obviously, you can translate that into the context of a reasonable patient."). See also *id.* at Comments of David Vance, attorney for Glaxo Wellcome ("We can't protect the idiot and I hope we won't . . . dumb down to the lowest common denominator.").

<sup>53</sup> Working against a looser standard, FDA traditionally has been skeptical of drug company efforts to market prescription drugs directly to consumers. See, e.g., 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), printed in Reichertz, *Legal Issues*, *supra* note 9, at 358. The Internet is in fact one of the fastest growing forms of direct-to-consumer (DTC) advertising. See F-D-C REP., *Internet Ads Can Jump Start Campaign*, *supra* note 30, at 23. For additional information on the rapid expansion of DTC marketing, see Rachel X. Weissman, *But First Call Your Drug Company*, 20 AM. DEMOGRAPHICS 10 (Oct. 1, 1998).

<sup>54</sup> See, e.g., Internet Conference, *supra* note 1, at Presentations, Comments of Lee Peeler, Associate Director for the Division of Advertising Practices at the Federal Trade Commission.

<sup>55</sup> See Opderbeck, *supra* note 6, at 60-61.

<sup>56</sup> *Id.*

<sup>57</sup> See, e.g., Internet Conference, *supra* note 1, at Discussion Group 1, Comments of Lou Morris, Branch Chief for the Marketing Practices and Communications Branch in CDER ("I guess one of the differences between searching through a medical journal and looking through the Internet is when I'm searching through a medical journal and I see an advertisement, it looks like an advertisement. When I click on the Internet, I don't know where I am. . . .").

<sup>58</sup> See *id.* at Discussion Group 1, Comments of Janis Kelly, medical journalist ("I think . . . funding for studies should be identified."). See also *id.* Comments of Mr. Whitaker (noting that, with respect to postings of clinical trials, "patients are likely to see that as just factual information when, in fact, on our site those are paid ads."); *Id.* at Discussion Group 4, Comments of Dr. Sara Stein, clinical research psychiatrist at Stanford University ("[S]earch engines have begun to sell a place in the list. . . . The first ten hits you get on any search there have been paid for. . . ."); F-D-C REP., *Internet Ads Can Jump Start Campaign*, *supra* note 30 (noting that by purchasing links on sites sponsored by reputable medical institutions, manufacturers can create in consumers' minds an image of "reliability and trustworthiness").

disclosure stating when a promotion was updated last is another type of information likely to be mandated.<sup>59</sup> A third area for general disclosure requirements relates to privacy.<sup>60</sup> While privacy concerns on the Internet are not limited to medical sites, information gathered from health-related sites may raise significant concerns given the sensitive nature of health information.<sup>61</sup> While some manufacturers voluntarily disclose their privacy policies, as well as sources of funding and post "last updated" dates in the absence of regulation, other sites have chosen not to do so.<sup>62</sup>

Specific mandatory requirements under the FDCA apply to both labeling and advertising. All drug labeling, for example, must contain "adequate directions for use."<sup>63</sup> Thus, FDA requires that manufacturers provide as much specific information about their products as is necessary for laymen to "use a drug safely and for the purposes which it is intended."<sup>64</sup> As for advertising, the FDCA requires advertisers to present a "fair balance" of information about their products.<sup>65</sup> The agency, however, has not defined what constitutes "fair balance."<sup>66</sup> Many commentators at the Internet Conference suggested that the agency should require simple warnings in laymen's terms on home pages, with links to more detailed information about the product.<sup>67</sup>

## 2. Prohibited Content

The fact that FDA prohibits certain content from appearing in drug promotions stems from the limited nature of drug approvals. Drug approvals confer on manu-

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<sup>59</sup> If regulators choose a more expansive monitoring duty, the scope of that duty could range from simply ensuring that sites are not altered by hackers to requirements that manufacturers actively correct outdated information on their sites or even monitor the veracity of information posted on sites to which they link. See Moberg, Wood & Dorfman, *supra* note 15, at 223.

<sup>60</sup> See, e.g., White House, A Framework for Global Electronic Commerce, available at <[www.whitehouse.gov/WH/New/Commerce/read.html](http://www.whitehouse.gov/WH/New/Commerce/read.html)> (noting that the Internet, "facilitates the collection, reuse, and instantaneous transmission of information [and] can, if not managed carefully, diminish personal privacy.>").

<sup>61</sup> Many health-related sites solicit fairly extensive personal information from visitors. For example, the pharmaceutical manufacturer Zeneca offers a \$5 rebate on its migraine treatment to patients who provide it with personal data by completing a survey. See F-D-C REP., *Internet Ads Can "Jump Start" Campaign*, *supra* note 30, at 23.

<sup>62</sup> Glaxo Wellcome, for example, offers a clearly labeled link to a detailed privacy policy. See *Glaxo Wellcome Inc. Internet Privacy Statement* (visited on Jan. 18, 1999) <[www.imgw.com/privacy.htm](http://www.imgw.com/privacy.htm)>. Another large manufacturer, Merck, also offers information about its privacy policy, though it does so through a link stating, "Confused by cookies?" See *Merck Homepage* (visited on Jan. 18, 1999) <[www.merck.com](http://www.merck.com)>. Smaller manufacturers, by contrast, seldom post privacy policies at all. See, e.g., *HIVhometest Homepage*, (visited Jan. 26, 1999) <[www.hivhometest.com](http://www.hivhometest.com)>.

<sup>63</sup> 21 U.S.C. § 502(f).

<sup>64</sup> 21 C.F.R. § 201.5.

<sup>65</sup> 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(5)(ii). Even where advertising space is limited, the Act requires a brief summary of the indications, contraindications, side effects and warnings for use of the product. 21 U.S.C. § 352(n).

<sup>66</sup> In its initial Federal Register notice announcing the 1996 meeting, FDA queried "should 'fair balance' be considered in the presentation of information on every screen? In every advertisement or promotional piece? Or on the entire website?" Notice of Public Meeting, *supra* note 4, at 47,809.

<sup>67</sup> See, e.g., Internet Conference, *supra* note 1, at Discussion Group 3, Comments of Phil McKee, National Consumers League. FDA, however, has indicated that a reference to full prescribing information may be insufficient to constitute fair balance in an Internet promotion. See Ronald M. Schwartz, *FDA Issues Warning on Wayward Website*, AM. DRUGGIST, Feb. 1997, available in WL 7972051. See also DDMAC UNTITLED LETTERS, WARNING LETTER BULLETIN, Nov. 23, 1998 (warning a manufacturer that a hypertext link to risk information was not sufficient to provide fair balance.) Presumably, the agency fears that consumers will fail to follow links and thus will miss detailed risk information if it is provided only through a link rather than directly on the homepage.

facturers only the right to promote their products for the specific FDA-approved use.<sup>68</sup> If manufacturers wish to promote products for different or "off-label" uses, they must gain additional FDA approval to do so.<sup>69</sup>

FDA claims that prohibiting promotion of off-label uses serves two goals. First, the agency claims that the prohibition helps protect against widespread use of drugs in a manner that has not been proven safe and effective.<sup>70</sup> Second, FDA argues that the prohibition on promotion of off-label uses gives manufacturers the incentive to conduct additional testing of their already-approved products to gain the authority to promote the new use.<sup>71</sup>

FDA's off-label policy presents one of the most difficult challenges to developing guidance for Internet regulation.<sup>72</sup> First, from a practical view, the difficulty arises because it may be impossible to suppress off-label information on the Internet. Second, from a policy standpoint, it may be undesirable to do so. Finally, even if suppression was a feasible and efficient approach, the First Amendment may bar FDA from adopting an approach restrictive of commercial speech.

#### a. *Practical Considerations Regarding Off-Label Policy on the Internet*

FDA already stated its intention to prohibit off-label promotions on the Internet, just as it has done with promotions on traditional media.<sup>73</sup> Attempting to effectuate such an approach, however, will involve significant practical hurdles. Primary among these is the fact that on the Internet manufacturers are not the only suppliers of information.

Off-label use information will be available from a wide range of non-manufacturer sources available on the Internet. Patient groups and individual patients, for example, frequently post information on the Web offering details about off-label uses.

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<sup>68</sup> In the 1962 amendments to the FDCA, Congress amended the definition of "new drug" to clarify that all drugs must be proven safe and effective for a particular use. See 21 U.S.C. § 321(p).

<sup>69</sup> Off-label uses include "treating a condition not indicated on the label, or treating the indicated condition but varying the dosing regimen or the patient population." *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998). The court in *Friedman* noted that "[f]or a manufacturer to promote its product for off-label use without gaining the necessary approval constitutes misbranding, and is prohibited. See 21 U.S.C. §§ 352, 331(b)." *Id.*

<sup>70</sup> For example, anti-arrhythmic drugs, once commonly prescribed off-label for heart attack survivors with a high rate of ventricular premature beats, later were found to increase mortality in those patients. FDA cites this and other cases in which health care professionals assumed an approved drug would work for additional uses, only to be proven wrong by later clinical testing, in a 1994 Federal Register notice. 59 Fed. Reg. 59,820, 59,825 (1994) See also *Schering Inron A and Genentech Pulmozyme Supplemental Applications Illustrate Importance of Clinical Evaluation of Off-Label Uses*, F-D-C REP. ("The Pink Sheet"), Feb. 26, 1996, at 6.

<sup>71</sup> 59 Fed. Reg. 59,820, 59,825 (1994); Apr. 1997 Hearing (comments of FDA officials Michael Friedman and William Schultz); Testimony of Michael Friedman, Deputy Commissioner for Operations, Food and Drug Administration, Department of Health and Human Services, House Government Reform and Oversight, Human Resources and Intergovernmental Relations, Fed. Doc. Clearing House, Inc., Sept. 12, 1996, available in LEXIS; *The FDA in the Senate*, WASH. POST, July 23, 1997, at A22; *Rep. Burr Drugs/Biologics Reform Bill Drops Information Dissemination Provisions; AAP Opposes Off-Label Promotion of Pediatric Information by Sponsors*, F-D-C REP. ("The Pink Sheet"), Apr. 18, 1997, at 8; Trade & Gov't Memos, F-D-C REP. ("The Pink Sheet"), Sept. 9, 1996, at T&G-1.

<sup>72</sup> For more information about FDA's problems with unapproved uses of approved drugs, see FOOD & DRUG LAW, *supra* note 3, at 462-66.

<sup>73</sup> For example, FDA cited Palomar Medical Technologies for using its website to promote an off-label use. The agency warned Palomar that, "promotional materials distributed via the Internet are regulated by the Agency in the same manner as materials distributed by other means. . . . If Palomar uses the Internet in the future, you should ensure that promotional claims are limited to the intended uses that were cleared in your 510(k) premarket notification." *Warning Letter to Positive Response Television* (July 9, 1996), printed in FDA ADVERTISING & PROMOTION MANUAL, App. IV, at C-225.

FDA does not propose to prohibit these groups from publishing such information.<sup>74</sup> Given the linked nature of the Web, however, it will be difficult for FDA to block links between non-commercial sources of off-label information and commercial sources.<sup>75</sup> As a participant at FDA's conference put it, "I don't think restricting access is a very doable solution. I really don't."<sup>76</sup>

Compounding problems, it would be difficult for FDA to stem the flow of off-label use information in view of the fact that manufacturers may disseminate such information under certain circumstances. The Food and Drug Administration Modernization Act of 1997 (FDAMA)<sup>77</sup> expanded this exception so that, at present, manufacturers who have stated an intention to seek FDA approval for a particular off-label use may disseminate to health care professionals and other specified recipients, peer-reviewed articles detailing that use.<sup>78</sup> There is nothing to prohibit the use of the Internet as a vehicle for such distribution, provided that manufacturers comply with the prerequisites necessary to fall within the exemption.<sup>79</sup>

Another problem in prohibiting off-label information may arise if other government agencies require manufacturers to place such information on the Internet. The Securities and Exchange Commission (SEC) rules, for example, may require that corporations publish information about investigational uses of their products as part of mandatory disclosure to investors. Although some commentators argue that manufacturers simply can organize sites to segregate such information, others contend that anyone using a search engine may end up reading prohibited information on the manufacturer's site regardless.<sup>80</sup>

### b. *Policy Considerations in Developing Off-Label Policy on the Internet*

Policy considerations may militate against a "suppression" approach to off-label use information on the Internet as well. Assuming that FDA is able to prevent manu-

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<sup>74</sup> See, e.g., Internet Conference, *supra* note 1, at Discussion Group 1, Comments of FDA Moderator Wayne Pines ("FDA certainly, while it can control what pharmaceutical companies and medical device companies and biologics companies put on the Internet, really can't control what consumers or what medical researchers independently put on the Internet."); *id.*, Comments of Bill Schultz, FDA Office of Policy (noting that with respect to publication of off-label information by "a medical journal, a patient group, a writer, the rules are very open and we don't really get involved"). See also Opderbeck, *supra* note 6, at 58.

<sup>75</sup> FDA might try to stop manufacturers from linking their sites to sites discussing exclusively off-label information uses. But conceptually, it would be more difficult for the agency to block links to sources like the New England Journal of Medicine, that only occasionally discuss off-label uses and that are available in print in public libraries. Moreover, enforcing a "no links to off-label information" policy would present huge administrative obstacles. Even if the agency could visit and review the complete contents of every site to which a manufacturer linked, it could never review all of the "third-generation sites," accessible through links from the linked site. See, e.g., *Internet Ads Can "Jump Start" Campaign*, *supra* note 30, at 23.

<sup>76</sup> Internet Conference, *supra* note 1, at Discussion Group 1, Comments of Janis Kelly, medical journalist. ("I think the idea of restricting access is not only not doable but a mistake in terms of communication and freedom of speech."); *id.* at Comments of Mario Cavallini, Web designer for medical publisher, Slack, Inc. ("I don't think it is going to be feasible to try and rule out cases, to say thou shalt not, because there are going to be all sorts of people who are going to 'shall' anyway.")

<sup>77</sup> Pub. L. No. 105-115, § 401, 111 Stat. 2296.

<sup>78</sup> See *id.* (describing additional conditions manufacturers must fulfill in order to promote off-label uses under this provision).

<sup>79</sup> FDA DIVISION OF DRUG MARKETING, ADVERTISING AND COMMUNICATIONS, CURRENT ISSUES AND PROCEDURES 6-7 (1994).

<sup>80</sup> See, e.g., Internet Conference, *supra* note 1, at Discussion Group 1, Comments of Becky Cleavenger, Regulatory Affairs Officer at AMGEN. *But see id.* at Comments of Janis Kelly, medical journalist.

facturers from promoting off-label uses of their products on the Internet, as noted above, it does not intend to prohibit other parties from publishing the same. Thus, in prohibiting manufacturers from presenting such information, FDA will silence only the speakers with the best information on the topic.<sup>81</sup>

This effect of a restrictive off-label information policy is troubling in light of recent trends in the health care industry making the need for accessible and accurate information acute.<sup>82</sup> In particular, the growth of managed care has forced consumers to take a more active role in monitoring their own health care. Patients no longer can expect to have a long-standing relationship with a doctor who will look out for their interests.<sup>83</sup>

FDA has recognized the utility of the Internet in helping to educate consumers in other contexts.<sup>84</sup> The FTC has emphasized the value of commercial information in making health care choices.<sup>85</sup> Thus, given the educational power of the Internet and the value of commercial information, policy decisions restricting educational potential should be scrutinized carefully.<sup>86</sup>

Further undermining the wisdom of the "suppression" approach, economists that study advertising repeatedly have found that government restrictions on advertising lead to higher prices, lower quality, and a reduced rate of innovation for the product.<sup>87</sup> Moreover, permitting manufacturers to distribute only partial information can be confusing to consumers.<sup>88</sup> Finally, and perhaps of greatest consequence, is the vacuum

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<sup>81</sup> See *id.* at Discussion Group 4, Comments of Dr. Allen Douma, Medical Director for Health Response Ability Systems ("I want to ask us all . . . why do we, in fact, want to prevent the distribution of off-label information by a certain subset of our society? In this case, it is people, perhaps who have a vested interest and that is our concern. But they also have the best information.").

<sup>82</sup> Rachel X. Weissman, *But First Call Your Drug Company*, (last visited on Nov. 6, 1999) <[www.demographic.com/Publications/AD/98\\_ad/9810\\_ad/ad981008.html](http://www.demographic.com/Publications/AD/98_ad/9810_ad/ad981008.html)> (noting that a 1997 study indicated that 54% of consumers think Health Maintenance Organizations are more interested in their bottom lines than they are in their patients' health and arguing that DTC advertising has played a useful role in offsetting high levels of distrust by facilitating increased self-education by patients).

<sup>83</sup> A 1998 study by Deloitte & Touche found that 25% of patients had changed physicians within the past two years and the amount of time patients spent with physicians on visits had dropped as well. See *id.*

<sup>84</sup> For example, in loosening the brief summary requirement for broadcast DTC promotions, FDA stated that the summary was unnecessary if the sponsor provides "an effective mechanism by which the majority of a potentially diverse audience can receive the advertised product's approved labeling," including by "(4) [p]roviding an address for an Internet Web page that includes the package insert." Guidance for Industry/Consumer-Directed Broadcast advertisements (visited Jan. 20, 1999) <[www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm)>.

<sup>85</sup> See, e.g., FTC, *In the Matter of Direct-to-Consumer Promotion*, *supra* note 16 ("Truthful and non-misleading advertising can help consumers manage their own health care. Advertisements can, for example, provide timely information regarding medical advances, remind consumers about good health care practices, and supply information needed by consumers to understand and evaluate their physician's recommendations. . . . With the growth of managed care organizations, consumers are expected to become more actively involved in their own health care decisions.").

<sup>86</sup> See, e.g., Internet Conference, *supra* note 1, at Discussion Group 1, Comments of Wendy Borow, President of the media division of Medicus ("Clearly, patients are taking more responsibility for their own healthcare. In the managed care environment in which we live, that is something we should all be encouraging and [the FDA has] a great role to play.").

<sup>87</sup> See, e.g., Lee Benham, *The Effect of Advertising on the Price of Eyeglasses*, 15 J.L. & ECON. 337 (1972); Ronald S. Bond et al., *Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry*, in FTC BUREAU OF ECONOMICS STAFF REPORT (1980); John R. Scroeter et al., *Advertising and Competition in Routine Legal Service Markets: An Empirical Investigation*, 36 J. INDUS. ECON. 49 (1987); JOHN F. CADY, *RESTRICTED ADVERTISING & COMPETITION: THE CASE OF RETAIL DRUGS* (American Enterprise Inst. 1976).

<sup>88</sup> For instance, restrictions on DTC advertising initially prevented drug companies from advertising the conditions which their products were intended to treat. As a result, many viewers of an early Claritin® commercial for "a clear day with Claritin®," assumed that the antihistamine was an antidepressant. See Weissman, *supra* note 82.

that manufacturer silence can create.<sup>89</sup> Anonymous organizations and individuals often have fewer incentives to provide information accurately, and if FDA prevents the more responsible voices from speaking, Internet users may find the “good” voices gone and be left only with the “bad.”<sup>90</sup>

*c. First Amendment Considerations in Off-Label Policy  
on the Internet*

Assuming that FDA could restrict information about off-label and investigational uses on the Internet, and assuming it wanted to do so, a series of court cases calls into question the constitutionality of such an approach. The First Amendment states that “Congress shall make no law . . . abridging the freedom of speech. . . .”<sup>91</sup> In the “commercial speech” cases of the 1970s, the Supreme Court indicated that even advertisements deserve protection under the First Amendment. These and subsequent cases illuminate the constitutionality of restricting manufacturers’ promotion of off-label information on the Internet.

In *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,<sup>92</sup> the Court considered the constitutionality of Virginia’s ban on price advertising for prescription drugs and stated, “[i]t is a matter of public interest that [purchasing] decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.”<sup>93</sup> The Court concluded that the government might restrict *misleading* commercial speech consistent with the First Amendment, but condemned any government decision to suppress truthful information simply out of fear that consumers might use such information unwisely.<sup>94</sup> The Court stated:

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to the end is to open the channels of communication rather than to close them. . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.<sup>95</sup>

The Court in *Virginia Board* concluded, however, that to prevent deception the government might require commercial messages to “appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary.”<sup>96</sup>

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<sup>89</sup> Most manufacturers have incentives to adhere to FDA guidelines because of their on-going relationship with the agency, their reputation with the public, and their desire to avoid lawsuits down the line. *See, e.g.*, Richard A. Merrill, *Symposium on Regulating Medical Innovation: The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1781 (1996) (noting the on-going relationship between FDA and the manufacturers it regulates).

<sup>90</sup> *See, e.g.*, Internet Conference, *supra* note 1, at Comments of Dan McKillen, Moderator (noting with respect to consumers’ ability to obtain information over the Internet, “[t]hey are going to get it one way or the other. It is just a matter of whether they get it right . . .”).

<sup>91</sup> U.S. CONST. amend. I.

<sup>92</sup> 425 U.S. 748 (1976).

<sup>93</sup> *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976) (footnotes omitted).

<sup>94</sup> *See id.* at 770.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 772, n.24.

In a 1980 case, *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*,<sup>97</sup> the Court elaborated on the permissible extent of commercial speech regulation. In doing so, it developed a four-prong test applied in subsequent commercial speech cases. First, the Court asked whether the speech at issue was protected by the First Amendment.<sup>98</sup> It noted that some forms of speech, including inherently misleading speech or speech concerning unlawful activity, would not qualify for protection.<sup>99</sup> Second, assuming that the speech qualified for First Amendment protection, the Court asked whether the government interest at stake was “substantial.”<sup>100</sup> Third, the Court asked whether the regulation directly advanced the government goal. Finally, the Court asked if the regulation was “not more extensive than necessary” to advance the stated interest.<sup>101</sup>

Two decades later, the Supreme Court applied the *Central Hudson* test in *44 Liquormart, Inc. v. Rhode Island*<sup>102</sup> and held that Rhode Island’s statutory ban on price advertising for alcohol violated the First Amendment. Although they agreed on the outcome, the justices disagreed on the proper approach to analyzing the question. The majority placed heavy emphasis on the importance of commercial speech:

Even in colonial days, the public relied on “commercial speech” for vital information about the market. . . . In accord with the role that commercial messages have long played, the law has developed to ensure that advertising provides consumers with accurate information about the availability of goods and services. . . . It was not until the 1970’s, however, that this Court held that the First Amendment protected the dissemination of truthful and nonmisleading commercial messages about lawful products and services.<sup>103</sup>

Applying the *Central Hudson* test, the majority found that the speech at issue was “commercial” and that the state had a substantial interest in promoting responsible use of alcohol. In applying the third and fourth prongs, however, the majority noted that “the First Amendment directs that government may not suppress speech as easily as it may suppress conduct, and . . . speech restrictions cannot be treated as simply another means that the government may use to achieve its ends.”<sup>104</sup> The Court held that the government bears the burden of justifying a decision to act through a ban on speech, rather than through another method. That burden not being met in the case at hand, the Court held Rhode Island’s ban unconstitutional.<sup>105</sup>

The justices who wrote separately echoed the majority’s desire to protect truthful commercial information. Justice Scalia, concurring in part, emphasized that he shared “Justice Stevens’ aversion toward paternalistic governmental policies that prevent men and women from hearing facts that might not be good for them.”<sup>106</sup> Justice Thomas, also concurring in part, indicated that he would reject *Central Hudson* and accord commercial speech the same degree of First Amendment protection as any other.<sup>107</sup>

<sup>97</sup> 447 U.S. 557 (1980).

<sup>98</sup> *Id.* at 566.

<sup>99</sup> *See id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> 517 U.S. 484 (1996).

<sup>103</sup> *44 Liquormart*, 517 U.S. at 495-96 (citing Kozinski & Banner, *The Anti-History and Pre-History of Commercial Speech*, 71 TEXAS L. REV. 747 (1993)).

<sup>104</sup> *44 Liquormart*, 517 U.S. at 512.

<sup>105</sup> *See id.* at 516.

<sup>106</sup> *Id.* at 517 (Scalia, J., concurring).

<sup>107</sup> *Id.* at 518 (Thomas, J., concurring) (“I do not see a philosophical or historical basis for asserting that ‘commercial’ speech is of ‘lower value’ than ‘noncommercial’ speech.”).

Justice O'Connor, joined by Chief Justice Rehnquist, Justice Souter, and Justice Breyer, concurred in the judgment only.<sup>108</sup> She concluded that Rhode Island's test met the first three requirements of *Central Hudson* and failed only because Rhode Island might have reduced alcohol consumption through measures less restrictive than outright suppression of price advertising, for example, by establishing minimum prices or increasing sales taxes.<sup>109</sup>

More recently FDA's policies regarding off-label use information came under direct fire in *Washington Legal Foundation v. Friedman*.<sup>110</sup> The case challenged FDA Guidance Documents regarding manufacturer sponsorship of Continuing Medical Education (CME) seminars discussing off-label uses and manufacturer distribution of articles and textbooks addressing such uses.<sup>111</sup> In considering the constitutionality of the Guidance Documents, the court applied the *Central Hudson* framework.

The court began by rejecting FDA arguments that speech regarding off-label uses falls outside the scope of the First Amendment. The court considered FDA's arguments to this effect, "at best questionable in light of the Supreme Court's most recent commercial speech cases."<sup>112</sup> The court pointed out that the majority in *44 Liquormart* specifically rejected arguments that speech subject to regulation may be suppressed without regard to the First Amendment because suppression "cannot be treated simply as another means that the government may use to achieve its ends."<sup>113</sup>

Finding FDA bound by the First Amendment, the court next considered whether the off-label speech affected by the Guidance Documents was "commercial." The court noted that the question was a complicated one because, "[t]ypical 'commercial speech' is authored and/or uttered directly by the commercial entity that wishes to financially benefit from the message . . . [whereas] the speech that the manufacturers wish to 'communicate' is the speech of others — the work product of scientists, physicians and other academics."<sup>114</sup> Ultimately, however, the court concluded that the speech at issue was "commercial" because the articles chosen by manufacturers for redistribution referred to a specific product, called attention to desirable qualities of that product in an attempt to arouse a desire to buy it, and were distributed with financially-driven motivations in mind.<sup>115</sup>

Given the commercial nature of the speech involved in *Friedman*, the court next applied *Central Hudson* to evaluate the constitutionality of the challenged FDA restrictions. In response to FDA arguments that off-label speech inherently is misleading and, hence, categorically "unprotected" until FDA approves the claims, the court stated that the agency "exaggerates its overall place in the universe. . . . Interestingly, and quite significantly, FDA has a categorically different view on whether article reprints or CME seminars addressing off-label treatments are 'inherently

<sup>108</sup> *Id.* at 528 (O'Connor, J., concurring).

<sup>109</sup> *See id.* at 529.

<sup>110</sup> 13 F. Supp. 2d 51 (D.D.C. 1998).

<sup>111</sup> *See id.* at 57 (citing 62 Fed. Reg. 64,074 (Dec. 3, 1997)). The district court noted that the latter guidance would be superseded by statute one year after the effective date of FDAMA.

<sup>112</sup> *Friedman*, 13 F. Supp. 2d at 61.

<sup>113</sup> *Id.* (quoting *44 Liquormart*, 517 U.S. at 512, "Any lingering doubt as to whether the government may impose restrictions upon speech without offending the First Amendment merely because it has the authority to regulate the underlying activity was resolved in *44 Liquormart*. . . .").

<sup>114</sup> *Id.* at 62.

<sup>115</sup> *Id.* at 64 (drawing the definition of commercial speech from *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983)). The *Bolger* test asks, "(1) whether the speech is concededly an advertisement; (2) whether the speech refers to a specific product; and (3) whether the speaker has an economic motivation for disseminating the speech." 463 U.S. at 66.

misleading' when anyone other than the drug manufacturer is responsible for their dissemination."<sup>116</sup>

Proceeding to the second prong of *Central Hudson*, FDA claimed that its policies served two significant government goals.<sup>117</sup> The court rejected the first claimed goal — that of ensuring that physicians receive only accurate information.<sup>118</sup> But, in light of Congress' clear desire for manufacturers to submit supplemental new drug applications (NDAs) for approval of off-label uses, the court found that FDA alleged a substantial governmental interest in its desire to create incentives for the submission of such applications.<sup>119</sup>

Moreover, the court held that the third prong was met. The court recognized that "drug manufacturers often would like to avoid having to submit previously approved drugs to the FDA for subsequent approvals . . ." and noted further that restricting manufacturers' marketing options was one of the few approaches by which the agency might encourage manufacturers to submit the supplemental NDAs that Congress desired.<sup>120</sup>

Nonetheless, the court in *Friedman* invalidated FDA Guidance on First Amendment grounds because it found that the documents substantially burdened more speech than necessary.<sup>121</sup> The court stated:

[T]here exist less-burdensome alternatives to this restriction on commercial speech. . . . The most obvious alternative is full, complete, and unambiguous disclosure by the manufacturer. . . . Full disclosure not only addresses all of the concerns advanced by the FDA, but addresses them more effectively. It is less restrictive on speech, while at the same time deals more precisely with the concerns of the FDA and Congress.<sup>122</sup>

Although permitting disclosure would not promote the submission of NDAs, the only goal that the court found "substantial," the court reasoned that suppression was not necessary to achieve such a goal. The court noted that:

Manufacturers still are proscribed from producing and distributing any internally-produced marketing materials to physicians concerning off-label uses. . . . Nor may they advertise off-label uses for previously approved drugs directly to the consumer. . . . The fact that these adequate incentives still exist to get off-label treatments on-label is central to this court's finding that the First Amendment is violated by the Guidance Documents. Were manufacturers permitted to engage in all forms of marketing of off-label treatments, a different result might be compelled.<sup>123</sup>

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<sup>116</sup> *Bolger*, 463 U.S. at 67.

<sup>117</sup> See *supra* notes 68-69 and accompanying text.

<sup>118</sup> *Friedman*, 13 F. Supp. 2d at 70 ("[T]he government's notion that the scientific research product which the manufacturers seek to distribute needs to be withheld for the 'good of the recipient' is even more unsupportable than usual. First, it must be noted that the manufacturers are not seeking to distribute this information to the general consumer public, who likely lack the knowledge or sophistication necessary to make informed choices on the efficacy of prescription drugs. . . . Rather, they seek to disseminate this information exclusively to physicians.").

<sup>119</sup> See *id.* at 71 ("Congress has concluded that it benefits the public health to require manufacturers to get all uses approved by [the] FDA . . . and has recently reaffirmed that position through the 1997 Food and Drug Amendments.").

<sup>120</sup> *Id.* at 72.

<sup>121</sup> See *id.* at 72-73.

<sup>122</sup> *Id.* at 73 (internal citations omitted).

<sup>123</sup> *Id.*

This qualification of the holding in *Friedman* offers a mixed message with respect to FDA policy on the Internet. If FDA was to permit manufacturers to post off-label information freely on the Internet, manufacturers would be able to distribute “internally produced marketing materials . . . directly to the consumer.” Still, despite this potential basis for distinguishing *Friedman*, a recent opinion by the D.C. Circuit adds further support to arguments that FDA might violate the First Amendment should it choose to adopt a policy of suppressing off-label information on the Internet.

In *Pearson v. Shalala*<sup>124</sup> the D.C. Circuit examined FDA’s refusal to authorize four separate health claims requested by the marketers of a dietary supplement.<sup>125</sup> The court rejected the agency’s argument that the speech at issue was “inherently misleading.”<sup>126</sup> Applying the other steps of *Central Hudson*, the court found that the government had a substantial interest “in ‘promoting the health, safety, and welfare of its citizens.’”<sup>127</sup> As for the third prong, the court was skeptical of FDA’s position that barring health claims advanced health, noting:

The government simply asserts its ‘common sense judgment’ that the health of consumers is advanced directly by barring any health claims not approved by the FDA. Because it is not claimed that the product is harmful, the government’s underlying — if unarticulated — premise must be that consumers have a limited amount of either attention or dollars that could be devoted to pursuing health through nutrition, and therefore products that are not indisputably health enhancing should be discouraged as threatening to crowd out more worthy expenditures. We are rather dubious that this simplistic view of human nature or market behavior is sound, but, in any event, it surely cannot be said that this notion — which the government does not even dare openly to set forth — is a direct pursuit of consumer health; it would seem a rather indirect route, to say the least.<sup>128</sup>

The court found that the third prong of the *Central Hudson* test was satisfied, however, concluding that, “it cannot be denied that requiring FDA pre-approval and setting the standard extremely, perhaps even impossibly, high will surely prevent any confusion among consumers.”<sup>129</sup>

As in *Friedman*, it was on the final step of the *Central Hudson* test that the court found the fatal First Amendment flaw. In determining whether a “reasonable fit” existed between the government goal and the means chosen to advance it, the court noted that the Supreme Court had “repeatedly point[ed] to disclaimers as constitutionally preferable to outright suppression” of potentially misleading speech. The court concluded that the means-ends fit of FDA’s health claims policy was not reasonable because “where there is no showing that disclosure would not suffice to cure misleadingness, government disregards a ‘far less restrictive means.’”<sup>130</sup>

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<sup>124</sup> 164 F.3rd 650 (D.C. Cir. 1999).

<sup>125</sup> *Id.*

<sup>126</sup> *See id.* at 655. (“As best we understand the government, its first argument runs along the following lines: that health claims lacking ‘significant scientific agreement’ are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous.”).

<sup>127</sup> *Id.* at 656 (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995)).

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 658.

Based on *44 Liquormart*, *Friedman*, and *Pearson*, the constitutionality of FDA's attempts to suppress off-label information on the Internet appears questionable. Under the precedents, FDA's safety and effectiveness concerns seem better advanced by requiring that off-label information appears in conjunction with disclaimers, rather than suppressing it entirely.<sup>131</sup> Should FDA seek to suppress off-label drug promotions on the Internet, its best legal approach appears to lie in emphasizing its lack of other methods for encouraging manufacturers to "get off-label treatments on-label."<sup>132</sup>

### C. Enforcement

After resolving problems of jurisdiction and establishing guidance for content, the third major consideration for drafters of FDA guidance is enforcement. The Internet presents unique enforcement challenges because it changes composition of the regulated field, it significantly expands the geographical scope of that field, and it vastly expands size of the field for which FDA bears regulatory responsibility.

#### 1. Composition of Regulated Field

The Internet changes the nature of the regulated field primarily because low entry costs on the Internet allow small operators to compete with larger, more established ones.<sup>133</sup> Although large operators retain many advantages, the Internet permits small competitors to market directly to a mass consumer base in a way previously not possible. In doing so, the Internet creates new enforcement problems for regulators.<sup>134</sup>

One enforcement problem arises because new entrants to the mass advertising arena often lack experience in complying with government regulation, frequently in the area of drug promotion.<sup>135</sup> In addition to inadvertent noncompliance, many of the

<sup>131</sup> If FDA chooses to regulate rather than suppress the information, it might require, for example, that off-label information be printed under the prominent title, "warning," along with a statement that FDA had not approved the use. FDA also might require disclosure of all studies relating to the off-label use, both favorable and unfavorable, or, at a minimum, links to sites detailing the studies.

<sup>132</sup> As noted above, the court in *Friedman* expressly conditioned its holding on a finding that adequate incentives remained to encourage manufacturers to submit supplemental NDAs. *See Friedman*, 880 F. Supp. 64, 73 (1998). Arguably, if manufacturers can provide promote off-label uses on the Internet without seeking supplemental approval, incentives to submit supplemental NDAs may be severely undermined. It can also be argued, however, that by permitting or even requiring the provision of information regarding off-label uses in conjunction with mandated warnings, FDA might mandate warnings sufficiently "scary" as to deter more people from using products for unapproved purposes. *See, e.g., J.L. Hamilton, The Effect of Cigarette Advertising Bans on Cigarette Consumption, in SMOKING & HEALTH: HEALTH CONSEQUENCES OF EDUCATION, CESSATION ACTIVITIES & GOVERNMENTAL ACTION* (J. Steinfeld et al. eds.) (1977) at 829-40 (demonstrating that a shift in regulatory policy to prohibit television and radio cigarette advertising actually increased smoking rates). Hamilton argues that the increase in smoking rates appears to have been attributable to the relatively greater deterrent value of permitting cigarette advertising but requiring that it be accompanied by warnings under "fair balance" requirements.

<sup>133</sup> *See, e.g., White House Briefing, Electronic Commerce: Comments of Vice President Albert Gore, Nov. 30, 1998* ("And in this emerging digital marketplace, nearly anyone with a good idea and a little software can set up shop and then become the corner store for an entire planet. Who would have imagined that someone who simply wanted to find other people who were also interested in collecting Pez candy dispensers would become eBay, one of the fastest-growing companies today. . . .").

<sup>134</sup> *See generally* Internet Conference, *supra* note 1, at Presentations, Comments of Lee Peeler, Associate Director for the Division of Advertising Practices at the FTC (noting that on the Internet "very small entities can become national advertisers at a very low cost. . . . This loss of the gatekeeper function served by traditional media will be added to by the number of marketers coming into this market that lack familiarity with some of the basics of consumer-protection issues.").

<sup>135</sup> *See Hall, supra* note 2, at A1 (quoting Dr. Helga Rippen, Director of the nonprofit Health Information Technology Institute: "[t]he problem is that many companies are not comfortable using the Internet and may not know how to effectively use it to market and sell their products while complying with FDA rules on advertisements.").

new, smaller speakers consciously choose not to comply with FDA regulations. If they do so, their relative obscurity may make it difficult for FDA to locate or enforce judgments against them.

One example of the new class of regulated entities involves dietary supplement marketers. Following the Dietary Supplement Health and Education Act of 1994 (DSHEA)<sup>136</sup> and the subsequent loosening of industry regulation by FDA, the field of dietary supplement manufacturers has expanded rapidly, with much of the growth occurring in online product marketing.<sup>137</sup> The convergence of the rapidly-growing Internet and the equally rapidly-growing dietary supplement industry is an example of the problems that can arise with new entrants. The new dietary supplement manufacturers are less familiar with and less respectful of FDA regulation. Many are likely to be too small to be deterred from making claims for product liability reasons, and may be so small as to make enforcement action against them exceedingly difficult.<sup>138</sup>

## 2. *Scope of Regulated Field*

Enforcing content regulation on the Internet raises difficult questions regarding the applicability of geographically bounded law to an unbounded medium. Already, domestic and foreign operators are promoting products over the Internet, some exploiting differences in international regulation of drugs.<sup>139</sup> As a threshold issue, FDA needs to address difficulties in establishing personal jurisdiction over foreign site operator defendants.<sup>140</sup> More difficult, however, will be determining the extent to which domestic law should apply to foreign defendants promoting drugs on the Internet.

These types of problems arise because of heterogeneity in international regulatory standards for drugs; uses that may be off-label in the United States may be approved elsewhere, and vice versa.<sup>141</sup> Some companies have addressed these concerns by creating promotions that comply with the laws of several different nations and then link the appropriate information to graphical links depicting the flag of each nation.<sup>142</sup> This method for handling variances in international drug regulation essen-

<sup>136</sup> Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301).

<sup>137</sup> See, e.g., *Public Voice Asks Follow-Up on Dietary Supplement "Drug" Claims Letter*, FOOD LABELING NEWS, Nov. 18, 1998 (quoting physician Bob Hoerr: "In the past six months I've seen individuals going from the pharmaceutical or clinical nutrition world ending up as senior research and development employees of dietary supplement companies. . . . In many cases, it's because of opportunity, downsizing and consolidation. . . . But it's also the opportunity for more junior people to make their mark in an area where there's substantial growth.").

<sup>138</sup> For typical infractions by an Internet-based dietary supplement marketer, see WARNING LETTER BULLETIN, Oct. 12, 1998 (FDA warning to USA Sports Labs for Web promotion of Herbal Phen-Thin, Herbal Phen-Thin II, Herbal Valium, Herbal PRO-S.A.C., Herbal Aspirin, and Shark Cartilage II. FDA considered the products to be "drugs" and objected to the use of trade names, labeling and catalogue information that the agency considered false and misleading. Additionally, FDA found "Herbal Aspirin" misbranded for its suggested equivalence to aspirin.).

<sup>139</sup> See, e.g., Schwartz, *Firm Closes Web Site*, *supra* note 22, at A-section (describing discount website operator importing drugs from Mexico without proof that drugs requested had been prescribed or even approved for prescription in the United States). See also Hall, *supra* note 2, at A1 (describing journalists' purchase of unapproved HIV test kit advertised on the Web: "The test came with an English-language label pasted on top of an original label printed in Russian. The package was shipped from Malta by a European company, Health Diagnostics Ltd., with offices in London, computer equipment in France and a Belgian president, Charles Dupont, who said he was in Monaco when he was interviewed by telephone.").

<sup>140</sup> Some companies intentionally may choose to base themselves in foreign nations for these very reasons. See, e.g., Hall, *supra* note 2, at A1.

<sup>141</sup> For example, although Viagra® is approved for prescription use in the United States, it has not been approved in other countries. See Watson, *supra* note 2.

<sup>142</sup> See, e.g., *Nutrition-City Website* (visited on Jan. 25, 1999) <www.nutrition-city.net/> (presenting information accessible through "flag links" for Australia, Canada, New Zealand, and the United Kingdom; the flag links do not have accompanying print identifying the country represented).

tially relies on an honor system principle; no technological barrier prevents, for example, users in the United States from clicking on the United Kingdom's flag and accessing information designed for consumers in that country. Most likely for this reason, an FDA official stated that the agency has "not looked too favorably on the use of country flags on disclaimers."<sup>143</sup>

### 3. *Size of the Regulated Field*

A final enforcement challenge on the Internet lies in designing a mechanism to effectuate drug regulation in light of the vast expansion in the size of the regulated field. FDA can rely on some degree of voluntary compliance;<sup>144</sup> some additional measure of compliance is likely to come through industry self-regulation.<sup>145</sup>

Voluntary measures are unlikely to produce full compliance, however, FDA might augment incentives for voluntary compliance by offering digital certificates to site operators meeting guideline criteria.<sup>146</sup> Nevertheless, additional enforcement will be necessary to achieve effective regulation of drug promotion on the Internet. Given agency resource constraints, the primary mechanism for detection of violations is likely to be competitors' reports. FDA will verify claims filed and prosecute violators when necessary. Such a system has the advantage of relying on regulated parties, that already are well-informed, to expend the resources necessary to uncover violations.<sup>147</sup>

The FTC also will play a role in enforcement. Like FDA, it receives complaints from competitors and others alleging false and misleading advertising.<sup>148</sup> The FTC also has a range of powerful sanctions at its disposal. The FTC might, for instance, seek civil penalties or a temporary restraining order seizing a violator's assets. In one reported case of FTC enforcement on the Internet, the FTC won an order forcing a company to post on its website a notice of the agency's action. The notice included a hypertext link to the FTC site where Internet users could read more information about the case.<sup>149</sup> Also, like FDA, the FTC will benefit from voluntary and self-regulation as

<sup>143</sup> *Device Information on Internet Home Pages Likely Constitutes Labeling*, M-D-D-I REP. ("The Gray Sheet"), July 15, 1996, at IW5, cited in Reichertz, *Legal Issues*, *supra* note 9, at 360.

<sup>144</sup> Parties will not want to offend FDA, and may hope that by adhering to all issued regulations they will be able to avoid product liability suits. *See, e.g.*, Reichertz, *Legal Issues*, *supra* note 9, at 364.

<sup>145</sup> The National Advertising Division (NAD) of the Council of Better Business Bureaus already has enforced standards on the Internet. In 1995, for example, the NAD addressed a website sponsored by the Infinity Distribution Company, claiming that its weight lifting aid was "far superior to any product or system ever developed." When the claim could not be substantiated, the NAD forced a settlement with the company under which the company agreed to modify future advertisements to comply with NAD guidelines. *See id.*

<sup>146</sup> Over time, people would learn to recognize FDA's approval and, presumably, would place greater stock in information read on approved sites. *See, e.g.*, *Cosmetic Ingredient Labeling*, 38 Fed. Reg. 28,912 (Oct. 17, 1973) ("The Commissioner recognizes that many consumers may initially be unfamiliar with certain cosmetic ingredients, but concludes that increasing familiarity will be acquired."). The digital certificate solution, however, has a number of flaws. First, it would involve heavy FDA involvement in development of content on the Internet, seriously impacting freedom of speech. Second, for FDA approval to convey meaningful legitimacy, the agency would have to conduct on-going supervision — a burden far in excess of the agency's reviewing capacity.

<sup>147</sup> *See, e.g.*, Green, *supra* note 23, at 376 (stating that "most medical industry whistleblowers are sales representatives from competing firms also subject to FDA regulation."); FDA ADVERTISING & PROMOTION MANUAL MONTHLY BULLETIN, Nov. 1995, at 4, cited in Reichertz, *Legal Issues*, *supra* note 9, at 361 (citing an FDA staffer as stating, "Ultimately, the FDA likely will rely heavily on competitor's reports of improper promotional activity on the Internet.").

<sup>148</sup> *See, e.g.*, *Life Plus' Ads for ShapePlus and Endogen Referred to FTC*, F-D-C REP. ("The Tan Sheet"), July 22, 1996, at 6-7.

<sup>149</sup> The case involved a Internet-assisted pyramid scheme promulgated by Fortuna Alliance, and is described in Green, *supra* note 23, at 377 (citing Thomas C. Morrison & Robert W. Lehrburger, *FTC Targets Deceptive Cyberspace Advertising*, NAT'L L.J., Aug. 12, 1996, at B7; 15 U.S.C. §§ 42, 52 (1994)) (noting that the FTC has already prosecuted "a dozen cases involving alleged online scams and false advertising).

well as competitors' reports, minimizing the agency's burden in enforcing drug regulation on the Internet.

### III. CONCLUSION

FDA should issue comprehensive guidance on drug promotion on the Internet by first resolving the jurisdictional issue under the third party approach. By defining manufacturers' home pages as "labeling" and information placed with third parties as "advertising," this approach will capitalize on the relative expertise of both FDA and the FTC.

In developing content requirements for Internet drug promotion, FDA should employ a "reasonable user" standard. Doing so will better accommodate the nature of the medium and the way in which users interact with it.<sup>150</sup> In creating affirmative content requirements, FDA should allow the FTC to take the lead in developing general disclosure requirements because of its greater expertise in the area developed in other contexts. But FDA should take an active role in developing guidelines for specific mandatory disclosure, and should illustrate such guidance with specific examples drawn from promotions available on the Internet.

In terms of prohibited content, FDA should break with traditional approaches and permit off-label promotions. Blocking off-label information on the Internet is, from a practical standpoint, impossible. Moreover, given the high need for information on health topics, the potential value of commercial speech, and the power of the Internet in making information accessible, suppressing off-label information appears to be a poor policy decision. Finally, in light of recent cases, suppressing such information may be found to violate the First Amendment. The only significant goal the courts have recognized is that of encouraging submission of supplemental NDAs. A preferable solution to this problem, however, would be to address it directly rather than suppress truthful information.

A direct approach to the supplemental NDA problem would need to address the high costs of the applications.<sup>151</sup> FDAMA seeks to alleviate these costs to some de-

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<sup>150</sup> FDA should sponsor on-going studies monitoring the ways in which consumers use the Internet.

<sup>151</sup> Developing studies necessary to support supplemental applications constitutes a large part of the expense. The Tufts Center for the Study of Drug Development estimates that developing data for a supplemental application is in the multi-million dollar range with an upper bound in the ballpark of \$312,000,000 — in 1997 dollars. See Letter from Peg Hewitt, Research Librarian, Tufts Center for the Study of Drug Development, Mar. 24, 1999 (on file with author). See also Joseph A. DiMasi, R.W. Hansen, H.G. Grabowski & Louis Lasagna, *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107 (1991). Time costs involved in submitting supplemental NDAs also are substantial; between 1989 and 1993, FDA took, on average, ten months longer to approve a supplemental application than it did to approve the original NDA for the same drug. See Louis Lasagna & Joseph A. DiMasi, *Let's Speed Up the Approval of New Indications for Old Drugs*, MED. MARKETING & MEDIA, Dec. 1996, at 88; Joseph A. DiMasi, Jeffrey S. Brown & Louis Lasagna, *An Analysis of Regulatory Review Times of Supplemental Indications for Already-Approved Drugs*, 30 DRUG INFO. J. 315 (1996). Longer lags in approval time for supplemental NDAs might seem to be a counterintuitive finding given that the "safety" of FDA's safety and effectiveness concerns is resolved in the agency's approval of the initial use. A partial response is that FDA may be using the supplemental application as an opportunity to review its initial conclusion regarding safety on the basis of subsequently developed data. See John Schwartz, *Is FDA Too Quick to Clear Drugs? Growing Recalls, Side Effect Risks Raise Questions*, WASH. POST, Mar. 23, 1999, at A1. Preliminary research indicates that the Prescription Drug User Fees Act of 1992 may have decreased the amount of time required for approvals of supplemental applications. See Food and Drug Admin./Dept. of Health and Human Services, Fourth Annual Performance Report/Prescription Drug User Fee Act of 1992/Fiscal Year 1996 Report to Congress 7 (1996). See also Merrill, *Symposium on Regulating Medical Innovation*, supra note 89, at 1795-96 (citing evidence regarding the effect of PDUFA on review time and costs for new and supplemental applications).

gree,<sup>152</sup> but because much of the benefit to be gained from supplemental NDA review accrues to society rather than manufacturers, a slight decrease in cost will not provide the optimal level of applications.<sup>153</sup>

Instead, Congress should create positive incentives for submissions through either transfer payments or patent extensions.<sup>154</sup> The first option, the transfer payment, is appealing because it would allow the government to calculate the reward more precisely than would a fixed patent extension.<sup>155</sup> Additionally, the transfer approach would be effective even if the initial patent had expired.<sup>156</sup> The patent-extension approach, however, appears to be a superior solution for several reasons. First, from a practical standpoint, it may be easier for politicians to endorse this less-direct transfer of wealth to producers. Second, the risk of unsuccessful testing would remain with the manufacturer.<sup>157</sup> Third, by allowing manufacturers to recoup supplemental NDA costs through supracompetitive pricing, the group benefiting most directly from the additional testing, consumers of the drug, would pay for the testing.

In addition, if carefully designed, the patent extension approach might meet the criticisms working in favor of a transfer solution.<sup>158</sup> For example, in reference to the possibility that generics already might have entered the market, Professor Peter Hutt suggested use of mandatory arbitration similar to that authorized under the Federal Pesticide Act of 1978 (FPA),<sup>159</sup> an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act.<sup>160</sup> The earlier act required applicants submitting "me-too" applications for Environmental Protection Agency (EPA) approval of pesticides to reimburse initial applicants for the benefit of relying on pioneers' previously submitted data.<sup>161</sup> Extensive litigation over the amount of compensation, however, led to the FPA amendment easing the burden on the EPA by authorizing private arbitration between the par-

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<sup>152</sup> FDAMA requires, *inter alia*, that FDA publish standards for review of supplemental applications. See Covington & Burling, Unpublished Memorandum: Food and Drug Administration Modernization Act of 1997, Dec. 12, 1997, at 88. FDAMA also requires FDA to work more closely with the National Institutes of Health and other medical and scientific entities in order to encourage manufacturers to submit supplemental applications and help them identify existing studies to use in doing so, thus decreasing manufacturers' costs in submitting supplemental applications. See *id.*

<sup>153</sup> In the past, the benefit of the new approval came largely through expanded sales that would result from the manufacturer's ability to promote the new use of its drug. But see Nicholas L. Ruggieri, *Implications of Regulatory Policies on Off-Label Uses for Industry Competitiveness*, 32 DRUG INFO. J. 379 (1998) (noting that manufacturers may also consider the potential benefit of expanded demand for their product should FDA approval lead insurers to permit reimbursement for the newly approved use).

<sup>154</sup> Congress has employed both transfer and exclusivity approaches to incentive creation in the prescription drug context in the past. See, e.g., Merrill, *supra* note 89, at 1790-91 (discussing dual incentive scheme under the Orphan Drug Amendments).

<sup>155</sup> The government would not know the competitive price for a pioneer drug, and permitting the extension of the manufacturer's market power would generate a reward to manufacturers of a magnitude not easily observable to government. As a result, the patent reward might allow a manufacturer to recover far more than its costs in applying for supplemental approval for an off-label use.

<sup>156</sup> The patent-extension approach would not be a viable alternative in such a scenario.

<sup>157</sup> Unlike direct reimbursement for research costs, patent extension conditional on supplemental approval would not create moral hazard by encouraging testing even where probability of approval is low.

<sup>158</sup> See, e.g., Merrill, *supra* note 89, at 1791 ("[T]he appeal of extended market exclusivity inspires many applications for orphan drug status.") (citing Joseph A. Levitt & John V. Kelsey, *The Orphan Drug Regulations and Related Issues*, 48 FOOD & DRUG L.J. 525, 531 (1993)). Merrill notes that the desire to gain market exclusivity has led to strategic maneuvering by manufacturers. Such lessons should inform drafting of any patent extension solution to the supplemental NDA problem.

<sup>159</sup> Pub. L. No. 95-396, 92 Stat. 819 (1978).

<sup>160</sup> See Federal Insecticide, Fungicide, and Rodenticide Act, 61 Stat. 163, as amended, 7 U.S.C. §§ 136 et seq.

<sup>161</sup> See Federal Pesticide Control Act of 1972, § 3(c)(1)(D), 86 Stat. 973 (1994). See also H.R. REP. NO. 95-663 (1977) at 17-18; S. REP. NO. 95-334 at 7, 33-44 (1977) (noting that establishing a limited proprietary interest in data generated to support pesticide registrations would serve as an additional incentive for research and development in pesticides).

ties setting compensation.<sup>162</sup> The Supreme Court upheld the constitutionality of this use of arbitration in *Thomas v. Union Carbide Agricultural Products*.<sup>163</sup>

Applying the pesticide approach to the supplemental NDA problem would create a viable incentive for submission even where generics already have entered the market.<sup>164</sup> Like arbitration over pesticide data compensation, this approach probably would be upheld as constitutionally permissible.<sup>165</sup> Grafting arbitration into the patent extension scheme might solve another concern with this approach as well; by setting a variable patent term susceptible to arbitration, Congress could reduce the likelihood that manufacturers would be overcompensated for submitting supplemental NDAs.<sup>166</sup>

Because the optimal solution to the supplemental NDA problem is a legislative one, the best approach for FDA guidance with respect to prohibited content, may be no approach at all. By permitting off-label promotions and admitting it cannot solve the supplemental NDA problem, FDA can show Congress that a legislative solution is needed if society is to capture all of the potential benefits of supplemental review of drugs.

Finally, with respect to issues of enforcement, FDA should encourage industry self-regulation. It should maintain a link on its own home page allowing direct submission of reported violations. International enforcement concerns can be addressed in the short run by the "flag method" or a similar method of segregating information

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<sup>162</sup> See *Thomas v. Union Carbide Agric. Prods.*, 473 U.S. 568 (1985).

<sup>163</sup> *Id.* Challengers unsuccessfully argued that the 1978 Act violated Article III of the Constitution by delegating judicial powers to a non-Article III tribunal.

<sup>164</sup> Thus, where generics have entered the market, the pesticide model would require manufacturers of generics to reimburse the pioneer manufacturer for the costs it occurred in submitting a supplemental NDA. Were the market perfectly competitive market, neither pioneers nor incumbent generic manufacturers would be able to pass supplemental NDA costs on to consumers through supracompetitive pricing. In fact, however, the market for drugs does not appear to be a perfectly competitive one; capital and advertising costs as well as extensive regulation contribute to barriers to entry.

<sup>165</sup> Compensation for submission of supplemental NDAs arguably is "an integral part of a program safeguarding the public health" delegable to an administrative agency under Article I of the Constitution without the provision of Article III adjudication. *Thomas*, 473 U.S. at 589 ("Congress, without implicating Article III, could have authorized [the agency] to charge follow-on registrants fees to cover the cost of data and could have directly subsidized FIFRA data submitters. . . . Instead it selected a framework that collapses these two steps into one, and permits the parties to fix the amount of compensation, with binding arbitration to resolve intractable disputes. Removing the task of valuation from agency personnel to civilian arbitrators, selected by agreement of the parties or appointed on a case-by-case basis by an independent federal agency, surely does not diminish the likelihood of impartial decision-making free from political influence.") *Id.* at 589-90 (internal citations omitted). In designing new legislation based on the pesticide model, Congress also can take affirmative steps to replicate the features of the pesticide scheme contributing to its status as an acceptable delegation. For example, the *Thomas* Court noted that, "FIFRA limits but does not preclude review of the arbitration proceeding by an Article III court . . . [and] at a minimum allows private parties to secure Article III review of the arbitrator's 'findings and determination' for fraud, misconduct, or misrepresentation." *Id.* at 592 (internal citations omitted).

<sup>166</sup> Setting only a single patent term for the submission of supplemental NDAs would be less efficient because it would be both over- and under-inclusive. Where costs of submitting are higher than the value of the patent extension (discounted for the risk of non-approval and the time costs of money), manufacturers would fail to submit even where doing so would be in society's best interest. At the same time, where costs of submission are lower than the discounted value of the extension, they would submit even where the value to society of the new submission is lower than the net loss in social welfare incurred through the increased period of monopoly pricing. Using a variable patent term subject to arbitration, neutral experts could take into consideration societal benefits as well as manufacturers' costs related to submission. Admittedly, value to society would be difficult to assess. But expert arbitrators might consider proxies, including how widespread off-label use was at the time of submission, how different the new approval is from the initially-approved one, and how great the potential danger of the particular untested uses might have been. Thus, where a supplemental application relied on prior studies instead of ones newly undertaken for purposes of the supplemental application, the benefit to society from the approval would be lower (consisting only of the value of FDA review rather than the value of newly produced studies), the manufacturers' costs would be lower, and the period of the patent extension that would be authorized as a reward to the manufacturer would be lower.

and, in the long run, by increased FDA cooperation with foreign nations in the international harmonization of drug regulations.<sup>167</sup>

Clear guidance from FDA provides consistency and predictability to the unruly and rapidly growing field of Internet drug promotion.<sup>168</sup> The existing challenges to comprehensive regulation are significant, but as the excitement at the 1996 Internet Conference made clear, the benefits to be gained through informed guidance are even greater. Nearly three years have elapsed since the Internet Conference, and it is time for FDA to issue its long-awaited guidance document.<sup>169</sup> The sooner the agency does so, the sooner it can begin the process of refining regulatory standards and taming the wild frontier of drug promotion on the Internet.

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<sup>167</sup> FDAMA in fact encouraged this type of cooperation. The Act contains two provisions encouraging FDA to seek conformity between its own requirements and broader international standards. Section 410(a) of the Act amends § 520(f)(1)(B) of the FDCA to require, to the greatest extent practicable, that device good manufacturing practice requirements conform to international device quality standards. Section 410(b) of FDAMA amends § 803 of the FDCA to add subsection (c) promoting internationally harmonized regulatory requirements where consistent with FDA's other obligations. Section 803(c)(3), in particular, requires FDA to participate in regular meetings with foreign governments to reach agreements regarding future harmonization of regulatory requirements.

<sup>168</sup> Some commentators have taken the opposite position, arguing that guidance for the Internet is of little value because technological change will render guidance obsolete. Such concerns can be allayed by "technology-neutral" standards, however. Technology-neutral standards have the added advantage of facilitating coordination with other regulators of the Internet. *See, e.g.,* White House, *A Framework for Global Electronic Commerce*, available at <[www.whitehouse.gov/WH/New/Commerce/read.html](http://www.whitehouse.gov/WH/New/Commerce/read.html)>.

<sup>169</sup> Under FDAMA, FDA may provide for public comment after it implements guidance. *See* FDAMA § 701(h)(1)(D), allowing the agency to revise guidance in light of feedback gained from practical experience under the new standards.

