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# THE PROMISE AND PERIL OF DIRECT-TO-CONSUMER PRESCRIPTION DRUG PROMOTION ON THE INTERNET

Timothy S. Hall\*

## INTRODUCTION

The Internet provides the pharmaceutical industry with an unparalleled opportunity to provide virtually unlimited amounts of information about its products to consumers and potential consumers of those products. Informed consumers, in turn, potentially could become safer, more cost-effective, more rational users of prescription drugs. Information sent directly to the consumer could improve patient satisfaction, compliance with treatment regimens and, ultimately, health care outcomes. However, to date, despite spending staggering amounts of money on direct-to-consumer (“DTC”) advertising to reach consumers and potential consumers of its product,<sup>1</sup> the industry has failed to take full advantage of this opportunity. First, it has failed to prevent the marketplace from being invaded by suboptimal purveyors of prescription drugs.<sup>2</sup> As a result, the dominant perception of Internet

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<sup>1</sup>Adwatch: *Featured Issue: Direct-to-Consumer Prescription Drug Advertising*, at <http://www.kaisernetwork.org/adwatch> (according to one estimate, the drug industry spent \$2.5 billion on DTC advertisements for prescription drugs in 2000, up 35% from the previous year).

<sup>2</sup>For a full discussion of the phenomenon of Internet drug sales, see John Michael Ward, *Online Pharmaceutical Regulation: An Avenue to a Safer World*, 24 J. LEGAL MED. 77 (2003); Charlotte Spears, *Consumer Protection: Online Sale of Prescription Drugs to Minors Not Unconscionable*, 30 J. L. MED. ETHICS 315 (2002); Ivette P. Gomez, Note, *Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Businesses*, 28 RUTGERS COMPUTER & TECH. L.J. 431 (2002); Mark Sweet, *Policing Online Pharmacies: Bioterrorism Meets the War on Drugs*, 2001 DUKE L. & TECH. REV. 41 (2001); Kristin Yoo, Comment, *Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet*, 20 J. MARSHALL J. COMPUTER & INFO. L. 57 (2001); Nicole A Rothstein,

drug information is that of the “snake-oil salespeople of the information age.”<sup>3</sup> Second, the industry has failed to assure that its own advertisements provide adequate information to the consumer to enhance the treatment process. Poorly designed, inadequately informational or (at worst) misleading advertisement contributes nothing to the health care decision-making process, and in fact, given the dangerous nature of prescription drugs, has the potential to do considerable harm. Commentators,<sup>4</sup> consumer advocates, legislators<sup>5</sup> and the World Health Organization<sup>6</sup> have expressed concern at the proliferation of Internet promotion of prescription drugs.

The first part of this Article will describe the current regulatory system for direct-to-consumer advertising of prescription drugs. This system was developed before the advent of Internet advertising, and has been slightly re-interpreted, but not wholly reformed, to take account of increased industry use of Internet and other mass media to communicate directly with consumers. The second part will describe the current state of the pharmaceutical industry’s Internet-based marketing efforts. Part three will explore the potential impact of these marketing efforts on the physician-patient relationship, emphasizing both the desirable and undesirable effects of Internet DTC advertising.

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Comment, *Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada*, 53 FED. COMM. L.J. 343 (2001); David B. Brushwood, *Responsive Regulation of Internet Pharmacy Practice*, 10 ANNALS HEALTH L. 75 (2001); Sara E. Zeman, *Regulation of Online Pharmacies: A Case for Cooperative Federalism*, 10 ANNALS HEALTH L. 105 (2001); Ty Clevenger, *Internet Pharmacies: Cyberspace v. the Regulatory State*, 15 J.L. & HEALTH 165 (2000); Sean P. Haney, Note, *Pharmaceutical Dispensing in the “Wild West”*: *Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies*, 42 WM. & MARY L. REV. 575 (2000); Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. MED. & ETHICS 98 (2000).

<sup>3</sup>Rothstein, *supra* note 2, at 347.

<sup>4</sup>See, e.g., Ellen ‘t Hoen, *Direct-to-consumer advertising: For better profits or for better health?* 55 AM J. HEALTH SYST. PHARM. 594, 596 (1998) (“[T]he U.S. model of drug advertising to consumers presents a risk that the pharmacist will end up as a mere extension of the DTC advertisement”).

<sup>5</sup>Concerns about the DTC advertising of prescription drugs have led legislators to try to discourage drug companies from such activity. In 2001, the Vermont General Assembly passed a resolution asking Congress to declare a moratorium on DTC advertising. H.R.J. RES. 60 (Vt. 2001). In 2001, bills were introduced in Congress and in California’s state legislature that would have disallowed a deduction from a drug company’s income for state tax purposes for any amount spent to advertise a prescription drug. H.R. NO. 2352, 107th Cong. (2001); S. NO 1099, 2001-02, Reg. Sess. (Cal. 2001). Although the proposed federal bill was targeted at DTC advertisements, the proposed California bill made no distinction between DTC promotion and traditional promotion to physicians. Neither bill was enacted.

<sup>6</sup>Press Release, World Health Organization, *The World Health Assembly Adopts a Resolution on the Sale of Medical Products Through the Internet* (May 12, 1997), <http://www.who.ch/>.

Finally, we will conclude with suggestions for reform of the regulation of Internet DTC advertising, and will propose that regulation of Internet DTC advertising explicitly consider the impact of such promotion on the physician-patient relationship.

## A SHORT HISTORY OF THE REGULATION OF DTC ADVERTISING

### FDA Jurisdiction over DTC Advertising

The Food and Drug Administration enjoys authority over the regulation of prescription drugs under the Federal Food, Drug and Cosmetics Act (FDCA).<sup>7</sup> Misleading or otherwise inappropriate advertising causes a drug to be considered a misbranded drug,<sup>8</sup> potentially subjecting the offending manufacturer to criminal and civil liability under the FDCA.<sup>9</sup> Although the FTC also has authority to regulate the advertising of drug products,<sup>10</sup> the FDA and FTC have entered into a letter of agreement<sup>11</sup> with the goal of avoiding unnecessary regulatory overlap between the agencies.<sup>12</sup> Pursuant to this agreement, the FTC has authority to regulate all drug advertising except advertising for prescription drugs, which is regulated by the FDA.<sup>13</sup>

When the FDA first regulated prescription drug advertising, such advertising was solely directed at physicians and other health care professionals.<sup>14</sup> Drugs were marketed through advertisements in medical journals and other publications designed to reach the health care industry; through other promotional materials distributed directly to physicians and other health care professionals; and through use of pharmaceutical industry representatives who made visits to physicians' offices to educate health care workers about and promote the use of their employers' products.<sup>15</sup> The FDA regulations were designed to

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<sup>7</sup>21 U.S.C.A. § 301 (West 2003).

<sup>8</sup>21 C.F.R. § 202.1(k) (2003).

<sup>9</sup>21 U.S.C.A. §§ 331(a), 333 (West 2003).

<sup>10</sup>15 U.S.C. §§ 52-55 (2003). For a discussion of interagency cooperation between FDA and FTC, see Paul E. Kalb et. al., *Direct-to-Consumer Marketing: The FDA is Not Alone*, 58 FOOD & DRUG L.J. 25 (2003).

<sup>11</sup>.01 FTC Act §§ 12-16, 15 U.S.C. §§ 52-56 (2001) [hereinafter Letter of Understanding].

<sup>12</sup>*Id.*

<sup>13</sup>*Id.* Although advertisements of over-the-counter drugs, dietary supplements, and other products raise interesting and important legal issues, this Article will confine its discussion to the advertisement of prescription drugs.

<sup>14</sup>See *Perez v. Wyeth Laboratories*, 734 A.2d 1245, 1247 (N.J. 1999).

<sup>15</sup>All of these promotional activities continue to this day, although the budget for them has not increased at the same rate as the budget for DTC promotions in recent years.

ensure that physicians were provided with adequate information to competently prescribe the product, and focused on disclosure to the physician of known contraindications, risks and side effects of the product being promoted.<sup>16</sup> Thus, all print advertisements are required to include a “brief summary” of the indications, contraindications and side effects of the drug in question.<sup>17</sup> This “brief summary” is ordinarily the same information that is provided in the Physician’s Desk Reference, is a subset of the required labeling of the drug, and is technical in nature.<sup>18</sup> “Reminder” advertisements, which merely consist of the name of the drug, but do not discuss dosage information or indications for the drug’s use, need not contain the brief summary.<sup>19</sup> “Help-seeking” ads, which do not state the name of a drug, but merely describe an illness or symptoms and advise the viewer or reader to “see your doctor” are not considered drug advertisements, and so are not regulated by the FDA.<sup>20</sup>

Despite this existing exercise of its authority to regulate advertisements of prescription drugs, DTC advertisements seemed to catch the FDA off guard. When the first DTC ads began to appear in the 1980s,<sup>21</sup> the response of the FDA was to request a voluntary

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<sup>16</sup>It is not at all clear that directing advertising material at physicians in fact accomplishes the goals of educating physicians and improving the quality of practice. Empirical research has shown that the more promotional material a physician is exposed to, the less rational is her prescribing practice. See Joel Lexchin, *Pharmaceutical Promotion in Canada: Convince Them or Confuse Them*, 17 INT’L J. HEALTH SERV. 77, 86 (1987) (“The more doctors rely on commercial services for their information about drugs, the less rational they are as prescribers.”).

<sup>17</sup>See David W. Opperbeck, *How Should FDA Regulate Prescription Drug Promotion on the Internet?*, 53 FOOD DRUG L.J. 47, 55 (1998)

<sup>18</sup>*Id.* (“Practically speaking, the brief summary is essentially the same as the prescribing information required under the labeling regulations.”).

<sup>19</sup>While a reminder ad might make sense directed to prescribing physicians by keeping the product in their minds, the same technique applied to consumer advertising, while successful in creating interest in and awareness of the drug brand, also created substantial confusion. Kelly Reeves, *Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population*, 53 FOOD DRUG L.J. 661 (1998) (describing the interest in Claritin generated by reminder ads, which caused patients to ask physicians about the drug with no idea what the drug’s indications or benefits were).

<sup>20</sup>DIV. DRUG MKTG., ADVER. & COMM., U.S. FOOD & DRUG ADMIN., STATEMENT OF NANCY M. OSTROVE, Ph.D. (2001) [hereinafter Statement of N. Ostrove]. Although the FDA does not regulate help-seeking ads, it has issued warning letters to drug companies based on these ads. *Id.* Warnings based on help-seeking ads generally allege that the ad states the name of a specific drug, or implies the identity of the drug being promoted. *Id.* Since help-seeking ads cannot mention the name of the drug, they are most often used for drugs which are the only treatment for a particular condition, or which are the market leader for treatment of that condition, and thus can expect to gain a large share of the demand created by the ad.

<sup>21</sup>The advertisements which caused the most controversy, and which are the subject of this Article, are the so-called “product claim” advertisements, which both name a specific drug

moratorium on DTC advertisements from the pharmaceutical industry while the FDA studied the appropriate approach to such advertisements.<sup>22</sup> This moratorium lasted from 1983 until 1985.<sup>23</sup>

After its initial study of the merits and detriments of DTC advertising, the FDA reversed its initial moratorium on such advertising.<sup>24</sup> The FDA stated at that time that it considered that no new regulation was required to specifically address direct to consumer advertising; rather, that existing regulations were sufficient to protect the health and safety of consumers.<sup>25</sup> This decision had the effect of allowing advertisements for prescription drugs to be placed in media directly marketed to consumers of prescription drugs rather than to health care professionals, but required that the advertisement contain all of the warning and side effect information presented to prescribing physicians in the “brief summary.”<sup>26</sup> After the FDA’s decision to lift the moratorium, print advertisements for prescription drugs flourished.<sup>27</sup> Due to the disclosure requirements, however, broadcast

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and make claims about the effectiveness of that drug. *See, e.g.*, 50 Fed. Reg. 36677 (voluntary moratorium on DTC ads only to “apply to all product-specific advertising that promoted a drug for its intended uses.”) Pharmaceutical companies have also engaged in so-called “reminder” advertisements, which mention the name of the drug but not its intended therapeutic use, and “help-seeking” advertisements, which invite sufferers from a particular ailment to “see your doctor” for information about treatments. *See* Statement of N. Ostrove, *supra* note 20. The scholarly literature on DTC advertisement has focused almost exclusively on product-claim advertisement.

<sup>22</sup>Direct-to-Consumer Advertising of Prescription Drugs: Withdrawal of Moratorium, 50 Fed. Reg. 36677 (Sept. 9, 1985) (describing speech by FDA Commissioner and Policy Statement of FDA requesting moratorium). At least one commentator has criticized the practice of the FDA in requesting a voluntary industry moratorium. Writing in response to FDA’s Request for Comment of First Amendment Issues (Docket No. 02N-0209), Patrick Maines and Richard T. Kaplar of The Media Institute criticize the FDA’s use of “extra-regulatory means such as ‘draft’ policy papers, ‘requests’ to drug companies, jawboning, and other techniques that yielded industry compliance without bothering with the Administrative Procedure Act or statutory provisions for rulemaking.” PATRICK MAINES & RICHARD T. KAPLAR, MEDIA INST., COMMENTS OF THE MEDIA INST. (2002), available at <http://www.fda.gov> (“Drug companies ... were forced to relinquish their constitutional rights rather than jeopardize their business interests by challenging FDA’s practices.”). Whether or not the drug industry found the FDA’s request for a moratorium coercive, there is little doubt that they substantially complied with the moratorium. Statement of N. Ostrove, *supra* note 19 (stating that industry complied with the moratorium).

<sup>23</sup>50 Fed. Reg. 36677 (withdrawing moratorium and allowing advertisement of prescription drugs to consumers based on existing regulations).

<sup>24</sup>*Id.*

<sup>25</sup>*Id.*

<sup>26</sup>21 U.S.C.A. § 352(n) (West Supp. 2003).

<sup>27</sup>Mae Joanne Rosok, Comment, *Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE U. L. REV. 629, 649 (2000) (describing “stead[y] increase” in direct-to-consumer spending after the withdrawal of the moratorium).

product claim advertisements were still discouraged due to the difficulty in providing the brief summary within the confines of a broadcast ad.<sup>28</sup>

In 1997, the FDA revisited the issue of broadcast prescription drug advertising to consumers. The FDA issued a draft industry guidance re-interpreting the regulations governing prescription drug advertising in broadcast media,<sup>29</sup> which guidance was issued in final form in 1999.<sup>30</sup> This re-interpretation had the effect of relaxing prior restrictions on broadcast DTC advertisements.<sup>31</sup> Under the Guidance, drug manufacturers are permitted to air product claim advertisements, so long as they also provide a statement in the advertisement itself of the major risks associated with the use of the drug, and the advertisement exhibits “fair balance” between the product claims and the risk disclosures.<sup>32</sup> Significantly, a broadcast advertisement need no longer carry the full text of the “brief summary” of information designed for the use of prescribing physicians.<sup>33</sup> In order to satisfy the requirement of the regulations that adequate provision be made for viewers of the ad to obtain the full labeling information for the drug,<sup>34</sup> FDA articulated four methods of providing that information which

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<sup>28</sup>Although existing regulations provide that, as an alternative to providing the brief summary within the ad itself, advertisers may make “adequate provision” for viewers of the ad to obtain the labeling information for the drug, uncertainty about what would constitute “adequate provision” discouraged widespread use of broadcast product claim ads until 1997. Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 148 (1997) (“the brief summary requirement makes non-print advertising virtually impossible ... and ... substantially increases the cost of print advertising.”).

<sup>29</sup>Broadcast media are defined as radio, television and telephonic communications. The Internet is not defined as a broadcast medium, and there is no reference to advertising over the Internet at all in the Guidance, only reference to the Internet as a conduit for the risk information for a drug advertised over broadcast media. CTR. FOR DRUG EVAL. & RES., *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (U.S. FOOD & DRUG ADMIN. 1999) available at <http://www.fda.gov/cder/guidance/index.htm> [hereinafter Broadcast Guidance].

<sup>30</sup>*Id.*

<sup>31</sup>See Hoen, *supra* note 4. The Broadcast Guidance does not apply to print DTC advertising, in which the “brief summary” must still be included. Broadcast Guidance, *supra* note 25. In 2001, the FDA issued a draft Guidance which would allow drug manufacturers to use FDA-approved patient labeling, rather than the more complex physician labeling, as their “brief summary,” provided that such approved patient labeling carries a complete statement of the drug’s “most serious and most common risks.” CTR. FOR DRUG EVAL. & RES., *Guidance for Industry, Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements*, (Draft Guidance) (U.S. FOOD & DRUG ADMIN. 2001) available at <http://www.fda.gov/cder/guidance/index.htm>.

<sup>32</sup>Broadcast Guidance, *supra* note 25, at 2.

<sup>33</sup>*Id.* at 1.

<sup>34</sup>*Id.* at 2.

would be deemed to constitute adequate provision.<sup>35</sup> First, the manufacturer could establish a toll-free phone number which consumers could call to either request a copy of the information or to have it read to them over the phone.<sup>36</sup> Second, the manufacturer could establish a website to provide the labeling information.<sup>37</sup> Third, the manufacturer could indicate to viewers that they could obtain further information about the drug from their doctor or pharmacist.<sup>38</sup> Fourth, the manufacturer must provide a means for consumers without access to “sophisticated technology” to obtain the information.<sup>39</sup> The Guidance indicates that a manufacturer could provide brochures containing the labeling in sufficient locations (such as grocery stores and pharmacies) that the intended audience of the ad could obtain it “without traveling beyond their normal range of activities.”<sup>40</sup> In making this provision, however, the manufacturer must be careful to consider the intended dissemination of the advertisement, and disseminate the labeling materials comparably.<sup>41</sup>

Interestingly, the Guidance explicitly treats telephone advertising differently than advertising over television or radio.<sup>42</sup> The Guidance states that “telephone advertisements are different from advertisements broadcast through television or radio. By participating in the telephone communication, the consumer has already indicated his or her willingness to discuss the topic or receive additional information. Consequently, adequate provision. . . may be achieved with fewer of the components. . . .”<sup>43</sup> This recognition that a motivated consumer may be expected to take more effort in locating warning information about the drug should be taken into account in devising adequate regulations for Internet advertisements.

Despite having no regulations specifically addressing Internet promotion of prescription drugs,<sup>44</sup> the FDA is actively enforcing its

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<sup>35</sup>*Id.* at 2-3.

<sup>36</sup>*Id.* at 2.

<sup>37</sup>Although existing regulations do not expressly regulate Internet advertising, they do provide that the Internet can be used to partially satisfy the requirements for adequate provision for access to the labeling information. *See* Broadcast Guidance, *supra* note 25, at 3.

<sup>38</sup>*Id.* at 3.

<sup>39</sup>Broadcast Guidance, *supra* note 25, at 2-3.

<sup>40</sup>*Id.* at 3.

<sup>41</sup>*See id.*

<sup>42</sup>*Id.*

<sup>43</sup>*Id.* at 3-4. The guidance indicates that telephone ads could satisfy adequate provision through offering to mail or read the labeling to the consumer, as well as telling the consumer to contact his doctor or pharmacist for more information. Broadcast Guidance, *supra* note 25, at 4.

<sup>44</sup>James D. Arden, *Unguided Missives: The FDA and Prescription Drug Promotion in Cyberspace*, 5 FOOD DRUG L. INST. (2001) available at <http://www.fdpi.org>.

existing regulations in cyberspace.<sup>45</sup> Issues raised by FDA enforcement letters to drug companies regarding their online advertising include: promotion of unapproved uses for a drug; advertisements lacking fair balance; outdated material remaining on a promotional website; and misleading claims in advertising.<sup>46</sup>

### FTC Jurisdiction over DTC Advertising

FTC jurisdiction over direct to consumer prescription drug advertising is limited by the letter of agreement between the FDA and FTC.<sup>47</sup> This letter gives the FDA jurisdiction over the truth or falsity of advertisements for prescription drugs, whether aimed at health care professionals or the public.<sup>48</sup> However, the FTC plays a large role in the regulation of advertisement of drugs generally. Advertisements of over-the-counter drugs are regulated by the FTC,<sup>49</sup> although the FDA still retains jurisdiction to the extent that materials disseminated by the drug manufacturer are deemed to be labeling.<sup>50</sup> Many of the criticisms of drug advertising discussed in this Article are equally appropriately leveled at manufacturers and resellers of OTC drugs.

Although the FTC has ceded jurisdiction over advertising of prescription drugs to the FDA, the FTC has apparently thought more about specific issues raised by Internet advertising than has the FDA. In 2000, the FTC produced a publication entitled “Dot Com Disclosures” as a guide for businesses advertising on the Internet.<sup>51</sup> While this document is not directly addressed to issues related to pharmaceuticals, it raises several interesting points about regulation of Internet advertising in general, which will be relevant to FDA regulation of Internet prescription drug advertising.<sup>52</sup>

First, the FTC reminds us that “fraud and deception are unlawful no matter what the medium.”<sup>53</sup> This reminds us that, while the Internet may have been trumpeted as a “new economy” and a revolutionary development, we must be careful not to overemphasize the uniqueness of the Internet.<sup>54</sup> Internet promotion is, after all, fundamentally still

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<sup>45</sup>Kalb et al., *supra* note 10.

<sup>46</sup>Arden, *supra* note 44.

<sup>47</sup>See Letter of Understanding, *supra* notes 11-13.

<sup>48</sup>*Id.*

<sup>49</sup>*Id.*

<sup>50</sup>*Id.*

<sup>51</sup>See Fed. Trade Commission, *Facts for Businesses: Dot Com Disclosures* (2000), [www.ftc.gov/bcp/online/pubs/buspubs/dotcom/index.html](http://www.ftc.gov/bcp/online/pubs/buspubs/dotcom/index.html) [hereinafter *Dot Com Disclosures*].

<sup>52</sup>*Id.*

<sup>53</sup>*Id.* at 1.

<sup>54</sup>See, e.g., Noah, *supra* note 24.

promotion, and the target audience of the Internet deserves the same protections as the target audiences of traditional print and broadcast advertisements, taking into account the diversity of the new media.

Second, the FTC gives some specific guidance on how to incorporate relevant disclosures into Internet promotions.<sup>55</sup> The FTC suggests, among other techniques, the following relevant points:

1. Disclosures should be placed on the same screen as the product claims.<sup>56</sup>
2. Relevant material should not be hidden at the bottom of pages without references in the viewable portion to tell visitors to scroll down.<sup>57</sup>
3. Hyperlinks to material presented on separate pages should be obvious, adequately labeled, placed near relevant information, and consistent throughout the site.<sup>58</sup>
4. Make sure that warning or risk information is prominently displayed in relation to other components of the site.<sup>59</sup>

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<sup>55</sup>Dot Com Disclosures, *supra* note 44.

<sup>56</sup>*Id.* This is probably not practical for the full package labeling. No one would expect the full package labeling to appear on the same web page as the main ad, and the FTC guidelines themselves recognize that “hyperlinked disclosures may be particularly useful if the disclosure is lengthy...” *Id.* However, a further issue is whether the “fair balance” requirement applies to the web site as a whole, or to each page in the site. The FTC guidance seems to suggest the latter approach. FTC notes that “consumers don’t read an entire web site, just as they don’t read every word on a printed page.” *Id.* Thus, it is not sufficient to “[m]ak[e] the disclosure available somewhere in the ad so that consumers who are looking for the information *might* find it...” *Id.* The FDA should adopt a similar approach to evaluation of promotional web sites.

<sup>57</sup>This is clearly relevant to drug home pages, as most of them provide links to the adequate provision material only through small type links at the bottom of the page. In addition, if risk information is presented on the home page, it is invariably placed in plain text at the bottom of the page. One thing that site designers must take account of in this context is that there is no fixed size for computer screens, and that the amount of text displayable on a 640x480 screen is less than that displayable on a 1200X1600 screen. The FTC advises advertisers to “be concerned about whether a required disclosure will appear [on a particular user’s computer.]” Dot Com Disclosures, *supra* note 44, at § III.C.1.c.

<sup>58</sup>The FTC makes the point that with available technologies, web designers can monitor the rates at which visitors to the site actually make use of hyperlinks to relevant risk information and warnings, and can use these data to modify the site design as needed to ensure that visitors are receiving fairly balanced information on the product. Dot Com Disclosures, *supra* note 44.

<sup>59</sup>*Id.* This includes several specific points: provision of risk information in the same format as the product claims (i.e., audio risk information if the product claim is made aurally); placement of disclosures in noticeable places on the page, and making them similar in look and feel to the product claim material; ensuring that the promotional material does not distract from the disclosure; and using consumer-friendly language in the disclosure. *Id.* Many drug promotion websites are marginal on many of these aspects of disclosure.

### Tort as Regulation of DTC Advertising

In addition to FDA and FTC rulemaking, tort law can also be considered a regulatory device.<sup>60</sup> Among the aims of tort law in this context are the deterrence of improper promotional devices and the allocation of harms to the party causing those harms.<sup>61</sup> To the extent that tort law seeks to impose the costs of both defective design and defective marketing on the entity responsible for placing products and marketing into the stream of commerce,<sup>62</sup> it is regulatory in purpose and effect. The relevant issue, then, is the effect of tort law on the market for DTC advertising of prescription drugs.

#### *The Learned Intermediary Rule*

Modern American products liability law provides for strict liability for harms caused by products which are introduced into the marketplace by, or pass through the hands of, a particular manufacturer or seller.<sup>63</sup> Liability may be premised on the defective design of the product in question, or on the manufacturer's or seller's failure to warn the customer of non-obvious harms arising from the use of the product.<sup>64</sup> Ordinarily, a warning must be communicated to the end user of the product in order to be legally sufficient.<sup>65</sup> However, in cases of prescription drugs, this rule has been substantially different. Under the Restatement (Second) of Torts, prescription drugs could not be considered defective in design merely by reason of injury resulting from the product.<sup>66</sup> The now-famous Comment k to section 402A of the Second Restatement provided for an exception to strict liability for "unavoidably dangerous" products (a category which includes prescription drugs) as long as a warning about their dangerousness has

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<sup>60</sup>Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163 (1998).

<sup>61</sup>See, e.g., Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1161 (speaking of a "coincidence of concerns between tort and regulation.")

<sup>62</sup>RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998).

<sup>63</sup>*Id.* ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.")

<sup>64</sup>RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1988). Claims involving harm caused by prescription drugs generally do not claim that the drug was improperly made, although such litigation is not unknown. FRANK WOODSIDE, DRUG PRODUCT LIABILITY § 14.01.

<sup>65</sup>*Id.* § 2, cmt. i.

<sup>66</sup>See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k. (1965). See also James Henderson and Aaron Twerski, *Drug Designs are Different*, 111 YALE L. J. 151 (2001); James A. Henderson, *Prescription Drug Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471 (1996).

been given.<sup>67</sup> The Restatement (Third) of Torts - Products Liability continues this basic rule.<sup>68</sup>

Although a legally adequate warning is ordinarily delivered to the ultimate user of the product, courts have uniformly applied the Learned Intermediary Rule ("LI Rule") to insulate drug manufacturers from liability for injuries caused by their products, as long as the drug manufacturer has taken adequate steps to warn prescribing physicians of known dangers of the drug.<sup>69</sup> However, the LI Rule is not an absolute immunity from liability for prescription drug manufacturers.

Courts have held that the Learned Intermediary Rule does not apply, and thus that drug manufacturers owe a duty to warn the individual patient directly, in situations involving mass immunizations.<sup>70</sup> In these cases, courts reason, the immunization is not delivered in the context of an existing doctor-patient relationship; thus, there is no effective "intermediary" between the patient and the drug manufacturer.<sup>71</sup> Because the patient cannot expect a full and fair disclosure of the risks and benefits of the treatment in the context of its delivery, courts have been willing to impose that duty on the drug manufacturer.<sup>72</sup> Note that this doctrine does not apply to immunizations carried out in the context of an existing physician-

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<sup>67</sup>RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

<sup>68</sup>The Third Restatement provides that a manufacturer or seller of a prescription drug is liable for harm caused by "defective" drugs. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998). "Defect" is defined, *inter alia*, as a failure to provide appropriate and adequate warnings and instructions for use of the product. *Id.* at § 6(d). In 1997, Professor Lars Noah suggested that, in light of the Restatement (3d) of Torts' suggestion that the learned intermediary doctrine may not apply where a drug manufacturer advertises directly to consumers, "pharmaceutical manufacturers may choose to discontinue most promotions directed to persons other than medical professionals." Noah, *supra* note 24. Clearly, this has not happened, and industry spending on direct-to-consumer advertising has continued to rise unabated.

<sup>69</sup>WOODSIDE, *supra* note 49, at § 14.02[1][b][ii]. Some courts have recognized an "overpromotion" theory to avoid the LI Rule's exemption from tort liability. *See, e.g.*, Stevens v. Parke, Davis & Co., 507 P.2d 653 (1973). Where a drug manufacturer delivers a technically accurate warning to prescribing physicians in the context of a promotional, highly positive communication, courts have held that the promotional nature of the communication outweighed and diluted the warning, and that the warning was thus insufficient to trigger the protections of the LI Rule. *Id.* at 661 ("an adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.").

<sup>70</sup>Petty v. U.S., 740 F.2d 1428, 1440 (8th Cir. 1984); *See also* Allison v. Merck & Co., 878 P.2d 948 (Nev. 1994).

<sup>71</sup>Petty, 740 F.2d at 1440 ("[I]n a mass-immunization context, where there is no learned intermediary, the duty extends to the ultimate recipient...").

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

patient relationship, where the considerations of the LI Rule would naturally apply with full force.<sup>73</sup>

In addition to mass immunizations, an exception has been carved out of the LI Rule for oral contraceptives.<sup>74</sup> Like the immunization rule, this exception rests at least in part on the absence of an effective physician-patient relationship.<sup>75</sup> Unlike the immunization rule, it does not depend for its effectiveness on whether a physician is involved in the administration of the drug.<sup>76</sup>

The birth control exception was created out of courts' recognition of the unusual nature of this product and the manner in which it is prescribed and used. Birth control drugs, while prescription pharmaceutical products, are ordinarily not used for the treatment of a specific illness, but out of a desire to prevent pregnancy.<sup>77</sup> The drug is thus more akin to a lifestyle choice than a medical choice.<sup>78</sup> Because of this, the decision to use the drug is much more in the hands of the patient than of the physician; that is, the use of birth control drugs is ordinarily not an exercise of medical judgment.<sup>79</sup> In addition to this, the product is ordinarily prescribed once per year, and the patient does not ordinarily return to the physician's office for further consultation more frequently than annually.<sup>80</sup> Thus, some courts have held that the LI Rule does not apply in this context.<sup>81</sup>

Finally, the FDA has mandated certain information to be provided directly to patients taking certain prescription drugs.<sup>82</sup> For this reason, some courts hold that the LI Rule is inapplicable, and that warnings about the product must be directed to the patient, based on the regulatory decision to mandate that information be provided to the

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<sup>73</sup>*Niemiera v. Schneider*, 555 A.2d 1112 (N.J. 1989); *See also Conafay v. Wyeth Laboratories*, 793 F.2d 350 (D.C. Cir. 1986).

<sup>74</sup>*See generally* *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981).

<sup>75</sup>*See* *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981).

<sup>76</sup>*See* *MacDonald v. Ortho Pharm.*, 475 N.E.2d 65, 66-67 (Mass. 1985) (plaintiff's prescription obtained from her personal gynecologist).

<sup>77</sup>*Id.* at 69 n. 10.

<sup>78</sup>*See id.*

<sup>79</sup>*Id.*

<sup>80</sup>*See id.* at 69 n.11.

<sup>81</sup>*But see* *Cobb v. Syntex Labs Inc.*, 444 So.2d 203 (La. Ct. App. 1983).

<sup>82</sup>*See* 21 C.F.R. §201.305; 310.515. Included in this list are oral contraceptives, so this rationale constitutes another justification for the contraceptive exception as well.

patient.<sup>83</sup> States are split on the question of whether compliance with the FDA mandate constitutes *per se* adequacy of warnings for the purpose of tort liability.<sup>84</sup>

### Critics of the Learned Intermediary Rule

The Learned Intermediary Rule has been the subject of intense scholarly criticism since the advent of direct-to-consumer advertising. In addition, since the advent of DTC advertising, the relevant provisions of the Restatement of Torts have been rewritten in a manner which arguably supports a DTC advertising exception to the Learned Intermediary Rule.<sup>85</sup> This section will explore these objections to the rule, and will suggest that DTC advertising, particularly advertising on the Internet, justifies abrogation of the LI Rule in limited circumstances.

In the early 1990s, scholarly commentary critical of the LI Rule as applied to cases involving DTC advertising began to appear in law journals.<sup>86</sup> Despite the scholarly criticism of the Rule in the DTC advertisement context, only one court to date has adopted the reasoning of the Rule's critics.

In *Perez v. Wyeth Laboratories*, the Supreme Court of New Jersey recognized an exception to the LI Rule where the drug manufacturer has engaged in extensive DTC advertising.<sup>87</sup> The plaintiffs in *Perez* were individuals who had used the long-term implantable contraceptive

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<sup>83</sup>See, e.g., *Edwards v. Basel Pharm.*, 116 F.3d 1341 (10th Cir., 1997); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981).

<sup>84</sup>See generally RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §6(c-d); comment b to §6 (takes the position that compliance with FDA requirements does not constitute *per se* adequacy of the warning as a matter of tort law).

<sup>85</sup>Restatement (Third) of Torts: Products Liability §6, reads in relevant part:

(d) A prescription drug or medical device is not reasonable safe due to inadequate warnings or instructions if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6

<sup>86</sup>See Timothy S. Hall, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 499 (1992); See also Patrick Cohoon, Comment, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediate Rule in The Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. TEX. L. REV. 1333 (2001); See also April L. Foreman, *Web of Manipulation, The Learned Intermediary Doctrine and Direct-to-Consumer Advertising on the World Wide Web*, 35 J. MARSHALL L. REV. 97 (2001).

<sup>87</sup>*Perez v. Wyeth Lab.*, 734 A.2d 1245 (N.J. 1999)

Norplant,<sup>88</sup> and who alleged that they were injured by side effects of the medication, as well as by pain and scarring caused during the removal of the device.<sup>89</sup> Although many physicians had published in medical journals reports of difficulties with the removal of Norplant capsules,<sup>90</sup> no mention of this fact, or of other known side effect of the medication,<sup>91</sup> was made in the extensive DTC advertising campaign undertaken by Wyeth to promote Norplant.<sup>92</sup>

The *Perez* court acknowledged that in product liability cases involving prescription drugs, the LI Rule is still the law of the State of New Jersey.<sup>93</sup> However, the court reasoned that the Rule is justified by certain assumptions about the marketing and sale of prescription drugs, which assumptions are not necessarily true in cases where prescription drugs have been marketed directly to the public.<sup>94</sup> The court articulated three rationales for abrogation of the LI Rule in cases involving extensive DTC advertising:

1. The shift to patient-centered ethics, centered on the doctrine of informed consent, the decline of paternalism, and the patient's right to participate in health care decision making;<sup>95</sup>
2. The effects of managed care on the doctor-patient relationship, which decreases the amount of time a doctor has to deliver an adequate warning to the patient;<sup>96</sup>
3. The development of communication from the drug manufacturers to patients and potential patients through mass media.<sup>97</sup>

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<sup>88</sup>Although the court acknowledged that, because of the nature of the Norplant product (the drug comes in capsules which are inserted under the skin of the patient and release the contraceptive drug continually into the bloodstream), the product might be thought of as a medical device instead of a drug, it analyzed the case as though Norplant were a drug, and this Article will also so assume. *Id.* at 1251.

<sup>89</sup>Although Norplant is a long-acting delivery system for contraceptive drugs, the capsules must be removed and replaced at periodic intervals.

<sup>90</sup>*Perez*, 734 A.2d at 1248.

<sup>91</sup>Side effects of Norplant included "weight gain, headaches, dizziness, nausea, diarrhea, acne, vomiting, fatigue, facial hair growth, numbness in the arms and legs, irregular menstruation, hair loss, leg cramps, anxiety and nervousness, vision problems, anemia, mood swings and depression, [and] high blood pressure[.]" *Id.*

<sup>92</sup>*Id.*

<sup>93</sup>*Perez*, 734 A.2d at 1250.

<sup>94</sup>*Id.* at 1252-53.

<sup>95</sup>See *id.* at 1255 ("The decision to take a drug is 'not exclusively a matter for medical judgment.'") (quoting Theresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 831 (1991)). See also BEAUCHAMP & CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (5th ed. 2002).

<sup>96</sup>*Id.*

Although the New Jersey court was willing to recognize an exception to the LI Rule for DTC promotion of prescription drugs, the actual contours of the rule are quite limited for potential plaintiffs.<sup>98</sup> The court held that compliance with FDA guidelines on DTC advertising would constitute a rebuttable presumption that the warning provided to patients was adequate to avoid tort liability.<sup>99</sup> In order to establish liability on the grounds of failure to warn through advertising, then, a plaintiff must prove either:

1. The drug manufacturer failed to abide by FDA guidelines for advertising prescription drugs to consumers;<sup>100</sup> or
2. The advertising material which met the FDA guidelines was nonetheless legally inadequate for some reason.<sup>101</sup>

#### The Persistence of the Learned Intermediary Rule

Despite these criticisms, and the adoption of the criticisms by the Supreme Court of New Jersey, other courts have been reluctant to abandon the LI Rule in the face of DTC advertising by drug manufacturers.<sup>102</sup> No other court has adopted the exception articulated by the New Jersey court in the four years since the *Perez* case. Further, scholarly objection to the LI Rule in this context is by no means unanimous – many learned commentators have opined that the LI Rule remains the appropriate lens through which to view the relationship between the drug manufacturer and the consumer of prescription drugs.<sup>103</sup>

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<sup>97</sup>*Id.*

<sup>98</sup>*See Perez*, 734 A.2d at 1250.

<sup>99</sup>*Id.* at 1257-59.

<sup>100</sup>To the extent that critics of the pharmaceutical industry are correct that drug companies often violate FDA guidelines in their DTC advertisements, however, this standard may not be an insurmountable bar to liability. *Id.* at 1259.

<sup>101</sup>*See id.*

<sup>102</sup>*See, e.g., In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374 (5th Cir. 1999).

<sup>103</sup>*See*, Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821 (1996); *See also* Noah, *supra* note 24, at 89; Jack B. Harrison, *Some Accurate Information is Better than no Information at All: Arguments Against an Exception to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising*, 78 OR. L. REV. 605 (1999); Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185 (1996); Barbara Pope Flannagan, Comment, *Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs*, 20 U. RICH. L. REV. 405 (1986).

### *Judicial Review of Advertising Content?*

In late 2002, a federal judge in California issued an injunction against GlaxoSmithKline, maker of the prescription antidepressant Paxil, ordering the company to cease airing television advertisements which claimed that Paxil was “non-habit forming.”<sup>104</sup> This injunction was granted in response to a motion from plaintiffs’ attorneys in a class action lawsuit alleging, *inter alia*, failure to warn plaintiffs of Paxil’s side effects.<sup>105</sup> Although the injunction was later denied upon defendant’s motion for reconsideration,<sup>106</sup> the opinion denying the motion contains language in dicta indicating that the court possesses the power to issue such an injunction in appropriate circumstances. This case drew a brief from the FDA arguing that such an injunction would create undesirable state-to-state variation in the legal requirements for prescription drug advertising.<sup>107</sup>

### **DTC ADVERTISING ON THE INTERNET – WHO, WHY AND HOW?**

Direct-to-consumer advertising is rapidly expanding, and companies are seeking more venues for targeting promotional messages to potential consumers.<sup>108</sup> Since the Internet is a richly varied medium, advertising practices on the Internet are similarly diverse. This section will provide a short synopsis of the major Internet advertising techniques. Although the Internet blurs the lines between advertisement and sale,<sup>109</sup> this Article will not address issues related to the sale of prescription drugs over the Internet.<sup>110</sup>

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<sup>104</sup>*In re Paxil Litigation*, No. CV 01-07937 MRP, 2002 WL 31375497 (C.D. Cal. Oct. 18, 2002).

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

<sup>106</sup>*Id.*

<sup>107</sup>Melody Petersen, *Judge Orders Drug Company to Alter Ads*, N.Y. TIMES, Aug. 21, 2002.

<sup>108</sup>*See* Suzanne Vranica, *Patient Channel to Blast Ads at Bedridden*, WALL ST. J., Sept. 26, 2002, at B1.

<sup>109</sup>Through the use of hyperlinking, pharmacies can make it easy for purchasers to move directly from a website extolling the virtues of a particular drug to ordering that drug. Contrast this to the ordinary relationship between advertising and purchase, where there is ordinarily a lengthy delay between viewing a print or broadcast advertisement, seeking an appointment with one’s physician to discuss the proposed treatment, and obtaining a prescription to be filled at a local pharmacy.

<sup>110</sup>Many if not all Internet pharmacies maintain web sites which may consist of both promotional materials as well opportunities to purchase drugs. For a discussion of the issues raised by Internet sales of prescription drugs, see Kristin Yoo, Comment, *Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet*, 20 J. MARSHALL J. COMPUTER & INFO. L. 57 (2001); Nicole A. Rothstein, Comment, *Protecting Privacy and Enabling*

### Economics of Internet Advertising

Since the Internet was first opened to commercial traffic in 1991,<sup>111</sup> the growth of “e-commerce” has been dramatic. With total sales of \$43.4 billion in 2002, up 25.6% from 2001 sales,<sup>112</sup> the Internet accounts for an increasing percentage of American commerce.<sup>113</sup> Further, the audience for Internet advertising is also growing dramatically, and is encompassing segments of the population attractive to marketers.

Use of the Internet is penetrating into virtually every sector of American society. Although experts have expressed concern at the “digital divide” that threatens to create a new categorization of “haves” and “have-nots,”<sup>114</sup> recent Census data show gains in Internet connectivity in households of every ethnic background.<sup>115</sup> In 2000, for the first time, more than half (51%) of American households owned a computer, and 41.5% of households had Internet access.<sup>116</sup> Overall, household Internet access grew 58% during the two-year period from 1998-2000.<sup>117</sup> In addition to those whose homes provide Internet access, 8.7% of the population reported accessing the Internet solely from outside the home – from computers at work, at school, or in other public facilities.<sup>118</sup>

Internet access correlates positively with household income, making Internet users an attractive group for the attention of marketers. While 41.5% of American households enjoy Internet connection, that number surges to 77.7% among households with annual incomes of \$75,000 per year or greater.<sup>119</sup>

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*Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada*, 53 FED. COMM. L.J. 343 (2001); David Brushwood, *Responsive Regulation of Internet Pharmacy Practice*, 10 ANNALS HEALTH L. 75 (2001); Ty Clevenger, *Internet Pharmacies: Cyberspace Versus the Regulatory State*, 15 J.L. & HEALTH 165 (2001); David Mills, *Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet*, 5 J. TECH. L. & PUBLIC POL'Y 1 (2000); Rebecca Porter, *Internet Pharmacies: Who's Minding the Store?*, 36 TRIAL 12 (May 2000).

<sup>111</sup>See Opderbeck, *supra* note 16, at 48.

<sup>112</sup>Retail sales numbers from U.S. Census data. U.S. CENSUS BUREAU, U.S. DEP'T OF COMMERCE NEWS (2003), available at <http://www.census.gov/mrts/www/current.html>.

<sup>113</sup>*Id.* Currently, Internet commerce accounts for approximately 1.5% of all retail sales in the United States.

<sup>114</sup>NAT'L TELECOMM. & INFO. ADMIN., *Falling Through the Net: Toward Digital Inclusion* (U.S. DEPT. OF COMMERCE Oct. 2000) at <http://purl.access.gpo.gov/GPO/LPS6464> [hereinafter *Falling Through the Net*].

<sup>115</sup>See *id.* at xvi.

<sup>116</sup>*Id.* at 1, Figure I-1.

<sup>117</sup>*Id.* at 2.

<sup>118</sup>*Id.* at 46.

<sup>119</sup>*Falling Through the Net*, *supra* note 104, at 9.

Drug manufacturers and retailers have found Internet advertising to be a cost-effective way of communicating with potential patients, compared to traditional advertising media such as television and print.<sup>120</sup> According to one analysis, Internet advertising cost the pharmaceutical industry \$54 per drug request resulting from Internet advertising, substantially less than the \$152 per drug request for television advertising and \$318 per request for print advertising.<sup>121</sup> Further, unlike print or television ads, which tend to be broadcast to a wide audience indiscriminately,<sup>122</sup> Internet ads can be targeted at those Internet users who are likely to be interested in purchasing the drug in question, as evidenced by either their having visited the promotional website of the manufacturer, a portal or support website dedicated to information about a particular disease or treatment, or through analysis of data collected about that user from the use of “spyware,” software which tracks a specific user’s Internet surfing habits and transmits data about those habits to a centralized database.<sup>123</sup> Health care advertising is a natural fit for the Internet, as studies report that a large percentage of the informational searches on the Internet are seeking health care related information.<sup>124</sup>

Studies have shown both that advertising raises awareness of prescription drug brands among consumers, and that Internet advertising results in specific requests to physicians for advertised drugs. FDA data, while not disaggregating Internet advertising from other DTC advertising, show that consumer awareness of DTC advertising in general is quite high, indicating that the advertisements are reaching the attention of the public. In surveys conducted in 2002, 81% of respondents reported awareness of DTC advertisements.<sup>125</sup> Of

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<sup>120</sup>Michael Pastore, *Drug Companies Fail to Harness Internet’s Marketing Potential* (citing Cyber Dialogue (Fulcrum Analytics) at <http://www.cyberdialogue.com>) at [http://www.cyberatlas.Internet.com/markets/healthcare/article/0,1323,10101\\_701591,00.html](http://www.cyberatlas.Internet.com/markets/healthcare/article/0,1323,10101_701591,00.html) (numbers from Cyber Dialogue).

<sup>121</sup>*Id.*

<sup>122</sup>See Vranica, *supra* note 112 (an example of television advertisements which is somewhat targeted to the intended audience: aimed at hospital patients).

<sup>123</sup>See Robert O’Harrow, Jr., *Firm Tracking Consumers on the Web for Drug Companies*, WASH. POST, Aug. 15, 2000, at E1.

<sup>124</sup>In 1996, more than 70 million Americans used the Internet to search for health information. Ross Silverman, *Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards*, 26 AM. J. L. & MED. 255 (2000).

<sup>125</sup>Kathryn J. Aikin, Ph.D., *Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results*, OFF. MED. POL’Y DIV. OF DRUG MKTG., ADVER., & COMM. (U.S. FOOD DRUG ADMIN.), at <http://www.fda.gov/cder/ddmac/Presentations/KitHMCC2002out> (Oct. 22, 2002).

these, 16% reported having seen an advertisement on the Internet.<sup>126</sup> Of those exposed to DTC advertisements, 43% reported that the advertisement led them to seek more information about the drug advertised.<sup>127</sup> Of these, 38% reported using the Internet to seek more information.<sup>128</sup>

### Models of Internet Advertising

Many drug companies, in addition to maintaining corporate websites with information about the company and its operations,<sup>129</sup> also maintain promotional websites dedicated to certain of the company's products.<sup>130</sup> These promotional websites are often linked off the company's main site, but to aid Internet users in locating them, often have separate domain names.<sup>131</sup> The domain names may be the name of the drug itself,<sup>132</sup> or may be descriptive of the drug<sup>133</sup> or related to the condition the drug is intended to treat.<sup>134</sup> Indeed, a company may register multiple domain names for a drug's website, in order to direct as many Internet searches as possible to its website.<sup>135</sup>

Drug company promotional websites, as is common with Internet site design, generally consist of a "home page" with multiple linked pages or sections from that home page. Each page is generally designed to be easily viewed on the average computer monitor, without requiring extensive scrolling. A drug promotional website's home page generally consists of both graphics and text. Often, images apparently intended to represent successful users of the product<sup>136</sup> are combined with text describing the benefits of the product. In keeping with the FDA's requirement that promotional information be balanced between descriptions of the benefits and descriptions of the risks, some websites, but not all, include on the home page a list of common side

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<sup>126</sup>*Id.*

<sup>127</sup>*Id.*

<sup>128</sup>*Id.* Use of the Internet to seek more information about an advertised drug more than doubled from 1999 to 2002, with 18% of respondents in 1999 reporting Internet searches, compared to 38% in 2002. *Id.*

<sup>129</sup>*See, e.g.*, <http://www.pfizer.com> (an example of a drug company corporate website).

<sup>130</sup>Product-specific promotional websites have been used since 1994, when Coors established a web site for its Zima alcoholic beverage brand. Gene Koprowski, *A Brief History of Advertising on the Web*, FORBES CRITICAL MASS, Fall 1999.

<sup>131</sup>*See, infra* notes 132-135.

<sup>132</sup>*See, e.g.*, <http://www.viagra.com>; *See also* <http://www.lipitor.com>.

<sup>133</sup>*See, e.g.*, <http://www.purplepill.com> (website for Nexium, a heartburn medication).

<sup>134</sup>*See, e.g.*, <http://www.allergyrelief.com>.

<sup>135</sup>*See id.* (redirecting Internet searchers to <http://www.clarinex.com>).

<sup>136</sup>*See, e.g.*, <http://www.claritin.com> (For example, an allergy medication may show images of individuals exercising outdoors, apparently unaffected by allergies.).

effects of the drug.<sup>137</sup> Other common elements of drug websites are: incentive offers to encourage visitors to seek prescriptions for the drug from their physicians,<sup>138</sup> information to help visitors control their symptoms,<sup>139</sup> self-diagnostic information to help the visitor decide if the promoted drug is appropriate;<sup>140</sup> and an invitation to submit personal information to the company.<sup>141</sup> Virtually all drug websites include a link to the approved patient package insert for the drug. However, in stark contrast to the highly polished, animated, attractive websites they accompany, the package insert files are generally merely scanned copies of the paper package insert,<sup>142</sup> characterized by small print, dense text and a lack of graphical or consumer-friendly content.<sup>143</sup>

One major difference between the visitor to a promotional website and a viewer of a print or broadcast ad is that the visitor to the website is presumably actively seeking information about the product. Broadcast and print advertisements in national media attempt to place information about the product in front of as many individuals as possible, in the hopes that those individuals for whom the information is relevant will read or view it. Internet websites, on the other hand, do not call themselves to the attention of a consumer.<sup>144</sup> Rather, the visitor to a promotional website must have first found the site. This could be by simply typing in the name of the product as part of a Uniform Resource Locator (“URL”) address.<sup>145</sup> Alternatively, the individual seeking information could have found a reference to the drug site on a

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<sup>137</sup> Compare <http://www.clarinex.com> and <http://www.viagra.com> (including at the bottom of the page a text-based description of several possible side effects of the drug) with <http://www.prozac.com> (including no risk information on the site’s home page). Note, however, that even the Clarinex and Viagra home pages require at least some users to scroll down the page in order to access the risk information, while the information presenting the benefits of the drug is featured prominently at the top of the page.

<sup>138</sup> See, e.g., <http://www.clarinex.com> (offering a free 7-day trial of the medication).

<sup>139</sup> See *id.* (offering information about pollen counts, weather forecasts and other allergy-related information through a free membership-based web service).

<sup>140</sup> See *id.*

<sup>141</sup> See *id.* (Personal information is solicited in order for the visitor to receive the promotional 7-day free trial. Access under “personalized” information on the website).

<sup>142</sup> See, e.g., <http://www.spfiles.com/piclarinex.pdf> (the patient package insert from the Clarinex website).

<sup>143</sup> Indeed, some online package inserts are virtually unreadable. See <http://www.astrazeneca-us.com/pi/nexium.pdf> (the linked page from the Nexium website, which opens an unresizable window which, at 100%, is completely unreadable).

<sup>144</sup> Of course, other Internet advertising techniques, such as mass email or banner or popup ads on related websites, may resemble print advertising much more closely in this regard than promotional web sites.

<sup>145</sup> Many companies have registered the names of their products as domain names on the Internet. See, e.g., <http://www.claritin.com>.

search engine such as Google,<sup>146</sup> or might have followed a link in a banner or “pop-up” advertisement from another website. Generally speaking, however, access to a promotional website requires an intent on the part of the visitor to find the information contained on that site.<sup>147</sup>

Because of the decentralized nature of the Internet, there are many sites of interest to individuals seeking any particular sort of health information. Some websites are set up as health “portals,” designed to provide users with a wide range of options, with information about and links to other sites providing further detail on, a wide variety of health issues.<sup>148</sup> Other sites are more specific, and may be designed and maintained by individual patients as online support groups and information resources for fellow sufferers, by foundations or other nonprofit institutions designed to provide resources and support for those with a particular illness,<sup>149</sup> or by for-profit companies seeking to provide information as an adjunct to their commercial services.

Because of the decentralized nature of the Internet, one of the earliest problems was how to direct Internet traffic to a particular website. A prominent method of Internet advertising is the “banner” ad. These advertisements consist of a small, oblong banner displayed as part of a website, which, when clicked by a user, direct the user’s browser the destination website of the advertiser.<sup>150</sup> Similar to banner ads are “pop-up” or “interstitial” ads, which do not display on the same web page, but open another browser window on top of (“pop-up”) or hidden underneath (“pop-under”) the window which the Internet user has visited. Like banner ads, these advertisements can convey

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<sup>146</sup>Although a search for “viagra” on Google returns 7,380,000 results as of the date of this writing (June 2, 2003), the first sponsored and non-sponsored links in the list are in fact the promotional site operated by Pfizer, the manufacturer of the drug. However, prominent placement on the Google results page is given to another “sponsored link” which is, in fact, the website of an Internet pharmacy offering Viagra by remote prescription. *See, e.g.*, <http://www.pillrx.com>.

<sup>147</sup>*See, e.g.*, Dot Com Disclosures, *supra* note 44 (“Even though consumers have control over what and how much information they view on Web sites, they may not be looking for – or expecting to find – disclosures. ... Accordingly, disclosures must be communicated effectively[.]”). Although the fact that the customer sought out the promotional material is relevant for site design and disclosure purposes, it certainly does not obviate the need to provide fair balance and make relevant disclosures. *See* Broadcast Guidance, *supra* note 25, at 4 (establishing lesser standards for adequate provision in telephone ads compared to broadcast ads).

<sup>148</sup>*See, e.g.* <http://www.drkoop.com>; *See also* <http://www.webmd.com>.

<sup>149</sup>*See, e.g.*, <http://www.lungusa.org> (website of the American Lung Association).

<sup>150</sup>BARBARA K. KAYE & NORMAN J. MEDOFF, JUST A CLICK AWAY: ADVERTISING ON THE INTERNET 36-37 (2001)

information as well as provide a link directly to the sponsor's main website.

Unfortunately, one of the most visible methods of prescription drug advertising on the Internet is also one of the most ethically and legally questionable. Unsolicited commercial email, popularly known as "spam,"<sup>151</sup> has experienced a dramatic rise along with the popularity and utility of the Internet. According to some estimates, spam constitutes approximately half of all email traffic on the Internet.<sup>152</sup> Although precise statistics on the amount and frequency of health-related spam are not available,<sup>153</sup> the prescription drug spam ad has become part of American pop culture. A recent article in *Time Magazine* hailing the fifth anniversary of the sexual-dysfunction drug Viagra began with the lead "If this article were an email, you would have deleted it by now,"<sup>154</sup> a clear reference to the ubiquity of spam ads for Viagra.

Spam is one of the cheapest forms of Internet advertising,<sup>155</sup> because it takes advantage of a free-rider phenomenon in American Internet pricing. Generally, American Internet users pay a flat fee for Internet access, and do not pay for access on either a time or bandwidth usage basis. However, ultimately, the social cost of the Internet is based on the amount of bandwidth used. Thus, Internet service providers ("ISPs") have an incentive to monitor and control the amount of bandwidth used by their customers; and in fact, spamming and other high-bandwidth uses (such as running a website server) are generally prohibited under most ISPs' standard user contracts. However, not every ISP enforces these limitations vigorously. Further, the ease of signing up for Internet access makes it relatively easy for a spammer to

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<sup>151</sup>Internet legend has it that the term "Spam" is derived from a skit performed by the comedy troupe Monty Python, which features a Spam-laden restaurant menu. Whether this legend is accurate or not, it has been enshrined in American case law. See *Compuserve v. Cyber Promotions Inc.*, 962 F.Supp. 1015, 1018 (S.D. Ohio 1997); See also *Hotmail Corp. v. Van\$ Money Pie Inc.*, No. C-98 JW PVT ENE, 1998 WL 388389, at \*1 (N.D. Cal. April 16, 1998). While unsolicited email is not as effective at generating response as emailing to individuals who have requested the information, it does generate up to five percent response rate. BILL CARMODY, *ONLINE PROMOTIONS* 249 (Wiley 2001).

<sup>152</sup>Mark Glassman, *Fortifying the In Box as Spammers Lay Siege*, N.Y. TIMES, July 31, 2003, at G8.

<sup>153</sup>One source claims that health-related spam constituted 6% of all spam in April 2002. Jennifer B. Lee, *Spam: An Escalating Attack of the Clones*, N.Y. TIMES, June 27, 2002, at G1.

<sup>154</sup>Christine Gorman, *Viagra Turns 5: Early Safety Concerns Proved Baseless, and Now the Competition is Heating up*, TIME, January 20, 2003, at 146.

<sup>155</sup>One estimate places the cost of sending an email solicitation to one million addresses as between \$200 and \$2,000. HERSHEL GORDON LEWIS & JAMIE MURPHY, *CYBERTALK THAT SELLS* 18 (Contemporary Books 1998).

repeatedly switch ISPs as his accounts are blocked for violations of his service providers' agreement. It is extraordinarily difficult to ban someone from the Internet, given the decentralization of the net and the lack of a central governing authority.

Spam is ordinarily not an advertising medium used by drug manufacturers, but tends to be sponsored by Internet pharmacies (generally those not operating within the boundaries of professional standards for Internet pharmacy practice).<sup>156</sup>

Drug manufacturers, while generally not sending indiscriminate emailings, do in fact collect lists of email addresses for targeted marketing. Although these mailings may not be "spam" in the strict sense of the word, they do constitute a potential violation of privacy interests (email accounts may not be private). However, to the extent that an individual has provided his email address to the company for this purpose, such mailings may have been consented to,<sup>157</sup> and thus not a violation of applicable privacy law.

In addition to delivering information via websites and email, and directing traffic to relevant websites via banner and pop-up and pop-under ads, drug companies and other drug advertisers may collect information about individual Internet users in order to make promotion of their products more cost-effective. Although the popular belief is that "on the Internet, no one knows you're a dog,"<sup>158</sup> in fact, there is a surprising amount of information available on the average user's Internet surfing habits. This information is collected, often surreptitiously, by software called "spyware" which is often installed without the user's knowledge or express consent along with other

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<sup>156</sup>In the author's experience, pharmaceutical spam is overwhelmingly from e-pharmacies offering to sell prescription drugs with "no prior prescription required," that is, by prescription with no physical exam or doctor-patient relationship. These prescribing practices are violations of the VIPPS standards established by the National Association of Boards of Pharmacy. For a description of the VIPPS program, see National Association of Boards of Pharmacy, Verified Internet Pharmacy Practice Sites, available at <http://www.nabp.net/vipps/>. For a discussion of the VIPPS standards, see John Michael Ward, *Online Pharmaceutical Regulation: An Avenue to a Safer World*, 24 J. LEGAL MED. 77, 85-90 (2003).

<sup>157</sup>BILL CARMODY, ONLINE PROMOTIONS 38-39 (Wiley 2001) (advising marketers to "create a compelling reason for someone to give you permission [to market to them] in the first place."). Thus, drug promotion websites often offer an inducement, such as a free trial coupon, in exchange for a visitor providing his email address for future marketing efforts. See, e.g., <http://www.clarinex.com>.

<sup>158</sup>Peter Steiner, NEW YORKER, July 5, 1993 (cited in Alfred C. Yen, *Western Frontier or Feudal Society? Metaphors and Perceptions of Cyberspace*, 17 BERKELEY TECH. L. J. 1207 (2002)).

software downloads from the Web,<sup>159</sup> and runs silently on a user's computer.<sup>160</sup> This software collects data about the user's Internet usage habits and transmits that information to a centralized database.<sup>161</sup> This information can then be used to more effectively target advertisements to the user.

## **DTC INTERNET ADVERTISING AND THE DOCTOR-PATIENT RELATIONSHIP**

### **Elements of the Doctor-Patient Relationship**

Although the doctor-patient relationship has been the subject of much scholarly attention over the years, the precise nature of the relationship has proven elusive and incapable of precise elucidation.<sup>162</sup> One popular description of the physician-patient relationship, and the analytical framework I shall use in this Article, is derived from the work of prominent bioethicists Nancy Dubler and Ezekiel Emanuel.<sup>163</sup> According to Dubler and Emanuel, the ideal trusting physician-patient relationship can be conceptualized as involving six elements, the "six C's: choice, competence, communication, compassion, continuity and (no) conflict of interest."<sup>164</sup> According to Emanuel and Dubler, these six elements are important in order to allow the therapeutic trust that is at the core of the physician-patient relationship to flourish.<sup>165</sup> Although trust is not one of the six elements, it is hypothesized to be the result of them.<sup>166</sup> In examining the impact of direct-to-consumer advertising and the Internet on the physician-patient relationship, therefore, we will use the lens of Emanuel and Dubler's six C's.

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<sup>159</sup>See Robert O'Harrow, Jr., *Firm Tracking Consumers on the Web for Drug Companies*, WASH. POST, Aug. 15, 2000, at E1. (describing litigation against the firm Pharmatrx).

<sup>160</sup>Gene Koprowski, *A Brief History of Advertising on the Web*, FORBES CRITICAL MASS, 1999 (discussing use of "cookie" technology to track consumer behavior on the Web).

<sup>161</sup>See Tim Wu, *When Code Isn't Law*, 89 VA. L. REV. 679, 749 n. 259 (2003).

<sup>162</sup>The legal status of the relationship is not entirely clear, either. Courts are split on such fundamental questions as whether a physician and a patient are in a fiduciary relationship. See *Dingle v. Belia*, 749 A.2d 157 (Md. 2000); *McCraw v. Mary Black Hosp.*, 565 S.E.2d 286 (S.C. 2002); *Newman v. Sonnenberg*, 81 P.3d 808 (Utah Ct. App. 2003).

<sup>163</sup>Ezekiel J. Emanuel, M.D., Ph.D. & Nancy Neveloff Dubler, L.L.B., *Preserving the Physician-Patient Relationship in the Era of Managed Care*, 273 JAMA 323 (1995).

<sup>164</sup>*Id.* at 323.

<sup>165</sup>See *id.* at 324.

<sup>166</sup>See *id.*

## Potential Effects of DTC Advertising

### *Choice*

One of the primary benefits touted by proponents of consumer-oriented prescription drug advertising is its enhancement of patient choice. According to these commentators, advertisement of prescription drugs adds more information into the marketplace, enhancing patient autonomy and increasing the number of choices available to patients. In an era when health care economics make it increasingly burdensome for physicians to talk to patients about alternative treatment regimens,<sup>167</sup> prescription drug advertising provides an alternative source of information with which patients can become true partners in their health care and can more effectively express their desires and values to their physicians,<sup>168</sup> ultimately improving patient compliance with treatment regimens as well as health outcomes.<sup>169</sup>

Choice is of no value, though, if not accompanied by full and accurate disclosure of the relevant data necessary to make that choice.<sup>170</sup> Although DTC advertising on the Internet has much promise, it has so far dangerously failed to live up to that promise by failing to make adequate disclosures of information relevant to patients' therapeutic choices. Scholars have criticized the quality of the information provided by drug companies to prescribing physicians.<sup>171</sup> However, practicing physicians have an enormous educational advantage over the average consumer exposed to DTC drug advertisements.<sup>172</sup>

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<sup>167</sup>Patient survey results show that patients are satisfied with physician responses to questions resulting from DTC advertisements. See Aikin, *supra* note 117. Only 3% of patients in 2002 reported their physician becoming "angry or upset" when asked about an advertised drug. *Id.*

<sup>168</sup>Research shows that DTC advertising does in fact lead patients to seek information from their physicians. *Id.* Among survey respondents who searched for more information as a result of exposure to a DTC advertisement, 89% sought information from their own physicians, and 25% sought information from a physician other than their own doctor. *Id.*

<sup>169</sup>Hoen, *supra* note 4, at 595 ("The belief that advertising may contribute to better use of medications seems to be one of the foundations for the [1997] FDA guidelines."). *But see* Lexchin, *supra* note 15 (suggesting that exposure to advertisements produces irrational behavior in both consumers and physicians).

<sup>170</sup>MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS AND ECONOMICS OF RATIONING MECHANISMS; *See also* Timothy S. Hall, *Bargaining with Hippocrates: Managed Care and the Doctor-Patient Relationship*, 54 S.C. L. REV. 689, 720 (2003).

<sup>171</sup>*See* Hoen, *supra* note 4, at 596.

<sup>172</sup>Encouragingly, patients surveyed by FDA rarely report visiting a physician expressly in order to obtain an advertised drug. Aikin, *supra* note 117 (4% of respondents). On the other hand, 50% of those who asked a physician about a specific advertised drug obtained a prescription for the drug. *Id.* The data do not reflect the extent to which this represents a change

### *Competence*

Direct-to-consumer promotion of prescription drugs also has the potential to enhance physician competence, albeit in an indirect manner. The pharmaceutical industry is a fast-paced industry, and many new drugs are approved for clinical use every year.<sup>173</sup> Physicians face a constant barrage of new approved medications in every specialty, and must devote substantial amounts of time to keeping current with new trends and developments in pharmacology. Direct-to-Consumer prescription drug advertising, by giving patients the tools with which to communicate their needs and values to their physicians, helps physicians keep up with new developments and with patient demand for cutting edge pharmaceutical therapies.

Direct-to-consumer advertising also has the potential to diminish, if not actual physician competence, at least the effect of physician competence. The primary reason for the requiring certain drugs to be dispensed only with a prescription is to protect the health of the patient from potentially harmful side effects, drug interactions and other unwanted consequences of the ingestion of prescription drugs. As prescription drugs increasingly are viewed as lifestyle choices rather than as medical choices, and as the Internet continues to create both demand and desire for drugs and the ability to gratify that desire without actually visiting a physicians and obtaining a prescription from someone with actual knowledge of the patient's health status and the wisdom of taking the drug in question,<sup>174</sup> the effective role of the physician as gatekeeper is reduced.<sup>175</sup> Further, although the patient may be empowered through information gained on the Internet to seek out alternative treatments and to become a partner in his own health care decisions, the danger is that the patient will demand certain treatments because of the glowing description of those treatments' efficacy in promotional materials, which may or may not be relevant or applicable to the patient's individual circumstances.<sup>176</sup> Although there is substantial educational value to information available through the

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in physician prescribing practices, i.e., the number of patients who would have received a prescription for the drug in question without specifically mentioning it. *Id.*

<sup>173</sup>The number of new drugs approved annually has doubled in the recent past. CTR. FOR DRUG EVAL. & RES., BENEFIT V. RISK: HOW CDER APPROVES NEW DRUGS, at <http://www.fda.gov/cder/about/whatwedo/testtube-5.pdf>.

<sup>174</sup>See *supra* note 2 (citing to articles discussing the sale of prescription drugs on the Internet in depth).

<sup>175</sup>Hoen, *supra* note 4, at 596 ("Pharmacists and physicians should set their own priorities on the basis of the health needs of the patients they care for, not according to the latest fashion in drug advertising.").

<sup>176</sup>See Lexchin, *supra* note 15.

Internet, in the end, communications to patients or potential patients from drug manufacturers and retailers are promotional messages,<sup>177</sup> and patients may not have the critical skills to separate the promotion from the data in making health care decisions.<sup>178</sup>

### *Communication*

Managed care has drastically affected the traditional doctor-patient relationship.<sup>179</sup> Doctors are continually under pressure to provide more services at less cost, and one casualty of this pressure is communication between doctor and patient.<sup>180</sup> By giving the patient the knowledge to initiate conversations about various drug therapies, DTC advertising has the potential to increase the efficiency of doctor-patient communication. If patients are armed with relevant knowledge gained from communications from the pharmaceutical industry, this relieves some of the pressure on physicians to perform the role of educator, and makes the patient more of a partner in his own health care decisions, rather than a passive consumer of choices made by the physician.<sup>181</sup> The Internet is a particularly promising medium for this educational role, since it promises a highly individualized, interactive medium for delivery of pharmaceutical knowledge, potentially tailored to the individual consumer's health needs as well as his level of comprehension and desire to learn about particular health conditions and treatment options.

If patients are driven by promotional communications to desire certain drugs,<sup>182</sup> this may interfere with the ability of their physicians to

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<sup>177</sup>See Timothy Hall, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 449, 462 (1993).

<sup>178</sup>See *id.* See also Hoen, *supra* note 4, at 595 ('Pharmaceutical marketing to prescribers, dispensers and consumers may contribute to irrational use [of prescription drugs]...') (quoting D.A. Fresle & C. Wolfheim, *Public education in rational drug use, a global survey*, 1997 WHO, (Action Programme on Essential Drugs, Geneva, Switzerland).

<sup>179</sup>See Emanuel & Dubler, *supra* note 155.

<sup>180</sup>For a discussion of the structural changes associated with managed care, see Timothy S. Hall, *Third-Party Payor Conflicts of Interest in Managed Care: A Proposal for Regulation Based on the Model Rules of Professional Conduct*, 29 SETON HALL L. REV. 95 (1998).

<sup>181</sup>For a discussion of the ethical desirability of patient autonomy in health care decision making, see BEAUCHAMP & CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 57-104 (5th ed. 2001).

<sup>182</sup>According to recent FDA data collected from a sample of patients, this does not seem to be the case. See Statement of N. Ostrove, *supra* note 20 (4% of patients report requesting specific drug from physician based on DTC advertisement).

exercise independent judgment on the patient's behalf.<sup>183</sup> Although an ethical ideal of the physician-patient relationship is one of patient empowerment and choice,<sup>184</sup> this ideal must be tempered with the understanding that the physician's extensive education, experience and relatively objective judgment must be brought to bear in the decision-making process.<sup>185</sup> If promotional information available on the Internet short-circuits that process to the extent that patients are showing up in doctors' offices having self-diagnosed and self-prescribed, seeking only a rubber stamp for their chosen therapy,<sup>186</sup> they may be reluctant to hear even the best efforts of the physician at communicating cheaper or safer alternatives. Internet advertising runs the risk of supplanting the doctor-patient relationship with a patient-advertiser relationship; a scenario in which the doctor is relegated to the role of facilitator.<sup>187</sup>

### *Compassion & Continuity*

To the extent that in person doctor-patient relationships are supplanted or supplemented with online prescribing practices that do not meet the relevant standard of care, both compassion and continuity are adversely affected.<sup>188</sup> Currently, several Internet pharmacies provide online "consultations" in which patients can obtain prescriptions for drugs simply by filling out an online form providing basic health information.<sup>189</sup> To the extent that prescription drugs are available in this manner, in the absence of a doctor-patient relationship, continuity of care is adversely affected. Not only might a patient believe that he is receiving quality care when in fact he is receiving nothing more than a rubber-stamped prescription that does not comply with the appropriate

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<sup>183</sup>Philip R. Alper, M.D., *Direct-to-Consumer Advertising: Education or Anathema?*, 282 JAMA 1226 (1999) (describing DTC advertisements as an "end run around the cost-containment efforts of health managers and physicians.").

<sup>184</sup>TOM L. BEAUCHAMP, PH.D. & JAMES F. CHILDRESS, PH.D., *PRINCIPLES OF BIOMEDICAL ETHICS* 57 (5th ed. 2001).

<sup>185</sup>*Id.* (discussion of autonomy "does not imply that this principle has priority over all other principles ...").

<sup>186</sup>*See* CEJA, *infra* note 184, at 124 (reiterating that physicians must comply with principles of informed consent when faced with specific requests for advertised drugs).

<sup>187</sup>*See* Hoen, *supra* note 4, at 596 (articulating the fear that doctors and pharmacists may be reduced to the role of adjunct to demand-creating DTC advertisements). To the extent that individuals are willing to bypass the doctor-patient relationship to order drugs from online pharmacies with no prescription, the ability of the health care professional to engage in an informed consent dialogue, as recommended by the AMA, is diminished. *See* CEJA, *infra* note 184, at 123-124.

<sup>188</sup>*See supra* note 2 (citing to articles discussing Internet prescribing practices in more detail).

<sup>189</sup>*See supra* note 2 (citing to articles discussing Internet prescribing practices in more detail).

standard of care, a patient's existing relationship with his regular physician may be harmed if the patient is engaging in drug-seeking behavior on the Internet without informing the physician of this fact.

### *(No) Conflict of Interest*

The topic of conflict of interest is a thorny one for the medical profession generally,<sup>190</sup> and the pharmaceutical industry in particular.<sup>191</sup> The history of promotion of prescription drugs to physicians is replete with industry practices of generous gifts and subsidies to physicians, often without an express demand for a *quid pro quo* response, but in the hope that industry generosity would be repaid with physician brand loyalty and prescribing patterns.<sup>192</sup> Only recently has the ethical condemnation of the practice of industry gifts to physicians resulted in the adoption of guidelines meant to reduce the appearance of impropriety in this area.<sup>193</sup> Even so, physicians and the medical industry rely heavily on subsidy from the pharmaceutical industry, and the potential for indirect pressure, if not a direct conflict of interest, still underlies the relationship between practicing physicians and the drug industry. Payment by drug companies to prescribing physicians or others in a position to influence prescribing or purchasing decisions creates an impermissible interference with the clinician's duties to the patient.<sup>194</sup>

The efficacy of DTC advertising might reduce the need for the drug industry to target physicians quite so lavishly in order to create brand loyalty. Although physicians by definition still exercise the final say in whether or not to prescribe a particular drug, clearly DTC advertising has resulted in a shift in power from the physician to the patient. Patients may now go to their doctors with a preferred therapy already in mind,<sup>195</sup> and may engage in active forum-shopping in order to obtain that treatment. This reduces the incentive for physicians to maintain an active gatekeeper function, and reduces the attractiveness of physicians as targets of lavish promotional spending by drug companies. Further, the rise of Internet pharmacies and Internet prescriptions, although condemned by much of the medical

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<sup>190</sup>For a discussion of conflicts of interest in managed care, see Hall, *supra* note 172.

<sup>191</sup>See, e.g., MARC A. RODWIN, *MEDICINE, MONEY AND MORALS* 107-111 (1993).

<sup>192</sup>See Council on Ethical and Judicial Affairs, *Gifts to Physicians From Industry*, available at [http://www.ama-assn.org/ama/upload/mm/369/ceja\\_report\\_030.pdf](http://www.ama-assn.org/ama/upload/mm/369/ceja_report_030.pdf) [hereinafter CEJA].

<sup>193</sup>*Id.*

<sup>194</sup>CEJA, *supra* note 184.

<sup>195</sup>Statement of N. Ostrove, *supra* note 20.

establishment, is placing even more power in the hands of the individual consumer, who can now obtain many, if not most, prescription medications without the need to visit a doctor at all.<sup>196</sup> These developments further undercut the role of the physician as gatekeeper and sole decision-maker in the choice of therapies, and may result in fewer conflicts of interest as drug makers scale back their physician advertising of certain drugs in favor of direct to consumer advertising.

### **Effect of DTC Advertisement on Health Outcomes**

Direct-to-consumer advertisement may have an ultimate effect on health outcomes in several ways, all related to the quality and completeness of the information provided, and the appropriateness of that information to the targeted audience.

First, the use of DTC advertisement may produce a preference in the minds of consumers for newer, more heavily advertised (and more expensive) drugs, rather than older therapies. This is so because it is during the first years of a drug's approval and marketing when prices for the drug are highest; while the drug still enjoys patent protection and generic drug manufacturers have not yet marketed alternatives. This preference for newer therapies may also arise from the nature of American consumerism, in which the "new and improved" is continually being promoted, perhaps leading to an association in the mind of the consumer between "new" and "improved."

This association is not necessarily correct in the case of prescription drugs, however. In fact, newer drugs may be notably less safe than their older counterparts, in part because less is known about the clinical efficacy and proper prescribing of the new drug.<sup>197</sup> Safety information is not fully developed at the time a new drug is approved, but continues to be collected as the drug is marketed.<sup>198</sup> Further, a new drug therapy may not provide enhanced therapeutic efficacy compared to a traditional alternative, or may not provide that enhanced efficacy in all cases or for all individuals.<sup>199</sup>

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<sup>196</sup>See *supra* note 2.

<sup>197</sup>Hoen, *supra* note 4, at 595.

<sup>198</sup>Julie Bietz, *Post Marketing Risk Assessment of Drug Products*, CTR. FOR DRUG EVAL. & RESEARCH, available at <http://www.fda.gov/cder/present/raps10-2002/juliebietz/>.

<sup>199</sup>See *That Money Show, Drug Advertising, at* <http://www.pbs.org/wnet/moneyshow/cover/033001.html>.

Further, the prevalence of DTC advertising may lead consumers to “self-medicate,”<sup>200</sup> procuring prescription pharmaceuticals from online pharmacies on the basis of information obtained from marketing websites and emails, without seeking the advice of a trained physician.<sup>201</sup> However, the lack of adequate information may make this practice risky or positively dangerous for consumers.<sup>202</sup>

Evidence suggests that patient exposure to DTC advertising may have negative health consequences as well. In one study of HIV-positive gay men in San Francisco, the investigators found a correlation between an individual’s exposure to DTC advertisement for HIV treatments and that individual’s perception on the seriousness of HIV infection.<sup>203</sup> Those with more exposure to DTC advertisements tended to view HIV infection as less serious.<sup>204</sup> These data suggest that exposure to such advertisements may directly affect in individual’s decision to engage in unsafe sexual behavior.<sup>205</sup>

### PROPOSALS FOR REGULATION OF ONLINE DTC ADVERTISING

The goal of regulation of direct-to-consumer advertising should be the protection and preservation of the physician-patient relationship. In fact, much of the regulation of the relationship between pharmaceutical companies and physicians has this same goal, in the form of protection of physicians from undue conflicts of interest.<sup>206</sup> We have already mentioned the history of unethical “gifts” and other subsidies to

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<sup>200</sup>See Study: *E-Pharmacies Could Harm Consumers’ Health*, Reuters Internet Report, April 8, 2003.

<sup>201</sup>Many of the emails touting e-pharmacy services emphasize the fact that no physician visit or “prior prescription” is required to obtain drugs.

<sup>202</sup>*Id.* (reporting that despite the existence of some Internet pharmacy practice standards, current e-pharmacies are failing to comply with good practices, and that more than half provided either no information or too little information to be of benefit to consumers). Study: *E-Pharmacies Could Harm Consumers’ Health*, *supra* note 200.

<sup>203</sup>Jeffrey D. Klausner, et al., *Are HIV Drug Advertisements Contributing to Increases in Risk Behavior Among Homosexual Men in San Francisco*, 2001?, 16 AIDS 2349 (2002).

<sup>204</sup>*Id.* (“HIV-Positive homosexual men who saw advertisements at least weekly were six times more likely to believe that HIV was less serious compared with HIV-positive homosexual men who saw advertisements less frequently[.]”).

<sup>205</sup>*Id.* at 2350 (“HIV-positive respondents with frequent advertisement exposure more often reported unprotected anal sex compared with HIV-positive respondents with infrequent exposure.”).

<sup>206</sup>For an extensive discussion of the phenomenon of conflicts of interest in medical practice, see MARC A. RODWIN, *MEDICINE, MONEY AND MORALS: PHYSICIANS’ CONFLICTS OF INTEREST* (1993).

physicians from drug manufacturers.<sup>207</sup> A prohibition of DTC advertising would prevent some of the abuses and detriments described above. It would certainly curtail the efforts and the spending of the major pharmaceutical manufacturers on DTC advertising. However, such a regulatory response is suboptimal for several reasons. First, it would not prevent or effectively prohibit all Internet advertising. The Internet effectively blurs national borders, and makes national laws of questionable efficiency in regulating online behavior.<sup>208</sup> Second, a ban on DTC advertising on the Internet would be against the current trend of increased information flow to consumers. Health information is one of the leading uses of the Internet,<sup>209</sup> and other authorities are considering relaxing rather than tightening restrictions on communications with consumers of prescription drugs.<sup>210</sup> Finally, a ban, while not eliminating all the poor information flowing into the marketplace,<sup>211</sup> would eliminate the possibility of use of the Internet to enhance the physician-patient relationship through increasing the patient's ability to exercise his autonomy and increasing the level of discourse that is possible between physician and patient about the patient's treatment options. The Internet also has the possibility of

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<sup>207</sup>*Id.* at 107-110.

<sup>208</sup>Similar problems exist in attempts to regulate online casinos and mass e-mailers, both of whom often operate from outside United States jurisdiction for the purposes of avoiding U.S. jurisdiction. See generally Lawrence G. Waters, *The Law of Online Gambling in the United States: - A Safe Bet, or Risky Business?*, 7 GAMING L. REV. 445, 446 (2003) ("Many hosting and software development companies have also been willing to roll the 'legal dice' by creating offshore casinos or sports betting sites and providing them bandwidth."); Paul Schiff Berman, *The Globalization of Jurisdiction*, 151 U. PA. L. REV. 311, 355 (2002) ("Gambling, child pornography or 'spam' operations targeting users in one jurisdiction will often locate their servers elsewhere.").

<sup>209</sup>See John Blum, *Internet Medicine and the Evolving Legal Status of the Physician-Patient Relationship*, 24 J. LEGAL MED. 413, 415 (2003) ("More than 52 million adults in the United States have searched the World Wide Web for health and medical information.").

<sup>210</sup>While only the United States and New Zealand currently allow DTC marketing of prescription drugs, the European Union is considering a proposal to allow limited promotion of prescription drugs in the categories of HIV/AIDS treatments, diabetes treatments and asthma. See Vanessa Fuhrmans & Gautam Naik, *Pushing Pills: In Europe, Prescription-Drug Ads Are Banned - and Health Costs Lower*, WALL ST. J., March 15, 2002, at B1 (describing pressure to relax regulation of drug marketing from drug companies and the Internet, and describing a proposed EU proposal to test DTC marketing); *Drugs on Net opens health-care debate*, BUS. & FIN. UK 22 (2002) (describing British regulations prohibiting DTC marketing and the current controversy over increasing the ability of drug companies to provide information to patients); Colin Meek, *Direct-to-consumer advertising (DTCA) of prescription medicines: second quarterly update-April to June 2002*, PROPOSED MODIFICATIONS OF DIRECTIVE 2001/83/EC ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE, ARTICLE 88 (2002).

<sup>211</sup>Fuhrmans & Naik, *supra* note 218 ("the Internet has already made the ban [on drug marketing to consumers] somewhat moot ...").

reducing the burden on physicians to educate their patients about treatment alternatives, including the alternative of prescription drugs.

### Potential FDA Regulation of DTC Advertising

The FDA should continue its role as the primary regulator of direct to consumer advertising of prescription drugs. The letter of agreement between the FDA and FTC establishes a comprehensible and workable sharing of authority, and is commendable to the extent it prevents overlapping enforcement efforts<sup>212</sup> or conflicting regulatory requirements. However, the FDA should reexamine its current regulatory scheme with respect to prescription drugs and make several changes.

The Internet, with its interactivity and opportunities for customization of information to the needs of the individual seeking it, can actually be a better medium for the complex information related to prescription pharmaceuticals.<sup>213</sup> However, regulatory attention is needed in order to help users navigate the sea of information available on the Internet. In considering how to apply existing regulations, and whether to adopt new regulations, I suggest that the FDA be guided by the following three principles:

1. The FDA should explicitly take account of the Internet's potential for interconnectivity, multimedia and other enhancements to either print or broadcast advertisements;<sup>214</sup>
2. The FDA should explicitly consider the implications of the fair balance, major statement and adequate provision rules in the online media; and

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<sup>212</sup>Letter of Understanding, *supra* note 11, at 7287.

<sup>213</sup>*See, e.g.,* Kristen Green, *Marketing Health Care Products on the Internet: A Proposal for Updated Federal Regulations*, 24 AM J.L. & MED. 365 (1998); *See also* Shane M. Ward, *WLF and the Two-Click Rule: The First Amendment Inequity of the Food and Drug Administration's Regulation of Off-Label Drug Use Information on the Internet*, 56 FOOD & DRUG L.J. 41,42 (2001) (noting that the hyperlinking capability of the Internet "potentially could offer capabilities superior to paper-based media for the purposes of presenting a complete and unbiased scientific perspective."); Noah, *supra* note 24, at 148 (noting that the existing brief summary requirement in print ads "substantially increases the cost" of such ads to the sponsor).

<sup>214</sup>*See, e.g.,* Ward, *supra* note 205 (advocating that the FDA regulations governing dissemination of information regarding off-label uses of prescription drugs be revised, or specific guidance be issued, taking account of the unique features of the Internet, which provides a low-cost, effective medium for such dissemination).

3. The FDA should encourage the final decision whether to take a prescription drug to be made by a patient and his physician in the context of a healthy physician-patient relationship.

FDA should explicitly take account of the Internet's potential for interconnectivity, multimedia and other enhancements to either print or broadcast advertisements

To date, the position of both the FDA and FTC has been that Internet advertisements are adequately regulated under existing schemes.<sup>215</sup> While this position contains a kernel of truth; namely, that fraud is fraud, whatever the medium,<sup>216</sup> the unique characteristics of the Internet deserve specific regulatory consideration, just as the specific characteristics of other media have generated specific regulatory approaches. While the underlying structure of the regulatory scheme is sound and provides a framework for regulation of online promotion, the FDA should explicitly articulate how the regulatory requirements are to be applied in the online medium. Although the FTC has provided some guidance to online advertisers in other industries, the FDA has to date not provided any guidance to industry addressing Internet promotion of prescription drugs.

Second, the Internet can enhance other forms of advertisements by acting as a repository for further information. Data collected by the FDA show that a significant percentage of those who seek additional information after viewing a DTC advertisement seek that information on the Internet.<sup>217</sup> The current regulatory scheme, by allowing the Internet to be a repository of warnings concerning the drug being advertised,<sup>218</sup> potentially threatens the balance of print and broadcast advertisements. There are no guarantees that individuals will seek out the warnings posted on the Internet and other sources that are alluded to in broadcast advertisements, and substantial evidence in the informed consent literature suggesting that they will not. Further, warnings on the Internet may be diluted in effect by exposure to further promotional material. The FDA must be careful in enforcing, not only the adequate

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<sup>215</sup>Letter of Understanding, *supra* notes 11-13.

<sup>216</sup>Noah, *supra* note 24, at 154 ("one should not exaggerate the supposed uniqueness" of the Internet.).

<sup>217</sup>See Kathryn J. Aikin, *Direct-To-Consumer Advertising of Prescription Drugs: Patient Survey Results*, FOOD & DRUG ADMIN. (2002) (38% of patients who seek additional information turn to the Internet for that information).

<sup>218</sup>See Broadcast Guidance, *supra* note 25.

provision requirement, but also the fair balance requirement in broadcast advertisements.

Currently, the FDA has insufficient resources to police the advertisement of prescription drugs directly to consumers.<sup>219</sup> The life cycle of a drug advertisement or promotional campaign is typically short, and the lack of prior review of advertisements guarantees that the FDA's enforcement mechanism will be limited to ordering manufacturers to pull misleading or fraudulent advertisement after it has had its impact on the marketplace.

The FDA should explicitly consider the implications of the brief summary, fair balance, major statement and adequate provision rules in the online media

Existing regulatory requirements are aimed at balancing the levels of promotion and warning provided to viewers of the advertisement, and should ideally give the viewer, whether a health care professional or a consumer, sufficient resources to critically examine whether the advertised product is appropriate. However, these requirements are not always clearly applicable in the online medium.

When applied to a print or broadcast advertisement, the FDA's fair balance requirement can be considered in light of a finite document – a one or two page print layout, a thirty-second television or radio ad, or a telephone script. However, on the Internet, the boundaries of the advertisement are not clearly delineated, and the requisite fair balance is unclear. Is the website's home page, or a small banner ad on a health portal site, to be examined for fair balance on its own? Or must fair balance be assessed with respect to each banner advertisement and each page of the manufacturer's website?

Internet website advertisements should be treated as print advertisements, rather than under the liberalized "adequate provision" rules for broadcast ads, if the Internet site is treated as a whole. Just as print ads must reproduce the entire approved package labeling as part of the ad,<sup>220</sup> there is no reason why the package labeling cannot be provided as part of the Internet website. However, smaller advertisements could be treated as analogous to a broadcast ad, with adequate provision made for delivery of the package labeling. Even a

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<sup>219</sup>See Council on Ethical and Judicial Affairs of the American Medical Association, *Direct-to-Consumer Advertisements of Prescription Drugs*, 55 FOOD & DRUG L.J. 119 (2000) (advocating health care professionals' involvement in policing DTC advertisements).

<sup>220</sup>But see criticism above that this risk information inadequately informs consumers, as opposed to physicians, of the actual risks of the drug. Does the "fair balance" rule, in combination with the "brief summary" rule, work to increase this protection?

banner ad can contain a link to the website containing the package labeling, and a toll-free number to contact for more information. With rotating banner ads, more text can be included, such as the “see your physician for more information” language from the Broadcast Guidance.<sup>221</sup>

Any regulation targeted at Internet advertising must be flexible enough to take account of changes in the capabilities of the medium.<sup>222</sup> For example, the Internet was originally a medium which primarily sent text messages from computer to computer.<sup>223</sup> As the bandwidth available to Internet users has grown, graphical media and animations became more and more common.<sup>224</sup> Lately, the advent of consumer-oriented DSL and cable modem technology has made it possible to stream video over the Internet.<sup>225</sup> It has been predicted that some day, Internet connections will be able to transmit full-screen, broadcast-quality video streams.<sup>226</sup> These changes have had enormous impact on the types of promotional messages and activities that are possible on the Internet, and no doubt the future will bring others, as yet unanticipated changes that will pose new challenges for regulators.

As an example of the regulation of Internet technology to enhance consumer understanding and critical evaluation of promotional materials, the FDA might choose to prohibit use of “framing” technologies on health care websites<sup>227</sup> This recommendation aims at preventing consumer confusion when a promotional website links to material on off-site servers. A “framed” web page opens a new web page only in part of the user’s computer monitor; other parts of the screen still display material from the linking site. Thus, a drug company could link to a professional society, charitable foundation, or

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<sup>221</sup>See Broadcast Guidance, *supra* note 25.

<sup>222</sup>Green, *supra* note 205, at 367-368.

<sup>223</sup>Int’l Trademark Ass’n, *The Intersection of Trademarks and Domain Names – INTA “White Paper”*, 87 TRADEMARK REP. 668 (1997) (In the 1980s, “the internet was impractical for mass consumer participation because it was a medium that allowed for transmission of text only ...”).

<sup>224</sup>Peter Yu, *Symposium-Bridging the Digital Divide: Equality in the Information Age: Introduction*, 20 CARDOZO ARTS & ENT. L.J. 1 (2002) (“With the increasing use of interactive graphics and multimedia technologies, ... high-speed Internet access may be needed to access information....”).

<sup>225</sup>Beth Simone Moveck, *Designing Deliberative Democracy in Cyberspace: The Role of the Cyber-Lawyer*, 9 B.U. J. SCI. & TECH. L. 1 (2003) (“With the development of improved streaming video over Internet technologies, the cost of video conferencing is coming down...”).

<sup>226</sup>See, e.g., Aaron Hurowitz, *Copyright in the New Millenium, Is the Case Against Replay TV a New Betamax for the Digital Age?*, 11 COMMLAW CONSPECTUS 145, note 208 (2003) (“In the future, consumers will be equipped with ultrafast home Internet connections that will allow for the real time upload and download of broadcast-quality video...”).

<sup>227</sup>Green, *supra* note 205, at 384-385.

scientific journal website discussing the product being promoted (but not subject to FDA regulations of promotional materials), while appearing to the visitor that the material being viewed is still part of the manufacturer's website. Banning the use of framing technology would be fairly easy to monitor by visiting the websites in question or examining the HTML coding of those sites; and would help consumers to accurately evaluate the information they are being provided by making clear the source of that information.

FDA regulations do not currently require sufficient disclosure to consumers of the health risks of prescription drugs. Although the brief summary and adequate provision requirements ensure that consumers at least have access to relevant technical data concerning a drug, this technical disclosure is insufficient to balance the florid praise and encomiums heaped on an advertised drug in the main portion of the advertisement.

The FDA should work with international organizations and other governments to internationalize the regulation of prescription drug advertising. A persistent problem with the regulation of the Internet is its transnational nature. A website hosted in South America is no more difficult to access than a website hosted in the same building as the user's computer, provided adequate infrastructure is in place to connect to the Internet. Thus, a significant danger exists that, no matter what regulation is put in place to govern the promotional activities of websites and companies within the US, international websites will still expose American citizens to false and misleading promotional materials.<sup>228</sup>

There is probably no way to entirely eliminate the problem of offshore Internet sites. As with the casino gaming industry, fly-by-night operators will be able to quickly set up and tear down sites to evade regulation. However, there are some actions that could help minimize the problem. First, the US government can work with international bodies and other countries to establish joint enforcement efforts and increase cooperation. Second, the FDA and FTC can help educate US consumers on the credibility of health claims made by e-

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<sup>228</sup>Of course, there has always been some chance that an American audience might have access to information published overseas which includes labeling information not approved by the FDA. Noah, *supra* note 24, at 154 ("the FDA has never before suggested that print advertisements in foreign publications should comply with its brief summary requirements simply because some consumers in the United States subscribe to these newspapers and magazines.") However, the potential reach of the Internet is potentially much greater, and there may be insufficient signal to the reader that the information he is accessing is not intended for an American audience.

pharmacies, and can help consumers choose reliable online sources for prescription drugs if online purchasing meets the consumers' needs. Finally, the FDA and FTC can work with customs and postal authorities to try to intercept at least some percentage of shipments of illegal prescription drugs into the United States.

In addition to the enforcement activities described above, tort law perhaps could help reduce the threat of fraudulent international promotional and sales activity. Commentators have explored expansion of tort law to encourage drug manufacturers to exercise due care to ensure that the companies to whom they sell prescription drugs for resale are not engaging in fraudulent or unethical behavior in selling to the public.<sup>229</sup> Since most pharmaceutical companies have a presence in the United States, they are subject to tort actions brought by individuals harmed by offshore sales of drugs in a way that the sellers are not. If the manufacturers of prescription drugs have a disincentive to provide drugs for resale to e-pharmacies engaging in unethical or fraudulent business practices, this would reduce the incidence of such sales into the United States.

The FDA should encourage the final decision whether to take a prescription drug to be made by a patient and his physician in the context of a healthy physician-patient relationship.

Careful and thoughtful regulation of Internet drug promotion can help capture the benefits of the Internet for prescription drug users, while minimizing the detrimental effects. Access to carefully balanced informational material can lead to increased awareness of and responsibility for one's own health care, and improve communication and compliance with treatment regimens. Information provided by drug manufacturers can help supplement information provided by physicians and other treating professionals, and the Internet's interactivity and communications tools can tailor information to the needs and values of each individual. Regulators must take care that promotional materials do not eclipse or supplant the traditional doctor-patient relationship, but merely enhance and complement it.

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<sup>229</sup>Bryce A. Jensen, Note, *From Tobacco to Health Care and Beyond: A Critique of lawsuits Targeting Unpopular Industries*, 86 CORNELL L. REV. 1334 (2001); Richard Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV., 97 (2002) (arguing against use of tort law to discourage overly aggressive marketing).

### ***Should Tort Play a Role in Regulation of DTC Advertising?***

Despite the encouragement of several critics of the Learned Intermediary Rule, courts have been reluctant to recognize the substantially changed circumstances relating to the sale and consumption of prescription drugs, but instead articulate an exception to the LI Rule. Tort should play a larger role in the regulation of direct-to-consumer prescription drug advertising, including advertising on the Internet. Even with the best of intentions, the FDA does not possess sufficient enforcement resources to police Internet advertising for violations of regulatory requirements or violation of basic fairness. Tort has the potential to create a legion of private attorneys general, who will be empowered to hold manufacturers accountable for failure to provide adequate information about a particular drug product. Although the tort system is certainly an imperfect regulatory vehicle, it can serve as a valuable adjunct to regulation by the FDA. Tort also has the advantage of providing for compensation of those injured by drugs insufficiently described in promotional materials, providing a retrospective remedy as well as the prospective remedies of the FDA.

Although tort is a valuable regulatory tool, it cannot achieve its promise without changes in the current black letter law governing failure to warn claims involving prescription drugs. Courts must critically examine the bases for the LI Rule, and should conclude that, where the role of the traditional physician-patient relationship is diminished through the use of direct communication between the drug promoter and the ultimate consumer of the drug, the justifications for the Learned Intermediary Rule no longer apply, and the rule should be abrogated.

In addition to abrogation of the LI Rule's protective function in appropriate circumstances, courts must examine carefully the question of compliance with the common law duty to warn. Because of the limitations of FDA regulation of direct-to-consumer prescription drug advertising, manufacturer compliance with FDA requirements should not be an absolute defense to tort liability for failure to warn.

### **CONCLUSION: ACHIEVING THE PROMISE OF INTERNET DTC ADVERTISING**

The Internet holds out much promise as a cyber-community where participants can access a virtually unlimited amount of information. Since health is one of the most important topics to human beings, it is no wonder that use of the Internet to search for health-related information has boomed in the last decade. This desire on the part of

many people to increase their knowledge of health-related issues has spawned a plethora of drug-related websites. It is only natural that the companies manufacturing drugs should be both interested in promulgating information about their products and in the best position to inform potential consumers. The Internet provides unparalleled interactivity between the consumer and the medium and allows drug manufacturers, merely by making information available online, to permit users to self-select the information they desire. However, the current regulatory environment fails to correct the perverse incentives in the marketplace to provide inadequate, incomplete information about drug products. When combined with the well-known phenomenon of the bounded rationality of health care consumers, and the current ease with which the Internet permits patients who want certain prescription drugs to bypass the requirement of a prescription from a licensed physician. These incentives result in the suboptimal delivery of health information and the suboptimal delivery of, and potential overuse and misuse of, dangerous drugs.

The legal system should act to rationally regulate the advertising of prescription drugs over the Internet in order both to reduce the incidence of injury or death due to the misuse of prescription drugs, and to encourage patients to be informed consumers and active participants in their own healthcare. This regulation takes the form of providing counterincentives to the natural incentives of the marketplace. FDA regulations targeted at direct-to-consumer Internet advertising should demand that drug promoters provide a true balance of information about their products, and not overpromote the potential benefits of the product. Further, the FDA should take care that the Internet does not become a dumping ground for patient warnings about dangerous drugs. Nor should the FDA allow advertisements in other media such as television and radio to become unmitigated glorification of the benefits of prescription drugs. Finally, state legislatures and courts must rationally reconsider the desirability and effect of the Learned Intermediary Rule. While this Rule is a rational response to the traditional doctor-patient relationship, modern alterations to that relationship, including the advent of direct to consumer advertising, managed care and the growth of Internet pharmacies, make the rule less desirable than it once was, and give drug manufacturers an unearned and undesirable immunity from responsibility for the consequences of their promotional activities. In all of this, regulators and the law should not lose sight of the central feature of the health care system: the doctor-patient relationship.

No regulatory system can possibly remove all risk from prescription pharmaceuticals. As the Restatement of Torts has recognized, these products are to a large extent unavoidably dangerous, and the decision to use them consists of a risk-benefit calculus that must be performed anew for each individual patient. While the Internet holds out much promise for empowering patients to make this decision on an informed basis in consultation with a competent, trusted physician, we must take care that the marketplace does not take advantage of individuals who, because of their illness, are predisposed to hear the good and discount the potential bad consequences of a particular drug therapy.

