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NATIONAL MARKETING GONE UNINTENTIONALLY GLOBAL: DIRECT-TO-CONSUMER ADVERTISING OF PHARMACEUTICAL PRODUCTS AND THE INTERNET

Jacqueline West*

I. INTRODUCTION

Take a moment to recall the last time you saw a prescription medication advertised on television or the radio. What was your perception of the information conveyed in the advertisement? Did you believe the claims the advertisement made? Now, take a moment to think about the last time you logged on to the Internet to research a medical symptom you, a family member, or a friend had experienced. Did you trust the information you found on the Internet, and if so, did you act upon it in some way? You are probably aware of, at least, a few people who have acted upon information they learned over the Internet regarding a prescription medication. Such actions may have been as casual as discussing the information with a friend, or as direct as going to a physician to request the researched medication.

Pharmaceutical advertising is an immense (and influential) business.¹ In 2009 the biopharmaceutical industry spent \$4.5 billion on direct-to-consumer (“DTC”) advertising in such media as television, radio and the Internet.² DTC advertising of pharmaceutical products has become an expected phenomenon in American life.³ This is not so in other countries, as only the U.S. and New Zealand allow DTC advertising of pharmaceutical products in any medium.⁴ However, searching for health information on the Internet is a widespread practice, both in the United States (“U.S.”)⁵ and in Europe.⁶ One study found that much of the health

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¹ In 2010, the pharmaceutical industry invested over \$67 billion dollars in research and development, and in 2008 contributed \$333 billion to the United States Gross Domestic Product, directly employed over 650,000 people, and indirectly employed over 3 million people. *Pharmaceutical Industry Profile 2011*, PHARMACEUTICAL MFRS. OF AMERICA (2011), at iii-8, available at http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf.

² Press Release, The Nielsen Co., U.S. Ad Spend Down Nine Percent in 2009, Nielsen Says (Feb. 24, 2010), available at <http://blog.nielsen.com/nielsenwire/wp-content/uploads/2010/02/2009-Year-End-Ad-Spend-Press-Release.pdf>.

³ Nathan Jessop, *Will DTC Advertising Appear in Europe?*, PHARMTECH.COM (Jan. 7, 2011), <http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=702161>. See also LEONARD J. WEBER, PROFITS BEFORE PEOPLE? ETHICAL STANDARDS AND THE MARKETING OF PRESCRIPTION DRUGS 164-66 (2006).

⁴ Bryan A. Liang & Tim Mackey, *Reforming Direct-to-Consumer Advertising*, 29 NATURE BIOTECHNOLOGY 397, 397 (2011).

⁵ PEW INTERNET & AMERICAN LIFE PROJECT, THE SHARED SEARCH FOR HEALTH INFORMATION ON THE INTERNET 2 (June 11, 2009), available at <http://pewresearch.org/pubs/1248/americans-look-online-for-health-information>.

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information sought on the Internet comes from the U.S.,⁷ thus potentially exposing those in Europe to DTC advertising that is otherwise illegal in their country.⁸

The promotion of pharmaceutical products directly to consumers has been highly contested for over fifteen years.⁹ Proponents of such advertising posit that it is beneficial because it promotes patient participation in their own medical treatment.¹⁰ Patients are better informed about treatment options due to their exposure to pharmaceutical advertising, which may lead to increased communication with their physicians.¹¹ That view is reflected in *Rimbert v. Eli Lilly and Co.*, where the Court opined that informed consumers are more likely to ask questions of their doctor, potentially increasing a patient's reliance on her doctor's input.¹² The Court acknowledged the argument that DTC advertising can lead to a patient demanding a prescription drug from the physician;¹³ however, the Court reasoned that when there is a more open dialog between patient and physician, the physician is in a better position to exercise his professional judgment.¹⁴ This is because "[d]octors know more than most that prescription drugs do not act the same in each person; indeed, because each body is unique, the drug will not work exactly the same in any two people."¹⁵ In the Court's view then, patient reliance on physician input is necessary to receive appropriate care. The Court thought it illogical that a better-informed doctor/patient relationship could be considered a *negative* outcome of DTC advertising.¹⁶

Finally, many advocates assert that DTC advertising encourages people with undertreated conditions to seek help.¹⁷ A 2003 study found that a quarter of the people who visited their doctor as a direct result of DTC advertising were diagnosed with a new condition, and nearly half of them were described as having a high-priority health problem.¹⁸ When such conditions are finally treated it not only improves patient health, but also has the potential to decrease overall costs by avoidance of expensive hospital or surgical interventions which may

⁶ A 2007 study of seven European countries found that approximately 52% of European adults search for health information online. Per Egil Kummervold, et al., *eHealth Trends in Europe 2005-2007: A Population-Based Survey*, 10 J. MED. INTERNET RES. e42 (2008), available at <http://www.jmir.org/2008/4/e42/>.

⁷ See *id.*

⁸ Frank Auton, *The Patient as Consumer: The Advertising of Pharmaceuticals Directly to Consumers Should Be Allowed and Encouraged*, ECON. AFF., June 2007, at 64.

⁹ Frank Auton, *Direct-to-Consumer Advertising (DTCA) of Pharmaceuticals: An Updated Review of the Literature Since 2003*, ECON. AFF., Sept. 2006, at 24.

¹⁰ John E. Calfee, *Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs*, 21 J. PUB. POLICY MKTG. 174, 176-77 (2002).

¹¹ *Id.*

¹² *Rimbert v. Eli Lilly and Co.*, 577 F.Supp.2d 1174, 1219 (D.N.M. 2008).

¹³ *Id.* at 1218.

¹⁴ *Id.* at 1219.

¹⁵ *Id.*

¹⁶ *Id.* at 1221.

¹⁷ See Auton, *supra* note 8, at 69. Undertreated conditions are those that may not have outward symptoms, such as depression, hypertension or high cholesterol. *Id.*

¹⁸ Joel S. Weissman, et al., *Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising*, HEALTH AFF. WEB EXCLUSIVE W3-82, 88 (Feb. 26, 2003), <http://content.healthaffairs.org/content/early/2003/02/26/hlthaff.w3.82.full.pdf+html>. The study used the 15 high-priority conditions adopted by the Institute of Medicine which include: cancer, diabetes, HIV/AIDS, emphysema, high cholesterol, asthma and Alzheimer's disease, among others. INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 91 (2001).

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be required if the condition goes untreated.¹⁹ Additionally, it is thought that informed patients are more likely to comply with treatment,²⁰ which also decreases overall healthcare costs.²¹

In contrast, many critics (often physicians and insurance companies) believe that DTC advertising puts consumers in the place of doctors who are trained to prescribe the necessary medications.²² Indeed, one study found that eighty percent (80%) of physicians surveyed believe that DTC advertising “encourages patients to seek treatments they do not need.”²³ Some physicians have reported that DTC advertising may cause a patient to “mis-perceive a drug’s effectiveness . . . and challenge[] [a] physicians’ influence and authority. . . .”²⁴ Moreover, some feel that DTC advertising affects the prescribing habits of doctors by undermining optimal prescribing by encouraging overtreatment of some conditions,²⁵ as well as by driving up the cost of name-brand drugs.²⁶

Some opponents believe that while DTC advertising may lead to more knowledgeable patients and prompt robust discussion between a patient and his doctor, it is detrimental in its wider effect on the public health in its current form.²⁷ One argument is that DTC advertising has a serious negative effect on public health because the advertisements are presented in a manner that provokes a consumer’s emotional response, in order to further the pharmaceutical industry’s goal of selling drugs.²⁸ Advertising based on emotional appeals may lead consumers to “seek treatment for clinically inappropriate reasons, such as fear, anticipated regret from not using the product, or expectations of happiness if they do use the product.”²⁹ Bioethicist Leonard J. Weber believes that these types of emotional appeals in DTC advertis-

¹⁹ Auton, *supra* note 8, at 70. See also Christopher Roebuck, Joshua N. Liberman, Marin Gemmill-Toyama & Troyen A Brennan, *Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending*, 30 HEALTH AFFAIRS 91, 91 (2011).

²⁰ See Angela Coulter, Vikki Entwistle & David Gilbert, *Sharing Decisions with Patients: Is the Information Good Enough?*, 318 BRIT. MED. J. 318 (1999).

²¹ A large study of patients suffering from chronic vascular disease (congestive heart failure, hypertension, diabetes and dyslipidemia were included in the study) found that the average annual medical spending for each condition were significantly reduced when patients were compliant with their treatment regimen, due to less hospitalization of those patients. Those with congestive heart failure saved nearly \$9,000, those with hypertension and diabetes saved over \$4,000 each, and those with dyslipidemia saved nearly \$2,000 annually. Roebuck, Liberman, Gemmill-Toyama & Brennan, *supra* note 19, at 93-97.

²² See Kurt C. Stange, *Time to Ban Direct-to-Consumer Prescription Drug Marketing*, 5 ANNALS FAM. MED. 101, 101 (March/April 2007).

²³ Matthew F. Hollon, *Direct-to-Consumer Advertising A Haphazard Approach to Health Promotion*, 293 JAMA 2030, 2031 (April 27, 2005).

²⁴ Joel S. Weissman, et al., *Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising*, HEALTH AFF. WEB EXCLUSIVE W4-219, 220 (Apr. 28, 2004), <http://content.healthaffairs.org/content/early/2004/04/28/hlthaff.w4.219.full.pdf+html>.

²⁵ Hollon, *supra* note 23, at 2031. But see WEBER, *supra* note 4, at 147-48, for the proposition that in healthcare, unlike other types of business, the customer is not always right and healthcare professionals have the duty to provide recommendations based on “professional standards and expertise” rather than because they want a certain treatment. *Id.* at 148.

²⁶ Calfee, *supra* note 10, at 177.

²⁷ See Stange, *supra* note 22, at 101. See generally Hollon, *supra* note 23.

²⁸ Jackie Glatter, *Promotion, Information and Advertising: Why Increasingly Blurred Boundaries Do Not Benefit the Public*, 1 J. GENERIC MEDS. 128, 129-30 (2004). Emotional appeal tactics can include depictions of loss of control, social approval distress, or endurance, among other depictions. Dominick L. Frosch, et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 ANNALS FAM. MED. 6, 9-10 (2007).

²⁹ Frosch, *supra* note 28 at 10.

ing are tantamount to manipulation because they do not rely on any rational persuasion.³⁰ Finally, critics also suggest that DTC advertising may have a negative influence on physician/patient communication in that a physician may spend so much time discussing why an advertised drug the patient requests is not appropriate, that other important conversations regarding the patient's health and treatment do not take place.³¹

Regardless of one's view on DTC advertising, people are now better informed than ever about their own health issues due to the advent and ever-expanding use of the Internet, and the various mobile applications and social media that go along with contemporary use of technology.³² The sheer amount of health information available on the Internet has led to much inaccurate, if not outright harmful, information and there is often no way to distinguish between accurate and inaccurate information without specialized health knowledge³³ or excellent Internet research skills.³⁴ The Internet poses an obstacle for DTC advertising by pharmaceutical companies in the U.S. because there has not been much guidance from the Food and Drug Administration ("FDA") relating to its use as an advertising platform, other than that any advertising on the Internet must comply with the regulations controlling DTC advertising in any other medium.³⁵ Members of the U.S. pharmaceutical industry presented possible solutions to the problems relating to promotion of their products on the Internet to the FDA at a hearing in Washington D.C. in 2009.³⁶ However, the FDA has yet to issue guidance³⁷ on the topic, leaving pharmaceutical companies largely in the dark about what is expected of them in a medium of unlimited time and space, unlike television or print advertising. Despite this lack of guidance, pharmaceutical manufacturers have attempted to keep their DTC advertising on the Internet within the bounds of current legislation.

While the European Union ("EU") has confronted the issue of DTC advertising many times,³⁸ they consistently refuse to change the law to allow the practice or even to allow the dissemination on the Internet of neutral, non-promotional information by pharmaceutical manufacturers about their products.³⁹ Pharmaceutical companies in the EU, who arguably know the most about their products and thus are in the best position to disseminate that infor-

³⁰ WEBER, *supra* note 3, at 166-69.

³¹ Stange, *supra* note 22, at 101.

³² See Calfee, *supra* note 10, at 176-77.

³³ Faisal Hanif, et al., *The Role of Quality Tools in Assessing Reliability of the Internet for Health Information*,

³⁴ INFORMATICS FOR HEALTH & SOCIAL CARE 231, 231-34 (2009).

³⁵ Wilfried Honekamp & Herwig Ostermann, *Anamneses-Based Internet Information Supply: Can a Combination of an Expert System and Meta-Search Engine Help Consumers Find the Health Information they Require?*, 4 OPEN MED. INFORMATICS J. 12, 12-13 (2010), available at <http://www.ncbi.nlm.nih.gov.ezproxy.hofstra.edu/pmc/articles/PMC2874219/pdf/TOMINFOJ-4-12.pdf?tool=pmcentrez>.

³⁶ Bryan A. Liang & Timothy Mackey, *Direct-to-Consumer Advertising with Interactive Internet Media: Global Regulation and Public Health Issues*, 305 JAMA 824, 824 (2011).

³⁷ See generally Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN. (Nov. 12, 2009) [hereinafter "Public Hearing on Promotion of FDA-Regulated Medical Products"] (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

³⁸ FDA guidance documents are non-binding but reflect the agency's "current thinking on a particular subject." *Guidances (Drugs)*, FOOD & DRUG ADMIN. (Feb. 9, 2012), <http://www.fda.gov/drugs/guidancecompliance/regulatoryinformation/guidances/default.htm>. Other approaches can be used so long as they adhere to the appropriate statute and regulations. *Id.*

³⁹ Auton, *supra* note 9, at 24.

⁴⁰ *Id.*

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mation, are left out of the discussion with patients completely, a point of view that the EU recognizes as important, but consistently fails to act upon.⁴⁰

It is likely that both the proponents and critics of DTC advertising have at least a few valid points. However, simply due to the sheer amount of information available on the Internet, it effectively does not matter whether one believes DTC advertising is “good” or “bad”, since its widespread use guarantees that people are going to get the information they seek. It is better for consumers to at least have the option to get the majority of their information from companies whose Internet presence is highly regulated, and thus likely to be accurate, rather than from unregulated sources which may contain inaccurate and biased information.

DTC advertising on the Internet can be an opportunity to educate patients and consumers about their health condition and possible treatment options but it cannot effectively be done without guidance from regulatory authorities in the U.S. and the EU. It is imperative that the FDA issue guidance documents to the U.S. pharmaceutical industry in a timely manner, as lack of clarity thus far has lead to pharmaceutical companies falling afoul of current regulations. Equally important, the EU should take seriously the amount of misleading and harmful health information available on the Internet and allow pharmaceutical companies to become involved in the education of EU citizens through dissemination of accurate information about their products, whether through limited DTC advertising or other means.

Section II of this note discusses the history of government regulation of DTC advertising in the U.S. and the EU. Section III gives an overview of the problems the Internet presents to pharmaceutical manufacturers in both regions. Finally, section IV offers suggestions for the standardization of DTC advertising of pharmaceutical products on the Internet, in order to improve access to fair and balanced information about such products.

II. BACKGROUND

Pharmaceutical companies in the United States were marketing their products to consumers long before the government began regulating direct-to-consumer (DTC) advertising.⁴¹ Such advertising initially consisted of promotion of a particular company, without mentioning the products they manufactured.⁴² In time, pharmaceutical companies began to engineer advertisements about particular drugs that were directed specifically at consumers.⁴³ At the same time, the FDA began requiring that patient package inserts be included with certain medications, to instruct the patient in their proper use,⁴⁴ or to inform the patient about the risks of the drug.⁴⁵ The first explicit DTC advertisements of pharmaceuticals in the early 1980s⁴⁶ prompted the FDA to promulgate guidelines for pharmaceutical companies who wished to advertise to the public.⁴⁷ Those initial guidelines focused on providing a substantial

⁴⁰ See Robert Geyer, *The Politics of EU Health Policy and the Case of Direct-to-Consumer Advertising for Prescription Drugs*, 13 J. ADVER. 586, 596 (2011).

⁴¹ Jeremy A. Greene & David Herzberg, *Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the Twentieth Century*, 100 AM. J. PUB. HEALTH 793, 794-96 (2010).

⁴² *Id.* at 795.

⁴³ *Id.* at 796-97.

⁴⁴ Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L. J. 489, 489-90 (1999).

⁴⁵ *Id.* at 490.

⁴⁶ *Id.* at 491.

⁴⁷ *Id.* at 493.

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amount of risk information in the advertisements.⁴⁸ Unfortunately for pharmaceutical companies, the amount of risk information the FDA required was difficult to fit into a short television commercial, which lead to advertisements that did not give enough information to require the summary of risk information.⁴⁹ Because of the confusion caused by vague advertisements, the FDA liberalized regulation of DTC advertising of product-specific pharmaceutical products in broadcast media in 1997.⁵⁰ The increasing prominence of Internet use has changed the way companies advertise to consumers, and pharmaceutical manufacturers in the U.S. are no exception.⁵¹

In contrast, the EU has remained steadfast in its opposition to DTC advertising⁵² although it is currently considering allowing European pharmaceutical companies to distribute non-promotional information on the Internet about their products to consumers.⁵³ This section looks at the history and development of DTC advertising regulations in the U.S. and the EU.

A. The History of Direct-to-Consumer Advertising in the United States

Pharmaceutical companies in the U.S. have an abundant and solid regulatory framework to which their DTC advertising must conform.⁵⁴ This framework has developed over many years of case law and incremental regulation, at least somewhat preparing the industry for the advent of the widespread advertising medium of the Internet. Prescription drug consumers have access to almost limitless information on medical conditions and the drugs that treat them through the Internet, and it is used extensively for that purpose.⁵⁵ The impact of free access to limitless information is that patients are becoming informed consumers of pharmaceutical products, and advocates for specific aspects of their medical care, rather than relying solely on their physicians' expertise when it comes to their own health care.⁵⁶

When the FDA first began formally regulating DTC advertising, its main focus was assuring that pharmaceutical companies complied with the brief summary requirement,⁵⁷ as mandated by the Federal Food, Drug, and Cosmetic Act.⁵⁸ Regulation of DTC advertising

⁴⁸ *Id.*

⁴⁹ Green & Herzberg, *supra* note 41, at 799-800.

⁵⁰ Pines, *supra* note 44, at 495.

⁵¹ Pharmaceutical companies in the late 1990s used websites to disperse information in both educational and humorous ways through cartoons and graphics, as well as trendy themes. See Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary?*, 42 ST. LOUIS U. L.J. 89, 104-07 (1998).

⁵² See generally Gayer, *supra* note 40, for a history of EU policy on DTC advertising.

⁵³ David Barratt, *Image Makeover: Europe Can Benefit from the US Experience of the DTC Advertising Model*, PMLiVE.COM, 51, (May/June 2010), http://www.eaca.be/hcc/May_June_2010-Image_makeover.pdf.

⁵⁴ See generally 21 C.F.R. § 202.1 (2011) (Federal DTC advertising regulations).

⁵⁵ See Plant, *supra* note 51, at 104-07; James M. Wood & Howard L. Dorfman, "Dot.Com Medicine" – Labeling in an Internet Age, 56 FOOD & DRUG L.J. 143, 143-44 (2001).

⁵⁶ Anthony N. DeMaria, *The Commercial Promotion of Medicine*, 40 J. AM. C. CARDIOLOGY 2060, 2060 (2002).

⁵⁷ Lance S. Gilgore, *A Consideration of Direct-to-Consumer Advertising of Prescription Drugs and Potential Legal Problems with the Brief Summary Requirement: Is the FDA's Regulatory Authority Illusory?*, 46 FOOD DRUG COSM. L.J. 849, 850-51 (1991). The brief summary requires a statement of the side effects, contraindications, and effectiveness of the advertised pharmaceutical product. 21 U.S.C. § 352(n). It was initially intended to reduce the promulgation of false or misleading information about pharmaceuticals to physicians. It was adopted in its original form for application to DTC advertising. Gilgore, *supra*, at 850-51.

⁵⁸ See 21 U.S.C. § 352(n).

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arose against the backdrop of the tort doctrine of the learned intermediary.⁵⁹ The doctrine posits that because the physician is a “learned intermediary” between the pharmaceutical company and the patient, the physician (as the prescriber of the drug) is in the best position to fully understand the risks and benefits of a particular drug for a particular patient, and is thus most capable to disseminate that information to the patient.⁶⁰ Thus, according to the doctrine, pharmaceutical companies must only warn the *physician* of the risks of a prescription drug in order to avoid liability.⁶¹

This rule was challenged with the development of the birth control pill. In the landmark Massachusetts case of *MacDonald v. Ortho Pharmaceutical Corp.*, the court ruled that oral contraceptives “bear peculiar characteristics” which require an exception to the learned intermediary rule.⁶² The court opined that “[w]hereas a patient’s involvement in decision-making concerning use of a prescription drug to treat a malady is typically minimal or nonexistent[,]” the pill is not prescribed to fix a medical problem, but is given to young, healthy females electively, allowing the patient to have a more active role in choosing which form of birth control she will use.⁶³ This thus “relegat[es] the prescribing physician. . . to a relatively passive role.”⁶⁴ Moreover, when a woman is prescribed oral contraceptives, it is usually during an annual appointment and she receives a prescription for the entire year, thus the physician’s ability to monitor the patient is further limited.⁶⁵ For these reasons, the court ultimately held that in the case of oral contraceptives the manufacturer has a duty to warn the patient of directly.⁶⁶ Thus, pharmaceutical manufacturers now have a duty to directly warn patients of the risks of certain drugs when their purpose is primarily preventative.⁶⁷ For other types of medications, pharmaceutical companies have no duty to warn patients directly of the risks associated with that medication.⁶⁸ *MacDonald*, along with a general increase in patient demand for access to health information, is purported to have had a large impact on the FDA’s relaxation of regulations relating to DTC advertising.⁶⁹ Arguably, DTC advertising has an impact similar to that of oral contraceptives on a patient’s self-involvement in her own health care decisions. Patients who see an advertisement and recognize their own symptoms or risk factors may then contact their physician to discuss their treatment options, thus participating

⁵⁹ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 (1998).

⁶⁰ *Id.*

⁶¹ *Id.* at cmt. e.

⁶² *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69 (1985).

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 70.

⁶⁶ *Id.* This is done in the form of patient package inserts. *Id.*

⁶⁷ This requirement has consistently been limited to prescription contraceptives and “vaccinations in clinics where mass inoculations are performed.” This is because in that type of environment each patient is generally not evaluated thoroughly prior to administration of the drug. Additionally the argument has been advanced that pharmaceutical manufacturers should be held to the same standard when the product has been advertised in mass media. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. e (1998).

⁶⁸ *Id.*

⁶⁹ The general public’s interest in health and medication related information began to flourish as more information became available. In the 1960s and 1970s the FDA began requiring more and more drugs to be given with a patient package insert to inform patients of the potential risks of the product. In the 1980s, books that had previously only been available to physicians began to pop up in regular consumer bookstores. The medical community began to realize that consumers were playing a larger role in health care decisions and when the first paid advertising directed at consumers was issued, though not in the form we generally see today, the FDA began to discuss the implications of paid advertising. See Pines, *supra* note 44, at 489-91.

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more fully in their own medical care.⁷⁰ Pharmaceutical manufacturers rely on patients' desire to participate in treatment decisions when they spend billions of dollars on DTC advertising per year.⁷¹

The FDA first claimed jurisdiction over DTC advertising in 1985 after requesting a voluntary moratorium resulting from two highly visible DTC advertisements in 1981 which concerned the FDA and caused it to address DTC advertising for the first time.⁷² The FDA determined that the standards of "fair balance"⁷³ and "brief summary"⁷⁴ would "provide American consumers with an adequate safeguard from deceptive or misleading claims."⁷⁵ Because the "brief summary" required was anything but brief, DTC advertising was effectively limited to print media, where the summary of risk information could be disseminated in fine print.⁷⁶ Broadcast advertising was thus limited to "help-seeking"⁷⁷ or "reminder"⁷⁸ type advertisements.⁷⁹ Although DTC advertising was never illegal,⁸⁰ drug companies were generally wary of it because it was considered unethical to market directly to consumers.⁸¹ Additionally, the requirement of an "adequate provision" made for "information in brief summary relating to side effects, contraindications, and effectiveness" was confusing and vague.⁸²

The FDA relaxed the rules of DTC advertising when it issued draft guidance in 1997 explicitly permitting television advertising of specific products for the first time.⁸³ The guidance, which was finalized in 1999, clarified the ways in which the "adequate provision" could be fulfilled in broadcast advertisements.⁸⁴ The guidance called for the presentation of a brief summary of all of the risks of the advertised drug⁸⁵ or, alternatively, to provide for the dissemination of the approved package labeling through one of four avenues: 1) disclosure of

⁷⁰ Alan F. Holmer, *Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians*, 281 JAMA 380 (1999).

⁷¹ See WEBER, *supra* note 3, at 166-69.

⁷² Greene & Herzberg, *supra* note 41, at 799.

⁷³ The fair balance requirement is fulfilled when the treatment of risk and benefit information provided in the advertisement are equally thorough and complete throughout the piece. 21 C.F.R. § 202.1(e)(5)(ii) (2008).

⁷⁴ "The 'brief summary' includes all the risk information about a prescription drug and is generally based on the prescribing information. [It] may leave out non-risk information, such as the chemical description of the drug, how it works in the body, and directions for using it. For DTC ads, we recommend that brief summaries be written in language that consumers can understand." *Prescription Drug Advertising: Questions and Answers*, FOOD & DRUG ADMIN. (June 23, 2009), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/UCM076768.htm#risk_information.

⁷⁵ Greene & Herzberg, *supra* note 41, at 799.

⁷⁶ *Id.*

⁷⁷ Help-seeking advertisements mention information (often simply that treatments are available) about a specific condition and encourage consumers to speak to their doctor. The ads may mention a drug manufacturer but not a particular drug or product, otherwise they would be subject to the "brief summary" requirement. Tamer Nordenburg, *Direct to You: TV Drug Ads that Make Sense*, 32 FDA CONSUMER 7 (1998).

⁷⁸ Reminder advertisements mention the name of the drug, but not the condition for which it is indicated. This also avoids the need for the "brief summary" requirement, but can lead to some confusion. *Id.*

⁷⁹ Greene & Herzberg, *supra* note 41, at 799-800.

⁸⁰ Auton, *supra* note 8, at 65.

⁸¹ See Greene & Herzberg, *supra* note 41, at 793.

⁸² Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Richard G. Frank & Arnold M. Epstein, *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498, 498 (2002).

⁸³ Pines, *supra* note 44, at 496.

⁸⁴ Rosenthal, Berndt, Donohue, Frank & Epstein, *supra* note 82, at 498-99.

⁸⁵ FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 1 (1999).

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a toll-free telephone number that consumers could call to request the package labeling information either through the mail, or read to them over the phone; 2) reference to a similar print advertisement that contained the brief summary of risk information; 3) a web address where the information could be located; or 4) a reference that more information could be learned from their health care provider.⁸⁶ Even while the FDA has stringent guidelines for DTC advertising, pharmaceutical manufacturers are not required to get *approval* from the FDA prior to broadcasting the advertisements, only to *submit* their advertising materials prior to broadcast.⁸⁷ The FDA reviews only a small percentage of the materials it receives and often doesn't send regulatory letters until long after the advertisement has been broadcast.⁸⁸ Thus, the practice is essentially self-regulated by the industry⁸⁹ and the industry is happy to comply.⁹⁰ Penalties are very rarely necessary because pharmaceutical companies are reluctant to fall afoul of the very agency that has the power to grant their products regulatory approval.⁹¹

In 1999, the New Jersey Supreme Court stated in *Perez v. Wyeth Labs., Inc.* that DTC advertising so profoundly impacts patients that “consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used.”⁹² Drug companies in New Jersey enjoy a rebuttable presumption that they are not liable for damages resulting from defective pharmaceutical products so long as they adhere to FDA DTC advertising guidelines, but that fact does not free manufacturers from liability in an instance where “misinformation was a substantial factor contributing to [a patient's] use of a defective pharmaceutical product.”⁹³

Perez demonstrated to pharmaceutical companies the importance of adhering to the FDA's regulations regarding DTC advertising. The plaintiffs in *Perez* asserted that the defendant, Wyeth, began advertising its surgically implantable contraceptive Norplant in 1991⁹⁴ without including a specific warning that the product could cause pain and scarring upon removal, among other side effects.⁹⁵ The plaintiffs further contended that there had been studies published in medical journals that indicated that Norplant had a high incidence of complication during removal.⁹⁶ Wyeth argued that it should not be liable for the patients' injuries because of the learned intermediary doctrine,⁹⁷ as Norplant is not an oral contracep-

⁸⁶ *Id.* at 2-4.

⁸⁷ Liang & Mackey, *supra* note 4, at 398.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ Calfee, *supra* note 10, at 175.

⁹¹ *Id.*

⁹² *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1256 (N.J. 1999).

⁹³ *Id.* at 1263.

⁹⁴ This was prior to the FDA's relaxation of restrictions on DTC advertising, and before DTC advertising became widely utilized in 1997. At the time of the Norplant print advertisements the FDA required that advertisements had to meet the same requirements as those directed at doctors: they had to be “fairly balanced” and must include a “brief summary” of the risks of the drug. Additionally, all other FDA regulations must be followed. Because the “brief summary” requirement was considered cumbersome (it is not “brief” at all), most companies created advertisements that did not direct consumers to a specific product, but detailed symptoms and encouraged them to see their doctor. Another type of “help-seeking” advertisement mentioned the name of a drug, without mentioning its purpose. See Pines, *supra* note 44, at 493-94.

⁹⁵ *Perez*, 734 A.2d at 1248.

⁹⁶ One study found that “fifty two percent of physicians reported complications during removal.” *Id.* at 1256.

⁹⁷ *Id.* at 1248-49.

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tive which would require direct warning from the manufacturer to the patient.⁹⁸ The Court came to the conclusion that pharmaceutical manufacturers who advertise directly to consumers are not automatically relieved of liability even if they comply with the requirement of warning the physician under the learned intermediary doctrine.⁹⁹ “The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product.”¹⁰⁰ Currently, New Jersey is the only state that maintains this position, while forty-four states adhere to the traditional learned intermediary doctrine in prescription drug cases.¹⁰¹ It is against this backdrop that the current FDA regulations have developed, and are continuing to be developed.

The FDA’s current DTC advertising regulations are housed in the Code of Federal Regulations at 21 C.F.R. § 202(1) (2011). The most important of these regulations, for the purposes of this Note, is undoubtedly the “brief summary” requirement. This provision requires a brief and true statement of the side effects, contraindications, and effectiveness of the advertised medication.¹⁰² The requirement is not satisfied if the statement presented is (a) false or misleading with respect to side effects, contraindications, and effectiveness; (b) does not present a fair balance between the effectiveness information and the side effect/contraindication information; or (c) there is a failure to reveal material facts about the consequences of taking the advertised medication.¹⁰³

Of the thirty-one warning letters sent by the Office of Prescription Drug Promotion (“OPDP”) (formerly the Division of Drug Marketing, Advertising, and Communications – “DDMAC”) in 2011, the majority fell into the categories of false/misleading or failure to present balanced information with respect to side effects, contraindications, and effectiveness.¹⁰⁴ The warning letters indicated diverse promotional methods including websites, brochures, videos, and both physician-directed and consumer-directed print ads, among other methods.¹⁰⁵ Most issues of misleading promotion in the Internet materials related to the placement of risk information and/or lack of prominence of such information.¹⁰⁶

⁹⁸ *Cf. MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (1985) (holding that oral contraceptives are an exception to the learned intermediary doctrine due the relatively passive role of the physician in the selection and monitoring of oral contraceptive consumption).

⁹⁹ *Perez* 734 A.2d, at 1262-64. Recall that the learned intermediary rule absolves pharmaceutical manufacturers of any liability toward patients so long as the information provided to the physician complied with FDA standards. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (1998).

¹⁰⁰ *Perez* 734 A.2d, at 1263.

¹⁰¹ *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 852 (10th Cir. 2003).

¹⁰² 21 C.F.R. § 202(1)(e)(1) (2011).

¹⁰³ *Id.* § 202(1)(e)(5)(i)-(iii).

¹⁰⁴ *See Warning Letters 2011*, FOOD & DRUG ADMIN., available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/ucm238583.htm>. At least fifteen cited either minimization of risk information or omission of risk information, or both, as a reason the product was considered “misbranded”. Risk information was mentioned thirty times overall. Unsubstantiated claims (including claims of superiority, safety, and/or efficacy) were mentioned thirteen times, and overstatement of efficacy was mentioned eleven times. Other issues, totaling twenty mentions, included promotion of unapproved use (two), inadequate communication of indication (four), omission of material facts (four), promotion of unapproved/investigational products (three), promotion of broadened indication (four), and misleading patient compliance claims (one). *Id.*

¹⁰⁵ *See id.*

¹⁰⁶ *See id.* One letter, to Cephalon, Inc., regarding its healthcare professional website for the drug “Trisenox” described misleading promotion due to an unfair balance of information. “Promotional materials are misleading if they fail to present information related to side effects and contraindications with a prominence and readability

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Seven, or approximately twenty-three percent, of the 2011 warning letters related to promotion on the Internet.¹⁰⁷ This is slightly less than in 2010, when fifty-one warning letters were sent, with fifteen, approximately twenty-nine percent, of them Internet related¹⁰⁸ and 2009, when approximately forty-four percent of the DDMAC warning letters related to Internet promotion.¹⁰⁹ The decrease in Internet promotion related warning letters does not necessarily mean that manufacturers are getting better at discerning what the FDA expects from this type of promotion. Rather, it appears to be due to manufacturers relying more on help-seeking and reminder type sponsored links in order to avoid the brief summary requirement.¹¹⁰

Although the U.S. has been regulating DTC Advertising for many years now, the flexibility and ever-changing nature of the Internet requires that some regulations be rethought. Some may not require much change; however, the FDA should address the unique nature of the Internet as an advertising platform so that pharmaceutical companies know what is expected of them. Unlike the U.S., the EU has traditionally provided significantly less commentary on the topic of DTC advertising, other than consistently rejecting proposals to allow the practice.¹¹¹

B. The History of Regulation of Direct-to-Consumer Advertising in Europe

The European Union Community Code relating to medicinal products for human use strictly forbids the advertising of medicinal products to the general public, and even to physicians, if those products are only available by prescription or contain psychotropic or narcotic substances.¹¹² The Directive defines advertising of medicinal products as including “any form of door-to-door information, canvassing activity or inducement designed to promote the pre-

reasonably comparable with the presentation of information on the effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve this emphasis.” Letter from Karen Rulli, Group Leader, Div. of Drug Mktg., Adver., and Comm’n’s, Food & Drug Admin., to Franklin Vairinhos, Dir., Regulatory Affairs, Cephalon, Inc. (June 21, 2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/UCM260575.pdf>.

¹⁰⁷ See *Warning Letters 2011*, *supra* note 104.

¹⁰⁸ See *Warning Letters 2010*, FOOD & DRUG ADMIN., available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/ucm197224.htm>.

¹⁰⁹ See *Warning Letters 2009*, FOOD & DRUG ADMIN., available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/ucm055773.htm>.

¹¹⁰ Google found that the click-through rate (the number of times an advertisement was clicked on by a user, divided by the number of times the advertisement was displayed) of sponsored advertisements decreased significantly after the FDA issued warning letters stating that having the risk information “one click away” was unacceptable. Google attributed that decrease to less clarity, and thus less utility for users, of help-seeking and reminder advertisements. Amy Cowan, Head of Indus., Google, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 438-40, (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

¹¹¹ See Geyer, *supra* note 40, at 590-97.

¹¹² Council Directive 2001/83/EC, art. 88, 2001 O.J. (L 311) 67, 92, as amended by Council Directive 2004/27/EC, O.J. (L 136) 34.

scription, supply, sale or consumption of medicinal products; it shall include in particular: - the advertising of medicinal products to the public”¹¹³ The drug’s label and accompanying package insert do not fall into the category of advertising.¹¹⁴

Since 1998 there have been many attempts by proponents of DTC advertising to convince the EU to loosen its stance on the practice, to little avail.¹¹⁵ In the year after the restrictions on DTC advertising were liberalized in the U.S., members of the industry and the EU Commission published a report claiming that the difference in DTC advertising regulations in the U.S. and EU created a problem for the transatlantic pharmaceutical industry.¹¹⁶ They posited that the ban was unfair to citizens in the EU who want information about pharmaceuticals, and was behind the technological curve.¹¹⁷ At least partly in response to that report, an EU task force was created to review policy concerning DTC advertising.¹¹⁸ The task force “began pushing for a new debate” on DTC advertising with a bent toward allowing pharmaceutical manufacturers to provide educational information to consumers.¹¹⁹

That, in turn, led to the first real attempt at changing EU policy in 2001, when a member of the European Commission (“EC”) proposed that pharmaceutical companies be allowed to “communicate information about drugs for asthma, diabetes and Aids [sic] directly to the public within ‘disease awareness’ campaigns.”¹²⁰ Although the Commissioner assured that the goal was not to allow DTC advertising,¹²¹ the proposal was soundly rejected by the European Parliament, which felt that approval would “let the genie out of the bottle, bringing a U.S. scenario to Europe.”¹²² The EC reconsidered its stance on DTC advertising once again in 2007.¹²³ Although it eventually maintained that the ban on DTC advertising should remain in force,¹²⁴ it acknowledged that “the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals throughout the EU.”¹²⁵ The Commission ultimately suggested that the difference between information and advertising should be further distinguished.¹²⁶

In December of 2008, the Commission submitted a proposal for amendments to both the EC Directives and Regulations which would allow for the distribution of non-promotional

¹¹³ *Id.* at 91.

¹¹⁴ *Id.* at 92.

¹¹⁵ See Geyer, *supra* note 40, at 590-97.

¹¹⁶ *Id.* at 593.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 594.

¹¹⁹ *Id.*

¹²⁰ Auton, *supra* note 9, at 29. See also Geyer, *supra* note 40, at 594.

¹²¹ Geyer, *supra* note 40, at 595.

¹²² *Id.*

¹²³ *Id.* at 596.

¹²⁴ *Communication from the Commission to the European Parliament and the Council Concerning the Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products*, at 10, COM (2007) 862 final (Dec. 20, 2007), available at http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments_en.htm.

¹²⁵ *Id.* at 9. Presumably the Commission meant that patients and healthcare professionals cannot get information other than the label and package insert information directly from the pharmaceutical company. It is also possible that they meant that the information cannot be accessed over the Internet. The Communication is not clear. See generally *id.* at 9-10.

¹²⁶ *Id.* at 9-10.

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information by pharmaceutical companies to the public.¹²⁷ The aim of the proposals was stated thus:

Provide for a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.¹²⁸

Although the Commission had no interest in raising the ban on DTC advertising,¹²⁹ it did strongly suggest that both the Regulation and Directive be altered to include a provision for dissemination of certain types of pre-approved consumer-directed information.¹³⁰ Specifically, it encouraged distribution of information “about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.”¹³¹ The proposed Directive specifically excludes television or radio as a medium for the distribution of this information, but would allow for distribution through medically related journals and Internet websites.¹³² The Directive was once again rejected by the Employment, Social Policy, Health and Consumer Affairs Council, which called for further “in-depth reflection” and requested that the Commission prepare a “‘thorough report’ of the impact of future measures.”¹³³

In 2010, the European Parliament approved an amended version of the previous proposal that would allow pharmaceutical companies to make limited information available to

¹²⁷ See *Proposal for a Directive of the European Parliament and of the Council Amending, as Regards Information to the General Public on Medicinal Products Subject to Medical Prescription*, Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, COM (2008) 663 final (Dec. 10, 2008) [hereinafter *Proposal for a Directive*, COM (2008) 663], available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0663:FIN:en:PDF>; *Proposal for a Regulation of the European Parliament and of the Council Amending, as Regards Information to the General Public on Medicinal Products for Human Use Subject to Medical Prescription*, Regulation (EC) No 726/2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, COM (2008) 662 final (Dec. 10, 2008) [hereinafter *Proposal for a Regulation*, COM (2008) 662], available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0662:FIN:en:PDF>.

¹²⁸ See *Proposal for a Directive*, COM (2008) 663, *supra* note 127, at 2; *Proposal for a Regulation*, COM (2008) 662, *supra* note 127, at 2.

¹²⁹ In preparation for the proposals, the Commission sought public consultation on the topic of DTC advertising versus the need for consumer information. The vast majority of respondents indicated that the ban on DTC advertising should be maintained. European Commission, *Summary of the Public Consultation Responses*, at 2, (May 22, 2008), available at http://ec.europa.eu/health/files/patients/docs/summary_publ_cons_220508_en.pdf.

¹³⁰ See, e.g., *Proposal for a Directive*, COM (2008) 663, *supra* note 127, at 6.

¹³¹ *Id.* at 13.

¹³² *Id.* at 13-14. The only significant changes offered in the proposed Regulation are a provision for the dissemination of information on medicinal products to the general public and regulations pertaining to oversight of the information, which is why it is not discussed at length here. See generally *Proposal for a Regulation*, COM (2008) 662, *supra* note 127.

¹³³ Geyer, *supra* note 40, at 597.

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consumers.¹³⁴ The EC approved a revised proposal late in 2011, and it has now been passed on to the European Parliament and Council of Ministers for further debate before final approval.¹³⁵ While the proposal extends the ban on DTC advertising to print advertisements, it allows pharmaceutical companies to provide objective information when it is requested by patients.¹³⁶ The proposal requires that the information be pre-approved by the competent authorities of the Member States and leaves no room for industry self-regulation, as it does in the U.S.¹³⁷ Similar to the FDA's "adequate provision" requirement,¹³⁸ the proposed Directive requires that contact information for the competent authority, as well as "a statement containing a reference to the most recent package leaflet or an indication as to where that text can be found," be included with the information.¹³⁹ With respect to Internet websites, the proposal requires that the information available to consumers comply with the Directive.¹⁴⁰ Additionally, pharmaceutical companies will be required to link their website to that of the recently-created European medicines web-portal, which contains information on pharmaceuticals available in the EU.¹⁴¹

Although the proposal has not yet been made law, it appears that the EU is finally taking a step towards providing more comprehensive information about pharmaceuticals to their citizens. It is an especially important step for a community such as the EU, where Member States do not all share the same language.¹⁴² This Directive, if passed, will allow patients in Member States to receive the information they seek in their native language, which is currently not the case because many, if not most, seekers of health information on the Internet in the EU turn to U.S.-based information.¹⁴³

III. THE PROBLEM OF THE INTERNET

With the increased use of the Internet in the late 1990s, the FDA contemplated the impact of that development on the existing DTC advertising regulations.¹⁴⁴ They have been slow to issue much guidance on Internet promotion in part for fear that it will impinge on the

¹³⁴ Lynne Taylor, *MEPs Vote for Pharma to "Inform not Advertise"*, PHARMATIMES ONLINE (Nov. 26, 2010), [http://www.pharmatimes.com/Article/10-11-26/MEPs_vote_for_pharma_to_"inform_not_advertise".aspx](http://www.pharmatimes.com/Article/10-11-26/MEPs_vote_for_pharma_to_).

¹³⁵ Press Release, European Commission, Empowering the Patient: European Commission Wants Clearer Rules for Information on Prescription Medicines (Oct. 11, 2011), available at http://ec.europa.eu/health/files/patients/ip_10-2011/i11_1171_en.pdf.

¹³⁶ *Amended Proposal for a Directive of the European Parliament and of the Council Amending Directive 2001/83/EC*, at 6, COM (2011) 633 final (Oct. 11, 2011) [hereinafter *Amended Proposal* COM (2011) 663].

¹³⁷ *Id.* But c.f. Liang & Mackey, *supra* note 4, at 398 (proposing that pharmaceutical advertising in the U.S. is largely self-regulated).

¹³⁸ See discussion *supra* Part II.A.

¹³⁹ *Amended Proposal* COM (2011) 633, *supra* note 136.

¹⁴⁰ *Id.* at 7-8.

¹⁴¹ *Id.* at 8. See also Regulation 1235/2010, of the European Parliament and of the Council of 15 December 2010 Amending, as Regards Pharmacovigilance of Medicinal Products for Human use, Regulation (EC) 726/2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary use and Establishing a European Medicines Agency, and Regulation (EC) 1394/2007 on Advanced Therapy Medicinal Products, 2010 O.J. (L 348) 10.

¹⁴² When a country joins the EU, they select one of their national languages to be an official language of the EU. There are currently 23 official languages in the EU. *Official EU Languages*, EUR. COMM. (Feb. 7, 2012), http://ec.europa.eu/languages/languages-of-europe/eu-languages_en.htm.

¹⁴³ Barratt, *supra* note 53, at 51.

¹⁴⁴ See Plant, *supra* note 51, at 108-10.

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free speech protections of the First Amendment.¹⁴⁵ Thus, the only guidance the FDA has provided is that websites promoting prescription drugs and any paid advertising on the Internet must comply with current DTC advertising regulations as they relate to print or broadcast advertisements.¹⁴⁶

According to a 2009 Pew Research study, eighty-three percent (83%) of Internet users look to the Internet when seeking health information.¹⁴⁷ Of those, forty-five percent (45%) look for information about prescription or over-the-counter drugs.¹⁴⁸ About sixty percent (60%) of those seeking health information online look to user-generated content such as blogs or health-related social media, rather than industry-generated content.¹⁴⁹ The vast majority found the information only somewhat helpful or not helpful at all.¹⁵⁰ Thus, because of the high percentage of Internet users seeking health information online there is a need for more accurate and helpful information on the Internet, the regulation of which is a necessary step to improving quality.

The Internet is equally powerful and problematic for drug companies and regulators alike, both in the U.S. and the EU because the sheer volume of information available on the Internet is a reality, as is the potential for misleading or inaccurate information, regardless of its nature. Additionally, Internet use is becoming more interactive and consumers no longer just look at information on the Internet, they are now able to participate in the conversation.¹⁵¹ While the stakes may not be so high when one is simply searching for information about their favorite celebrity or reading news stories from various sites, when it comes to health information, accuracy is of the highest importance, because incorrect information carries the potential for adverse effects on both individual and public health.¹⁵² The following section explores how the U.S. and the EU have addressed, or are attempting to address, DTC advertising specifically as it relates to the unique challenges the Internet poses.

A. How DTC Advertising on the Internet Has Been Addressed in the United States

In September 2009, the FDA began soliciting comments from interested parties that would address the issues of control of, and liability for, information about regulated medical products posted on the Internet, among several other issues.¹⁵³ The FDA inquired as to how the public, members of the industry, and health care providers thought that blogs,¹⁵⁴ microblogs,¹⁵⁵ podcasts,¹⁵⁶ video sharing,¹⁵⁷ social networks and online communities,¹⁵⁸

¹⁴⁵ Auton, *supra* note 8, at 66.

¹⁴⁶ See generally *Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, FOOD & DRUG ADMIN. (Jan. 29, 2012), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm>.

¹⁴⁷ Pew Internet & American Life Project, *supra* note 5, at 11.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 3.

¹⁵⁰ *Id.* at 20.

¹⁵¹ Liang & Mackey, *supra* note 35, at 824.

¹⁵² See *id.* at 825.

¹⁵³ Notice of Public Hearing, 74 Fed. Reg. 48083 (Sept. 21, 2009).

¹⁵⁴ Web logs, or "blogs," are generally informal journal-type updates that often encourage dialog about the subject matter. *Id.* at 48085.

¹⁵⁵ A "microblog" is similar to a blog but much shorter. Twitter is a microblog service. *Id.*

widgets,¹⁵⁹ and wikis¹⁶⁰ could be used to promote regulated medical products “in a truthful, nonmisleading, and balanced manner.”¹⁶¹ The FDA requested feedback on several key issues, including liability for online content, the posting of corrective information, fulfillment of regulatory requirements in limited space, and the appropriate use of links.¹⁶² In November 2009, the FDA held a public hearing on promotion of FDA-regulated medical products using the Internet and social media tools, where many people gave short presentations addressing the FDA’s concerns.¹⁶³ The presenters included pharmaceutical manufacturers, Internet marketing groups, health care advocacy groups, and health care bloggers, among others.¹⁶⁴

One concern brought out at the public hearing relates to liability of pharmaceutical manufacturer and their responsibility for misinformation by third parties on pharmaceutical company controlled or influenced websites.¹⁶⁵ For example, the introduction of Google’s “Sidewiki” application made it possible for anybody viewing a website to comment on it in a sidebar, and left no control over the content of the Sidewiki to the owner of the site.¹⁶⁶ Although site owners could claim the first comment position so that it was always the first post Sidewiki users saw, a representative for Eli Lilly states that the company decided to refuse the spot because they were unsure if it would open them up to liability for the rest of the Sidewiki content, including off-label information,¹⁶⁷ which they could not correct and had no control over.¹⁶⁸

¹⁵⁶ Podcasts are video or audio clips that users can listen to or watch from a remote location using a computer, iPod, or smartphone (among other things). *Id.*

¹⁵⁷ Video sharing allows the public to upload video clips to the internet. YouTube is an example of a video sharing site. *Id.*

¹⁵⁸ Social networks and online communities allow users to connect with others. These include sites like Facebook and LinkedIn. *Id.*

¹⁵⁹ The FDA defines widgets as “a graphic control on a Web page that allows the user to interact with it in some way. Widgets can also be posted on multiple Web sites, have the added benefit of hosting ‘live’ content, and often take the form of on-screen tools. . .” which include stock tickers, countdowns, weather updates, etc. *Id.*

¹⁶⁰ Wikis are web pages that anyone with access can modify. Wikipedia is an example of a wiki that anyone can modify. *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.* at 48086-87. The FDA also solicited comments on internet adverse event reporting, which is not a topic addressed by this note.

¹⁶³ See Public Hearing on Promotion of FDA-Regulated Medical Products, *supra* note 36.

¹⁶⁴ See *id.* at 1-5.

¹⁶⁵ See Notice of Public Hearing, *supra* note 153, at 48086.

¹⁶⁶ Public Hearing on Promotion of FDA-Regulated Medical Products, *supra* note 36, at 33-34. It is noted that as of September 2, 2011, Sidewiki has been discontinued by Google in order to “focus instead on [their] broader social initiatives.” A *Fall Spring-Clean*, OFFICIAL GOOGLE BLOG, (Sept. 2, 2011, 12:45 PM), <http://googleblog.blogspot.com/2011/09/fall-spring-clean.html>.

¹⁶⁷ Off-label use refers to a physician’s prescribing of a drug for a purpose other than what the FDA has approved it for. Such use is acceptable “when the intent is the practice of medicine[.]” FOOD & DRUG ADMIN., “Off-Label” and Investigative Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet (Sept. 10, 2011), <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>.

¹⁶⁸ Michele Sharp, Senior Director of U.S. Regulatory Affairs, Eli Lilly & Co., Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 34 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

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Another concern relating to pharmaceutical company liability is misleading information on third party websites.¹⁶⁹ In the initial call for comments,¹⁷⁰ the FDA had requested commentary about the feasibility of companies policing the entirety of the Internet for false or misleading information about their products, such as information concerning off-label use,¹⁷¹ and correcting it if possible.¹⁷² Specifically, the FDA questioned whether there were any “criteria that could be used to determine the appropriateness of correcting misinformation and/or [the] scope of information a company can provide when trying to correct misinformation on a Web site outside a company’s control.”¹⁷³ The FDA also asked whether or not the type of website (blog, reference page, etc.), its prominence (how many people view the website), and its intended audience should be considered when determining whether corrective action is necessary.¹⁷⁴ If, for example, a drug company is made aware of misinformation being distributed on a website, comments page, or blog of some kind that they do not control or influence, the general consensus at the FDA hearing was that companies should not be *required* to correct the information.¹⁷⁵ Many presenters agreed, however, that it is in a company’s best interest to keep an eye out for misinformation and attempt to correct it if at all possible.¹⁷⁶ It was also suggested that the corrective information be just that: information, not promotion.¹⁷⁷

Additionally, there was a general consensus at the FDA hearing that whenever an individual who works for a pharmaceutical company posts corrective or other information, or contributes to a blog or other forum, full disclosure should be made about the relationship of the author to the company.¹⁷⁸ Several speakers at the hearing suggested that such transparency falls, could fall, or should fall under the Federal Trade Commission’s (“FTC”) consumer protection laws requiring prominently placed disclosures when a blogger has been paid or influenced by an advertiser.¹⁷⁹ It was offered that this type of disclosure should be included

¹⁶⁹ Notice of Public Hearing, *supra* note 153, at 48087.

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 48086. See also text accompanying note 167.

¹⁷² Notice of Public Hearing, *supra* note 153, at 48086.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ See, e.g., Rohit Bhargava, Senior Vice President, Ogilvy 360 Digital Influence, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 64, (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>); John Mack, Publisher, Pharma Marketing News, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 90 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>); Maureen Miller, Account Supervisor & Social Media Lead, Compass Healthcare Communications, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 407 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

¹⁷⁶ Miller, *supra* note 175, at 407.

¹⁷⁷ *Id.*

¹⁷⁸ See, e.g., Wayne Gattinella, President & Chief Executive Officer, WebMD, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 162-63 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>). See also Jeremy A. Greene & Aaron S. Kesselheim, *Pharmaceutical Marketing and the New Social Media*, 363 NEW ENG. J. MED. 2087, 2088 (2011).

¹⁷⁹ See, e.g., Christopher Schroeder, Chief Executive Officer, HealthCentral, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 13, 2009), at 256 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/Officeof>

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on any website, blog, or other communication which the company wrote, financed, or had other influence over, such as sponsorship.¹⁸⁰ It was asserted that transparency promotes trust with consumers who view the information¹⁸¹ and helps avoid confusion about the source of the information provided in order to aid consumers in their search for accurate information.¹⁸²

Perhaps the biggest challenge and concern for the FDA and pharmaceutical industry is fulfilling the brief summary requirement on the Internet, specifically in a small amount of space, such as a Tweet or one or two line sponsored advertisement, without falling afoul of the current regulations¹⁸³ and what role links play in that equation.¹⁸⁴ Pharmaceutical companies have generally followed a “one-click” rule in regards to links on the Internet.¹⁸⁵ The one-click rule is an industry-created practice that assumes that it is sufficient to present some information about a drug, absent risk disclosure, so long as information regarding risk is only “one click away”.¹⁸⁶ This practice was widespread until 2009, when the FDA sent warning letters to fourteen pharmaceutical manufacturers relating to sponsored links on an Internet search engine.¹⁸⁷ The letters to Pfizer, for example, described links that were just above the search results on a page and highlighted in a light peach color with the words “sponsored link” in the upper right hand corner.¹⁸⁸ The FDA found that each sponsored link was misleading because they made efficacy claims about the drug without providing any risk information at all.¹⁸⁹ The one line ads said things such as “learn about AROMASIN, a treatment for women with breast cancer”, “www.LYRICA.com Diabetic Nerve Pain, Add-on for Partial Seizures & Fibromyalgia”, and “CADUET.com Treat High Blood Pressure and High Cholesterol with One Pill.”¹⁹⁰ The FDA told Pfizer that while they recognized that they could access the full drug information by clicking on the link, it was “insufficient to mitigate the misleading omission of

MedicalProductsandTobacco/CDER/UCM193463.pdf); Arnold Friede, Principal, Arnold I. Friede & Assoc., Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 103-08 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

¹⁸⁰ See, e.g., Tiffany Mura, Director of Digital Strategy, Consensus Interactive, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 220-24 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

¹⁸¹ Jack Barrette, Chief Executive Officer, WEGO Health, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 183, (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

¹⁸² Schroeder, *supra* note 179, at 255. See also Greene & Kesselheim, *supra* note 178.

¹⁸³ Greene & Kesselheim, *supra* note 178, at 2088.

¹⁸⁴ Notice of Public Hearing, *supra* note 153, at 48087.

¹⁸⁵ Doug Flora, *The FDA and Social Media: A Primer*, THE FOSBURY FLOP (Sept. 27, 2010), <http://thefosburyflop.com/2010/09/27/the-fda-and-social-media-a-primer/>.

¹⁸⁶ *Id.*

¹⁸⁷ See Greene & Kesselheim, *supra* note 178.

¹⁸⁸ To view screenshots of the promotional material in question, see Presentation of Amy Cowan, Head of Indus., Google, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM195758.pdf>.

¹⁸⁹ Letter from Shefali Doshi, Division of Drug Marketing, Advertising, and Communications, FOOD & DRUG ADMIN., to Robert B. Clark, Vice-President, U.S. Regulatory, Pfizer, Inc. (March 26, 2009), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM143487.pdf>.

¹⁹⁰ *Id.*

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risk information from these promotional materials.”¹⁹¹ The FDA was especially concerned because one of the medications had a boxed warning, and another a bolded warning.¹⁹²

At the hearing, the one-click rule garnered both support and criticism. One presenter suggested that it is the most effective way to include important information without hindering a company’s ability to participate in media with space constraints such as Twitter.¹⁹³ Another claimed that because clicking through to other information is the “de facto way a consumer navigates, [and] accesses information” on the Internet, the one-click rule should be the standard.¹⁹⁴ The representative from WEGO Health provided data from a survey they conducted¹⁹⁵ which found that nearly seventy-two percent of respondents agreed that pharmaceutical companies should be required to make the regulatory-mandated information available “one click away”.¹⁹⁶ It was pointed out, however, that the one-click rule actually violates the FDA regulation requiring a fair balance of information if the one or two line sponsored ad makes indication and/or efficacy claims paired with the branded name of the drug absent risk information.¹⁹⁷

Donna Wray, Executive Director of TGaS Advisors, recognized that the FDA has indicated that the one-click rule is not enough, and thus recommends that sponsored advertisements should be in the form of reminder or unbranded help-seeking type advertisements, at least until the FDA issues clear guidance.¹⁹⁸ After an assessment of click-through rates on sponsored advertisements before and after the FDA’s 2009 warning letters were issued, Google believes that the reminder and help-seeking advertisements are not as relevant, transparent or useful to a user’s search as traditional sponsored advertisements.¹⁹⁹ They suggested a new format for sponsored advertisements²⁰⁰ that would include both the brand name and generic, as well as indication, benefit, and risk information.²⁰¹ The advertisement would in-

¹⁹¹ *Id.*

¹⁹² *Id.* Boxed warnings can indicate (among other things) that a drug has the potential for an “adverse reaction so serious in proportion to the potential benefit from the drug . . . that it is essential that it be considered in assessing the risks and benefits of using the drug.” FOOD & DRUG ADMIN., Guidance for Industry on Warning and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drugs and Biological Products – Content and Format, 11 (Oct. 2011) available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf>.

¹⁹³ Bhargava, *supra* note 175, at 63-64.

¹⁹⁴ Ben Wolen, Chief Executive Officer, Waterfront Media, Inc., Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FDA, (Nov. 12, 2009), at 295 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

¹⁹⁵ The survey respondents were members of WEGO Health’s “social network”. Jack Barrette, the CEO, states that they are the “top ten percent of creators and editors who really do create content on average for an audience of 10,000 or more people every month. . .” Barrette, *supra* note 181, at 174-75. Author’s note: It is unknown how many people were surveyed.

¹⁹⁶ *Id.* at 187.

¹⁹⁷ Mack, *supra* note 175, at 88.

¹⁹⁸ Donna Wray, Executive Director, NGaS Advisors, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 13, 2009), at 308 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193463.pdf>).

¹⁹⁹ Cowan, *supra* note 110, at 438-40.

²⁰⁰ An example of this proposed format can be found in the Google hearing presentation. Presentation of Amy Cowan, *supra* note 188.

²⁰¹ Cowan, *supra* note 110, at 440-441.

clude two links, one that lands on the company-sponsored product website and another, directly following the risk information, which links directly to the relevant safety information.²⁰² Google also presented a template for sponsored advertisements for drugs that have a boxed warning.²⁰³ In their model, they have the same two line set-up as with a regular advertisement, but the risk information states: "Click to see full prescribing and risk information, including boxed warning."²⁰⁴ The advertisement for a drug with a boxed warning does not give the indication of efficacy information for the drug, to avoid falling afoul of the brief summary requirement.²⁰⁵

Although one presenter thought that "one click away is one click away too many" for risk information,²⁰⁶ another made the argument that having the risk information merely a click away makes it more likely that people will actually see the important risk information.²⁰⁷ When "adequate provision" is made in a television ad, for example, viewers are directed to look for full prescribing and risk information either on the Internet or in a print advertisement due to the lack of time or space to present all of the necessary information in that media.²⁰⁸ Arnold Friede, a Food and Drug attorney who once worked in the FDA's Office of the General Counsel, sees the adequate provision requirement as broad enough to include disclosures on the Internet.²⁰⁹ Wayne Gattinella of WebMD posited that the Internet is unique in that the information is all right at hand and easily accessible; thus if an individual were directed to click a link to receive risk information, they would be more likely to do that than they would be to look up risk information in a print source after seeing a similar advertisement on television.²¹⁰

Finally, there was discussion about how to verify that the information consumers are linking to is fair and unbiased.²¹¹ For example, Jeffrey Francer of PhRMA suggested that there could be a type of official FDA logo or symbol that could be placed next to a standardized link that states "All drugs have risks. Click here for important safety information from the manufacturer."²¹² Francer believes that the use of the FDA's own logo and consistent, standardized use of the link would lend credibility to the linked information, allowing consumers to easily identify FDA-regulated information.²¹³ When one of the FDA panelists asked for clarification about the information that would be on the linked website, Francer indicated that the content on that site should be something that the FDA has actually reviewed and approved,

²⁰² *Id.*

²⁰³ See *supra* text accompanying note 192.

²⁰⁴ See Cowan, *supra* note 110.

²⁰⁵ See *id.*

²⁰⁶ Diana Zuckerman, President, Nat'l Research Ctr. for Women and Families, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 194 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

²⁰⁷ Gattinella, *supra* note 178, at 158-60.

²⁰⁸ *Id.* at 158-60.

²⁰⁹ Friede, *supra* note 179, at 104-06.

²¹⁰ Gattinella, *supra* note 178, at 158-60.

²¹¹ See e.g. Jeffrey Francer, Assistant Gen. Counsel, PhRMA, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 12, 2009), at 75-76, (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193462.pdf>).

²¹² *Id.*

²¹³ *Id.* at 75-77.

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such as the labeling or package insert, not just information meeting the fair balance requirement.²¹⁴ Additionally, Francer does not think that just anybody should be able to use the symbol and standardized link, but only those who have submitted the linked information to the FDA, i.e. manufacturers exclusively.²¹⁵

Two years after the FDA public hearing, the FDA finally released a draft guidance relating to social media.²¹⁶ Unfortunately for those awaiting this exciting development, the guidance did not address DTC advertising at all, but only addressed how pharmaceutical companies should respond to unsolicited requests for off-label information about their products.²¹⁷ In the public context of a company controlled or third-party website or blog, for example, the FDA recommends responding to a question about off-label use of the company's drug with a statement that the question concerns an unapproved use and with contact information for further inquiries.²¹⁸ As yet, there has not been any indication from the FDA as to when guidance will be issued regarding DTC advertising specifically, although an FDA spokesperson suggested that this guidance was only one of many to come.²¹⁹

B. How DTC Advertising on the Internet Has Been Addressed in the EU

Other than the outright ban on DTC advertising and the proposed Directive that allows for the dissemination of objective pharmaceutical product information directly to consumers,²²⁰ the EU has not directly addressed the problem of the Internet in the same manner as the U.S. It appears that the EU's main focus is ensuring that consumers are only able to "pull" information from Internet sources²²¹ such as U.S. pharmaceutical company websites.²²² It is suggested that the EU "tend[s] to turn a blind eye to the fact that DTC advertising is currently a reality for patients globally. . ."²²³ i.e., that the information is, in fact, being "pushed" at Internet users in the form of DTC advertising currently.

There have been two recent decisions handed down by the Court of Justice of the European Union concerning DTC advertising on the Internet that shed some light on the EU's position.²²⁴ The first was a criminal proceeding against Frede Damgaard, a journalist who had a history of writing about natural products on the Internet.²²⁵ The proceedings against Damgaard were brought by the public prosecutor of Denmark, who claimed that Damgaard had

²¹⁴ *Id.* at 83-84.

²¹⁵ *Id.* at 84-85.

²¹⁶ See GUIDANCE FOR INDUSTRY: RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES, FOOD & DRUG ADMIN. (2011).

²¹⁷ Rich Thomaselli, *FDA's Social Media 'Guidelines' Befuddle Big Pharma*, AD AGE DIGITAL (Dec. 30, 2011), <http://adage.com/article/digital/fda-s-social-media-guidelines-befuddle-big-pharma/231855/>.

²¹⁸ GUIDANCE FOR INDUSTRY, *supra* note 216, at 11.

²¹⁹ Thomaselli, *supra* note 217.

²²⁰ See *supra* Part II.B.

²²¹ Barratt, *supra* note 53, at 51.

²²² *Id.*

²²³ *Id.*

²²⁴ Case C-421/07, Criminal Proceedings Against Frede Damgaard, 2009 E.C.R. I-02629; Case C-316/09, MSD Sharp & Dohme GmbH v. Merckle GmbH, May 5, 2011 (not yet published), available at <http://crui.europa.eu>.

²²⁵ The ANH Team, *European Court Ruling Infringes Freedom of Speech*, ALLIANCE FOR NATURAL HEALTH (Apr. 3, 2009), <http://www.anh-europe.org/news/european-court-ruling-infringes-freedom-of-speech>.

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violated the Community Directive²²⁶ relating to medicinal products for human use.²²⁷ Damgaard had written an article about a natural remedy, and reported that the treatment contained rosehip powder, for which he stated the product's usage indications.²²⁸ Although Damgaard had absolutely no connection to the company that produced the product, nor any other similar company,²²⁹ the Court found that "the wording of Directive 2001/83 does not rule out the possibility that a message originating from an independent third party may constitute advertising. Nor does the directive require a message be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising."²³⁰ Thus, it may possible for anyone who disseminates information about the indications for use of a medicinal product (in this case not even a product requiring a prescription) to be held criminally liable for violation of the EU policy on medicinal products advertising.²³¹

The second case of interest relates to information obtained via a pharmaceutical company's website.²³² There were two questions presented in the case: whether or not Directive 2001/83 extends to "advertising [that] contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible . . . to every person acquiring the product . . ."²³³ and whether the Directive extends to cases where the information is not unsolicited, but "can be accessed only through the Internet when the party concerned takes steps to do so[.]"²³⁴ The information in question was a direct recitation of the packaging, the instructions in the package leaflet, and the therapeutic indications for the medications in question.²³⁵

On the first question, the Court held that when the information distributed is a direct recitation of the already-approved packaging and leaflet information, it is acceptable that it be provided on the company's website.²³⁶ Interestingly, the Court also declared that such objective information, when obtained prior to a medical appointment, could contribute to the prescribing of an appropriate medication, "in so far as there may be a more fruitful dialogue between the doctor and the informed patient"²³⁷ and that it could help avoid "uninformed self-medication" by patients who no longer had access to the package leaflet for the medication they had been prescribed.²³⁸

On the second question, the Court made a distinction between the "push" and "pull" of information from the Internet.²³⁹ In noting that the information on the website could only be accessed by "pulling" it, the Court posited that "[t]hat means of communicating information with the assistance of a passive presentation platform is not, in principle, intrusive and

²²⁶ See generally Council Directive 2001/83/EC, *supra* note 111.

²²⁷ Case C-421/07, Criminal Proceedings Against Frede Damgaard, 2009 E.C.R. I-02629.

²²⁸ *Id.* at ¶ 10-11.

²²⁹ *Id.* at ¶ 12.

²³⁰ *Id.* at ¶ 21.

²³¹ It is noted that Denmark, which brought the proceedings against Mr. Damgaard, does not allow advertisement even of non-prescription medications. *Id.* at ¶ 12. This, however, does not affect the Court of Justice's reasoning that such activity could be deemed "advertising".

²³² See Case C-316/09, *supra* note 224.

²³³ *Id.* at ¶ 19.

²³⁴ *Id.*

²³⁵ *Id.* at ¶ 40.

²³⁶ *Id.* at ¶ 43.

²³⁷ *Id.* at ¶ 38.

²³⁸ *Id.* at ¶ 39.

²³⁹ *Id.* at ¶ 47.

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does not impose itself unexpectedly on the general public.”²⁴⁰ It is thus distinguishable from “push” services, “in which an Internet user is confronted, without searching for it, with that kind of content by means of intrusive windows called ‘pop-ups’, . . . from which situation a strong presumption of advertising must, by contrast, be inferred.”²⁴¹ Essentially, this holding had firmly planted at least part of the Commission’s rejected 2008 proposed Directive into EU law²⁴² even before the new proposal was approved.

It appears that by only addressing the type of information that can or cannot be “pushed” on consumers, the EU is missing the point. Internet users who seek out health information are still going to have advertising “pushed” at them in the form of sponsored links if their search leads them to information from the U.S., thus the distinction is nearly meaningless. If the EU’s purpose is truly to “better protect [the] health of EU citizens,”²⁴³ it must address, and perhaps even legalize and regulate, the use of DTC advertising on the Internet by pharmaceutical companies in the EU. The question then turns to how U.S. and EU regulatory agencies can go about undertaking the monumental task of creating a standardized regulatory framework which promotes accurate information, and in which pharmaceutical companies can participate in the consumer market by advertising their products without fear of liability.

IV. WHERE DO WE GO FROM HERE?

It would be impossible to completely harmonize and integrate the use of DTC advertising between the U.S. and the EU, if only due to the fact that different drugs are approved in different countries, and often for different purposes.²⁴⁴ That does not, however, mean that those regions that have a high incidence of Internet health information seeking by the lay public cannot attempt to *standardize* DTC advertising so that it is clear to the consumer from the outset what type of information they are looking at. As the sheer quantity of presentations at the FDA hearing show,²⁴⁵ pharmaceutical advertising on the Internet is an important issue involving many stakeholders, and not just in the United States. While the European Union faces similar challenges regarding DTC advertising over the Internet, they do not take as proactive a stance as the FDA does. The use of the Internet as an advertising mechanism has huge potential to educate the public about health and medical treatment. The FDA and European Parliament should take this opportunity to enhance the quality and insure the standardization of information being distributed to the public through that medium. That is not to say that DTC advertising on the Internet should be eliminated and replaced solely with educa-

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² Although the language is not the same, the effect of the ruling is directly in line with the proposal, which stated that information “be made available through . . . internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof.” *Proposal for a Directive*, COM (2008) 663, *supra* note 127, at 14.

²⁴³ *Amended Proposal* COM (2011) 663, *supra* note 136, at 2.

²⁴⁴ See generally Lisa Richwine, *Study: Cancer Drugs Approved in U.S. Before Europe*, REUTERS (June 16, 2011), <http://www.reuters.com/article/2011/06/16/us-cancer-drugs-approval-idUSTRE75F1CD20110616> (indicating that different countries approve different drugs).

²⁴⁵ There were fifty presentations relating to the issues discussed *supra* at the two-day hearing, not including the presentations dealing only with the Adverse Event Reporting issue. See *Presentations from Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm192703.htm> (last updated Feb. 25, 2010).

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tional content, as that would probably create a severe conflict of interest.²⁴⁶ DTC advertising is most likely here to stay and probably does provide at least some benefit to the public health by encouraging consumers to seek more information and talk to their doctor.²⁴⁷

The nature of the Internet and pharmaceutical advertising in that medium ameliorates some of the negative impacts of DTC advertising put forth by critics.²⁴⁸ Because the majority of pharmaceutical promotion on the Internet is in the form of one or two line, text only advertisements,²⁴⁹ it is possible to promote prescription drugs without the fear of making emotional or manipulative appeals to consumers and patients.²⁵⁰ That type of sponsored advertisement does not leave room for emotional appeals or manipulation, at least during the patient's first contact with it.²⁵¹ From there, the first information a consumer sees should be a fair and balanced portrayal of the risks and benefits of the drug prominently placed on the screen, much like what is currently required by the regulations for print advertisements.²⁵² It is imperative that the information presented uses clear language that allows a person of average intelligence to understand it fully.²⁵³

Potentially, the nearly unlimited amount of space available on the Internet gives pharmaceutical companies less incentive to make advertisements biased or unbalanced. Rather than pharmaceutical companies picking and choosing which information they want to convey, they can convey all such information through a system of web pages connected with links. While it is true that the purpose of pharmaceutical advertising is to make a profit,²⁵⁴ that primary goal does not necessarily preclude the possibility that advertising can be of some educational value.²⁵⁵ If companies are not constrained to two pages in a magazine or a thirty or sixty second television spot, it is less likely that they will try to fit all of the "good" information in, while leaving out the "bad," thus relieving some of the concern over biased information.²⁵⁶

The allowance of the use of the one-click rule is imperative to pharmaceutical companies' ability to sponsor advertisements on search pages and to participate in some forms of social media, such as Twitter or Facebook.²⁵⁷ Although the FDA has indicated that reliance

²⁴⁶ See WEBER, *supra* note 3, at 161-64.

²⁴⁷ *Id.*

²⁴⁸ See *supra* Part I.

²⁴⁹ See *supra* Part III.A.

²⁵⁰ See *supra* Part II.A.

²⁵¹ See Presentation of Amy Cowan, *supra* note 188, at 12-13.

²⁵² See 21 C.F.R. § 202.1(e)(1) (2011).

²⁵³ See, e.g., Bill Drummy, CEO, Heartbeat Digital, Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, FOOD & DRUG ADMIN., (Nov. 13, 2009), at 273-86 (transcript available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM193463.pdf>).

²⁵⁴ See WEBER, *supra* note 3, at 162.

²⁵⁵ See *id.* at 162-63. Weber believes that there is an inherent tension between the goal of advertising (profits) and the goal of educating the public. "Given [pharmaceutical companies'] commercial goals, it is not reasonable to expect that they have the kind of objectivity that is essential for true education." See *id.* at 163. He does think that consumers can gain knowledge from advertisements and that combining that knowledge with other information they receive can lead to improved healthcare. *Id.*; but see MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES* 250-53 (2004).

²⁵⁶ See *supra* Part I.

²⁵⁷ See *supra* Part III.

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on the one-click rule is not acceptable,²⁵⁸ it probably complies *better* with the adequate provision requirement than traditional television or radio broadcasting, if only because the information is immediately accessible with one easy click. As was mentioned at the FDA hearing,²⁵⁹ links are the quintessential way that Internet users navigate for information,²⁶⁰ thus having risk information merely one click away from the sponsored advertisement or Twitter post would seem to be a logical progression for Internet users. This rule should be paired with a fairly-balanced sponsored advertisement, such as the one proposed by Google which would list the pertinent information and provide two links, one to the company website and the other to safety information.²⁶¹ The use of the term “box warning” in an advertisement is probably ill-advised, as it is unlikely that most consumers would understand that such language indicates heightened risk information.

Consistent with clear language and fairly-balanced information, several speakers at the FDA hearing mentioned the possibility of some type of “seal of approval” that could be placed on websites bearing pharmaceutical information.²⁶² This idea has potential in that it would help consumers immediately determine whether or not the FDA, or perhaps an international third-party organization that would specialize in such certification, has approved of the information. Stringent guidelines for seal approval would have to be in place, and they should not be fulfilled easily. However, if a device or seal were standard across the Internet, consumers would at least have some guidance as to the quality of information they were receiving.²⁶³ Of course, consumers would still be free to seek out uncertified information, but having a seal of approval would make quality health information more readily apparent to the consumer, which would probably benefit many users, especially those without much knowledge of the Internet.

Finally, as the majority of speakers at the FDA hearing agreed, pharmaceutical companies should only be responsible for the information they create and control.²⁶⁴ Companies should have the option to attempt to correct inaccurate information about their products on the Internet whether it is posted on their website or on a third-party website, and it is in their best interest to do so in order to help protect the public health.²⁶⁵ It would be asking too much of any company, not just those that manufacture pharmaceuticals, to police the entirety of the Internet for every inaccurate mention of their product. Liability for misinformation, though, should include any information over which the company has control or influence, and such connections should be displayed prominently to further clarify to consumers the source of the information.²⁶⁶

²⁵⁸ See *supra* Part III.A. See also *supra* text accompanying note 110.

²⁵⁹ See *supra* Part III.A.

²⁶⁰ See *Id.*

²⁶¹ See *supra* part III.

²⁶² See *Id.*

²⁶³ See Rafael Bauschke, *Regulatory Agencies, Pharmaceutical Information and the Internet: A European Perspective*, 104 HEALTH POL’Y 12, 13 (2012).

²⁶⁴ See *supra* part III.

²⁶⁵ See *Id.*

²⁶⁶ See *Id.*

V. CONCLUSION

The FDA has considerable work ahead of it. Implementing changes of the magnitude necessary to fully standardize the way DTC advertising is practiced on the Internet will take time and ingenuity, primarily because the way that users interact with the Internet is constantly changing. Of some consolation is the fact that the FDA already has many of the necessary regulations in place,²⁶⁷ and many may only require clarification or extensions relating to their application to DTC advertising on the Internet specifically. Confusion over how to fulfill the brief summary requirement, for example, could easily be mitigated by standardization of sponsored links and the endorsement of the one-click rule. Ultimately the FDA must provide clarification for the pharmaceutical industry. The FDA must issue guidance indicating what forms of advertising on the Internet are acceptable.

The EU should rethink its stance on the practice of DTC advertising, especially on the Internet. By completely rejecting the idea of DTC advertising, they are rejecting an opportunity to influence the information that consumers receive despite the EU's objections. By allowing some forms of strictly regulated DTC advertising, even if it only applies to the Internet, the EU will be in a position to have at least some control over the type of information consumers see. It is better to have strictly regulated but helpful information advertised to consumers, than it is to have consumers seek out information that may or may not be accurate or useful. By ignoring the fact that consumers in the EU seek information about pharmaceuticals on the Internet and are often exposed to DTC advertising, the EU is doing a disservice to their citizens.

²⁶⁷ See *supra* part II.A.

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