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**DIRECT-TO-CONSUMER ADVERTISING AND THE INTERNET:  
INFORMATIONAL PRIVACY, PRODUCT LIABILITY AND  
ORGANIZATIONAL RESPONSIBILITY**

AUDIEY C. KAO\* AND ERICA OZANNE LINDEN\*\*

I. INTRODUCTION

The emergence of the Internet as a social and economic force in shaping the interactions of individuals and institutions in modern society is unprecedented. The reality and future of this technology to link participants at any place, any time and for a countless number of ends provides buyers and sellers, creators and thinkers, citizens and polity with the power to transact, innovate and connect with increasing efficiency and effectiveness. In the realm of health and health care, the Internet provides patients, physicians and others in the health care delivery system with the potential to provide medical care more cost-effectively, improve the quality of care that is delivered and broaden access to necessary health information and services.

One aspect of the Internet's impact on medicine is the rapid proliferation of health-related information, valid and invalid, to patients and the public. Thousands of health websites, patient support listserves and health-related advertisement banners are readily accessible by Internet users and offer a new medium for third parties to engage in conventional activities in very different ways. One such activity is direct-to-consumer (DTC) advertising.

In DTC advertising, health-related manufacturers and companies offer product-related information to the public with the expectation of increasing demand for their products. Until recently, DTC advertisers exclusively disseminated product-related information to a mass audience through print and television. The rise of the Internet, however, has ushered in an entirely new dynamic whereby third parties can deliver customized information to individual patients. Proponents of DTC advertising argue that product-related information empowers consumers to take more control of their personal health and health care, further bolstering patient autonomy.

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While the Internet offers many benefits, there are significant risks that accompany this technology, and the growth of DTC advertising on the Internet is not immune to such hazards. Privacy advocates are concerned about unauthorized access by third parties to individually identifiable health information. With delivery of more customized information, DTC advertising begins to take on features that could be better described as direct-to-patient advising, and as such, new product liabilities may arise. But beyond any new legal liabilities, pharmaceutical companies, medical device manufacturers and other health-related companies have responsibilities as corporate citizens, especially as patients and the public rely more on the health information that they provide. Therefore in this Article, some key emerging ethical, legal and societal concerns presented by DTC advertising on the Internet are examined including: (1) informational privacy, (2) product liability and (3) organizational responsibility.

## II. DIRECT-TO-CONSUMER ADVERTISING AND THE FDA

In recent years, there has burst upon the scene a brand new way of reaching consumers with information about new drugs and other health products. The Food and Drug Administration (FDA), which has regulatory jurisdiction over advertisement for prescription drugs, permitted product-specific television advertising for the first time in August 1997.<sup>1</sup> In the year prior to this FDA decision, annual spending on DTC advertising was \$600 million.<sup>2</sup> By 1999, expenditures exceeded \$1.5 billion with trends for advertising spending, primarily on television, expected to continue for the foreseeable future.<sup>3</sup>

FDA regulations on advertising are based on the premise that the advertisement is truthful, presenting a fair balance of risks and effectiveness to the consumer. As such, product-specific advertisements were required to include information in "brief summary" relating to the product's side effects, contraindications and effectiveness.<sup>4</sup> In the print ad form, advertisers could

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1. The Federal Food, Drug and Cosmetic Act of 1938 established the U.S. Food and Drug Administration (FDA). *See* 21 U.S.C. §§ 301-395 (1994). The FDA was given authority over the labeling of pharmaceuticals, both prescription and over-the-counter medication. However, control over drug advertising remained with the Federal Trade Commission (FTC). In 1962, the Kefauver-Harris amendments to the original 1938 Act transferred authority for prescription drug advertisement from the FTC to the FDA.

2. Jeffrey T. Berger et al., *Direct-to-Consumer Drug Marketing: Public Service or Disservice?*, 68 MOUNT SINAI J. MED. 197, 197 (2001).

3. *Id.*

4. Drug advertisements generally fall into three categories. Health-seeking advertisements educate consumers about a disease or medical condition without a specific mention of a drug. However, this form of advertisement is prohibited if the associated product is the only treatment available for the disease or medical condition. Reminder advertisements provide the name of the

readily comply with this requirement for a brief summary. With expansion into television advertising, providing information about a product's safety and efficacy—even in a brief summary—was limited by the substantial time constraints placed on this newly available communication medium.

Recognizing the difficulty of communicating the information required in the brief summary effectively in a television ad of reasonable length, the revised FDA regulations tried to balance the advertisers' need for flexibility with the regulators' obligation to protect the consumer. The draft FDA guidelines first issued in 1997 and finalized in August 1999,<sup>5</sup> established several requirements for third parties such as pharmaceutical companies who want to market their products via television.

Advertisers who wish to market prescription drugs on television, for example, are required to present the drug's major risk factors as part of a "major statement" in either the audio or audio and visual parts of the television ad.<sup>6</sup> In addition, they must provide "adequate provision" for the dissemination of the approved labeling to satisfy requirements set out by the brief summary standard.<sup>7</sup> The guidelines outline an acceptable approach to fulfilling these requirements, which includes the following components:<sup>8</sup>

- Disclosure of an operating toll-free phone number to call for approved package labeling in which customers are given the option of having the labeling mailed to them or read over the phone.
- Disclosure in the ad of an Internet web address for package labeling.
- Reference to mechanisms to provide package labeling to consumers with restricted access to technology, such as the Internet, by (a) providing additional product information in print ad form in publications that reach the broadcast audience, or (b) ensuring the availability of a sufficient amount of brochures containing package

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drug and other minimal information, but say nothing about the drug's use, effectiveness or safety. Product-specific advertisements, which represent the vast majority of prescription drug advertisements, mention a drug therapy by name, describe its therapeutic use(s), and make representations about its safety and effectiveness. The FDA regulations that require advertisers to provide extensive product information such as through a brief summary apply only to product-specific advertisements.

5. U.S. Department of Health and Human Services et al., *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (Aug. 1999), available at <http://www.fda.gov/cder/guidance/index.htm>.

6. *Id.* at 1.

7. *Id.*

8. *Id.* at 2.

labeling in publicly accessible sites (for instance, pharmacies, doctor's offices and grocery stores).

- Disclosure in the ad that healthcare providers may offer additional information to consumers.<sup>9</sup>

Despite the public's expectation to the contrary, the FDA does not require product-specific television advertisements to be pre-screened for regulatory compliance.<sup>10</sup> Advertisements may be voluntarily submitted for pre-clearance before broadcast, and the FDA will then deem it appropriate or send the marketing campaign back for revision and editing. In summary, the FDA regulations outlined above are based on these assumptions: the advertisements are not false or misleading; there is a fair balance between the product's benefits and risks; and all information relating to important risks and approved uses and limitations are in consumer-friendly language.

### III. THE POWER OF THE INTERNET: FROM DIRECT-TO-CONSUMER ADVERTISING TO DIRECT-TO-PATIENT ADVISING

As many of us have experienced, one benefit of the Internet is its ability to deliver relevant information to a specific user at anytime, about almost anything and seemingly anywhere. The power to deliver individually relevant information is based largely on the Internet's ability to identify the specific person who is online. An example of this technological ability is exemplified by Amazon.com, the world's largest Internet consumer commerce site. Whenever I visit Amazon.com, the following message always appears: "Hello, Audiey Kao, we have recommendations for you." First, Amazon.com is able to identify the user based on information that has been voluntarily provided to them. Second, a review of previous purchases allows Amazon.com to recommend products such as CDs or books that may be of interest. Lastly, Amazon.com has agreed not to share the kind of information noted above with third parties without explicit consent of the user.

Amazon.com's ability to create a personal experience for their consumers is attainable by almost all entities doing business on the Internet, including those engaged in DTC advertising. For example, a pharmaceutical company

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9. *Id.* at 3.

10. According to a study by Robert Bell, Richard Kravitz and Michael Wilkes, a large number of consumers incorrectly believe that DTC ads carry the imprimatur of the federal government. Based on a survey of consumers, half of all respondents believed that DTC ads had to be submitted to the government for prior approval, 43% believed that only "completely safe" drugs could be advertised directly to consumers, 22% thought that advertising of drugs with serious side effects had been banned and 21% believed that only "extremely effective" drugs could be marketed directly to consumers. Robert A. Bell et al., *Direct-to-Consumer Prescription Drug Advertising and the Public*, 14 J. GEN. INTERNAL MED. 651, 654-55 (1999).

has the same capability of user identification based on information provided by a patient. A review of individually identifiable health information permits a pharmaceutical company to better target its products to a patient's medical problems. With these capabilities, web-based advertisement banners purchased by a pharmaceutical company could read as follows: "Hello, Audiey Kao, we have recommendations for treating your gout."

In this case, a pharmaceutical company is acting less like a traditional advertiser, but more like an adviser who recommends certain treatments that may be of benefit to the patient. Research on the impact of DTC advertising on consumer behavior reveals that many patients, especially those diagnosed with a condition for which a given drug was advertised, are likely to ask their physician to prescribe the advertised medication by name.<sup>11</sup> As DTC advertising becomes more customized to the individual health circumstances of the patient, the effect on consumer behavior as it relates to the demand for such advertised products is likely to increase. Therefore, given the power offered by the Internet to pharmaceutical companies and others, a shift from DTC advertising to direct-to-patient advising may have a significant impact on both the cost and quality of medical care.

This conceivable transformation from direct-to-consumer advertising to direct-to-patient advising depends on a company's access to individually identifiable health information, especially detailed health information held by entities such as pharmacies and health plans. Concerns about protecting the privacy of individually identifiable health information will be addressed in the next section. For the remainder of this section, we briefly review the variety of ways that third parties can obtain individually identifiable health information without consent, and how this information can be used by third parties such as pharmaceutical companies to identify patients and provide them with product-specific information that may affect their medical decision-making and behavior.

Like other personal information, individually identifiable health information can be obtained by third parties without the knowledge or consent of the concerned individual. Entities ranging from pharmacies and life insurance companies to health plans and hospitals collect information about an individual's health conditions and status as part of their routine business practices. Data brokers or information clearinghouses can purchase some of this information for various purposes, including product marketing.

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11. Prevention & American Pharmaceutical Association, *Navigating the Medication Marketplace: How Consumers Choose* (1997), available at <http://www.aphanet.org/lead/execsumm.html> (last visited Sept. 30, 2001). In this survey, more than one-third of respondents reported asking their doctors for information about a drug they had seen or heard advertised, and nearly a quarter asked for the drug itself. Of those, three-quarters reported that their doctors provided the requested prescription.

A number of examples demonstrate how third parties gain access to personal health information without consent. One example centers on participation in informal health screenings.<sup>12</sup> Free or low-cost screenings are often offered to the public to test blood pressure, cholesterol levels, physical fitness and weight.<sup>13</sup> These screenings usually occur in non-health care settings such as pharmacies, shopping centers or the workplace.<sup>14</sup> The data collected has the potential to end up in the data banks of third parties. These third parties are often pharmaceutical manufacturers or medical device companies that have products to sell related to the test.<sup>15</sup> Another example involves practices by companies such as Medical Marketing Service, which advertised a database to pharmaceutical marketers that includes the names of several million people with allergies, bladder control problems and depression.<sup>16</sup> In another example, the pharmaceutical benefits manager, RxAmerica used patient data to solicit business for its owner, American Drug Stores.<sup>17</sup> Patients were asked to switch drug stores and patronize a drug store chain owned by American Drug Stores.<sup>18</sup> One final example concerns the pharmacy chain, CVS. A class-action lawsuit was filed against the drug store alleging that CVS gave patient prescription records to a marketing firm to send letters to customers and that the funds for the mailing were provided by pharmaceutical companies.<sup>19</sup>

In addition to health-related entities selling individually identifiable health information, companies have now learned how to collect health information from individuals who use the Internet. One way of collecting health information via the Internet is through the keywords individuals use when visiting search engine sites.<sup>20</sup> For example, DoubleClick, an Internet ad company, allows advertisers to “purchase” keywords.<sup>21</sup> This enables

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12. Privacy Rights Clearinghouse, *Fact Sheet 8: How Private Is My Medical Information?* (2001), at <http://www.privacyrights.org/fs/fs8-med.htm> (last visited Oct. 3, 2001).

13. *Id.*

14. *Id.*

15. *Id.*

16. Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, *Medical Privacy Stories*, at [http://www.healthprivacy.org/usr\\_doc/mprivacystories%2Epdf](http://www.healthprivacy.org/usr_doc/mprivacystories%2Epdf) (last modified July 21, 2001).

17. *Id.*

18. *Id.*

19. *State's Highest Court Allows Class Action Suit Against CVS*, ASSOCIATED PRESS NEWSWIREs, May 2, 2001; *See Weld v. Glaxo Wellcome, Inc.*, 746 N.E.2d 522, 526 (Mass. 2001).

20. *On Internet Privacy and Profiling Before the Senate Commerce Committee* (June 13, 2000) (statement of Richard M. Smith, Internet Consultant from Brookline, Massachusetts), available at <http://www.senate.gov/~commerce/hearings/0613smi.pdf> (last visited Nov. 13, 2001) [hereinafter Smith statement].

21. *Id.*

companies to monitor topics of interest to web users. When a company owns a specific keyword like “depression,” that company’s banner ads will appear on the search results page when that phrase or word is used.<sup>22</sup>

Internet ad companies also collect personal information from Internet users via a system termed online profiling through which they build individualized profiles of people.<sup>23</sup> A profile rates a person on his or her level of interest in certain areas, allowing companies to target users with specific ads and information.<sup>24</sup> A profile is automatically created when a user is shown a banner ad from an Internet ad network.<sup>25</sup> The user is assigned a customer identification (ID) number that is stored with the profile.<sup>26</sup> This ID number, called a “cookie” is sent back to the user’s computer.<sup>27</sup> By synchronizing cookies, Web sites can provide Internet ad companies with personal data about users.<sup>28</sup> This means that once a single company knows an Internet user’s identity, any of the other companies in the advertising network can identify the user when the user visits their sites.<sup>29</sup>

Internet ad companies also track users with “Web Bugs.”<sup>30</sup> Web Bugs are invisible images on Web pages that send back cookies to Internet ad company servers and track the pages that Internet users access.<sup>31</sup> Web Bugs are used to “see who has come to a Web site after viewing a banner ad, to transfer both personal and non-personal information from a Web site to an Internet ad company, to provide data to an online profile, [and] to count ad impression and page hits.”<sup>32</sup>

#### IV. INFORMATIONAL PRIVACY AND DIRECT-TO-CONSUMER ADVERTISING

DTC advertising raises concerns about the privacy of personal health information. For third parties such as pharmaceutical companies to better target advertising directly to patients, they must have some level of personal health information about the patients. As noted above, this information can be obtained in a variety of ways, ranging from information given voluntarily by

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22. *Id.*

23. *Id.*

24. *Id.*

25. Smith statement, *supra* note 20.

26. *Id.*

27. *Id.* The term “cookie” is a computer science term used to describe pieces of data held by an intermediary. David Whalen, Cookie Central, *The Unofficial Cookie FAQ*, at <http://www.cookiecentral.com/faq/> (last modified May 10, 1999).

28. *Id.*

29. Electronic Privacy Information Center, *The Cookies Page*, at <http://www.epic.org/privacy/internet/cookies/default.html> (last visited Sept. 30, 2001).

30. Smith statement, *supra* note 20.

31. *Id.*

32. *Id.*



individuals to patient lists or medical records purchased from health care organizations. While there are potential benefits to DTC advertising, accessing and using one's individually identifiable information without his or her consent is a violation of privacy that can have broad and detrimental consequences—from securing health insurance coverage to employment discrimination.

In 1996, Congress began to address the issue of the privacy of individually identifiable health information by enacting the Health Insurance Portability and Accountability Act (HIPAA).<sup>33</sup> The law included provisions that facilitated electronic transactions of individually identifiable health information.<sup>34</sup> In addition, it established new regulations to protect the security and confidentiality of such information. The Department of Health and Human Services (HHS) promulgated the requisite standards, entitled Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule), which came into effect on April 14, 2001.<sup>35</sup> Most health plans and health care providers covered by the rule must comply with the new standards by April 14, 2003.<sup>36</sup>

Information that is protected under the Privacy Rule includes all individually identifiable health information used or disclosed by an entity covered under the regulations.<sup>37</sup> The form the disclosure takes, whether electronic, oral or on paper, is irrelevant.<sup>38</sup> Entities covered by the rule ("covered entities") are health plans, health care providers and health care clearinghouses.<sup>39</sup> While not directly covered, included in the regulations are standards relevant to the use of protected health information (PHI) by third parties. These standards restrict the information that health care plans and providers can give or sell—to pharmaceutical companies, for example—thus reducing the pool of information available to companies for use in marketing and DTC advertising.

The Privacy Rule specifically addresses the use and disclosure of PHI for marketing purposes.<sup>40</sup> The rule defines marketing, sets limits on the kind of marketing that can be done and requires authorization for all other uses or disclosures of PHI for marketing purposes.<sup>41</sup> Marketing is defined as making

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33. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

34. *Id.*

35. Standards for Privacy of Individually Identifiable Health Information, 66 Fed. Reg. 12,434, 12,434 (Feb. 26, 2001) (to be codified at 45 C.F.R. pt. 160 and 164).

36. *Id.*

37. 45 C.F.R. § 164.501 (2001).

38. U.S. Department of Health and Human Services, HHS Fact Sheet, *Protecting the Privacy of Patients' Health Information* (July 6, 2001), at <http://hhs.gov/news/press/2001pres/01fsprivacy.html> (last visited Sept. 30, 2001) [hereinafter HHS Fact Sheet].

39. 45 C.F.R. § 164.501.

40. See §§ 164.501, 164.514(e).

41. § 164.501; HHS Fact Sheet, *supra* note 38.

“a communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service.”<sup>42</sup> The Rule excludes certain activities from the definition of marketing, including describing participating plans or providers in a network and describing the services and benefits covered by a health plan.<sup>43</sup>

The Privacy Rule places very stringent requirements on the use of PHI by covered entities for marketing purposes. In general, covered entities must obtain specific authorization to use or disclose PHI in a marketing communication.<sup>44</sup> There are, however, certain activities that are exempt from the authorization requirements. These include face-to-face communications with an individual and communications in which the products involved are of nominal value.<sup>45</sup> Covered entities are also exempted from the requirements if the communication identifies the entity, states whether the entity is being compensated for making the communication and explains to individuals how to opt out of further communications.<sup>46</sup>

While the Privacy Rule pertains only to covered entities and not to third parties, such as medical device companies and pharmaceutical companies, the standards for marketing indirectly apply to such companies. Covered entities are allowed to disclose PHI for marketing purposes only to a “business associate that assists the covered entity with such communications.”<sup>47</sup> For a third party to qualify as a business associate, the covered entity and the third party must enter into a contractual agreement which stipulates that the PHI can only be used for the entity’s own marketing activities.<sup>48</sup> Entities are permitted to disclose PHI for their own marketing activities and not for any other reason.<sup>49</sup> This means that covered entities cannot give or sell any form of protected health information, including lists of patients, to third parties without obtaining consent from the individual.<sup>50</sup>

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42. § 164.501.

43. A covered entity is not marketing when it describes the entities participating in a health care provider network or a health plan network or when it describes the services offered or the benefits covered by the health plan. A covered entity is also not marketing when the communication is tailored to the circumstances of a particular individual as long as the communication is 1) “[m]ade by a health care provider to an individual as part of the treatment of the individual, and for the purpose of furthering the treatment of that individual”; or 2) “[m]ade by a health care provider or health plan to an individual in the course of managing the treatment of that individual, or for the purpose of directing or recommending to that individual alternative treatments, therapies, health care providers, or settings of care.” § 164.501.

44. 45 C.F.R. § 164.508 (2001).

45. § 164.514(e).

46. *Id.*

47. § 164.514(e)(2)(ii).

48. HHS Fact Sheet, *supra* note 38.

49. *Id.*

50. *See id.*

This standard severely limits the information that can be obtained from health care organizations. Prior to the promulgation of the Rule, absent any relevant state law, health care organizations could sell PHI to third parties for any use or disclose it to third parties who could then use the information for their own marketing purposes.<sup>51</sup> Now, under the new rule, physicians can no longer provide patient lists or other PHI to pharmaceutical companies to be used for those companies' product promotions unless all the appropriate individuals consent.<sup>52</sup> Obtaining this consent is likely to be economically and logistically unfeasible.

These restrictions on the identifiable medical information available to third parties are likely to directly impinge on DTC advertising. Without pertinent data, companies cannot efficiently target specific individuals or groups of individuals for advice. While personal information is available from other sources, such as Internet tracking and online profiling, the Privacy Rule provides some level of protection against unauthorized use of protected medical information.

#### V. PRODUCT LIABILITY AND DIRECT-TO-CONSUMER ADVERTISING

Traditionally, patients go to physicians for their expertise and advice on treatment options. Physicians, not patients, make the decisions as to what drugs to prescribe. Today, as more patients obtain medical advice and information from pharmaceutical companies via the Internet, questions arise about who should be held liable for misinformation about prescription drugs: the physician or the pharmaceutical company itself.

Back when the physician was the sole decision-maker, liability generally rested on the physician because he or she was deemed to be a "learned intermediary" between the pharmaceutical company and the patient.<sup>53</sup> In part because pharmaceutical manufacturers lacked the means to educate patients directly, it was the physician's responsibility to inform the patient of the risks of the drug, thus relieving the pharmaceutical company of liability.<sup>54</sup> But as manufacturers advertise directly to consumers and bypass physicians, one may argue that these manufacturers should no longer be immune from liability.<sup>55</sup> A pure disclaimer may no longer be sufficient; instead, the argument is that the manufacturer has a legal obligation to directly warn the patient about the potential risks and complications. An exception to the "learned intermediary" doctrine, whereby manufacturers could no longer rely on physicians to disclose risks but would have to do so themselves, may require consideration.

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51. *Id.*

52. *Id.*

53. *See* *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999).

54. *Id.* at 1246.

55. *Id.*

First articulated in 1966, the “learned intermediary” rule holds that prescription drug manufacturers are exempt from the legal duty to warn the ultimate user about the risks of prescription drugs.<sup>56</sup> Instead, the manufacturer’s duty to warn extends to the physician.<sup>57</sup> The prescribing physician then acts as a “learned intermediary” between the patient and the manufacturer and warns the patient of the drug’s potential risks.<sup>58</sup>

The Restatement (Third) of Torts adopts the “learned intermediary” doctrine.<sup>59</sup> Section 6(d) sets forth the traditional rule of the learned intermediary:

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings 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.<sup>60</sup>

The learned intermediary rule is an accepted doctrine; however, there are exceptions to the rule which recognize that direct warnings to patients are necessary for drugs dispensed without the personal intervention or evaluation of a health care provider.<sup>61</sup> One example, discussed in comment (e) to Section 6 of the Restatement, is mass inoculations.<sup>62</sup> In mass vaccination programs, physicians are not in the position to evaluate individual patients and relate the potential risks of the drug to each patient.<sup>63</sup> Courts have held manufacturers responsible for informing the patient directly of the risks associated with the drug where there is no health care provider serving as a learned intermediary between the manufacturer and the patient.<sup>64</sup>

Whether an exception to the “learned intermediary” doctrine should be applied to DTC advertising is unclear in the courts. When manufacturers advertise a prescription drug in the mass media, FDA regulations require that the advertisement be coupled with information that discloses the major side effects and contraindications of the drug. The question is whether sufficient warnings to the health care provider insulate the manufacturer from tort

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56. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

57. *Id.*

58. *Id.*

59. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1997).

60. *Id.*

61. *See id.* § 6(d) cmt. e.

62. *Id.*

63. *Id.*

64. *See* *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) (imposing a duty on the manufacturer to warn the patient in polio vaccine cases).

liability.<sup>65</sup> Manufacturers contend that the “learned intermediary” rule should apply, arguing that despite DTC advertising, drugs cannot be prescribed unless a physician makes an individualized assessment of the patient.<sup>66</sup> The physician still serves as a “learned intermediary,” thereby insulating manufacturers from liability. Others argue for an exception to the “learned intermediary” rule under which manufacturers must warn patients directly. Comment (e) to the Restatement states that “developing case law” should determine whether there should be an exception to the “learned intermediary” rule in these situations.<sup>67</sup>

A New Jersey Supreme Court case, *Perez v. Wyeth Laboratories, Inc.*, is the only case thus far to recognize an exception to the “learned intermediary doctrine” when a manufacturer advertises directly to consumers.<sup>68</sup> In *Perez*, Wyeth undertook a massive advertising campaign for Norplant that was directed at women instead of their doctors.<sup>69</sup> The advertisements did not warn consumers of any potential risks posed by Norplant.<sup>70</sup> The plaintiffs, who suffered from the side effects of Norplant, argued that an exception to the “learned intermediary doctrine” should be recognized because the manufacturer advertised directly to the consumer.<sup>71</sup> The trial court held that the “learned intermediary doctrine” applied, and the New Jersey Appellate Division affirmed the trial court’s determination.<sup>72</sup> The New Jersey Supreme Court reversed the lower courts’ decisions and held that the “learned intermediary doctrine” does not apply to the direct marketing of drugs to consumers.<sup>73</sup> The court held that “[p]rescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product’s dangerous propensities.”<sup>74</sup>

The *Perez* court argued that DTC advertising conflicts with the premises on which the “learned intermediary doctrine” is based and renders the traditional model obsolete.<sup>75</sup> According to the court, those premises are “(1) reluctance to undermine the doctor-patient relationship; (2) absence in the era of ‘doctor knows best’ of need for the patient’s informed consent; (3) inability of drug manufacturers to communicate with patients; and (4) complexity of the

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65. See RESTATEMENT (THIRD) OF TORTS § 6(d) cmt. e.

66. *Id.*

67. *Id.*

68. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999).

69. *Id.* at 1248.

70. *Id.*

71. *Id.*

72. *Id.* at 1249.

73. *Perez*, 734 A.2d at 1257.

74. *Id.*

75. *Id.* at 1256.

subject.”<sup>76</sup> The court pointed out that all of these, with the possible exception of the last, are absent in the direct-to-consumer advertising of prescription drugs.<sup>77</sup>

With respect to the first two premises, the court stated that the paternalistic “Norman Rockwell” image of the family doctor was, for the most part, obsolete.<sup>78</sup> Informed consent requirements have transformed the model into a patient-based decision, as opposed to a solely physician-based model.<sup>79</sup> With respect to the second premise, the court noted that due to current managed care restraints, “physicians have significantly less time to inform patients of the risks and benefits of the drug.”<sup>80</sup> Finally, the court stated that given the large sums of money spent on advertising, drug manufacturers could not claim that they had ineffective means by which to communicate directly with patients.<sup>81</sup> Given all this, the court argued that DTC advertising runs counter to the premises upon which the “learned intermediary doctrine” is based.<sup>82</sup>

The court contended that consumers today are active participants in their health care decisions and do not rely solely on physicians to decide whether a drug should be used.<sup>83</sup> The court also stated that it did not make sense that requiring manufacturers to provide direct warnings to a consumer would undermine the patient-physician relationship because DTC advertising intruded on that relationship by encouraging consumers to ask their doctors for specific drugs.<sup>84</sup> Finally, the court explained that DTC advertising rebuts the notion that the risks of prescription drugs are too complex to be communicated to consumers.<sup>85</sup> The court further explained that because the FDA mandates warnings for prescription drugs, the consumer might presume that the manufacturer guarantees these warnings.<sup>86</sup> Therefore, the court held, “the common law duty to warn the consumer should apply.”<sup>87</sup>

As noted by the court, manufacturers have presumptively met their duty to warn physicians about risks of prescription drugs if they are in compliance with federal labeling standards.<sup>88</sup> This presumption, however, is a rebuttable one.<sup>89</sup> The court held that in the area of DTC advertising of pharmaceuticals,

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76. *Id.* at 1255.

77. *Id.*

78. *Perez*, 734 A.2d at 1255.

79. *Id.*

80. *Id.*

81. *Id.* at 1255-56.

82. *Id.* at 1256.

83. *Perez*, 734 A.2d at 1256.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Perez*, 734 A.2d at 1259.

89. *Id.*

the same rebuttable presumption exists when a manufacturer has complied with FDA advertising, labeling and warning requirements.<sup>90</sup> The rationale behind the ruling was that the approach

harmonizes the manufacturer's duty to doctors and to the public when it chooses to directly advertise its products, and simultaneously recognizes the public interest in informing patients about new pharmaceutical developments. Moreover, a rebuttable presumption that the duty to consumers is met by compliance with FDA regulations helps to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have a 'significant anti-utilitarian effect.'<sup>91</sup>

The final issue in the *Perez* case involved proximate cause, that is, whether the misinformation supplied by Wyeth concerning Norplant was a substantial contributing factor to the harm suffered.<sup>92</sup> If that is the case, the next question is whether the role of the physician breaks the chain of causation.<sup>93</sup> The court noted that the arrival of DTC advertising has altered the role of the physician.<sup>94</sup> Traditionally, the physician has been the ultimate decision maker when choosing which prescription drug to prescribe for a patient. While DTC advertising provides some health information to consumers, it is usually not comprehensive information, which may lead to patients having an incomplete or improper understanding of a drug.<sup>95</sup> As the *Perez* court noted, patients often arrive at physicians' offices with preconceived and incorrect notions of which drug treatment is appropriate.<sup>96</sup> Physicians often feel pressured by their patients to prescribe a specific drug the patient has seen advertised, regardless of whether the drug best suits the individual patient.<sup>97</sup> Given that most physicians cannot afford to lose patients, the court stated that many physicians might relent to this pressure.<sup>98</sup>

The court maintained that this change in the nature of the physician's role meant that the physician's intervention did not necessarily break the chain of causation.<sup>99</sup> The court held that "in the case of direct marketing of drugs, we believe that neither the physician nor the manufacturer should be entirely relieved of their respective duties to warn. Pharmaceutical manufacturers may

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90. *Id.*

91. *Id.*

92. *Id.* at 1260.

93. *Perez*, 734 A.2d at 1260.

94. *Id.*

95. See The Council on Ethical and Judicial Affairs of the American Medical Association, *Direct-to-Consumer Advertisements of Prescription Drugs*, 55 FOOD DRUG L.J. 119, 120 (2000).

96. *Perez*, 734 A.2d at 1260.

97. See *id.*

98. See *id.*

99. See generally *id.* at 1260-63.

seek contribution, indemnity or exoneration because of the physician's deficient role in prescribing the drug."<sup>100</sup> To date, no other courts have followed the decision in *Perez*. However, as DTC advertising becomes more prolific, *Perez* may foreshadow a transformation away from the traditional application of the "learned intermediary doctrine."<sup>101</sup>

#### VI. ORGANIZATIONAL RESPONSIBILITY AND DIRECT-TO-CONSUMER ADVERTISING

Beyond any new legal liabilities surrounding DTC advertising, companies that engage in such activities have certain social responsibilities dictated by their roles as corporate citizens in a business which has profound impact on the health and well being of the public. On one side, there are some who argue that by tracking individually identifiable health information and tailoring DTC advertising to patients, pharmaceutical companies have an incredible opportunity to provide the public with information about diseases and treatment alternatives, encouraging them to seek care and speak with physicians. Some also contend that DTC advertising has the potential to decrease prescription prices by increasing competition between pharmaceutical manufacturers.<sup>102</sup> This is especially critical considering our overall health care system accounts for nearly fifteen percent of our Gross Domestic Product (GDP).<sup>103</sup>

On the other side, some ask whether DTC advertising could serve two masters: the promotional interest of the pharmaceutical industry and the public health's needs.<sup>104</sup> Companies are ultimately responsible to their shareholders, not patients, and shareholders' desires for increased sales are often at odds with patients' needs for rational drug prescribing.<sup>105</sup> Others contend that it is difficult to believe that DTC advertising can lower the cost of health care when medications selected for advertisement are expensive ones with large profit margins. In addition, these drugs often present few advantages over older drugs and have safety profiles that are less understood.<sup>106</sup>

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100. *Id.* at 1263.

101. *See Perez*, 734 A.2d at 1261-64.

102. *See* Steven W. Kopp, *Direct-to-Consumer Advertising and Consumer Prescription Prices*, 30 DRUG INFO. J. 59, 64 (1996).

103. National health care expenditures totaled 13.0% of GDP in 1999 and are projected to reach 15.9% of GDP by 2010. Health Care Financing Administration, *National Health Expenditures Projections: 2000-2010*, at <http://www.hcfa.gov/stats/NHE-Proj/proj2000/default.htm> (last visited Sept. 28, 2001).

104. *See* Lynette R. Bradley & Julie Magno Zito, *Direct-to-Consumer Prescription Drug Advertising*, 35 MED. CARE 86, 88 (1997).

105. *See* Ellen T' Hoen, *Direct-to-Consumer Advertising: For Better Profits or for Better Health?*, 55 AM. J. HEALTH-SYS. PHARMACY 594, 595 (1998).

106. *Id.*



In light of these conflicting views surrounding the impact of DTC advertising, the social obligations and ethical conduct of corporations such as pharmaceutical companies will be increasingly scrutinized. Until recently, the traditional context for questions of ethics in health care involved a focus on individual choices.<sup>107</sup> Today, however, we must conceive of ethical issues not only for individual persons, but also for systems and social structures.<sup>108</sup> Much of this realization resulted from the emergence and proliferation of managed care organizations as a means of delivering health care in the United States. As decisions by patients and their physicians are no longer free of third party influences, the managed care industry's initial lack of attention to the symbolic and instrumental importance of its role as a corporate citizen has spawned efforts to regulate its affairs and impose new legal liabilities on its actions.<sup>109</sup>

In many ways, the managed care industry's fate could befall the pharmaceutical industry if it does not constructively address the reality that its actions are viewed with increasing skepticism. The escalating costs of life prolonging and saving medications are increasingly unaffordable for the most vulnerable among us. Some contend that the pharmaceutical industry benefits from taxpayer funded biomedical research without paying for these benefits. This "free rider" problem is especially difficult for some consumer advocates to accept given that the pharmaceutical industry has historically been one of the most profitable sectors of the economy.

However, recent efforts of pharmaceutical companies to address the AIDS epidemic in Africa suggest that they realize their larger responsibilities to not only their shareholders, but also to the larger community.<sup>110</sup> As opposed to the tobacco industry, pharmaceutical companies produce and market products that rational individuals want and desire. Therefore, it is in the self-interest of pharmaceutical companies to behave in a way that contributes to the establishment of a social and legal marketplace that permits them to make a

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107. See Ezekiel J. Emanuel, *Medical Ethics in the Era of Managed Care: the Need for Institutional Structures Instead of Principles of Individual Cases*, 6 J. CLINICAL ETHICS 335, 335 (1995).

108. *Id.* at 335-36.

109. Pending legislation addresses liability for actions by health plans. The legislation, termed the Bipartisan Patient Protection Act of 2001 and also known as the Patient's Bill of Rights, includes patient protections to ensure access to high quality health care for Americans with private health insurance coverage. The protections range from access to emergency care to access to clinical trials and ensure that health professionals are able to provide information about medical treatment options. The bill provides that cases of injury or death involving administrative decisions would be heard in federal court; cases that involve medically reviewable decisions would be heard in state court. Health care plans can therefore be held accountable when the plan makes a decision that injures or kills someone. The Bipartisan Patient Protection Act of 2001, H.R. 2563, 107th Cong. (2001), available at <http://thomas.loc.gov> (July 19, 2001).

110. David Pilling, *International Economy: Rivals in race to cut price of Africa's Aids drugs*, FINANCIAL TIMES (London), Mar. 15, 2001, at 12.

reasonable return on their investment, while satisfying their role as corporate citizens. Ultimately, it is not only the right thing to do, but it is the smart thing to act with institutional integrity and conscience.

## VII. CONCLUSION

The emergence of DTC advertising on the Internet has the potential to provide patients with information that will empower them to make more informed decisions about their health and health care. While the prospect of a more informed patient is a worthy objective, these developments also raise ethical concerns about privacy, new potential product liabilities for third parties and considerations about the social responsibilities of corporations whose business has a profound impact on the health and well being of the public. Therefore, greater attention needs to be paid to the implications of DTC advertising via the Internet as increasingly more human activity and endeavors, including those in medicine, are lived on the World Wide Web.

