

## DISEASE-BRANDING AND DRUG-MONGERING: COULD PHARMACEUTICAL INDUSTRY PROMOTIONAL PRACTICES RESULT IN TORT LIABILITY?

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### I. INTRODUCTION

Imagine a forty-five-year-old woman who has been happily married for fifteen years presenting to her physician with complaints of infrequent sexual thoughts and fantasies.<sup>1</sup> After a history and physical examination, the physician diagnoses her as having low sexual desire.<sup>2</sup> But does she have an actual disease? A few decades ago, this woman would not have had a recognizable disease, and there was no official diagnosis.<sup>3</sup> Today, she could be diagnosed with some form of Female Sexual Dysfunction (FSD)<sup>4</sup> or Hypoactive Sexual Desire Disorder (HSDD).<sup>5</sup> The evolution of these symptoms into a recogniza-

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<sup>1</sup> See Rosemary Basson, *Sexual Desire and Arousal Disorders in Women*, 354 NEW ENG. J. MED. 1497, 1497 (2006).

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

<sup>3</sup> See *Sexual Dysfunction—Sexual Desire Disorders, Sexual Arousal Disorders, Orgasm Disorders, Sexual Pain Disorders, Sex Therapy*, JRANK: MARRIAGE AND FAM. ENCYCLOPEDIA, <http://family.jrank.org/pages/1508/Sexual-Dysfunction.html> (last visited Feb. 4, 2012) (“Psychosexual disorders were listed for the first time in 1980 in the third edition of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders (DSM-III), a handbook used by almost all mental health professionals.”). Compare AM. PSYCHIATRIC ASS’N., DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (2d ed., 1968), and AM. PSYCHIATRIC ASS’N., DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (3d ed., 1980), with AM. PSYCHIATRIC ASS’N., DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 293 (3d rev. ed., 1987) (containing Hypoactive Sexual Desire Disorder, Diagnostic Code 302.71), and AM. PSYCHIATRIC ASS’N., DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 541 (4th ed., text rev., 2000) [hereinafter DSM-IV-TR, 2000] (same).

<sup>4</sup> Ray Moynihan, *The Marketing of a Disease: Female Sexual Dysfunction*, 330 BRIT. MED. J. 192, 192 (2005), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC545000/pdf/bmj33000192.pdf>.

<sup>5</sup> *Id.*; see also DSM-IV-TR, 2000, *supra* note 3, at 541; Basson, *supra* note 1, at 1498 tbl.2.

ble disease occurred through a process of social construction and medicalization. It is called disease-branding, and HSDD provides a quintessential example of this practice.<sup>6</sup>

Disease-branding is the pharmaceutical advertising practice of transforming symptoms into disease-states and coining new clinical names to identify them.<sup>7</sup> This practice legitimizes diseases in the eyes of consumer-patients as a pretext to push drug treatments on them.<sup>8</sup> The concept of disease-branding has gained heightened attention in the media.<sup>9</sup> In October 2010, the New York Times' resident lexicog-

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<sup>6</sup> See Andrew Moseman, *Skeptics of "Female Viagra" Say Drug Co's Are "Disease Branding."* 80BEATS (June 18, 2010, 9:59 AM), <http://blogs.discovermagazine.com/80beats/2010/06/18/skeptics-of-female-viagra-say-drug-cos-are-disease-branding/>. The creation of "Metabolic Syndrome" provides another example of disease branding:

Most people may not have heard of metabolic syndrome, but that is likely to change. Once known mysteriously as Syndrome X, the condition, a precursor to heart disease and type 2 diabetes, is about to be transformed into a household name by the US pharmaceutical industry and its partners in the medical profession. A society dedicated to addressing the condition has been organized, a journal has been started, and an education campaign launched. Patients are already being tested for metabolic syndrome. As the trade publication *Pharmaceutical Executive* said in its January 2004 issue: "A new disease is being born."

Howard Wolinsky, *Disease Mongering and Drug Marketing: Does the Pharmaceutical Industry Manufacture Diseases as Well as Drugs?*, 6 EUR. MOLECULAR BIOLOGY ORG. REP. 612, 612 (2005) (emphasis added) (internal citation omitted), available at <http://www.nature.com/embor/journal/v6/n7/pdf/7400476.pdf>.

<sup>7</sup> Ray Moynihan, *The Merging of Marketing and Medical Science*, ABC NEWS ONLINE (Aug. 30, 2010), <http://www.abc.net.au/unleashed/stories/s2996546.htm>. See generally Anne Landman, *Branding Diseases to Sell Cures*, PR WATCH BLOG (Oct. 12, 2010, 12:44 PM), <http://www.prwatch.org/node/9529> ("Once people are convinced they have a new condition, they will seek treatment on their own, and new drugs will sell themselves."); Vince Parry, *Branding Disease*, PHARM. EXEC. (Oct. 15, 2007), <http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=465561&pageID=1&sk=&date=>.

<sup>8</sup> See Wolinsky, *supra* note 6, at 612.

<sup>9</sup> See, e.g., Elizabeth Mari, *New Buzzword of 2010: "Disease Branding."* BEYOND MY TWO CENTS (Oct. 14, 2010), <http://www.beyondmytwocents.com/new-buzzword-of-2010-disease-branding/>; Ben Schott, *Disease Branding*, SCHOTT'S VOCAB (Oct. 18, 2010, 1:30 PM), <http://schott.blogs.nytimes.com/2010/10/18/disease-branding/>. Comedians and pundits in the popular media have also observed this phenomenon. See, e.g., *Bill Maher-Anti-Pharma Rant*, YOUTUBE (Sept. 30, 2007), <http://www.youtube.com/watch?v=rHXXTCc-IVg&feature=related>.

Because you see the government isn't your nanny, they're your dealer. And they subsidize illness in America. They have to; there's too much money in it. You see, there's no money in healthy people. And there's no money in dead people. The money is in the middle. People who are alive, sort of. But with one or more chronic conditions that puts them in need of Celebrex, or Nasonex, or Valtrex, or Lunesta. . . .

rapher, blogging about the recent coinage of “disease-branding,” defined it as the practice of “[h]yping the profile of a medical condition in order to sell its treatment.”<sup>10</sup> In its more extreme form, critics have pejoratively characterized disease-branding as the practice of “trying to convince essentially well people that they are sick, or slightly sick people that they are very ill.”<sup>11</sup> Disease-branding has even been referred to as “the most insidious of the various forms that medical advertising . . . and medical diagnosis can take.”<sup>12</sup>

When pharmaceutical companies attempt to push drug treatments on patients through disease-branding strategies such as direct-to-consumer (DTC) advertising, they are engaging in a practice called “drug-mongering.”<sup>13</sup> Drug-mongering is inextricably linked to disease-branding: it refers to the practice of persuading consumers that they are afflicted with the branded disease and thus require the advertised drug treatment. Bioethicist Professor Dr. Carl Elliot explains this as a two-part process in which drug companies sell their drugs by selling the diseases they treat.<sup>14</sup> Essentially, branding a disease “is to shape its public perception in order to make it more palatable to potential patients.”<sup>15</sup> Once a disease is successfully branded, drug companies engage in drug-mongering by persuading consumer-patients that they need to use the company’s drugs to treat the disease.<sup>16</sup> The confluence of disease-branding and drug-mongering is

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[There are emerging epidemics and] a long list of ailments, which used to be rare and have now been mainstreamed.

*Id.* Bill Maher is correct that there is money in drug-mongering because treating chronic conditions is much more profitable than curing them. The suggestion that the FDA, however, as the representative agency of the government, implicitly legitimizes the mainstreaming of ailments through its approval process misconstrues the FDA’s mandate, which is to approve drugs as safe and effective for their intended use, not to determine what the intended use is or should be. *See infra* Part II.B.

<sup>10</sup> Schott, *supra* note 9.

<sup>11</sup> Wolinsky, *supra* note 6, at 612 (internal quotation marks and citation omitted).

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

<sup>13</sup> Although the term “drug-mongering” does not seem to be used in the literature—“disease-mongering” is the preferred terminology—this Comment uses the concepts of “disease-branding” and “drug-mongering” as separate practices that are intimately related, are complementary, and act synergistically for pharmaceutical promotional practices to be effective.

<sup>14</sup> Carl Elliott, *How to Brand a Disease—and Sell a Cure*, CNN.COM (Oct. 11, 2010, 2:07 PM), <http://www.cnn.com/2010/OPINION/10/11/elliott.branding.disease/index.html?iref=allsearch>.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* (“Once a branded disease has achieved a degree of cultural legitimacy, there is no need to convince anyone that a drug to treat it is necessary. It will come to him as his own idea.”).

the essence of pharmaceutical promotional practices, and these promotional practices provide the context and analytical framework for this Comment.

The development of HSDD demonstrates a disease-branding and drug-mongering strategy.<sup>17</sup> According to Ray Moynihan, an investigative journalist and vocal opponent of pharmaceutical promotional practices, drug companies have diligently tried to convince women that they need a drug to treat low libido.<sup>18</sup> He notes that pharmaceutical companies “have helped create the measurement and diagnostic instruments to persuade women that their sexual difficulties deserve a medical label and treatment.”<sup>19</sup>

Flibanserin is a drug that was developed to treat HSDD, and the drug sponsor’s briefing document, prepared for the Food and Drug Administration’s (FDA) Reproductive Health Drugs Advisory Committee<sup>20</sup> meeting regarding flibanserin’s New Drug Application (NDA), reported positive safety and efficacy data.<sup>21</sup> But the FDA’s

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<sup>17</sup> Moseman, *supra* note 6 (“This is really a classic case of disease branding. . . . The messages are aimed at medicalizing normal conditions, and also preying on the insecurity of both the clinician and the patient.” (internal quotation marks and citation omitted)). *Contra* Nancy Zielinski, *Treatments Needed to Treat Female Sexual Dysfunction Experts Say*, EXAMINER.COM (Jan. 10, 2011, 11:12 AM), <http://www.examiner.com/sexual-health-in-grand-rapids/treatments-needed-to-treat-female-sexual-dysfunction-experts-say?cid=parsey#parsey> (noting that ninety percent of doctors surveyed accept the need for an FDA-approved treatment).

<sup>18</sup> Kathleen Blanchard, *Female Sexual Dysfunction: Are Drug Companies Manufacturing a Disease?*, EXAMINER.COM (Oct. 2, 2010, 2:45 PM), <http://www.examiner.com/women-s-health-in-national/female-sexual-dysfunction-are-drug-companies-manufacturing-a-disease>.

<sup>19</sup> *Id.* (internal quotation marks omitted).

<sup>20</sup> An advisory committee is composed of outside scientific and medical experts as well as industry, consumer, and patient representatives who provide the FDA with independent advice on regulatory decisions. *See Questions and Answers Regarding Advisory Committee Membership*, FDA, <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm117646.htm> (last visited Jan. 20, 2012); *see also* U.S. FOOD AND DRUG ADMIN., DRAFT GUIDANCE FOR THE PUBLIC AND FDA STAFF ON CONVENING ADVISORY COMMITTEE MEETINGS 3 (2008), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651.pdf> (“FDA’s advisory committees provide independent expert advice to the agency on a range of complex scientific, technical, and policy issues. An advisory committee meeting also provides a forum for a public hearing on important matters. Although advisory committees provide recommendations to FDA, FDA makes the final decisions.”).

<sup>21</sup> BOEHRINGER INGELHEIM, FLIBANSERIN BRIEFING DOCUMENT 22 (2010), *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM215438.pdf>.

Flibanserin therapy, at the recommended dosing regimen . . . resulted in statistically significant and clinically relevant improvements of the

Advisory Committee unanimously rejected flibanserin,<sup>22</sup> and the sponsor discontinued seeking approval before the FDA could take final regulatory action on the NDA.<sup>23</sup> Although HSDD has evolved into a recognized disease, its treatment has failed to co-evolve—there are currently no FDA-approved pharmaceutical options available to treat this condition.<sup>24</sup> Without a drug to sell, drug companies are unable

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hallmark symptoms of HSDD in premenopausal women based on patient-based assessments of sexual desire, sexual distress, sexual activity, sexual function, and overall patient benefit. In general, flibanserin is well-tolerated as the AEs reported during the development program were non-serious and mild in severity. Currently, women face extremely limited options when seeking help for HSDD. It is important that women suffering from HSDD and their health care providers have an approved treatment option available to them. As the first pharmacologic therapy for HSDD in premenopausal women, if approved, Flibanserin would appreciably expand the HSDD treatment armamentarium and the choices available to women.

*Id.*; see also Press Release, Boehringer Ingelheim, Women with Hypoactive Sexual Desire Disorder (HSDD) Report That Flibanserin Increased Their Sexual Desire and Reduced Associated Distress (May 19, 2010), available at [http://www.boehringer-ingelheim.com/news/news\\_releases/press\\_releases/2010/19\\_may\\_2010.html](http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2010/19_may_2010.html).

<sup>22</sup> Emily P. Walker, *Company Halts “Female Viagra” Development*, MEDPAGE TODAY (Oct. 12, 2010), <http://www.medpagetoday.com/ProductAlert/Prescriptions/22697> (“The committee also voted 11 to 0 that the company failed to demonstrate that the benefits of flibanserin outweigh the risks, which include fainting, accidental injury, insomnia, and fatigue.”); see also Duff Wilson, *Drug for Sexual Desire Disorder Opposed by Panel*, N.Y. TIMES, June 19, 2010, at B3; *“Female Viagra” Falls Short, FDA Says*, MSNBC.COM (June 16, 2010, 2:35 PM), <http://www.msnbc.msn.com/id/37727629/>; David W. Freeman, *“Female Viagra” a Flop, Says FDA Panel*, CBS NEWS (June 17, 2010), <http://www.cbsnews.com/stories/2010/06/17/health/main6591413.shtml>.

<sup>23</sup> Press Release, Boehringer Ingelheim, Following Regulatory Feedback Boehringer Ingelheim Decides to Discontinue Flibanserin Development (Oct. 8, 2010), available at [http://www.boehringer-ingelheim.com/news/news\\_releases/press\\_releases/2010/08\\_october\\_2010\\_fliba.html](http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2010/08_october_2010_fliba.html).

Boehringer Ingelheim announced today the decision to discontinue the development of its investigational compound flibanserin for the treatment of Hypoactive Sexual Desire Disorder (HSDD). The company continues to believe in the value that flibanserin would have for women suffering with HSDD, a significant and recognized medical condition which impacts the lives of many women around the world.

*Id.*; *Boehringer Pulls the Plug on “Pink Viagra,”* REUTERS (Oct. 8, 2010, 11:55 AM), <http://www.reuters.com/article/2010/10/08/us-boehringer-flibanserin-idUSTRE6970TN20101008>.

<sup>24</sup> Jennifer Corbett Dooren, *FDA Questions Safety of “Female Viagra,”* WALL ST. J., June 17, 2010, at D2 [hereinafter Dooren, *FDA Questions*]; Jennifer Corbett Dooren, *Panel Rejects “Pink Viagra” to Boost Female Libido*, WALL ST. J. (June 18, 2010, 5:50 PM), <http://online.wsj.com/article/SB10001424052748704122904575315140487376022.html>; cf. Basson, *supra* note 1, at 1502–03 tbl.4 (noting the absence of FDA-approved

to engage in drug-mongering, but flibanserin still remains one of the most recent attempts at disease-branding.<sup>25</sup> Despite the lack of an FDA-approved drug to treat HSDD, the controversy surrounding the branding of this disease remains.<sup>26</sup> Annemarie Jutel, a medical sociologist, suggests that

[i]n a society which portrays female hypersexuality as desirable, and where women's tumultuous lives don't usually result in perfectly timed and balanced sexual urges, it hasn't been hard to describe low libido as abnormal in order to sell an expensive cure . . . . The problem is the hidden commercial interests behind the science . . . . Sexuality is a complex expression of social, cultural, psychological, and physiological factors and many of us struggle with it, without being "sick." Don't let the pharmaceutical industry tell you otherwise.<sup>27</sup>

Commenting on the controversy surrounding the definition of HSDD, Psychiatry Professor Dr. Ronald Pies notes that "in weighing this spectrum of divergent views, it's clear that much turns on our philosophical understanding of terms such as 'disease,' 'disorder,'

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medications, but the possibility of off-label uses). In a hypothetical case study of a woman with low sexual desire, Dr. Basson stated that

[o]n the basis of clinical experience and limited data on outcomes, I would recommend a combination of cognitive behavioral therapy and sex therapy . . . . Any apparent interpersonal problems should be addressed before further sexual therapy is pursued. At the present time, I would not recommend any pharmacologic therapy, pending the availability of more (and longer-term) data in support of such treatment.

*Id.* at 1504–05.

<sup>25</sup> See Moseman, *supra* note 6; Press Release, BioSante Pharmaceuticals Reports Positive LibiGel® Safety Data Review for Phase III Program (Feb. 9, 2012), available at <http://www.biosantepharm.com/News-Releases.php?ID=020912> (describing LibiGel as a drug "in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women.").

<sup>26</sup> See, e.g., Moynihan, *supra* note 4; Leonore Tiefer, *Female Sexual Dysfunction: A Case Study of Disease Mongering and Activist Resistance*, 3 PLOS MED. 436, 436 (2006), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0030178>; Natasha Singer, *Sex and the Single Drug*, N.Y. TIMES, June 27, 2010, at BU3; Duff Wilson, *Push to Market Pill Stirs Debate on Sexual Desire*, N.Y. TIMES, June 17, 2010, at A1; Annemarie Jutel, *Why the Cure for Flagging Female Libido is Hard to Swallow*, BRISBANE TIMES (Dec. 8, 2009), <http://www.brisbanetimes.com.au/lifestyle/diet-and-fitness/why-the-cure-for-flagging-female-libido-is-hard-to-swallow-20091207-ketm.html>; Ray Moynihan, *Sex Drugs for Women Don't Seem to Be Working*, ABC NEWS ONLINE (Sept. 1, 2010), <http://www.abc.net.au/unleashed/stories/s2998870.htm>; Susan Seligson, *Female Libido Pill Leaves Ethicist Cold*, BU TODAY ONLINE (June 25, 2010), <http://www.bu.edu/today/node/11179>.

<sup>27</sup> Jutel, *supra* note 26.

‘dysfunction,’ and ‘medical condition.’”<sup>28</sup> The controversy essentially encompasses the cultural, social, medical, and (in this Comment) legal significance of disease-branding and drug-mongering—their impact on regulatory decision-making, interaction with statutory rules, and other potential legal ramifications.

Disease-branding and drug-mongering are the pharmaceutical promotional practices of “selling sickness” by widening the boundaries of diagnosable illnesses in order to expand the market for drug treatments.<sup>29</sup> They are “a process that encourages the conversion of socially created anxiety into medical diagnoses suitable for pharmacological treatment.”<sup>30</sup> Critics argue that these promotional practices “turn[] healthy people into patients, waste[] precious resources, and cause[] iatrogenic harm.”<sup>31</sup>

Despite the growing attention to disease-branding and drug-mongering in the public health, sociology-of-health, economic, and advertising fields, there appears to be a critical abstinence in the legal realm. There is a dearth of legal literature addressing these practices as a unique phenomenon or evaluating the regulatory issues and liability implications for the pharmaceutical industry that stem from them.<sup>32</sup> This Comment concedes that opposition to the phenomena of disease-branding and drug-mongering, which critics of the pharmaceutical industry and of the FDA have expounded, is valid from a sociology-of-health perspective. But such criticism is inappropriate

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<sup>28</sup> Ronald W. Pies, *FDA Lacks Desire for Fibanserin—but Does Hypoactive Sexual Desire Disorder Even Exist?*, PSYCHIATRIC TIMES (Aug. 4, 2010), <http://www.psychiatristimes.com/sexual-disorders/content/article/10168/1632801>. For a discussion of how the term “disease” is defined, see *infra* Part III.B.

<sup>29</sup> Ray Moynihan & David Henry, *The Fight Against Disease Mongering: Generating Knowledge for Action*, 3 PLOS MED. 425, 425 (2006), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0030191>.

<sup>30</sup> Tiefer, *supra* note 26, at 436.

<sup>31</sup> Moynihan & Henry, *supra* note 29, at 425. An iatrogenic injury is one “induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures.” *Iatrogenic Definition*, MERRIAM-WEBSTER’S MED. DICTIONARY, <http://www.merriam-webster.com/medical/iatrogenic> (last visited Mar. 2, 2012).

<sup>32</sup> See Lars Noah, *Pigeonholing Illness: Medical Diagnosis as a Legal Construct*, 50 HASTINGS L.J. 241, 242 (1999) (“Little or no attention is paid to the ways in which medical professionals react to the external pressures emanating from, or mediated by, legal institutions with regard to defining and diagnosing disease conditions.”). A LexisNexis search of the “U.S. Law Reviews and Journals, Combined” database reveals zero hits for “drug mongering,” zero hits for “disease branding,” and sixteen hits for “disease mongering” (the majority of which are simply quoting works by Ray Moynihan).

from a regulatory point of view. This Comment argues that the practices of disease-branding and drug-mongering comply with the Food, Drug, and Cosmetic Act (“FD&C Act”)<sup>33</sup> and its accompanying regulations addressing prescription drug advertising.<sup>34</sup> Because this Comment concludes that critics are unlikely to succeed in challenging these practices from an administrative-law perspective, it will consider the viability of a legal cause of action against such practices, using the common law torts of intentional infliction of emotional distress (IIED), negligent infliction of emotional distress (NIED), and medical malpractice. Upon analyzing these litigation strategies, the Comment concludes that a claim for IIED, NIED, or medical malpractice could possibly survive a motion to dismiss and could be decided on its merits. Nevertheless, such a claim would be unlikely to succeed and, if it did, would ultimately be ineffective as a comprehensive reform measure. Accordingly, the most successful and effective route to change these practices on a systemic level is in the legislative arena. Therefore, this Comment considers a previously introduced congressional bill, the Independent Drug Education and Outreach Act (IDEA), and proposes and evaluates possible amendments to this bill that would address the negative effects of disease-branding and drug-mongering practices. Through medical education strategies, such as “academic detailing” of physicians, critics can combat what they perceive as pervasive and insidious pharmaceutical promotional practices.

Part II of this Comment examines the historical and legal development of the FDA’s regulatory framework as well as the evolution of the federal drug approval process and DTC advertising of approved prescription drugs. Part III discusses the sociology-of-health analytical framework and considers how the social construction and medicalization of disease enables disease-branding and drug-mongering. Part IV examines potential causes of action that critics can use to challenge the pharmaceutical industry in the tort arena through claims for IIED, NIED, and medical malpractice. It then considers legislative and educational reform efforts as a prospective remedy to combat the negative effects of disease-branding and drug-mongering. Part V concludes.

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<sup>33</sup> 21 U.S.C. §§ 301–399d (2006).

<sup>34</sup> See generally 21 C.F.R. § 202.1 (2011) (prescription drug advertisements).



## II. THE HISTORY OF DRUG REGULATION AND THE CURRENT LEGAL FRAMEWORK

### A. *Historical Development of the Statutory Definition of a “Drug”*

The development of a regulatory framework for approving drugs began in 1906,<sup>35</sup> but the relevant statutory definition of “drug” was first amended in 1938.<sup>36</sup> The legislative history of the FD&C Act reveals the evolution of the definition.<sup>37</sup> During the congressional hearings leading up to the 1938 Act, there was growing concern about the lack of jurisdictional reach. The “definition for the term ‘drug’ fail[ed] to cover drugs invented to alter the structure or function of the body,”<sup>38</sup> as opposed to those “substances intended to be used for the cure, mitigation, or prevention of disease,”<sup>39</sup> to which the 1906 Act definition was limited. The principal way in which the 1938 amendments altered the definition of “drug” was that “[d]rugs intended for diagnosing illness or for remedying underweight or overweight or for otherwise affecting bodily structure or function [were] subjected to regulation.”<sup>40</sup> The 1938 amendments added § 321(g)(3),<sup>41</sup> which defined the structure/function drugs to include all products “which are sold to correct the function and structure of the body, such as obesity preparations which were not covered by the act.”<sup>42</sup> The purpose of this broadened and inclusive definition was “to reach the use of fat reducers, particularly since obesity may not be a disease.”<sup>43</sup>

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<sup>35</sup> See Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

<sup>36</sup> Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 201(g), 52 Stat. 1040, 1041 (current version at 21 U.S.C. § 321(g)(1) (2006)).

<sup>37</sup> See generally LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG & COSMETIC ACT AND ITS AMENDMENTS (1979) [hereinafter LEGISLATIVE HISTORY FD&C ACT].

<sup>38</sup> 81 CONG. REC. 1947 (1937) (statement of Rep. Edward H. Rees), reprinted in 5 LEGISLATIVE HISTORY FD&C ACT, *supra* note 37, at 816, 816.

<sup>39</sup> § 7, 34 Stat. at 769.

<sup>40</sup> S. REP. NO. 75-2139, at 2 (1938), reprinted in 6 LEGISLATIVE HISTORY OF FD&C ACT, *supra* note 37, at 300, 301.

<sup>41</sup> § 201(g), 52 Stat. at 1041 (current version at 21 U.S.C. § 321(g)(1)(C) (2006)).

<sup>42</sup> *Food, Drugs, and Cosmetics: Hearings on S. 5 Before the Subcomm. of the S. Comm. on Commerce*, 74th Cong. 29 (1935) (statement of Charles Wesley Dunn), reprinted in 3 LEGISLATIVE HISTORY FD&C ACT, *supra* note 37, at 192, 224. At this hearing, Mr. Dunn was representing the Associated Grocery Manufacturers of America, Inc., the American Pharmaceutical Manufacturers Association, the National Association of Dog Food Manufacturers, and himself.

<sup>43</sup> *Food, Drugs, and Cosmetics: Hearings on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 Before the Subcomm. of the H. Comm. on Interstate and Foreign Commerce*, 74th Cong. 55

One should consider the FDA's regulatory capacity over obesity drugs in order to analyze how "structure/function" drugs became subject to FDA regulation. Prior to 1938, obesity drugs were outside the FDA's jurisdictional scope, but now, especially within the past couple of years, the FDA has taken several decisive regulatory actions with respect to obesity drugs. On October 8, 2010, Abbott Labs withdrew the diet drug Meridia from the market.<sup>44</sup> A week later, the FDA "declined to approve what would have been the first new prescription diet pill in more than a decade."<sup>45</sup> Shortly thereafter, the FDA rejected another diet pill, called Qnexa.<sup>46</sup> Dr. Ken Fujioka, Director of the Center for Weight Management at the Scripps Clinic in San Diego, commented how "[i]t looks pretty bleak out there for anyone trying to get a drug approval for weight loss."<sup>47</sup>

This observation would have seemed absurd to any drug manufacturer prior to the 1938 Act, which expanded the definition of drug to include structure/function drugs specifically in order to place obesity drugs within its regulatory jurisdiction.<sup>48</sup> Prior to 1938, obesity was not considered a disease and obesity drugs could only be regulated through FDA's enforcement authority over adulteration and mis-

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(1935) (statement of Walter G. Campbell, Chief, Food and Drug Administration) [hereinafter *Food, Drug, and Cosmetics*], reprinted in 4 LEGISLATIVE HISTORY FD&C ACT, *supra* note 37, at 312, 370; cf. Annemarie Jutel, *Sociology of Diagnosis, A Preliminary Review*, 31 SOC. HEALTH & ILLNESS 278, 292 (2009) ("Commercial interests have an important stake in highlighting overweight as a medical diagnosis, rather than a statistical deviation from normative weight.").

<sup>44</sup> Andrew Pollack, *Abbott Labs Withdraws Meridia from the Market*, N.Y. TIMES, Oct. 9, 2010, at B3.

<sup>45</sup> Andrew Pollack, *No F.D.A. Approval for New Diet Pill*, N.Y. TIMES, Oct. 24, 2010, at A27; see also Andrew Pollack, *F.D.A. Panel Urges Denial of Diet Drug*, N.Y. TIMES, Sept. 17, 2010, at B1 [hereinafter Pollack, *F.D.A. Panel Urges*]. An FDA advisory panel recommended against approval of a new diet pill, the latest setback in efforts to develop treatments for the nation's obesity epidemic . . . . The negative vote is the second setback this year in attempts to win approval for what would be the first new prescription weight-loss drug in more than a decade.

Pollack, *F.D.A. Panel Urges*, *supra*.

<sup>46</sup> Andrew Pollack, *F.D.A. Rejects Qnexa, a Third Weight-Loss Drug*, N.Y. TIMES, Oct. 29, 2010, at A1.

<sup>47</sup> *Id.* But see Andrew Pollack, *Advisory Panel Favors Approval for Weight-Loss Drug*, N.Y. TIMES, Feb. 23, 2012, at B1 (noting that the advisory committee recommended approval of Qnexa and that the FDA is expected to decide whether to approve the drug by April 17, 2012).

<sup>48</sup> See *supra* notes 40–43 and accompanying text.

branding;<sup>49</sup> now, because approval is required, the FDA has taken regulatory action on three obesity drugs in a single month, and obesity is considered not only a disease, but an epidemic.<sup>50</sup>

A drug is now defined as any article intended to diagnose, cure, mitigate, treat, or prevent disease (“disease drug”) or any article intended to affect the structure or function of the body (“structure/function drug”).<sup>51</sup> The addition of structure/function drugs into the regulatory scheme is relevant for the discussion of disease-branding because it rebuts the critics’ argument that the FDA approves drugs to treat non-diseases or industry-invented ailments.<sup>52</sup>

#### B. Regulatory Classification and Approval of a Drug

Drugs are classified as either “new drugs” or drugs that are “generally recognized as safe and effective” (GRASE).<sup>53</sup> Before a new drug can be marketed, the FDA requires approval of an NDA under 21 U.S.C. § 355(b)(1), of an Abbreviated New Drug Application under 21 U.S.C. § 355(j), or through the hybrid 21 U.S.C. § 355(b)(2) process.<sup>54</sup> GRASE drugs can be marketed without these approvals if they comply with an over-the-counter (OTC) drug monograph.<sup>55</sup> Whether drugs are “disease drugs” or “structure/function drugs” is largely irrelevant for regulatory purposes because both must be safe and effec-

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<sup>49</sup> For a discussion of how the FD&C Act’s definition of drug was amended because obesity was not considered a disease, and thus articles intended to remedy obesity escaped classification and regulation, see *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983). For a suggestion that obesity is not a disease, see *Food, Drug, and Cosmetics*, *supra* note 43, at 370.

<sup>50</sup> Benjamin Caballero, *The Global Epidemic of Obesity: An Overview*, 29 EPIDEMIOLOGIC REV. 1, 1 (2007), available at <http://epirev.oxfordjournals.org/content/29/1/1.full.pdf>.

<sup>51</sup> 21 U.S.C. § 321(g)(1)(B)–(C) (2006) (“[A drug includes] articles *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) *intended* to affect the structure or any function of the body of man or other animals . . .” (emphasis added)).

<sup>52</sup> See *infra* Part II.B (discussing that the safety-and-efficacy standard of approval is the same for all new drugs).

<sup>53</sup> § 321(p)(1) (“[New drug is a]ny drug . . . the composition of which is such that such drug is *not generally recognized*, among experts qualified . . . to evaluate the safety and effectiveness of drugs, *as safe and effective* for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .” (emphasis added)).

<sup>54</sup> *Id.* § 355(a).

<sup>55</sup> 21 C.F.R. § 330.1 (2011) (“[An OTC drug] is generally recognized as safe and effective and is not misbranded if it meets . . . each of the conditions contained in any applicable monograph.”). Although there are three routes to market for new drugs, this Comment will focus on brand name drugs that require an NDA.

tive for their intended use.<sup>56</sup> But whether the drug's intended use involves the treatment of certain diseases is relevant because "the status of a health condition as a disease potentially affects a number of [the FDA's] regulatory decisions."<sup>57</sup> For example, the FDA gives accelerated approval for certain fast-track products that are "intended for the treatment of a serious or life-threatening condition,"<sup>58</sup> priority review status for new drugs that treat tropical diseases,<sup>59</sup> and orphan drug status, which includes licensing incentives,<sup>60</sup> to products intended for the treatment of rare diseases.<sup>61</sup> Outside of these specific provisions, however, classifying drugs into disease drugs or structure/function drugs is largely irrelevant because the regulatory approval process is the same. Although the concept of "disease" has important applications in federal drug regulation, it is only relevant to the initial approval.<sup>62</sup> The FDA's regulation of the subsequent advertising and promotional practices does not consider, nor do the agency's regulators monitor, the status of the disease, as long as the advertisement is not misleading and the drug remains safe and effective for its intended use, whatever that use may be.<sup>63</sup>

The FDA's decision to approve a new drug "entail[s] a risk-benefit calculation, so the perceived importance of the therapeutic benefit naturally will influence the Agency's licensing judgments."<sup>64</sup> Although this observation may be important for the initial approval process, once the drug is approved and marketed, categorizing products as disease or structure/function drugs sets up a false dichotomy

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<sup>56</sup> Compare § 355(a) (safety and efficacy requirement for new drugs), with § 330.10 (safety-and-efficacy requirement for OTC drugs).

<sup>57</sup> Noah, *supra* note 32, at 259.

<sup>58</sup> 21 U.S.C. § 356(a)(1) (2006).

<sup>59</sup> *Id.* § 360n. See generally *Health Topics—Tropical Diseases*, WORLD HEALTH ORG., [http://www.who.int/topics/tropical\\_diseases/en/](http://www.who.int/topics/tropical_diseases/en/) (last visited Feb. 4, 2012) ("Tropical diseases encompass all diseases that occur solely, or principally, in the tropics. In practice, the term is often taken to refer to infectious diseases that thrive in hot, humid conditions . . .").

<sup>60</sup> *Id.* § 360cc(a)(2) (seven-year exclusive licensing period).

<sup>61</sup> *Id.* § 360bb(a)(2).

<sup>62</sup> Noah, *supra* note 32, at 242 ("[The concept of disease] helps to inform . . . risk-benefit calculations performed by regulatory agencies charged with licensing therapeutic products . . .").

<sup>63</sup> See generally 21 C.F.R. § 202.1(e)(1) (2011) (noting that the focus of regulating direct-to-consumer prescription drug advertisements is not on the disease but on ensuring that the advertisements "include information relating to the major side effects and contraindications of the advertised drugs").

<sup>64</sup> Noah, *supra* note 32, at 261.

because every drug must comply with the same laws and regulations. Approval is based on safety and efficacy, and although the risk-calculus might be different for drugs that treat life-threatening diseases as compared to those drugs that treat less dire lifestyle problems, the regulatory approval standard is the same.

An application for FDA approval to market a new drug requires, in part, a summary with a “statement identifying the pharmacologic class of the drug and a discussion of the scientific rationale for the drug, its intended use, and the potential clinical benefits of the drug product.”<sup>65</sup> Once the application is received, the “FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, [and] labeling.”<sup>66</sup> Through the approval of an NDA, the most rigorous procedural mechanism of pharmaceutical regulation, the FDA acts as a gatekeeper by determining which drugs enter and exit the marketplace.<sup>67</sup> The FDA uses this gate-keeping authority to approve a drug company’s NDA and regulate the flow of drugs to the market.<sup>68</sup>

For example, consider Nuedexta, a drug that was recently approved to treat pseudobulbar affect (PBA),<sup>69</sup> a condition “characterized by involuntary, sudden, and frequent episodes of laughing and/or crying . . . [which] typically occur out of proportion or incongruent to the underlying emotional state.”<sup>70</sup> Critics of disease-branding may question whether episodes of laughing and crying constitute a disease—that is, whether PBA is an industry-invented disease that the drug sponsor created in order to provide the FDA with a jurisdictional hook under § 321(g)(1)(B) and thus approve Nuedexta as a “disease” drug. PBA, however, is classified in the International Classification of Diseases as “[o]ther specified nonpsychotic mental

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<sup>65</sup> 21 C.F.R. § 314.50(c)(2)(ii) (2011); *see also* 21 U.S.C. § 355(d) (2006).

<sup>66</sup> *Id.* § 314.105(c); *see also* § 355(d).

<sup>67</sup> *See* Daniel Carpenter, *Reputation, Gatekeeping, and the Politics of Post-Marketing Drug Regulation*, 8 VIRTUAL MENTOR: AM. MED. ASS’N J. ETHICS 403, 404 (2006), *available at* <http://virtualmentor.ama-assn.org/2006/06/pdf/pfor1-0606.pdf>.

<sup>68</sup> *See* Daniel Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy*, 23 HEALTH AFF. 52, 52 (2004), *available at* <http://content.healthaffairs.org/content/23/1/52.full.pdf+html>.

<sup>69</sup> Letter from Russell Katz, Dir., Div. of Neurology Prods., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, to Randall Kaye, Vice President, Clinical & Med. Affairs, Avanir Pharm. (Oct. 29, 2010), *available at* [http://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2010/021879s000ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021879s000ltr.pdf).

<sup>70</sup> NUEDEXTA, FULL PRESCRIBING INFORMATION 3 (2010) [hereinafter, NUEDEXTA], *available at* [http://www.nuedexta.com/NUEDEXTA\\_Full\\_Prescribing\\_Information-1.pdf](http://www.nuedexta.com/NUEDEXTA_Full_Prescribing_Information-1.pdf).

disorders following organic brain damage.”<sup>71</sup> In other words, PBA accompanies serious disease states, such as amyotrophic lateral sclerosis or multiple sclerosis,<sup>72</sup> and Nuedexta treats specific functions of the body, the abnormality of which constitutes symptoms of these diseases.<sup>73</sup> Thus, although distinctions between disease drugs and structure/function drugs may be nebulous and overlapping, the status of the drug as one intending to treat diseases or affect bodily structures/functions is legally irrelevant because both classifications of drugs require proof of safety and efficacy prior to approval.<sup>74</sup>

### C. DTC Advertising

Once a drug and its labeling are approved,<sup>75</sup> the drug sponsor can promote the drug and legally use DTC advertising as part of a comprehensive marketing and promotional strategy.<sup>76</sup> The distinct—yet occasionally overlapping—regulatory roles of the FDA and the Federal Trade Commission (FTC) in the marketing and advertising of approved drugs are important to consider. Based on the FTC-FDA Memorandum of Understanding,<sup>77</sup> the FDA has jurisdiction over DTC advertising of prescription drugs.<sup>78</sup> The FDA’s rules and regulations control the industry, and the FDA’s Office of Prescription Drug Pro-

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<sup>71</sup> *Diseases Tabular List and Index*, INT’L CLASSIFICATION OF DISEASES-9-CM, <http://www.icd9cm.net/> (search “Search Diseases” for “Pseudobulbar affect”; then follow “Pseudobulbar affect (PBA) 310.8” hyperlink) (last updated Apr. 9, 2011).

<sup>72</sup> See NUEDEXTA, *supra* note 70, at 3.

<sup>73</sup> *Id.*

<sup>74</sup> The same analysis applies to obesity drugs, which affect the structure/function of the body, but also treat a disease (assuming that obesity is properly classified as a disease).

<sup>75</sup> See 21 U.S.C. § 321(m) (2006) (definition of labeling); *id.* § 355(b)(1)(F) (labeling included in NDA).

<sup>76</sup> See generally 21 C.F.R. § 202.1(e) (2011) (describing prescription drug advertisements broadcasted through television).

<sup>77</sup> FDA-FTC Memorandum of Understanding, 36 Fed. Reg. 18539 (Sept. 16, 1971). See generally Thomas B. Leary, *The Ongoing Dialogue Between the Food and Drug Administration and the Federal Trade Commission*, 59 FOOD & DRUG L.J. 209 (2004) (describing the different roles of the FDA and FTC in regulating drug labeling and advertisements, specifically in reference to DTC advertising of prescription drugs).

<sup>78</sup> FDA-FTC Memorandum of Understanding, 36 Fed. Reg. at 18539 (“The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of *prescription drug advertising*.” (emphasis added)). A drug is classified as a prescription (Rx) drug if “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1)(A) (2006).

motion (OPDP), formerly the Division of Drug Marketing, Advertising and Communications, enforces the laws.<sup>79</sup>

A prescription drug DTC advertisement must present a fair balance between risks and benefits<sup>80</sup> and will be deemed misbranded unless it contains a “major statement” describing side effects and contraindications.<sup>81</sup> In addition, sponsors of DTC broadcast advertisements are required to present a brief summary of the necessary side effects and contraindications or, alternatively, may make an “adequate provision . . . for dissemination of the approved . . . labeling in connection with the broadcast presentation.”<sup>82</sup>

In order to understand how these regulations govern disease-branding and drug-mongering one must examine the FDA’s current interpretation of rules governing DTC broadcast advertising. In August 1999, the FDA issued a final guidance entitled *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (“*Guidance*”), which broadened the scope of permissible DTC advertising of pharmaceuti-

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<sup>79</sup> *The Office of Prescription Drug Promotion (OPDP)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm> (last updated Jan. 5, 2012).

<sup>80</sup> *Drug Advertising: A Glossary of Terms*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#> (last visited Jan. 20, 2012) [hereinafter *Drug Advertising: A Glossary of Terms*] (“[Product-claim ads must] give a ‘fair balance’ of information about drug risks as compared with information about drug benefits. This means that the content and presentation of a drug’s most important risks must be reasonably similar to the content and presentation of its benefits.”).

<sup>81</sup> See 21 U.S.C. § 352(n) (2006).

In the case of an advertisement for a drug subject to section 503(b)(1) [prescription drug status] presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral matter.

*Id.*; see also *Drug Advertising: A Glossary of Terms*, *supra* note 80 (defining “major statement”).

<sup>82</sup> 21 C.F.R. § 202.1(e)(1) (2011).

Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications.

*Id.*

cal products to consumers.<sup>83</sup> In the *Guidance*, the FDA expanded the scope of acceptable advertising practices by allowing for an alternative method of complying with the brief summary requirement in 21 C.F.R. § 201(e)(1).<sup>84</sup> The FDA concluded that the major statement of side effects, coupled with the adequate provision for disseminating approved labeling, “can provide the information disclosure required for [DTC] broadcast advertisements.”<sup>85</sup>

The *Guidance* explains different approaches that satisfy the adequate-provision requirement.<sup>86</sup> These approaches include telling patients that physicians can provide more information, disclosing a website that provides access to the package labeling, and explaining the location of a concurrent print advertisement appearing in a publication.<sup>87</sup> Applying OPDP rules and regulations to DTC advertising suggests that the drugs are not misbranded in violation of the FD&C Act because the advertisements contain a major statement with adequate provisions; therefore, the disease-branding and drug-mongering promotional strategies are fully compliant with the FD&C Act.

For example, a Zelnorm DTC advertisement contains the following major statement: “You should not take Zelnorm if you have a history of diarrhea, kidney, liver, or gall bladder disease, intestinal blockage or adhesions. Tell your doctor if you get diarrhea or cramping, worsening of abdominal pain, dizziness, or headache.”<sup>88</sup> The adequate provision is the statement on the bottom of the screen: “See our ad in *SHAPE* magazine.”<sup>89</sup> A Toviaz DTC advertisement contains the following major statement: “If you have certain stomach problems or glaucoma or cannot empty your bladder you should not take Toviaz. Toviaz can cause blurred vision and drowsiness so use caution when driving or doing unsafe tasks. The most common side ef-

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<sup>83</sup> See U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY—CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070065.pdf>.

<sup>84</sup> Bernard J. Garbutt III & Melinda E. Hofmann, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium*, 58 FOOD & DRUG L.J. 269, 274 (2003).

<sup>85</sup> U.S. FOOD AND DRUG ADMIN., *supra* note 83, at 3.

<sup>86</sup> *Id.* at 2–3.

<sup>87</sup> *Id.*

<sup>88</sup> *Zelnorm TV Ad (2003)*, YOUTUBE (Aug. 8, 2010), <http://www.youtube.com/watch?v=81IVMc5EFN0&feature=related> [hereinafter *Zelnorm TV Ad (2003)*].

<sup>89</sup> *Id.*



fects are dry mouth and constipation.”<sup>90</sup> The adequate provision states: “See our ad in *Cooking Light*.”<sup>91</sup> In addition, a Latisse advertisement includes the following:

If you are using prescription products for lowering eye pressure . . . only use Latisse under close doctor care. May cause eyelid skin darkening which may be reversible and there is potential for increased brown iris pigmentation which is likely permanent . . . Common side effects include itchy eyes and eye redness.<sup>92</sup>

The adequate provision includes a website, a telephone number, and the following statement at the bottom of the screen: “See our ad in *Allure* magazine.”<sup>93</sup>

This is not to say that all DTC broadcast advertising is legal per se. There are countless examples (beginning with the first ever DTC advertisement) of the FDA taking regulatory actions against pharmaceutical companies because of false and misleading promotional materials.<sup>94</sup> In addition, the FDA has required corrective action for DTC broadcast advertisements that violate the balance requirement, for example, when an advertisement overstates benefits, expands intended uses, or minimizes side effects.<sup>95</sup> Nevertheless, individual instances of misleading advertisements represent mere isolated *tactical* mistakes by drug companies because disease-branding and drug-mongering, as

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<sup>90</sup> *CR AdWatch: Toviaz*, CONSUMER REP., <http://bcove.me/3232jaew> (last visited Feb. 4, 2012) [hereinafter *CR AdWatch: Toviaz*].

<sup>91</sup> *Id.*

<sup>92</sup> *Latisse Brooke Shields Commercial*, YOUTUBE (July 15, 2009), <http://www.youtube.com/watch?v=VqRyv8abWR4> [hereinafter *Latisse Brooke Shields Commercial*].

<sup>93</sup> *Id.*

<sup>94</sup> See, e.g., Letter from Tracy L. Acker, Regulatory Review Officer, Div. of Drug Mktg., Adver., and Commc’n, Food and Drug Admin., to Sam Boddapati, Dir., Regulatory Affairs, SuperGen, Inc. (Jan. 6, 1997), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM169185.pdf>.

<sup>95</sup> See, e.g., *Yaz FDA Required “Clear Up,”* YOUTUBE (Feb. 26, 2009), <http://www.youtube.com/watch?v=EO-G8O0IHq0> (Bayer’s corrective advertisement for Yaz made pursuant to the Warning Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Adver., & Commc’n, to Reinhard Franzen, President & Chief Exec. Officer, Bayer HealthCare Pharm., Inc. 1 (Oct. 3, 2008), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm053993.pdf> (“The TV Ads are misleading because they broaden the drug’s indication, overstate the efficacy of YAZ, and minimize serious risks associated with the use of the drug.”)).

a holistic, comprehensive promotional *strategy*, are legal from a regulatory perspective.

Furthermore, the focus on the major statement to achieve compliance only applies to product-claim ads.<sup>96</sup> Reminder ads, which call attention to a brand name drug but do not include indicated uses,<sup>97</sup> and help-seeking ads or disease-awareness ads, which describe a disease but do not recommend a specific drug,<sup>98</sup> are exempt from the provisions that require a major statement about side effects.<sup>99</sup> These types of ads are relevant for this Comment's later discussion about how DTC advertising enables disease-branding.<sup>100</sup>

### III. THE MEDICALIZATION AND SOCIAL CONSTRUCTION OF DISEASE

The phenomena of disease medicalization and the social construction of disease provide the background and theoretical framework for analyzing disease-branding and drug-mongering strategies.<sup>101</sup> This framework provides a better understanding of the disease-branding and drug-mongering strategies that the pharmaceutical industry employs because once a company defines the disease—and treatment of the disease in terms of the drug's intended use—the drug can be legally marketed in the form of DTC advertising.<sup>102</sup> Accordingly, a crucial initial inquiry is what is the definition of disease for the purpose of DTC advertising?

#### A. *Defining Disease*

One medical dictionary defines “disease” as “any deviation from or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of symptoms and signs and whose etiology,

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<sup>96</sup> See 21 C.F.R. § 202.1(e)(1)(2011); *Basics of Drug Ads*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm> (last updated June 24, 2009) [hereinafter *Basics of Drug Ads*]. See generally *Prescription Drug Advertising*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/default.htm> (last updated May 26, 2011) (presenting examples of the different types of prescription drug advertisements).

<sup>97</sup> § 202.1(e)(2)(i).

<sup>98</sup> *Basics of Drug Ads*, *supra* note 96.

<sup>99</sup> See *id.*; § 202.1(e)(2)(i).

<sup>100</sup> See *infra* Part IV.B.1.c (illustrating the strategies used by various DTC drug advertisements).

<sup>101</sup> See *infra* Part III.B.

<sup>102</sup> See *supra* notes 75–76 and accompanying text.

pathology, and prognosis may be known or unknown.”<sup>103</sup> A legal dictionary defines “disease” as “a deviation from the healthy and normal functioning of the body.”<sup>104</sup> But, “it may be absurd to decide on a concept of disease . . . [because] [t]here will always be ‘normal’ people who will want treatment and ‘sick’ people who will refuse it.”<sup>105</sup> Ultimately, the concept of disease appears to be malleable,<sup>106</sup> and the definition can change through social forces and marketing campaigns.<sup>107</sup> That the definition is imprecise has been confirmed through empirical study:

In 1979, a study conducted by a group of Canadian researchers sought a unifying definition of “disease” by asking doctors to classify 34 different conditions as diseases or non-diseases. . . . The study concluded with the observation . . . [that] “there is no general agreement on the definition of ‘a disease.’”<sup>108</sup>

This Comment uses “disease” to refer to the term that the FDA interprets in the FD&C Act, but explains that its medico-legal definition is ambiguous and thus susceptible to exploitation by pharmaceutical marketing. Using the sociology-of-health framework, this Comment exposes, explains, and clarifies the medico-legal implications of defining drugs and disease without reshaping the contours of the FD&C Act definition. That the disease concept is malleable is significant, not necessarily from a regulatory-approval perspective, but for the purposes of DTC advertising. Because there is no precise definition, drug companies have capitalized on this ambiguity to create diseases for marketing and promotional purposes.<sup>109</sup> Revealing this malleability clarifies the FDA’s purpose in this area—regulating the safety and efficacy of drugs, not the authenticity of diseases—and provides a

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<sup>103</sup> Noah, *supra* note 32, at 244 (quoting DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 481 (27th ed. 1988)) (internal quotation marks omitted).

<sup>104</sup> BLACK’S LAW DICTIONARY 535 (9th ed. 2009).

<sup>105</sup> P.R. Shankar & P. Subish, *Disease Mongering*, 48 SING. MED. J. 275, 277 (2007).

<sup>106</sup> Noah, *supra* note 32, at 243 (“[S]cholars and physicians alike have recognized that diseases are socially constructed and mutable.”).

<sup>107</sup> See, e.g., *infra* note 139 and accompanying text (discussing how FSD became HSDD).

<sup>108</sup> Eric J. Gouvin, *Drunk Driving and the Alcoholic Offender: A New Approach to an Old Problem*, 12 AM. J.L. & MED. 99, 104–05 (1986) (quoting E.J.M. Cambell et al., *The Concept of Disease*, 2 BRIT. MED. J. 757, 757 (1979)).

<sup>109</sup> See, e.g., Marc Kaufman, *Hormone Replacement Gets New Scrutiny: Finding of Increased Risks Prompts Federal Effort*, WASH. POST, Aug. 14, 2002, at A1 (“[F]ederal officials want to explore whether hormone therapies and their producers have encouraged women to believe menopause is a condition to be treated, rather than an inevitable and natural set of changes to be managed.”).

framework for analyzing DTC promotional practices based on intended use.

*B. The Medicalization of Disease*

Medicalization is the process “through which aspects of life previously outside the jurisdiction of medicine come to be construed as medical problems.”<sup>110</sup> The sociology-of-health framework of medicalization explains that medicine is “understood as a social and cultural enterprise as well as a medico-scientific one,” such that disease is defined through socio-cultural forces, rather than clear scientific consensus.<sup>111</sup> Essentially, disease is a social construction: “In examining the social meaning of illness, we focus on the role of social and cultural values that shape the perception of a disease or malady.”<sup>112</sup> The medicalization of disease is the underlying theoretical framework through which one can analyze how disease-branding and drug-mongering occur in practice. Accordingly, the medicalization concept elucidates why and how the definition of disease is malleable and how it is both outside the scope of the FDA’s jurisdiction and ripe for pharmaceutical promotional exploitation.

The study of medicalization does not belong solely to the sociology-of-health realm because nosology—the branch of medicine concerned with the classification and description of known diseases—has a particular and significant application in the law. One commentator, Professor of Law Lars Noah, has noted that “no one has systematically assessed the role that the law plays in the diagnostic enterprise . . . [but that] the law and lawyers have played a subtle, but often significant, role in ‘framing’ disease.”<sup>113</sup> The way that diseases are framed or defined in the socio-cultural milieu and later accepted in the mainstream impacts the regulatory status of drugs used to treat

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<sup>110</sup> Adele E. Clarke et al., *Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine*, in *THE SOCIOLOGY OF HEALTH & ILLNESS: CRITICAL PERSPECTIVES* 442, 442 (Peter Conrad ed., 2005); see also Shankar & Subish, *supra* note 105, at 275 (“Medicalisation is the process of turning ordinary life events and its customary ups and downs into medical conditions.”).

<sup>111</sup> Clarke et al., *supra* note 110, at 443.

<sup>112</sup> Peter Conrad, *The Social and Cultural Meanings of Illness*, in *THE SOCIOLOGY OF HEALTH & ILLNESS: CRITICAL PERSPECTIVES*, *supra* note 110, at 104, 104.

<sup>113</sup> Noah, *supra* note 32, at 252 (internal quotation marks and citations omitted).

these diseases as well as how pharmaceutical companies create advertising campaigns.<sup>114</sup>

Sociologists have explained that “recognizing that drugs are concrete material objects does not prevent their simultaneous analysis as complex social phenomena.”<sup>115</sup> The “illness identity” concept helps explain how this social phenomenon emerges: “[A]n illness identity refers to an understanding of self, and affiliation with others, on the basis of shared experiences of symptoms and suffering.”<sup>116</sup> The illness identity subsequently becomes associated with particular pharmaceutical treatments.<sup>117</sup> For example, consider how menopause, which used to be described as “a natural life event for women, became defined as a ‘deficiency disease’ in the 1960s when medical therapy became readily available to treat it.”<sup>118</sup>

The concept of disease, and its impact on promoted drug treatments, is malleable especially as medicines become “increasingly available for conditions which have so far been regarded as the natural result of ageing or as a part of the normal range of human emotions.”<sup>119</sup> Thus, “although biological and clinical factors have set boundaries for which symptoms might plausibly be linked in a disease concept, social influences have largely determined which symptom clusters have become diseases.”<sup>120</sup> The pharmaceutical industry and marketing firms have played an important role in perpetuating this process: “Sadness, or sexual problems, both arguably non-medical in nature, but variably transformed by the diagnostic labels ‘depression’

<sup>114</sup> See, e.g., Ed Silverman, *Disease Mongering? The Selling of Fibromyalgia*, PHARMALOT BLOG (Jan. 14, 2008, 7:50 AM), <http://www.pharmalot.com/2008/01/disease-mongering-the-selling-of-fibromyalgia/> (describing the case of fibromyalgia).

<sup>115</sup> David Cohen et al., *Medications and the Pharmaceutical Industry*, in THE SOCIOLOGY OF HEALTH & ILLNESS: CRITICAL PERSPECTIVES, *supra* note 110, at 275, 278.

<sup>116</sup> Kristin Barker, *Self-Help Literature and the Making of an Illness Identity: The Case of Fibromyalgia Syndrome (FMS)*, in THE SOCIOLOGY OF HEALTH & ILLNESS: CRITICAL PERSPECTIVES, *supra* note 110, at 133, 135.

<sup>117</sup> See, e.g., “Facing Fibromyalgia, Finding Hope” PSA by the NFA, YOUTUBE (Sept. 12, 2007), <http://www.youtube.com/watch?v=SMCECMsW1RE&feature=related> [hereinafter *Facing Fibromyalgia, Finding Hope*] (the public service announcement by the National Fibromyalgia Association, co-sponsored by Pfizer, the maker of Lyrica, the first FDA-approved treatment for fibromyalgia).

<sup>118</sup> Conrad, *supra* note 112, at 105; see also Kaufman, *supra* note 109 (“[F]ederal officials want to explore whether hormone therapies and their producers have encouraged women to believe menopause is a condition to be treated, rather than an inevitable and natural set of changes to be managed.”).

<sup>119</sup> Shankar & Subish, *supra* note 105, at 276.

<sup>120</sup> Jutel, *supra* note 43, at 281 (quoting R. Aronowitz, *When Do Symptoms Become a Disease?*, 134 ANNALS OF INTERNAL MED. 9, pt. 2, 803 (2001)).

and ‘erectile dysfunction’, both of which trigger an army of medicalised actions, therapies and processes.”<sup>121</sup>

Fibromyalgia, or fibromyalgia syndrome (FMS)—“a chronic disorder characterized by widespread pain, tenderness, and stiffness of muscles . . . that is typically accompanied by fatigue, headache, and sleep disturbances”<sup>122</sup>—is a classic example of the social construction of disease.<sup>123</sup> While medical accounts of patients suffering from symptoms associated with this illness have existed for hundreds of years, the actual disease “has existed as a specific diagnosis only since the mid-1970s.”<sup>124</sup> FMS is a controversial pain disorder because “there is no commonly accepted medical or organic explanation.”<sup>125</sup> FMS is a “contested illness” because many people suffer from it, but physicians “tend to be skeptical about its organic origin.”<sup>126</sup> Some doctors who do not consider FMS a medically diagnosable disease suggest that “diagnosing the condition actually worsens suffering by causing patients to obsess over aches that other people simply tolerate.”<sup>127</sup> In fact, Dr. Frederick Wolfe, the lead author of the seminal paper that first defined the diagnostic criteria for FMS, is “cynical and discouraged about the diagnosis . . . [and] now considers the condition a physical response to stress, depression, and economic and social anxiety.”<sup>128</sup> He explained that “[s]ome of us in those days thought that we had actually identified a disease, which this clearly is not . . . . To make people ill, to give them an illness, was the wrong thing.”<sup>129</sup> The New York Times reported, however, that “[d]octors who specialize in treating [FMS] say that the disorder is undertreated and that its sufferers have been stigmatized as chronic complainers.”<sup>130</sup> Accordingly,

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<sup>121</sup> *Id.* at 285.

<sup>122</sup> *Fibromyalgia Definition*, MERRIAM-WEBSTER’S MED. DICTIONARY, <http://www.merriam-webster.com/medical/fibromyalgia> (last visited Feb. 4, 2012).

<sup>123</sup> Barker, *supra* note 116, at 133.

<sup>124</sup> *Id.* at 133–34.

<sup>125</sup> Peter Conrad, *The Experience of Illness, in* THE SOCIOLOGY OF HEALTH & ILLNESS: CRITICAL PERSPECTIVES, *supra* note 110, at 130, 130.

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

<sup>127</sup> Alex Berenson, *Drug Approved. Is Disease Real?* N.Y. TIMES (Jan. 14, 2008), [http://www.nytimes.com/2008/01/14/health/14pain.html?\\_r=1&pagewanted=all](http://www.nytimes.com/2008/01/14/health/14pain.html?_r=1&pagewanted=all).

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

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

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

disease-branding reduces the stigma associated with this condition and helps legitimize it as a medical condition.<sup>131</sup>

The most prominent reason for the FMS controversy is its “biomedical invisibility” because there are neither objective indicators nor diagnostic tests for the disease.<sup>132</sup> Although “the American College of Rheumatology established criteria for the classification of FMS in 1990,”<sup>133</sup> there is still no specific and conclusive diagnostic test, so doctors make a diagnosis by evaluating subjective symptoms.<sup>134</sup> Thus,

the biomedical uncertainty about FMS stands in sharp contrast to the subjective experiences of individuals diagnosed with FMS. . . . The outcome of this paradox for many with FMS is that they find themselves in an epistemological purgatory in which they question their own sanity precisely because of their certainty about the realness of their experience in the face of public doubt.<sup>135</sup>

The “epistemological purgatory” is where pharmaceutical companies thrive—and where the FDA is properly absent. The FDA’s role in disease-creation is outside the scope of its legislative mandate; the Agency only regulates the advertising of drugs, not the authenticity of diseases. Pharmaceutical companies exploit this opportunity through their advertising power in order to construct knowledge about the existence and reality of the disease and promote their newly approved drug treatment.<sup>136</sup>

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<sup>131</sup> The president of the National Fibromyalgia Association proclaimed that “[t]he day that the F.D.A. approved a drug and we had a public service announcement, my pain became real to people.” *Id.* (internal quotation marks omitted).

<sup>132</sup> Barker, *supra* note 116, at 134; *see also About Fibromyalgia*, NAT’L FIBROMYALGIA ASS’N, <http://www.fmaware.org/PageServerded3.html?pagename=fibromyalgia> (last visited Feb. 4, 2012) (“Unlike a disease, which is a medical condition with a specific cause or causes and recognizable signs and symptoms, a syndrome is a collection of signs, symptoms, and medical problems that tend to occur together but are *not* related to a specific, identifiable cause.” (emphasis added)).

<sup>133</sup> Barker, *supra* note 116, at 134.

<sup>134</sup> *See* FOOD & DRUG ADMIN., LIVING WITH FIBROMYALGIA, DRUGS APPROVED TO MANAGE PAIN 2 (2008), *available at* <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm107805.pdf>.

<sup>135</sup> Barker, *supra* note 116, at 134.

<sup>136</sup> *See infra* Part IV.B.1.c (illustrating the promotional strategies used by various DTC drug ads). Interestingly, promotional practices can sometimes precede FDA approval when pharmaceutical companies brand diseases and physicians create new diagnostic criteria listing symptoms of the disease that the drug will be able to treat. *See* Cohen et al., *supra* note 115, at 277 (“[P]romotion of a drug by its manufacturers may actually precede the clinical trials . . . . The promotion may involve funding professional committees working on the creation of a new psychiatric diagnostic category listing specific target symptoms, treatment of which the new drug is then expected to improve.”).

Furthermore, the history of flibanserin and FSD/HSDD provides a unique illustration of the interrelationship between medicalization and the pharmaceutical industry. Flibanserin's origin is as an unintended side effect of a treatment for an unrelated disease. Essentially, it demonstrates the interplay between research, development, and marketing tactics as a drug developed for one purpose can be marketed as a treatment for another disease:

Studies of [flibanserin] showed it didn't work well as an antidepressant but showed that it didn't appear to damp sexual desire as some antidepressants do. The FDA said antidepressant studies showed flibanserin was superior to placebo and a comparator drug with respect to a question about "how strong is your sex drive" on a sexual-experience scale. That finding led Boehringer Ingelheim to develop the product as a treatment for women with HSDD.<sup>137</sup>

Another crucial observation concerns how the name of the disease changed from FSD to HSDD. The history of the disease shows that "it was a convergence of pharmaceutical companies, urologists closely associated with th[e] industry, and media-savvy sex therapists . . . which resulted in the creation and promotion of a diagnosis of 'female sexual dysfunction.'" <sup>138</sup> One scholar noted how "[t]he unnoticed shift in 2004 in FSD identity and promotion from female sexual arousal disorder to hypoactive sexual desire disorder is another hallmark moment in the FSD story, illustrating how the effort to match up some drug with FSD moved freely among symptoms and labels."<sup>139</sup>

Industry-invented diseases exist and continue to proliferate due to the pervasive effect of medicalization. Medicalizing normal conditions into treatable diseases is the undercurrent upon which some prescription drugs drift into the marketplace. Because medicalization is a sociological mechanism, it is outside the FDA's jurisdiction; it is an unregulated yet effective instrument within the drug companies' marketing toolbox.

*C. How Drug Companies Advertise: Explaining the Disease-Branding/Drug-Mongering Strategy*

Critics condemn the pharmaceutical industry for its promotional practices of medicalizing non-disease conditions in order to create

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<sup>137</sup> Dooren, *FDA Questions*, *supra* note 24.

<sup>138</sup> Jutel, *supra* note 43, at 292.

<sup>139</sup> Tiefer, *supra* note 26, at 4.



new markets for drug treatments.<sup>140</sup> Disease-branding turns “ordinary ailments into medical problems, see[s] mild symptoms as serious, treat[s] personal problems as medical ones, see[s] risks as diseases, and frame[s] prevalence estimates to increase potential markets.”<sup>141</sup> Disease-branding convinces healthy people they are sick, while drug-mongering convinces these newfound patients that they need drugs.<sup>142</sup>

Havidol is a realistic parody of a disease-branding and drug-mongering campaign; although fictitious and satirical, it is nevertheless representative of the promotional practice. Australian artist Justine Cooper created a DTC advertising campaign to promote the fake drug Havidol to treat the farcical disease Dysphoric Social Attention Consumption Deficit Anxiety Disorder.<sup>143</sup> According to its website and prescribing information, Havidol is “the only known medication available for this newly recognized disorder.”<sup>144</sup> The public response to the exhibit has been surprising.<sup>145</sup> The exhibit, which includes a mock website and television and print advertisements, is so believable that people think it is an authentic DTC advertising campaign.<sup>146</sup> A review of the exhibit describes Havidol as

a frightening approximation of the real thing. Parody gives way to possibility as Cooper recreates the entire drug marketing process—from the invention of a new disorder (wherein a need is first found and then the disorder is penned) to the branding pro-

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<sup>140</sup> E.g., NIKOLAS ROSE, *THE POLITICS OF LIFE ITSELF: BIOMEDICINE, POWER, AND SUBJECTIVITY IN THE TWENTY-FIRST CENTURY 2* (2007) (“Pharmaceutical companies have been singled out for particular criticism, accused of selling many new drugs at inflated prices and with false promises, ignoring potentially dangerous side effects, and medicalizing nondisease conditions such as baldness or lack of libido to create new markets in the ruthless pursuit of shareholder value.” (citations omitted)).

<sup>141</sup> Shankar & Subish, *supra* note 105, at 275.

<sup>142</sup> *Id.*

<sup>143</sup> *Fake Drug, Fake Illness—and People Believe It!*, REUTERS, Feb. 16, 2007, available at <http://www.reuters.com/article/2007/02/16/us-drug-fake-idUSL165119520070216> [hereinafter *Fake Drug, Fake Illness—and People Believe It!*].

<sup>144</sup> *Understanding Havidol*, HAVIDOL, <http://www.havidol.com/understanding.html> (last visited Feb. 4, 2012).

<sup>145</sup> *Consumers Fall for Havidol Pharmaceutical Parody that Promotes a Fictitious Anxiety Disorder*, NAT. NEWS.COM (Mar. 1, 2007), <http://www.naturalnews.com/021660.html> [hereinafter *Consumers Fall for Havidol Parody*].

<sup>146</sup> *Fake Drug, Fake Illness—and People Believe It!*, *supra* note 143; see also Marylyn Donahue, *When Branding Is Art*, PHARM. EXEC. (Oct. 15, 2007), <http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=465558&sk=&date=&&pageID=1> (discussing the trade magazine *Pharmaceutical Executive's* response to the Havidol campaign).

cess of naming the drug, its pill and logo design, promotional merchandise, and finally its website, TV and print advertisements.<sup>147</sup>

Cooper, commenting on her exhibit and the “comedic” nature of real drug advertisements, states: “I couldn’t be outrageously spoofy so I really wanted it to be a more subtle kind of parody that draws you in, makes you want this thing and then makes you wonder why you want it and maybe where you can get it.”<sup>148</sup> This strategy for a successful parody parallels the actual DTC advertising strategy used in pharmaceutical promotional practices.<sup>149</sup> Critics of this strategy would reject the arguably comedic nature of these commercials because the fact that viewers were persuaded that they have a fake disease and need a fake drug treatment demonstrates just how easily pharmaceutical companies can succeed in marketing legitimate, albeit controversial, diseases and drugs.<sup>150</sup>

Dr. Carl Elliot explains that disease-branding works very well in two situations: (1) “the shameful condition that can be destigmatized”<sup>151</sup> and (2) “a condition that can be plausibly portrayed as under-diagnosed.”<sup>152</sup> During the process of DTC advertising, dis-

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<sup>147</sup> Justine Cooper, *Havidol*, DANEYAL MAHMOOD GALLERY, <http://daneymahmood.com/ArtistsPages/Justine/PastExhibitions/JustineHavidol.html> (last visited Feb. 4, 2012).

<sup>148</sup> *Fake Drug, Fake Illness—and People Believe It!*, *supra* note 143.

<sup>149</sup> For a description of various drug DTC advertising strategies, see *infra* Part IV.B.1.c.

<sup>150</sup> For a discussion of the “outrageousness” of DTC advertising, see *infra* Part IV.B.1.b. If Havidol were real and provided a safe and effective remedy, then the FDA should approve it because it is inappropriate paternalism for the FDA to prevent this drug from entering the market based on the controversy surrounding the existence of the disease. Doctors and patients, in an informative, interactive process, should determine the utility of the drug for each patient’s individual needs. For discussion of Academic Detailing as a way to strengthen this interactive process, see *supra* Part IV.C.

<sup>151</sup> Elliott, *supra* note 14.

For instance, when Pharmacia launched Detrol in the late 1990s, the condition the drug treated was known to doctors as “urge incontinence.” Patients called it “accidentally peeing in my pants” and were embarrassed to bring it up with their physicians. Pharmacia fixed the problem by rebranding the condition as “overactive bladder.”

*Id.*

<sup>152</sup> *Id.*

Branding such a condition assures potential patients that they are part of a large and credible community of sufferers. For example, in 1999, the FDA approved the antidepressant Paxil for the treatment of “social anxiety disorder,” a condition previously known as “shyness.” In order to convince shy people they had social anxiety disorder, Glax-

eases and drugs become “adjectival.”<sup>153</sup> A psychological connection between disease and drug develops when symptoms (e.g., inability to achieve or maintain an erection or high cholesterol levels) are medicalized into disease-like states (e.g., erectile dysfunction or hyperlipidemia/hypercholesterolemia) because the disease becomes synonymous and psychologically associated with the advertised drug treatment (e.g., Viagra or Lipitor).<sup>154</sup> An inextricable link develops between the disease and the drug in the minds of consumers when a branded disease is attached to a brand name drug; it is the essence of pharmaceutical promotional practices.

Although “consumption of medical and pharmaceutical products is itself shaped by brand images and brand loyalty,”<sup>155</sup> disease-branding is a distinct concept from advertising the brand of the drug (i.e., drug-mongering) because disease-branding creates a brand for the *disease itself*. Used together, however, they create a truly effective pharmaceutical promotional campaign as disease-awareness ads become inextricably linked in consumers’ minds with the brand name drug that treats the disease.<sup>156</sup>

Pharmaceutical marketing aimed at destigmatizing conditions so that people feel comfortable seeking help can promote the public health; thus, the FDA will allow this form of promotion as long as the drug continues to be safe and effective and the drug’s DTC advertis-

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oSmithKline, the maker of Paxil, hired a PR firm . . . [to] put together a public awareness campaign called “Imagine being allergic to people.”

*Id.*

<sup>153</sup> SUSAN SONTAG, *ILLNESS AS METAPHOR AND AIDS AND ITS METAPHORS* 58 (1989).

<sup>154</sup> See generally Tanuja Singh & Donnavieve Smith, *Direct-to-Consumer Prescription Drug Advertising: A Study of Consumer Attitudes and Behavioral Intentions*, 22 J. CONSUMER MKTG. 369 (2005) (analyzing consumers’ perceptions of DTC drug advertisements and requests for brand name drugs); Tim Scott et al., *Killing Me Softly: Myth in Pharmaceutical Advertising*, 329 BRIT. MED. J. 1484 (2004) (examining how drug advertisements use visual and linguistic imagery to create associations between diseases and products).

<sup>155</sup> ROSE, *supra* note 140, at 30.

<sup>156</sup> See U.S. FOOD AND DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: “HELP-SEEKING” AND OTHER DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG AND DEVICE FIRMS 6 (2004), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf> (“Psychology and marketing research suggests that the greater the perceptual similarity between disease awareness communications and reminder or product claim promotions . . . the more likely it is that the separate messages contained in the two pieces will be remembered together in memory as one entity.” (citation omitted)).

ing complies with federal statutes and regulations.<sup>157</sup> Nevertheless, although this practice can be positive, it can simultaneously be extremely harmful as it “turns healthy people into patients, wastes precious resources, and causes iatrogenic harm.”<sup>158</sup>

#### IV. A CASE STUDY OF LEGAL AND LEGISLATIVE REMEDIES FOR PHARMACEUTICAL PROMOTIONAL PRACTICES

##### A. *The FDA’s Role in Defining Disease and Regulating Disease-Branding*

The FDA’s mandate, according to the FD&C Act and its accompanying legislative history, is to approve drugs that are safe and effective for their intended use.<sup>159</sup> The role of the FDA vis-à-vis the pharmaceutical industry is to act as a regulatory gate-keeper by determining which drugs enter the market.<sup>160</sup> The FDA approves a drug for market if it is safe and effective for its intended use; therefore, it is an inappropriate expansion of its grant of authority for the FDA to consider the legitimacy of diseases. The FDA is an active gate-keeper and regulator of the pharmaceutical industry, but not a paternalistic agency or a national scientific arbiter of disease classification. The critique that the pharmaceutical industry is economically exploiting the public by turning Americans into medical consumers need not concern the FDA as this is beyond its legislative mandate. Thus, while disease-branding may be a valid critique of the drug industry, it should not implicate the FDA because the Agency regulates neither diseases nor doctors’ treatment of these diseases. The FDA approves drugs as safe and effective in order to provide doctors with an arsenal of treatment options; doctors ultimately make the treatment decision by determining whether a particular patient suffers from a disease and how to best treat that patient.<sup>161</sup>

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<sup>157</sup> *Id.* at 3. Disease-awareness communication is not subject to risk-disclosure requirements; however, “in other situations where a supposed disease awareness communication is determined to, by implication, identify a particular drug . . . the communication can be considered labeling or advertising and can therefore be subject to regulation by FDA.” *Id.*

<sup>158</sup> Moynihan & Henry, *supra* note 29, at 425.

<sup>159</sup> *See supra* Part II.B.

<sup>160</sup> *See* Carpenter, *supra* note 67, at 404.

<sup>161</sup> *See* 21 U.S.C. § 396 (2006) (“Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”).

The limited scope of the FDA's role in defining disease depends on a multifaceted consideration of its legislative mandate—promoting and protecting the public health—juxtaposed against the social, political, and medical milieu: what drugs pharmaceutical companies are developing and for what conditions, what advisory committees are recommending, and how patient advocacy groups are responding. As mentioned above, the FDA does play some role in defining, or legitimizing, diseases because the perception of the disease may shape the regulatory approval process.<sup>162</sup> A drug's risk-benefit calculus is dependent on the FDA's perception of the disease, the drug's intended use, and the treatment population. For example, the FDA must consider whether a drug cures cancer, baldness, or shyness and whether these cures have risks, including morbidity and mortality, because these factors alter the drug's respective risk-benefit profiles for approval purposes. An effective cure for a deadly cancer with potentially lethal side effects has a high efficacy rating, and although the risk of death gives the drug a low safety rating, the overall risk-benefit profile weighs in favor of approval for a specific patient population because of the drug's positive effect on the cancer's mortality rate. By contrast, an effective baldness or shyness cure that is associated with a high risk of death may have a high efficacy rating, but its overall public health benefit of curing these benign conditions cannot outweigh the high risk of death associated with the treatment. Thus the risk is probably so high that the overall risk-benefit profile weighs in favor of rejection. In addition, FDA regulators (the individuals rather than the institutional entity) are social beings who can be influenced by the medicalization of disease-branding. If they consider the disease more severe than it actually is or are persuaded by disease-awareness ads and other forms of disease promotion that a normal condition ought to be treated, they may be more inclined to give less weight to adverse events associated with a drug intended to treat the industry-invented disease in their risk-benefit calculus.<sup>163</sup>

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<sup>162</sup> See *supra* Part II.B (discussing accelerated product review and orphan-drug status).

<sup>163</sup> For example, Pfizer's NDA for Viagra convinced the FDA that erectile dysfunction is severe enough and the benefits of Viagra are sufficient to outweigh the risks of the drug. See Approval Letter from Robert Temple, Dir., Office of Drug Evaluation, Ctr. for Drug Evaluation & Research, to Sandra J. Croak-Brossman, Pfizer Pharms. Prod. Corp. Ltd. (Mar. 27, 2010), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/1998/208951tr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/208951tr.pdf). But see *supra* notes 22–23 and accompanying text (explaining that Boehringer Ingelheim could not convince the Advisory Panel that HSDD was sufficiently severe and that the benefits of flibanserin were great enough, to outweigh the drug's adverse side effects).

Regardless of the FDA's limited purpose in defining diseases for the approval process, it has no role in regulating disease-branding strategies beyond ensuring that the advertisements are not false or misleading.<sup>164</sup> Advertisements can shape the public's perception of a disease and encourage treatment with a drug, while complying fully with the FD&C Act and its regulations.<sup>165</sup> Because these promotional practices do not violate the regulatory scheme instituted to prevent the adulteration and misbranding of drugs, critics of these practices are left without a viable administrative tool to remedy the problems that stem from these practices.

*B. Legal Remedies: Possible Causes of Action for Disease-Branding and Drug-Mongering*

The determination whether an ailment is a disease is a complex socially constructed process.<sup>166</sup> Although it may have implications for FDA approval, it should be reiterated that the FDA's regulatory function in determining what constitutes a drug is purely statutory interpretation and that the Agency's decision to approve a drug for the market is based on its evaluation of the safety and efficacy of the drug's intended use.<sup>167</sup> Because the disease-branding and drug-mongering advertising strategies appear, as a general matter, to be legal and in compliance with the FD&C Act, it seems that there are no statutory or regulatory bars to this form of pharmaceutical promotion. If labeling and DTC advertising are legal, an argument that drug companies are misbranding in violation of the Act will fail.

Thus, if the FDA does not have jurisdiction in this area because the overall strategy complies with federal drug laws and disease-branding by Big Pharma continues unabated by regulatory restrictions (provided that the advertisements remain compliant), then what is left of the critique of disease-branding and drug-mongering? Because the argument that this practice harms society and public health is still valid from the sociology-of-health perspective, this Comment considers whether there are any legal remedies available for people who suffer injuries as a result of these practices. Relying

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<sup>164</sup> It seems difficult to prove that disease-branding could be considered misleading in violation of 21 C.F.R. § 202.1(e)(3) because there is justified medical science supporting the legitimacy of the disease, regardless of any surrounding controversy.

<sup>165</sup> See *supra* Part II.C (describing how DTC broadcast advertising generally complies with the federal regulatory scheme).

<sup>166</sup> For a discussion of the social construction of disease, see *supra* Part III.B.

<sup>167</sup> See *supra* Part II.B (discussing the role of the FDA as a regulatory agency that approves drugs for market if they are safe and effective for their intended use).

on the sociology-of-health and medicalization frameworks, critics can use expert testimony from sociology, consumer-psychology, and medical scholarship to provide evidence that the promotional practices are tortious. Consequently, it seems that the critics' only option to hold pharmaceutical companies liable for the arguably egregious practices of disease-branding and drug-mongering would be to file a test case in which a plaintiff with standing sues a drug company in tort for intentional infliction of emotional distress (IIED) or negligent infliction of emotional distress (NIED) or sues his or her doctors for medical malpractice, which, in a circuitous way, could affect drug companies' advertising practices.

It is crucial to note at the outset that the fact that these drugs have been approved by the FDA does not exempt drug companies from liability.<sup>168</sup> Because FDA approval does not preempt state-law tort claims for drugs approved through the NDA process, compliance with the FD&C Act is not necessarily a safe-harbor or a complete defense to tort claims.<sup>169</sup> Accordingly, the Supreme Court held in *Wyeth v. Levine* that brand name drug companies are amenable to suit under state tort law.<sup>170</sup> Thus, even if drug companies comply with the rules and regulations for DTC advertising, plaintiffs will not be preempted from suing them for disease-branding and drug-mongering advertising campaigns if these claims fit into state negligence regimes. The following sections analyze potential claims for IIED, NIED, and medical malpractice.

### 1. Intentional Infliction of Emotional Distress (IIED)

Havidol, the brilliant parody of prescription drug advertising,<sup>171</sup> can act as a hypothetical case study for the possibility of an IIED claim.<sup>172</sup> One article commented how the "media exhibit featuring a campaign for a fake drug to treat a fictitious illness is causing a stir

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<sup>168</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187, 1204 (2009).

<sup>169</sup> *Id.* at 1191.

<sup>170</sup> *Id.* at 1202 ("In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation."). *Contra* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (holding that federal drug regulations applicable to generic drugs preempt state tort claims).

<sup>171</sup> See *supra* notes 143–44 and accompanying text.

<sup>172</sup> Although Future Pharms, Inc., the manufacturer of Havidol, is not amenable to a lawsuit because fictitious defendants cannot be served with process, the evidence that consumers legitimately believe that the invented disease and drug are real reveals consumers' propensity to be influenced by pharmaceutical advertising.

because some people think the illness is real.”<sup>173</sup> Another article asked, “What happens if you create a fake disorder and offer a fake drug to treat it? You get thousands of people *fooled* that they might have an *invented disease*.”<sup>174</sup> If an artist can convince ordinary people that they have a purely imaginary disease that could be treated with a fictional drug, then surely an otherwise healthy and reasonable person could be convinced that he or she suffers from an industry-invented disease that can be treated by the pharmaceutical company’s real drug bearing an FDA-stamp-of-approval. Thus, a crucial legal question emerges as to whether this conduct is sufficiently outrageous to support a cause of action.

The tort of IIED may provide a viable cause of action that could be used to challenge these pharmaceutical promotional practices, and which would not be preempted under *Wyeth*.<sup>175</sup> IIED is a relatively recent tort,<sup>176</sup> and, although every state recognizes it as an independent cause of action,<sup>177</sup> the area of law is unsettled.<sup>178</sup> Even if courts have yet to recognize an IIED claim premised on disease-branding and drug-mongering,<sup>179</sup> this does not mean that such a claim would be precluded, and thus should not deter critics from exploring the possibility of filing a complaint.

There is at least one reported case analyzing an IIED claim that is premised on a patient watching television, which can be used as a foundation to develop the test case.<sup>180</sup> In *Brinkman v. Shiley, Inc.*, a patient received a heart-valve replacement, and after watching a television program discussing incidents of the valve malfunctioning, expe-

<sup>173</sup> *Fake Drug, Fake Illness—and People Believe It!*, *supra* note 143.

<sup>174</sup> *Consumers Fall for Havidol Parody*, *supra* note 145 (emphasis added).

<sup>175</sup> If the test-case plaintiff has *not* suffered physical injury, IIED would be the only legal recourse because the other negligence-based torts require physical impact or injury. See *infra* Part IV.B.2 (discussing NIED).

<sup>176</sup> Karen Markin, *The Truth Hurts: Intentional Infliction of Emotional Distress as a Cause of Action Against the Media*, 5 COMM. L. & POL’Y 469, 472 (2000) (citing *State Rubbish Collectors Ass’n v. Siliznoff*, 240 P.2d 282, 337 (Cal. 1952)) (showing that California was the first state to recognize IIED as a cause of action); see also 4 NEIL M. LEVY ET AL., CALIFORNIA TORTS § 44.01 (2011) (describing how the first California court to recognize IIED as an independent cause of action viewed the tort as protecting the right to be free from invasions of “emotional and mental tranquility”).

<sup>177</sup> Markin, *supra* note 176, at 472 n.17 (collecting cases).

<sup>178</sup> RESTATEMENT (SECOND) OF TORTS § 46 cmt. c (1965) (“The law is still in a stage of development, and the ultimate limits of this tort are not yet determined.”).

<sup>179</sup> As of March 2012, no reported cases on LexisNexis contain the phrase “disease branding” or “drug mongering.”

<sup>180</sup> *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33 (M.D. Pa. 1989).



rienced severe emotional distress.<sup>181</sup> Although the court held that plaintiff's emotional distress was related to the show's content and not to the defective device,<sup>182</sup> this situation is clearly distinguishable from the test case. The fear associated with watching a television news show that is not affiliated with a drug company and is intended to inform the viewer is different from the fear resulting from watching a drug-company-created and sponsored advertising campaign (which, arguably, is intended to induce a sense of fear or "health anxiety"<sup>183</sup> in consumers to persuade viewers to purchase their drugs).

a. Elements of an IIED Cause of Action

According to the *Restatement (Second) of Torts*, the prima facie case for "outrageous conduct causing severe emotional distress" (better known as IIED) is satisfied when a plaintiff alleges that a defendant, "by extreme and outrageous conduct[,] intentionally or recklessly causes severe emotional distress to another."<sup>184</sup> Recovery is possible for "mental distress or disturbance . . . even in the absence of physical injury or any other actionable injury."<sup>185</sup>

First, "[t]he element of moral outrage may well be the critical element."<sup>186</sup> The plaintiff must allege that the defendant's conduct was extreme, which is satisfied "only if the defendant's conduct is so outrageous in character, and so extreme in degree, as to go beyond all possible grounds of decency, that it must be regarded as atrocious and utterly intolerable in a civilized community."<sup>187</sup> According to the *Restatement*, "the recitation of the facts to an average member of the community would arouse his resentment against the actor, and lead him to exclaim, 'Outrageous!'"<sup>188</sup> Here, the role of "applied psychology" is imperative because marketing-psychology experts can interpret advertising campaigns and give expert testimony about the causal link between disease-branding and drug-mongering tactics and the

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<sup>181</sup> *Id.*

<sup>182</sup> *Id.* at 35.

<sup>183</sup> See *infra* Part IV.B.1.b (discussing hypochondria and health anxiety).

<sup>184</sup> RESTATEMENT (SECOND) OF TORTS § 46(1) (1965) (emphasis added).

<sup>185</sup> 13 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, PERSONAL INJURY—ACTIONS, DEFENSES, DAMAGES § 55A.02 (2011).

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*; see also John J. Kircher, *The Four Faces of Tort Law: Liability for Emotional Harm*, 90 MARQ. L. REV. 789, 799 (2007) (citing RESTATEMENT (SECOND) OF TORTS § 46 cmt. d (1965)).

<sup>188</sup> RESTATEMENT (SECOND) OF TORTS § 46 cmt. d (1965).

resulting emotional distress.<sup>189</sup> The distress could be characterized as the psychological manipulation of an otherwise healthy person into believing that he or she has a disease that is treatable with drugs, coupled with the iatrogenic harm resulting from this pharmaceutical treatment that the patient would not have experienced had the patient not been convinced that he or she needed the drug. Moreover, although consumers would not be shocked to learn that the drug companies advertise to make a profit, they could be shocked to learn that the drug companies are inventing diseases and convincing healthy people that they are sick; this could very well cross the threshold from persuasive advertising tactics to outrageous marketing behavior. Accordingly, the quest for profit fails to address or identify the issue; attention in evaluating the extreme or outrageous conduct, which is the necessary element of the cause of action, should be focused on the means, not the ends.

Second, in order for conduct to be considered intentional or reckless, the plaintiff must show that the defendant “intended his specific conduct and knew or should have known that emotional distress would likely result.”<sup>190</sup> It is important to note that

[a]ctual intent to cause emotional distress is *not* necessary, because the willful wrongdoer is charged with the duty of foreseeing the mental and emotional consequences that would naturally flow from his or her conduct. If the actor did not undertake the offensive conduct for the purpose of causing the harm received, proof of the intent of the actor to cause that harm may nevertheless be implied by evidence of circumstances showing that the conduct was of a nature that reasonably should have been recognized as likely to cause the harm sustained.<sup>191</sup>

Finally, the emotional distress “must be reasonably foreseeable and justified under the circumstances, attributing to the plaintiff the sensibility of a reasonable person,”<sup>192</sup> unless the defendant knew or

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<sup>189</sup> For example, in *United States v. 38 Dozen Bottles, More or Less, Labeled in Part Tryptacin*, 114 F. Supp. 461 (D. Minn. 1953), the federal district court judge qualified two experts in the field of advertising and marketing psychology to testify whether drugs were misbranded in violation of the FD&C Act. The judge explained that the witnesses “presented exhaustive analyses of the content of the advertisement and the effect which it was intended to have upon the prospective purchaser of the drug.” *Id.* at 462; accord *Applied Psychology in Action: Legal Status of Advertising and Marketing Psychology Experts*, 38 J. APPLIED PSYCHOLOGY 276, 276 (1954) (discussing the same case).

<sup>190</sup> *Womack v. Eldridge*, 210 S.E.2d 145, 148 (Va. 1974). This was the first time when the Virginia Supreme Court recognized the cause of action for IIED.

<sup>191</sup> 13 FRUMER & FRIEDMAN, *supra* note 185, § 55A.02 (emphasis added).

<sup>192</sup> *Id.*

took advantage of plaintiff's "peculiar susceptibility to emotional distress."<sup>193</sup>

Because several cases rely on this standard to evaluate IIED claims, analyzing them is important to understand how they would apply in the test case. In a federal case in Pennsylvania, *Michtavi v. United States*, the plaintiff was a prisoner who alleged that his fellow inmates attempted to scam him and, as a result, he suffered from depression, which required treatment with the prescription medication Prozac.<sup>194</sup> Plaintiff's IIED claim, based on the *Restatement (Second) of Torts'* definition,<sup>195</sup> failed because the court concluded that the plaintiff did not allege any conduct that was sufficiently extreme or outrageous.<sup>196</sup> *Michtavi* is a clear example of the high burden that plaintiffs must meet in order to successfully bring an action for IIED.

In *Estate of Duckett v. Cable News Network, LLLP*, a federal court applying Florida law recognized that conduct involving the use of television broadcasts could rise to the level of extreme and outrageous conduct.<sup>197</sup> The court noted, however, that a successful claim for IIED under Florida law is extremely rare, as only ten reported cases were found in which a judgment was entered for a successful plaintiff and affirmed on appeal.<sup>198</sup> In other words, "a cause of action for intentional infliction of emotional distress is one thing, avoiding summary judgment or prevailing at trial is quite another."<sup>199</sup> In this case, defendants CNN and Nancy Grace, the star and moderator of the

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

<sup>194</sup> No. 4:07-CV-0628, 2009 U.S. Dist. LEXIS 18926, at \*6-8 (M.D. Pa. Mar. 4, 2009), *aff'd*, 345 F. App'x. 727 (3d Cir. 2009).

<sup>195</sup> *Id.* at \*20 n.7 ("The Pennsylvania Supreme Court has not expressly recognized a cause of action for intentional infliction of emotional distress, but has consistently held that, if this cause of action were recognized, the Restatement would set forth the minimum elements necessary to state such a claim.")

<sup>196</sup> *Id.* at \*22. *But see* *Chuy v. Phila. Eagles Football Club*, 595 F.2d 1265 (3d Cir. 1979) (applying Pennsylvania law and holding that the knowing release of false information that a player was suffering from a fatal disease by a professional football team's doctor could constitute outrageous conduct for the purposes of IIED); *Johnson v. Caparelli*, 625 A.2d 668 (Pa. Super. Ct. 1993) (holding that a priest's sexual molestation of an altar boy constituted the same, although the claim was ultimately rejected on other grounds); *Field v. Phila. Elec. Co.*, 565 A.2d 1170 (Pa. Super. Ct. 1989) (holding that an energy company deliberately venting radioactive steam on an employee and concealing the extent of exposure constituted the same).

<sup>197</sup> No. 5:06-cv-44, 2008 U.S. Dist. LEXIS 88667, at \*21-23 (M.D. Fla. July 31, 2008); *see also* *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33, 33 (M.D. Pa. 1989) (discussing an IIED claim premised on media broadcasts).

<sup>198</sup> *Estate of Duckett*, 2008 U.S. Dist. LEXIS 88667, at \*14.

<sup>199</sup> *Id.*

*Nancy Grace* show, recorded a telephone interview with Duckett after her child went missing.<sup>200</sup> The interview was scheduled to be televised the following day, but hours before the show was to air, Duckett committed suicide. After the defendant aired the interview, Duckett's parents began suffering from severe and debilitating emotional distress.<sup>201</sup> The plaintiffs successfully alleged at the pleading stage that the decision to air the show following their daughter's suicide was sufficiently extreme and outrageous conduct to state a cause of action for IIED.<sup>202</sup>

In *Lamothe v. Russell*, a Connecticut state court denied defendant's motion to strike the complaint for IIED in an employment context when the allegation included disparaging remarks about health problems.<sup>203</sup> The court held that, under Connecticut law, sufficiently extreme and outrageous conduct had occurred when an employer constantly belittled the plaintiff by telling her that she had health problems because she was overweight.<sup>204</sup> Analogously, pharmaceutical companies' advertising campaigns attempt, in a way, to belittle healthy consumers by persuading them that they are sick. Although the *Lamothe* court distinguished ordinary comments from those made by people in positions of control, this should not be an obstacle for the test case plaintiffs because pharmaceutical companies are in a position of power as experts in the field of drug promotion and marketing.

In *Elson v. Consolidated Edison, Co.*, an employer subjected the employee-plaintiff to eight hours of interrogation, knowing of the employee's underlying psychological condition for which he was receiving treatment.<sup>205</sup> As a result, he suffered mental anguish, and the court concluded that these facts stated a cause of action for IIED because the conduct complained of could be found to be extreme and outrageous.<sup>206</sup> Although pharmaceutical and advertising companies are, or should be, aware of the existence of hypochondria in the general population, it would be impossible to plead with particularity that a company knew that the *specific* plaintiff suffered from hypo-

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<sup>200</sup> *Id.* at \*2-3.

<sup>201</sup> *Id.* at \*21.

<sup>202</sup> *Id.* at \*22-23.

<sup>203</sup> No. CV074022729S, 2009 Conn. Super. LEXIS 775, at \*15 (Conn. Super. Ct. Mar. 25, 2009).

<sup>204</sup> *Id.* at \*4.

<sup>205</sup> 641 N.Y.S.2d 294, 294 (N.Y. App. Div. 1996).

<sup>206</sup> *Id.* at 294-95.

chondria<sup>207</sup> and was thus extraordinarily susceptible to suffering extreme emotional distress from disease-branding and drug-mongering. Therefore, unlike the *Elson* defendant, pharmaceutical companies may be able to escape liability because the plaintiff would probably be unable to prove that the company was aware of the plaintiff's particular sensitivities and predilection to mental distress.<sup>208</sup>

Because it is clear that the companies intend to produce a disease-branding and drug-mongering campaign,<sup>209</sup> the plaintiff can plead the "specific conduct" necessary for the intentional or recklessness element.<sup>210</sup> Although the companies know that some consumers would be convinced to seek the advertised drug, the plaintiff would have to show that the recognition that one might have a newfound disease is tantamount to experiencing emotional distress. Even though emotional distress can be a consequence of the self-diagnosis that accompanies disease-branding, the plaintiff would need to allege that this was the logical consequence of seeing the campaign. In other words, the plaintiff must allege that a drug company intended or should have known that emotional distress would likely follow from viewing the advertisement, rather than merely showing that learning of a new disease would result in the consumer experiencing emotional distress.

In California, outrageous conduct that is sustained or persistent and which affects the plaintiff over an extended period of time is more likely to be considered outrageous than conduct which is short-lived.<sup>211</sup> In addition, other cases recognize that individual acts may be insufficient, but the cumulative effect of these acts, when viewed as a pattern or course of conduct, could rise to the level of outrageous conduct.<sup>212</sup> Thus, if one looks at disease-branding and drug-mongering as a cumulative advertising campaign, rather than count-

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<sup>207</sup> See *infra* note 226 and accompany text (discussing hypochondria).

<sup>208</sup> In a class action, however, it might be possible to argue that pharmaceutical companies and their advertising companies had constructive knowledge of general rates of hypochondria such that the court could infer that the defendant took advantage of the plaintiffs' peculiar susceptibility.

<sup>209</sup> See, e.g., Landman, *supra* note 7; Vince Parry, *Disease Branding: What Is It, Why it Works, and How to Do It—A Win-Win Marketing Strategy that Illuminates, Educates, and Promotes at the Same Time*, PHARM. EXEC. (Oct. 1, 2007), <http://pharmexec.findpharma.com/pharmexec/Supplements/BrandingDisease/ArticleStandard/Article/detail/465561>.

<sup>210</sup> *Womack v. Eldridge*, 210 S.E.2d 145, 148 (Va. 1974).

<sup>211</sup> LEVY ET AL., *supra* note 176, § 44.01 & n.55.

<sup>212</sup> *Id.* § 44.01 & n.56.

ing each time a consumer views a commercial as a discrete event, it is likely to satisfy California's duration and cumulative-effect standard for determining whether alleged conduct is outrageous.

In another Pennsylvania case, *Rideout v. Hershey Medical Center*, the plaintiffs' child was diagnosed with a brain tumor, which they wanted to treat aggressively.<sup>213</sup> Due to the child's deteriorating condition and likely imminent demise, however, the hospital's Ethics Committee decided that further treatment would be futile and disconnected the child's ventilator without the parents' presence.<sup>214</sup> The parents suffered severe emotional anguish as a result of hearing over the loudspeaker that the ventilator had been disconnected and subsequently witnessing their daughter's death.<sup>215</sup> The hospital argued that the IIED claim failed because the plaintiffs were not present when the ventilator was disconnected; however, the court concluded that "aural and contemporaneous perception of the removal of the ventilator is sufficient to allege presence."<sup>216</sup> Furthermore, the hospital asserted that its decision to disconnect the ventilator "was a thoroughly reasoned exercise of professional judgment and that accordingly, as a matter of law, it did not act outrageously."<sup>217</sup> The court held that although the hospital's decision to remove life support may have been *reasonable*, the conduct could still be considered extreme and outrageous to support a claim for IIED.<sup>218</sup>

Analogously, in the test case, a plaintiff who views the advertisement on television is "present" in the location where the intentional conduct occurs precisely because he or she perceives aurally and visually the substance of the commercial. In addition, just like in *Estate of Duckett*, the plaintiff can witness the advertisements through broadcast media because there does not seem to be a limiting principle stating that the conduct must be witnessed live. Moreover, presence is crucial for advertising success; the defendant pharmaceutical company is not only aware of but intends the plaintiff's presence in front of the television so that the plaintiff views the commercial. In addition, despite the ostensible reasonableness of the drug advertising campaign for the legitimate corporate goals of promoting sales and increasing profits, a court using the *Rideout* standard could still con-

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<sup>213</sup> 30 Pa. D. & C. 4th 57, 59-60 (C.P. Dauphin 1995).

<sup>214</sup> *Id.* at 61-63.

<sup>215</sup> *Id.* at 63.

<sup>216</sup> *Id.* at 69.

<sup>217</sup> *Id.*

<sup>218</sup> *Id.*

clude that disease-branding and drug-mongering conduct is extreme and outrageous.

b. Disease-Branding and Drug-Mongering as “Outrageous Conduct”

In order to establish the first element, the plaintiff must allege that disease-branding and drug-mongering constitute outrageous conduct. The question is whether the medicalization of arguably ordinary behavior into symptoms characterizing a disease (i.e., disease-branding) and the psychological manipulation of healthy people to think that they are sick and require pharmaceutical treatment (i.e., drug-mongering) are evidence of outrageous conduct. This section argues that drug-mongering, through DTC advertising campaigns, is probative of the outrageous conduct required to satisfy a prima facie case for IIED, despite the fact the advertisements otherwise comply with the FD&C Act and accompanying regulations.

Although there is some research on the relationship between DTC advertising and consumer perceptions of drugs,<sup>219</sup> consumer demand,<sup>220</sup> and physician prescribing patterns,<sup>221</sup> there is no research on the psychological effects of emotional distress associated with disease-branding and drug-mongering. Nevertheless, this does not mean that the theory is wrong or that the alleged conduct is not outrageous; it just requires plaintiffs to overcome the pleading burden by alleging sufficient facts that state a claim for relief that is plausible on its face.<sup>222</sup>

In addition, at least one scholar has evaluated successful IIED claims in the media context.<sup>223</sup> According to Professor Markin’s article, the majority of successful claims resulted from outrageous “news-

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<sup>219</sup> See Deborah F. Spake & Mathew Joseph, *Consumer Opinion and Effectiveness of Direct-to-Consumer Advertising*, 24 J. CONSUMER MKTG. 283, 283 (2007) (“Limited research has been done on the relationship between consumer perceptions of DTC advertising and its impact on consumer requests for pharmaceutical products.”).

<sup>220</sup> See, e.g., Matthew F. Hollon, *Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand*, 281 JAMA 382 (1999) (discussing the effect of DTC advertising on consumer demand for prescription drugs).

<sup>221</sup> See, e.g., W.M. Zachry et al., *Relationship Between Direct-to-Consumer Advertising and Physician Diagnosing and Prescribing*, 59 AM. J. HEALTH-SYS. PHARMACY 42 (2002) (discussing the relationship between DTC advertising and physician diagnoses and prescriptions associated with the advertised products).

<sup>222</sup> See *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (explaining the “plausibility” standard under Federal Rule of Civil Procedure 8(a)(2)).

<sup>223</sup> See Markin, *supra* note 176.

gathering behavior.”<sup>224</sup> Relevant to the test case, however, are “content” claims where the content of the media message is the outrageous conduct.<sup>225</sup> Although Professor Markin’s article does not discuss any case of pharmaceutical advertising, this does not preclude a court from concluding that a disease-branding and drug-mongering allegation entails sufficiently extreme and outrageous conduct for an IIED claim.

Consider a plaintiff with hypochondria who is subjected to a disease-branding and drug-mongering advertising campaign.<sup>226</sup> Hypochondriacs believe that ordinary physical symptoms are signs of more serious diseases.<sup>227</sup> It is a psychosomatic disorder, which means that the etiology of the disorder is psychological, but it manifests in physical symptoms.<sup>228</sup> This “health anxiety,” which affects up to twenty percent of the population, is a mental illness in which worrying about

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<sup>224</sup> *Id.* at 479 (discussing *Barrett v. Outlet Broad., Inc.*, 22 F. Supp. 2d 726 (S.D. Ohio 1997) (holding that a reasonable jury could conclude that defendant-journalist’s invasion of the plaintiff’s home and the broadcasting of images of her mother’s dead body was extreme and outrageous conduct)); *see also id.* at 481 (discussing *KOVR-TV v. Superior Court*, 37 Cal. Rptr. 2d 431, 435 (Cal. Ct. App. 1995) (“[A] jury could find that a television reporter who attempts deliberately to manipulate the emotions of young children [by recording an interview with the children about their neighbors’ murder-suicide] . . . has engaged in conduct ‘so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency . . . .’”)).

<sup>225</sup> *Id.* at 484 (discussing *Murray v. Schollosser*, 574 A.2d 1339, 1340 (Conn. Super. Ct. 1990) (denying defendant’s motion to strike plaintiff’s complaint of IIED when radio host “stated, in reference to the photograph of the named plaintiff, that she was ‘too ugly to even rate,’ in light of her physical attractiveness and sexual desirability, and that she had won the ‘dog of the week’ prize consisting of a case of Ken-L-Ration and a dog collar”); *see also id.* at 485 (discussing *Armstrong v. H&C Commc’ns, Inc.*, 575 So. 2d 280, 282 (Fla. Dist. Ct. App. 1991) (holding that an evening news broadcast airing gruesome close-up footage of a murdered child’s skull constitutes outrageous conduct)).

<sup>226</sup> Although a hypochondriac may not represent a “reasonable” person, if the defendant-drug company knew of plaintiff’s particular susceptibility to hypochondria, the company could still be liable. *See supra* text accompanying note 193. Although it might be a dispositive defense to prove that the defendant lacked knowledge of a particular plaintiff’s hypochondria, the availability of the defense does not alter the viability of the prima facie case at the pleading stage. Thus, although the case may be resolved in defendant’s favor at the summary judgment stage, the complaint could initially survive a motion to dismiss for failure to state a claim. *See supra* text accompanying note 199.

<sup>227</sup> *Hypochondria*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/001236.htm> (last updated Jan. 26, 2012); *see also* DSM-IV-TR, 2000, *supra* note 3, at 504–07.

<sup>228</sup> *Hypochondria—Definition*, MAYO CLINIC, <http://www.mayoclinic.com/health/hypochondria/DS00841> (last updated Nov. 23, 2010).



potentially getting sick, or confusing minor symptoms for an undiagnosed condition, can result in actual physical sickness.<sup>229</sup> The primary symptom of hypochondria is “intense fear or anxiety about having a serious disease or health condition,”<sup>230</sup> and this fear can result from “[t]hinking [that one] ha[s] a disease after reading or hearing about it.”<sup>231</sup> Although such people may realize that they are exaggerating their symptoms, it is difficult for them to cope, so they seek doctors and treatment. Accordingly, pharmaceutical companies take advantage of consumers’ propensity for hypochondria by vigorously engaging in disease-branding and drug-mongering and by preying on their health anxieties.

The symptoms of hypochondria are exacerbated by the media,<sup>232</sup> so an analogy can be drawn to pharmaceutical company’s “disease-awareness” ads, which implant the idea that potentially minor symptoms represent a major health concern. Disease-awareness or help-seeking ads are a form of disease-branding that “involves using public awareness campaigns in the media to encourage people to seek new treatments.”<sup>233</sup> Accordingly, there is a thin line between promoting knowledge of diseases and the drug-mongering that is associated with branding diseases.<sup>234</sup> As such, disease-branding “is the most insidious of the various forms that medical advertising . . . can take.”<sup>235</sup>

Moreover, the symptoms that ordinarily accompany experiencing stress (e.g., fast heart beat, headache, and gastrointestinal problems)<sup>236</sup> are readily confused with symptoms of very serious diseases

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<sup>229</sup> See, e.g., *Today Show: Tips to Overcome Your Medical Fears*, BING VIDEOS (Oct. 10, 2010), <http://www.bing.com/videos/watch/video/tips-to-overcome-your-medical-fears/6lrdd5r> [hereinafter *Today Show*].

<sup>230</sup> *Hypochondria—Symptoms*, MAYO CLINIC (Nov. 23, 2010), <http://www.mayoclinic.com/health/hypochondria/DS00841/DSECTION=symptoms> [hereinafter *Hypochondria—Symptoms*].

<sup>231</sup> *Id.*

<sup>232</sup> See *id.* (“It’s become easier to search out health information on the Internet in recent years. Having easy access to information about every possible thing that could be wrong can fuel your anxiety.”); see also *Today Show*, *supra* note 229 (“[Hypochondria is] certainly prevalent and of course it gets worse depending on the news. . . , [for example,] the skin cancer warnings in the summer and the breast cancer warnings all the time.”)

<sup>233</sup> Shankar & Subish, *supra* note 105, at 275–76.

<sup>234</sup> *Id.* at 277.

<sup>235</sup> Wolinsky, *supra* note 6, at 612.

<sup>236</sup> *Stress and Anxiety*, TIMES HEALTH GUIDE, <http://health.nytimes.com/health/guides/symptoms/stress-and-anxiety/overview.html#Considerations> (last updated June 16, 2011).

such as heart disease, brain tumor, and stomach cancer.<sup>237</sup> Accordingly, the advertising campaigns that rely on fear mongering to brand diseases—commercially that are extremely stress-inducing—can worsen a consumer's ordinary stress levels into a full-blown episode of hypochondria. The purpose of inducing episodes of hypochondria is to motivate the consumer-patient to self-diagnose and seek the prescription drug to treat the advertised disease. Thus, a crucial component of disease-branding seems to be the utilization of stress to exacerbate hypochondria. Because DTC advertising exacerbates hypochondria, plaintiffs could plausibly allege that drug companies capitalize on their particular susceptibility through these promotional strategies.

The outrageous act does not only encompass the exploitation of hypochondriacs; in some cases, the advertisements can be so extreme that an objectively reasonable person (that is, somebody without hypochondria) could be convinced that he or she suffers from the advertised disease. For example, a reasonable man who experiences rare or occasional sexual problems could be persuaded that he suffers from the disease of erectile dysfunction (ED) and requires pharmacotherapy. Indeed, Pfizer's DTC advertising campaign for the ED drug Viagra was an attempt to "ensure that the drug was seen as legitimate therapy for *almost any man*."<sup>238</sup> Because Viagra was never marketed as a niche drug but rather as a treatment for any man with subjective perceptions of sexual insecurities, "[t]he perceived prevalence of ED needed to be expanded"<sup>239</sup> in order to broaden the market.<sup>240</sup> In this regard, the Viagra website explains that "ED is more common than you think. More than half of men over 40 have *some degree* of ED."<sup>241</sup>

This ambiguous statistic focuses on different degrees of ED—some of which could be considered within the normal range—and expands the definition by medicalizing slight deviations of normal

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<sup>237</sup> See *Today Show*, *supra* note 229 ("It's not that [those with health anxiety] don't have physical symptoms, it's that they misinterpret things. Like if their heart skips a beat it must be heart disease or a routine headache equals brain tumor.").

<sup>238</sup> Joel Lexchin, *Bigger and Better: How Pfizer Redefined Erectile Dysfunction*, 3 PLOS MED. 429, 429 (2006), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0030132> (emphasis added).

<sup>239</sup> *Id.*

<sup>240</sup> See, e.g., Elizabeth Lambdin, Note, *A New Disease Born Every Minute: The Marketing of Pathology and the Exploitation of Gender-Based Insecurities and Sexuality to Sell Drugs*, 13 CARDOZO J.L. & GENDER 145, 153 (2006).

<sup>241</sup> *Common Questions—How Can I Tell if It's Erectile Dysfunction (ED)?*, VIAGRA (Aug. 20, 2010), [http://www.viagra.com/questions.aspx#/SD\\_FCP.1.1/2/](http://www.viagra.com/questions.aspx#/SD_FCP.1.1/2/) (emphasis added).

functioning into a “disease.”<sup>242</sup> Pfizer’s disease-branding and drug-mongering campaign medicalized “rare or transitory failures to achieve or maintain erections”<sup>243</sup> into degrees of ED that could be treated with a prescription for Viagra. Thus, a reasonable man with a relatively normal sex life could be convinced, through this DTC broadcasting campaign, that he has a medical condition requiring pharmaceutical treatment simply because, for example, his penis was “hard enough for penetration but not completely hard.”<sup>244</sup> The pervasiveness of Viagra’s promotional campaign coupled with the subjectivity of ED symptoms and diagnosis<sup>245</sup> increase the efficacy of—and intensify the problems associated with—disease-branding and drug-mongering, even for reasonable, non-hypochondriacs.

### c. DTC Advertisements: Examples and Analysis

DTC broadcast advertisements follow a distinct, almost boilerplate form, in which a list of vague and common symptoms are described and linked to a disease (the disease-branding part of the advertisement), followed by a discussion of a prescription drug that will treat this disease and a recommendation to talk to one’s doctor to obtain this drug (the drug-mongering part of the ad). There is a plethora of DTC commercials that utilize this form.

Consider, for example, the Requip commercial for Restless Leg Syndrome (RLS), which exemplifies this formulaic advertising strategy.<sup>246</sup> It opens with a downward angle shot of a woman; with eerie music sounding in the background, she looks up into the camera and says: “[I]t was so frustrating, like a mystery I couldn’t solve.”<sup>247</sup> After listing symptoms of “strange sensations” and linking these symptoms

<sup>242</sup> Even the Viagra website recognizes that transient episodes of abnormal functioning constitute ED. *Erectile Dysfunction Symptoms*, VIAGRA (Aug. 20, 2010), <http://www.viagra.com/about-erectile-dysfunction/erectile-dysfunction-symptoms.aspx> (“[E]rectile dysfunction symptoms can happen just once in a while.”).

<sup>243</sup> Lexchin, *supra* note 238, at 430.

<sup>244</sup> *The Erection Hardness Score*, VIAGRA (Aug. 20, 2010), <http://www.viagra.com/about-erectile-dysfunction/erectile-dysfunction-symptoms/erection-hardness-score.aspx> (“If you’re concerned about your hardness score, ask your doctor if VIAGRA can help.”).

<sup>245</sup> *The “ED Test” is Usually Just a Talk*, VIAGRA (Aug. 20, 2010), <http://www.viagra.com/about-erectile-dysfunction/ed-test.aspx> (stating that the “ED Test” is usually just a conversation with your physician about your symptoms).

<sup>246</sup> *Requip*, YOUTUBE (Jan. 5, 2007), <http://www.youtube.com/watch?v=PL3G1MngqK4>.

<sup>247</sup> *Id.*

to the disease name, the commercial transitions aurally—the eerie music changes into an ethereal, delicate, and comforting sound as a doctor discusses a treatment option in the form of a prescription pharmaceutical.

The Zelnorm commercial<sup>248</sup> for Irritable Bowel Syndrome (IBS) is also illustrative of the fear-inducement that stems from drug advertising. The voiceover begins by asking, “[A]re you one of the *millions* who feel twisted and bloated?”<sup>249</sup> Immediately, the commercial destigmatizes and legitimizes the soon-to-be-mentioned disease and then begins to latch onto consumer health anxiety by exposing the mystery of the disease: “[I]s your body telling you something is wrong, but you’re not sure why?”<sup>250</sup> The commercial then lists symptoms, “abdominal pain or discomfort, bloating and constipation,” and suggests that you “see your doctor” because “[y]ou may have a medical condition called IBS with constipation.”<sup>251</sup> Many people occasionally suffer from IBS symptoms.<sup>252</sup> Thus, not only does this commercial brand the disease through a litany of common symptoms, but most importantly, it references a prescription drug that treats the disease in order to legitimize both the disease and the drug treatment by the full weight of an FDA approval.

Similarly, the Toviaz commercial for overactive bladder (OAB) begins with a voiceover: “Erin wants to get up and go without always *worrying* about where to go.”<sup>253</sup> The emphasis on “worrying” appears to link the disease symptoms to the stress and anxiety associated with hypochondria. One could argue that this is an attempt to exploit potential consumers’ psychological predisposition to hypochondria in order to convince them that they have a disease and then inform them of the drug that will treat it. Pharmaceutical companies can al-

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<sup>248</sup> *Zelnorm TV Ad (2003)*, *supra* note 88. Although Zelnorm was withdrawn from the market and Amitiza is currently the only FDA-approved drug to treat IBS, Andrew Pollack, *Drug for Irritable Bowel Achieves Goals in Trial*, N.Y. TIMES, Sept. 14, 2010, at B6, the Zelnorm commercial still represents a typical example of the disease-branding of IBS. Cf. *Amitiza Multiple Plus Onstar*, YOUTUBE (Apr. 12, 2009), <http://www.youtube.com/watch?v=LsPPwxXVs8w>.

<sup>249</sup> *Zelnorm TV Ad (2003)*, *supra* note 88.

<sup>250</sup> *Id.*

<sup>251</sup> *Id.*

<sup>252</sup> P.D. Higgins & J.F. Johanson, *Epidemiology of Constipation in North America: A Systematic Review*, 99 AM. J. GASTROENTEROLOGY 750 (2004) (“Constipation is very common, as approximately 63 million people in North America meet the Rome II criteria for constipation.”); *see also infra* note 306 and accompanying text (explaining how FMS and IBS may be related).

<sup>253</sup> *CR AdWatch: Toviaz*, *supra* note 90.

so take advantage of ordinary people's health anxiety because reasonable consumers (who are not hypochondriacs) who watch these commercials and identify with the actors' experience of vague, common, and ordinary symptoms may logically conclude that they also have the advertised disease. The commercial continues, "[I]f you have overactive bladder *symptoms*, today is the day to talk to your doctor and ask about prescription Toviaz."<sup>254</sup> By strengthening the disease-drug connection, this marketing campaign generated a new market niche of patient-consumers.<sup>255</sup> Upon visiting the website, one learns that the primary symptom of OAB, "urgency," is a medical condition, rather than a normal bodily function. To reinforce this notion, the website purposely emphasizes that "[o]veractive bladder (OAB) is a *real medical condition* [that is] more common than you may think,"<sup>256</sup> in order to convince the skeptical consumer that the urgent need to urinate is a treatable medical condition.

In addition, the website explains that

[o]ver 33 million men and women in the United States have OAB. That's 1 in 6 adults. So if you think you may have OAB, you're not alone. OAB is not necessarily a normal part of aging. Prevalence increases as you get older. But the truth is that OAB can affect anyone at any age.<sup>257</sup>

Herein lies the psychological manipulation underlying disease-branding and drug-mongering: the commercial provides a vague explanation of the symptoms (because everybody sometimes has strong urges to urinate), and immediately links it to a disease (thus legitimizing and medicalizing the symptoms). Then its accompanying website reinforces the vague symptoms and suggests that the disease is underdiagnosed and can affect anyone at any age. Thus, if you merely think you have OAB, then it is entirely likely that you do because one in six adults have it, and if you think you experience these symptoms,

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<sup>254</sup> *Id.*

<sup>255</sup> See Anne Landman, *Branding Diseases to Sell Cures*, PR WATCH BLOG (Oct. 12, 2010, 12:44 PM), <http://www.prwatch.org/node/9529> ("By making people think they have a new condition called 'overactive bladder,' the company created a market of 21 million potential patients."); John Mack, *Overactive Bladder: "Pharmacia Instrumental in Creating New Disease" Says Former VP*, PHARMA MKTG. BLOG (Apr. 5, 2009, 8:49 AM), <http://pharmamktg.blogspot.com/2009/04/overactive-bladder-pharmacia.html>.

<sup>256</sup> *What Is Overactive Bladder (OAB)?*, TOVIAZ, <http://www.toviaz.com/overactive-bladder.aspx> (last updated Nov. 10, 2011).

<sup>257</sup> *How Common Is OAB?*, TOVIAZ, <http://www.toviaz.com/how-common-is-overactive-bladder.aspx> (last updated Nov. 10, 2011).

you should immediately consult your physician for pharmaceutical treatment.

The Latisse commercials provide another example of disease-branding and drug-mongering. The advertisement begins like a typical cosmetic commercial for a new mascara product; however, the ad quickly medicalizes “inadequate or not enough lashes” into “hypotrichosis” using a combination of loud, upbeat music and stunning close-ups of eyeshadowed eyes with full lashes.<sup>258</sup> Then, Brooke Shields enters the screen asking how it is possible to grow lashes; she proclaims, “I’m using Latisse, the first and only FDA-approved prescription treatment.”<sup>259</sup> The advertisement ends with Shields saying, “Ask your doctor if Latisse is right for you,”<sup>260</sup> but then *suggests* to “find a doctor at Latisse.com today.”<sup>261</sup> One might question why one’s regular primary-care physician would not diagnose eyelash hypotrichosis or prescribe Latisse. It seems clear that this statement is an example of drug-mongering: instead of discussing the condition or drug with one’s primary care physician, the advertisement suggests that the drug’s website will allow one to easily find a doctor, presumably affiliated with the drug sponsor, who is more likely to prescribe the drug.<sup>262</sup>

Searching the website for the “Find a Doctor” link reveals the following statement: “While any doctor can prescribe LATISSE®, some may be more familiar with it than others. When making an appointment, be sure to say that you want to find out more about LATISSE®.”<sup>263</sup> Clearly, the advertising campaign (including the commercial and the website) is branding the disease, promoting not just awareness of the condition but the existence and availability of doctors who will essentially push the drug. The question is whether it is outrageous conduct to convince the viewer that the viewer has inadequate eyelashes (especially in relation to the eyelash models’ exquisitely long and lush lashes) and is in need of pharmaceutical treatment. In another version, the commercial ends with Claire Danes proclaiming that Latisse is “from Allergan, a company with six-

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<sup>258</sup> *Latisse Brooke Shields Commercial*, *supra* note 92.

<sup>259</sup> *Id.*

<sup>260</sup> *Id.*

<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Find a Doctor*, LATISSE, <http://www.latisse.com/FindaDoctor.aspx?state=18> (last visited Feb. 4, 2012).

ty years of eye-care expertise.”<sup>264</sup> This clearly intends to add legitimacy to the product because the company’s history of eye-care experience should quell any doubts a consumer might have about the company’s ability to manufacture this product.

Critics’ analysis of these commercials is fundamentally flawed. The Consumer Report AdWatch analyzes the fine-print of the commercial and explains that Latisse is “[f]or inadequate or not enough lashes, also known as hypotrichosis.”<sup>265</sup> The report states, “[I]n order to get FDA approval, a drug must be used to diagnose, prevent, treat, or cure a disease.”<sup>266</sup> As discussed above, one of the definitions of “drug” in the FD&C Act is an article “intended to affect the structure or any function of the body of man.”<sup>267</sup> Thus, whether hypotrichosis is a disease is irrelevant;<sup>268</sup> as long as Latisse is intended to affect the structure of the eyelash, it is a drug and can be FDA-approved if it is safe and effective for this intended use. Nevertheless, this disease-branding strategy utilizes the hypotrichosis terminology in order to medicalize what could be considered a normal condition. Due to the fact that the diagnosis is subjective (the meaning of “not enough eyelashes” is unclear), patients are more comfortable discussing their feelings of inadequacy with their doctors because it seems more real when it is a medical condition with an FDA-approved prescription treatment.

Finally, a fibromyalgia public service announcement, ostensibly sponsored by the National Fibromyalgia Association (but co-sponsored by Pfizer, the maker of a fibromyalgia drug), demonstrates the full extent of a disease-branding and drug-mongering campaign. Although it appears to be a help-seeking ad,<sup>269</sup> the public service announcement directs the consumer to a website sponsored by Pfizer,

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<sup>264</sup> *Latisse*—“*When Your Lashes Grow, Your Lashes Show*” (feat. Claire Danes), YOUTUBE (July 7, 2010), [http://www.youtube.com/watch?v=ZZ1\\_CQD1jS8](http://www.youtube.com/watch?v=ZZ1_CQD1jS8).

<sup>265</sup> *CR AdWatch: Latisse*, CONSUMER REPS., <http://bcove.me/3cn3q2sx> (last visited Feb. 4, 2011).

<sup>266</sup> *Id.*

<sup>267</sup> 21 U.S.C. § 321(g)(1)(C) (2006).

<sup>268</sup> Regardless, according to the International Classification of Diseases (ICD-9-CM) diagnosis 374.55, eyelash hypotrichosis is the “condition of having inadequate or not enough eyelashes.” AM. OPTOMETRIC ASS’N CLINICAL CARE GRP., BULLETIN NO. 4, 1 (2009), available at <http://www.aoa.org/documents/Latisse-Bulletin-March-18-2009.pdf>.

<sup>269</sup> For a discussion of the types of DTC advertisements, see *supra* notes 96–98 and accompanying text.

which contains a link to Pfizer's Lyrica website.<sup>270</sup> Thus, this help-seeking ad seems to be a disguised product-claim ad and seems inextricably linked to a DTC drug advertisement, that is, the Lyrica website.<sup>271</sup> This example is evidence of the scope of Pfizer's disease-branding and drug-mongering campaign for fibromyalgia and Lyrica.

The public service announcement begins with a quick cut to patients in visible distress, with tears streaming down their faces, lamenting the intense and inexplicable pain they experience.<sup>272</sup> The voiceover begins, "[I]magine feeling this kind of pain and nobody knows what it is or believes you even have it."<sup>273</sup> It continues, "This is fibromyalgia, very real widespread pain and tenderness that affects millions. . . . There is hope, there is help. If you're suffering, talk to your doctor and visit fibrohope.org."<sup>274</sup> After quickly browsing the website,<sup>275</sup> one can find a link to "Explore a Fibromyalgia Prescription Treatment Option," which takes the consumer to "a product-branded Web site from Pfizer" referring to Lyrica. Thus, while the commercial and the website are seemingly designed to raise disease awareness, they are inextricably linked to the prescription drug.<sup>276</sup>

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<sup>270</sup> *Facing Fibromyalgia, Finding Hope*, *supra* note 117. Lyrica is the first FDA-approved drug to treat FMS. FDA News Release, FDA Approves First Drug for Treating Fibromyalgia (June 21, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108936.htm>.

<sup>271</sup> It should be noted that

[w]hen done properly, help-seeking ads are not considered to be drug ads. Therefore, [FDA] do[es] not regulate true help-seeking ads, but the FTC does regulate them. If an ad recommends or suggests the use of a specific drug, however, it is considered a product claim ad that must comply with FDA rules.

*Basics of Drug Ads*, *supra* note 96.

<sup>272</sup> *Facing Fibromyalgia, Finding Hope*, *supra* note 117.

<sup>273</sup> *Id.*; see also Berenson, *supra* note 127.

Fibromyalgia is a real disease. Or so says Pfizer in a new television advertising campaign for Lyrica, the first medicine approved to treat the pain condition, whose very existence is questioned by some doctors. . . . Many of its sufferers are afflicted by other similarly nebulous conditions, like irritable bowel syndrome.

*Id.*

<sup>274</sup> *Facing Fibromyalgia, Finding Hope*, *supra* note 117.

<sup>275</sup> Although the link for [www.fibrohope.org](http://www.fibrohope.org) at the end of the commercial no longer exists, the first link on a Google search of "fibromyalgia and Pfizer" reveals [www.fibrocenter.com](http://www.fibrocenter.com), which leads to a similar website. See FIBROCENTER, <http://www.fibrocenter.com> (last visited Feb. 4, 2012).

<sup>276</sup> It is possible that this promotion is misbranded. See U.S. FOOD AND DRUG ADMIN., *supra* note 156, at 6 ("If a disease awareness or help-seeking piece and a re-



As demonstrated by these examples, disease-branding and drug-mongering in the form of DTC advertising intend to make consumers believe that they suffer from serious medical conditions. Consequently, there seems to be sufficient evidence to conclude that DTC advertising campaigns could constitute outrageous conduct.

## 2. Negligent Infliction of Emotional Distress(NIED)

If the iatrogenic effects from taking the medication are considered,<sup>277</sup> then a plaintiff may have a successful argument for the physical impact or injury necessary to establish a prima facie case of NIED.<sup>278</sup> There is no recovery in tort for NIED unless the plaintiff falls within a recovery-permitting category; the relevant category for the test case is emotional harm that accompanies a physical impact or injury.<sup>279</sup> Thus, the law permits a plaintiff to recover for emotional distress when the plaintiff sustains a physical injury that results from a defendant's negligence.<sup>280</sup>

In *Metro-North Commuter Railroad Co. v. Buckley*, the plaintiff argued that he suffered severe emotional distress from fear of developing cancer after he was negligently exposed to excessive amounts of asbestos.<sup>281</sup> The physical contact with asbestos did not amount to physical impact sufficient for an NIED claim because the plaintiff was

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minder advertisement are presented in a manner that causes their messages to be linked together by the audience, the failure of the combined communication to include the risk [information] . . . would cause the advertised product to be misbranded.”).

<sup>277</sup> Dr. Jutel explains the dangers of iatrogenic effects as follows:

The expansion of diagnostic categories is not without risk and can have severe iatrogenic results. The concordant treatment which accompanies a diagnosis may expose an individual to undesirable, or unintended, secondary effects. The medicalisation of shyness which results in the diagnoses of Social Phobia, Social Anxiety Disorder and Avoidant Personality Disorder, as one example, encourages patients to request, and doctors to recommend, the use of pharmaceutical remedies, some of which have led to reports of devastating side effects.

Jutel, *supra* note 43, at 286.

<sup>278</sup> The side effects would be insufficient for a products liability claim, so this cause of action is not considered in this Comment. Moreover, the argument is not related to the product itself because the plaintiff would not be alleging a failure to warn, design defect, or manufacturing defect. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998).

<sup>279</sup> *Metro-N. Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 430 (1997).

<sup>280</sup> *Id.*

<sup>281</sup> *Id.* at 427. Although *Buckley* arose under the Federal Employer's Liability Act, the Court relied on common-law tort principles, *see id.* at 429, thus making the analysis relevant and applicable for our test case.

asymptomatic.<sup>282</sup> In addition, the Supreme Court explained that a “‘physical impact’ . . . does not include a simple physical contact with a substance that might cause a disease at a substantially later time—where that substance, or related circumstance, threatens no harm other than that disease-related risk.”<sup>283</sup> Accordingly, the rule gleaned from *Buckley* is that the mere exposure to deleterious substances or the possible risk of developing a disease are insufficient for an NIED claim; rather, some sort of actual physical injury is required.

In *Michtavi*, the court noted that under the Federal Tort Claims Act (FTCA), a prisoner-plaintiff must suffer “less-than-significant-but-more-than-*de minimis* physical injury” before a civil action can be brought for mental distress.<sup>284</sup> The plaintiff did not allege that the prison officials physically harmed him; rather, the plaintiff merely alleged that the prison officials were negligent in allowing fellow inmates to succeed in their schemes to defraud him.<sup>285</sup> Thus, the court concluded that the FTCA claim failed because “the fact that [plaintiff’s] mental condition is treated with medication does not mean these emotional problems are physical injury. . . . [T]he fact that [the plaintiff] physically takes medication, or that the medication works on his physical body, does not mean that the medication is treating physical injury.”<sup>286</sup>

Although taking medication for emotional problems does not mean that the medication is treating a physical injury, the iatrogenic effects of the treatment may *result* in physical injury. This distinction is relevant to remove the test case from the *Michtavi* rule. Thus, although the plaintiff in this Comment’s test case is not taking the drug for emotional distress, a physical injury may arise as an unintended consequence (side effect) of the pharmaceutical treatment. Accordingly, the physical effect of the drug could become, in essence, the physical impact element for the cause of action.

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<sup>282</sup> *Id.* at 432.

<sup>283</sup> *Id.* at 430.

<sup>284</sup> *Michtavi v. United States*, No. 4:07-CV-0628, 2009 U.S. Dist. LEXIS 18926, at \*12 (M.D. Pa. Mar. 4, 2009), *aff’d*, 345 F. App’x. 727 (3d Cir. 2009). Although this case arose under the FTCA, the court applied the substantive law of the state where the act occurred. *Id.*; see 28 U.S.C. § 1346(b)(1) (2006). Thus, the discussion of a physical-injury requirement is analogous to the test case for NIED because it explains that receiving pharmaceutical treatment for a mental disorder does not establish that the plaintiff has suffered a physical injury.

<sup>285</sup> *Michtavi*, 2009 U.S. Dist. LEXIS 18926, at \*14-15.

<sup>286</sup> *Id.* at \*15.

But in Pennsylvania, for example, a plaintiff alleging an NIED claim “must suffer *immediate* and *substantial* physical harm.”<sup>287</sup> In the test case, this contemporaneous element is missing because the physical impact of the side effect occurs *after* the plaintiff experiences emotional distress upon being subjected to the disease-branding and drug-mongering campaign. Logically, a second bout of emotional distress could accompany the physical symptoms of suffering from side effects, but this would remove the analysis from the disease-branding and drug-mongering scenario. Because the second bout of emotional distress would be proximately caused by the side effects, the claim arising in this case would be an emotional distress claim accompanying a products-liability case.<sup>288</sup> Thus, to correctly isolate and define disease-branding and drug-mongering as the causative factors, one has to assume that the initial bout of emotional distress was proximately caused by, and directly preceded by, the advertising campaign. But if this were the case, then the physical injury element necessary for the NIED claim could not be satisfied due to lack of contemporaneousness: the emotional distress would have preceded the physical injury, which is caused by the drug’s side effects. Therefore, it seems that an NIED cause of action would likely fail.

Furthermore, the “learned intermediary doctrine” might provide a defense to pharmaceutical company liability. According to this doctrine, which almost every jurisdiction has adopted,<sup>289</sup> pharmaceutical companies have a duty to warn the physician, rather than the consumer as the end user, of a prescription drug’s side effects through adequate labeling.<sup>290</sup> If the warning is adequate, then the drug company essentially delegates its duty to warn to the physician and shields itself from liability.<sup>291</sup>

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<sup>287</sup> Doe v. Phila. Cmty. Health Alts. AIDS Task Force, 745 A.2d 25, 28 (Pa. Super. Ct. 2000).

<sup>288</sup> See *supra* note 278 (discussing a product liability claim).

<sup>289</sup> See Garbutt & Hofmann, *supra* note 84, at 273. But see Perez v. Wyeth Labs. Inc., 734 A.2d 1245 (N.J. 1999) (refusing to shield drug companies from liability based on the “learned intermediary doctrine” in the context of mass-marketed drugs through DTC advertising).

<sup>290</sup> Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 1 (1998).

<sup>291</sup> See, e.g., Pustejovsky v. PLIVA, Inc., 623 F.3d 271, 276 (5th Cir. 2010) (“Under the doctrine, the manufacturer may rely on the doctor—the learned intermediary—to pass on its warnings. Thus, so long as the drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug.”).

But New Jersey, for example, does not apply the learned intermediary doctrine to drug companies when they engage in mass-marketing of drugs because the premises on which the doctrine relies are absent in the DTC advertising context.<sup>292</sup> In *Perez v. Wyeth Laboratories Inc.*, the New Jersey Supreme Court held that the learned intermediary doctrine will not apply when a prescription drug manufacturer uses DTC advertising to market its drug;<sup>293</sup> instead, drug companies have a duty to warn patients directly and cannot rely on the prescribing physician's knowledge and position of authority to convey warnings. Essentially, the court explained that "[w]hen mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers . . . should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product."<sup>294</sup>

Although *Perez* concerns a failure-to-warn claim, the fact that the learned intermediary doctrine may not apply to DTC advertising is relevant to an NIED claim based on disease-branding and drug-mongering. In New Jersey, the learned intermediary doctrine would probably not apply to a claim for NIED premised on disease-branding and drug-mongering; however, in any other jurisdiction, the doctrine would most likely shield drug companies from liability.<sup>295</sup>

Furthermore, the element of "physical impact" in the NIED context raises an interesting and troublesome question as to the proper defendant. The drug company's disease-branding and drug-mongering caused the emotional distress and the drug caused the injury, but the company was not negligent in providing the plaintiff with the injury-causing drug. Thus, in the test case, it seems that the

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<sup>292</sup> *Perez*, 734 A.2d at 1255.

<sup>293</sup> *Id.* at 1257; see also *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 811–12 (E.D. Tex. 2002) (analyzing *Perez*). See generally Garbutt & Hofmann, *supra* note 84, at 273. ("[DTC advertising] essentially bypasses the 'intermediary' . . . . Thus, the role of the physician . . . is greatly diminished and pharmaceutical companies should not be able to benefit from the learned intermediary doctrine.")

<sup>294</sup> *Perez*, 734 A.2d at 1247.

<sup>295</sup> New Jersey seems to be the only jurisdiction to recognize a DTC-advertising exception to the learned intermediary doctrine. See *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376–77 (S.D. Fla. 2007) ("While the *Perez* court found that the law should be changing in response to changes in marketing strategies by drug manufacturers, New Jersey is the only state to have done so. It is now eight years since *Perez* was decided, and no other state has followed suit."). But see *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 508 (Tex. App. 2010) ("[T]he theoretical underpinnings of the 'learned intermediary' doctrine do not apply when a drug manufacturer directly markets to its consumers, the patients."), *review granted* (Aug. 11, 2011).

plaintiff's emotional distress cannot be attributed to a drug company's negligent conduct. The drug company is not liable for negligence for the physical injury sustained by the plaintiff because the plaintiff autonomously purchased and ingested a drug that the FDA approved as safe and effective, and the physical injury (side effect) occurred afterward. Thus, the only potential party whose negligent conduct caused a physical injury to the plaintiff would be the treating physician. Consequently, the plaintiff may have an alternative cause of action for medical malpractice for wrongful diagnosis or negligent prescribing practices.

### 3. Medical Malpractice

A plaintiff alleging medical malpractice premised on a theory of negligent diagnosis and treatment must establish four elements: duty, breach, causation, and damages.<sup>296</sup> The breach element may be satisfied if the doctor's "actions demonstrate either a lack of skill or care, or failure to give careful and proper attention to his patient."<sup>297</sup> Failure to consider a differential diagnosis<sup>298</sup> may violate the standard of care and establish breach, as it provides evidence of the physician's lack of proper attention to the patient's case.<sup>299</sup> This is because

[a]n incorrect diagnosis of a patient's condition may produce harmful results either by inducing the patient to forgo the proper treatment which would have corrected the illness, or by leading the defendant to give treatment which is harmful in and of itself, aside from the failure to treat the condition with which the plaintiff is actually afflicted.<sup>300</sup>

In *Wojton v. United States*, for example, the plaintiff alleged four acts of negligence against the Veterans Administration for: (1) wrongful diagnosis of schizophrenia, (2) wrongful prescribing of schizophrenia medication, (3) failure to diagnose PTSD, and (4) failure to prescribe

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<sup>296</sup> See 22 FRUMER & FRIEDMAN, *supra* note 185, § 106.02.

<sup>297</sup> *Heimlicher v. Steele*, 615 F. Supp. 2d 884, 910 (N.D. Iowa 2009).

<sup>298</sup> Differential diagnosis is "[t]he method of distinguishing between two or more diseases having similar symptoms by carefully comparing and evaluating the few dissimilar characteristics and signs, and thus making a final diagnosis." 2-D ATTORNEYS' DICTIONARY OF MEDICINE D-34474 (2009).

<sup>299</sup> *E.g.*, *Trowbridge v. United States*, 703 F. Supp. 2d 1129, 1142 (D. Idaho 2010) (holding that a doctor breached the standard of care in formulating differential diagnoses and treatment plans).

<sup>300</sup> W.E. Shipley, Annotation, *Proximate Cause in Malpractice Cases*, 13 A.L.R.2d 11 (2008).

PTSD medication.<sup>301</sup> Although neither the plaintiff nor the court addressed these claims in terms of failure to consider a differential diagnosis, the diagnostic criteria for these mental disorders suggest that the inference is clear.<sup>302</sup> Misdiagnosing these two disorders is common due to the subjective experience of hallucinations.

Analogously, because of the subjective diagnostic criteria of FMS and IBS, a medical malpractice claim could arise if the physician negligently failed to consider the vast array of differential diagnoses for these disorders. A differential diagnosis is critical when evaluating FMS because “[t]here are no tests and no combination of symptoms and signs that signify without doubt that a patient has fibromyalgia.”<sup>303</sup> Thus, “a number of distinctive disorders may share a few or several signs and symptoms with fibromyalgia, sometimes making a distinction very difficult.”<sup>304</sup> For example, hypothyroidism may cause fatigue and widespread soft tissue tenderness and thus can masquerade as fibromyalgia.<sup>305</sup> An article on the differential diagnosis of fibromyalgia notes that

[t]he multiple symptoms of fibromyalgia often overlap with those of related disorders and may further complicate the diagnosis. One of the most challenging diagnostic dilemmas that clinicians face is distinguishing fibromyalgia from other central pain disorders (e.g., irritable bowel syndrome, chronic fatigue syndrome, migraine) . . . . To date, there is no “gold standard” for diagnosing fibromyalgia. Until a better clinical case definition of fibromyalgia exists, all diagnostic criteria should be interpreted with caution, considered rudimentary, and subject to modification.<sup>306</sup>

Similarly, “[b]ecause there are usually no physical signs to definitively diagnose irritable bowel syndrome, diagnosis is often a process of

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<sup>301</sup> 199 F. Supp. 2d 722, 724 (D. Ohio 2002).

<sup>302</sup> See DSM-IV-TR, 2000, *supra* note 3, at 467 (“Flashbacks in Posttraumatic Stress Disorder must be distinguished from illusions, hallucinations, and other perceptual disturbances that may occur in Schizophrenia . . . .”); 2 DAVID L. FAIGMAN ET AL. MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 9:33 (2011–12) (noting that flashbacks are the “the PTSD symptoms . . . [that] appear to involve a level of reality distortion comparable to that in schizophrenia”).

<sup>303</sup> David A. Cramer, *Fibromyalgia—Clinical Features and Diagnosis*, in 6 ATTORNEYS’ TEXTBOOK OF MEDICINE 25.30, 25.30 (Roscoe N. Gray & Louise J. Gordy eds., 3d ed., 2011).

<sup>304</sup> *Id.* at 25.37.

<sup>305</sup> *Id.*

<sup>306</sup> D.L. Goldenberg, *Diagnosis and Differential Diagnosis of Fibromyalgia*, 122 AM. J. MED. (12 Supp.) S14, S14 (2009).

elimination.<sup>307</sup> Differential diagnoses for IBS include ulcerative colitis, diverticulitis, and Crohn's disease.<sup>308</sup> In addition, celiac disease and lactose intolerance may cause signs and symptoms similar to IBS.<sup>309</sup>

Thus, one could imagine a cause of action parallel to *Wojton* for FMS or IBS: (1) wrongful diagnosis of FMS or IBS, (2) wrongful prescribing of Lyrica or Zelnorm, (3) failure to diagnose, for example, hypothyroidism or Crohn's disease, and (4) failure to prescribe drugs for these conditions. A patient presenting with gastrointestinal complaints who self-diagnoses as having IBS and seeks a prescription for Zelnorm (based on the cumulative impact of a disease-mongering campaign), may in fact have a number of other diseases. If the doctor fails to consider these differential diagnoses, fails to order appropriate tests, and thereby wrongfully diagnoses IBS, the doctor may be liable for malpractice if the patient suffers adverse reactions to Zelnorm.

Medical malpractice lawsuits could be a weapon against disease-branding and drug-mongering, but they only work in individual cases against individual doctors. Although individual incidents may be remedied through medical malpractice cases, this would not produce systemic change in pharmaceutical companies' promotion of their products. And while successful medical malpractice claims create precedent for which other victims of disease-branding and drug-mongering could rely, this would probably only affect doctors' diagnostic procedures rather than their prescribing habits. In other words, when patients complain of disease-branded symptoms, physicians would be more likely to consider differential diagnoses, rather than refuse to prescribe a drug and facilitate the drug-mongering. Thus, any attempt to "starve the pharmaceutical beast" by suing doctors in an effort to prevent drug overprescribing would likely fail to address the institutionalized practice of DTC advertising central to disease-branding and drug-mongering campaigns.

Ultimately, it seems possible to file a complaint for IIED based on the alleged outrageousness of DTC advertising campaigns, and

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<sup>307</sup> *Irritable Bowel Syndrome—Tests and Diagnoses*, MAYO CLINIC (July 29, 2011), <http://www.mayoclinic.com/health/irritable-bowel-syndrome/DS00106/DSECTION=tests-and-diagnosis> [hereinafter *Irritable Bowel Syndrome—Tests and Diagnoses*].

<sup>308</sup> 3 ATTORNEYS' DICTIONARY OF MEDICINE I-62839 (2009); see also Hans Tester, *Ulcerative Colitis*, in 16 ATTORNEYS' TEXTBOOK OF MEDICINE, *supra* note 303, at 231.50, 231.54(3).

<sup>309</sup> *Irritable Bowel Syndrome—Tests and Diagnoses*, *supra* note 307.

while the case may reach adjudication on the merits, it seems insufficient to significantly alter pharmaceutical promotional practices. In addition, an NIED claim would probably fail due to the lack of contemporaneousness between emotional distress and injury; also the learned intermediary doctrine would pose a formidable defense to an NIED case. Finally, medical malpractice claims seem to be a viable, although still insufficient, option that could circuitously influence how pharmaceutical companies advertise. Notwithstanding the potential for establishing precedent, even if a test case is won and affirmed on appeal, these litigious retrospective strategies would ultimately be ineffective at producing real, systemic change in disease-branding and drug-mongering promotional practices. Therefore, the critics of these practices should look to the legislative arena to combat the specific pharmaceutical promotional strategies that they consider particularly egregious and detrimental to public health. Legislative reform, as a prospective remedy, can address the practices on a comprehensive, collaborative, and systemic level, without resorting to the expensive, time-consuming, and highly-particularized adversarial process.

C. *Legislative Prescriptions for Reform: Understanding and Promoting “Academic Detailing”*

Rather than relying on the inherently retrospective remedy of litigation, it is possible to construct prospective policy solutions.<sup>310</sup> For example, educating doctors about drug-mongering and disease-branding, through a process called “academic detailing,” could curb the arguably detrimental effects of these advertising practices.<sup>311</sup> Academic detailing is the process by which non-profit entities send trained healthcare professionals to physicians’ offices to educate

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<sup>310</sup> Cf. Lambdin, *supra* note 240, at 170–71.

While it may ultimately be out of the hands of the courts and the FDA to impose harsher restrictions on direct-to-consumer advertising, if the public continues to hear statements [warning how DTC marketing has led to irresponsible prescribing practices that jeopardize patient safety], it is highly likely that it will be able to initiate reform on its own, as the pendulum of public perception swings from one of acceptance to suspicion in the realm of direct-to-consumer advertising.

*Id.*

<sup>311</sup> But see Iona Heath, *Combating Disease Mongering: Daunting but Nonetheless Essential*, 3 PLOS MED. 448, 448 (2006), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0030146> (“The challenges of combating the current epidemic of disease mongering is daunting, and anyone looking for ready solutions should read no further.”).



them about drugs and prescribing practices.<sup>312</sup> Essentially, qualified experts, “[u]sing some of the techniques of behavioral science that drug reps use, but without the financial incentives of gifts and samples,” train doctors about drug-treatment options and prescribing practices.<sup>313</sup>

The most important techniques of academic detailing include “conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns . . . [and] establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues.”<sup>314</sup> Accordingly, academic detailing “combat[s] pharmaceutical sales reps['] influence on prescribing, and help[s] get doctors the best evidence—without the sales pitch.”<sup>315</sup> Because DTC advertising gives consumers increased access to information, academic detailing will allow doctors to regain their medical authority by becoming knowledgeable about pharmaceutical promotional practices in an effort to combat the effects of DTC advertising on patients.<sup>316</sup>

Doctors should be aware of disease-branding and drug-mongering.<sup>317</sup> They “should be wary of exaggerated claims and should place the same amount of scrutiny on ads for prescription drugs as [they] would on any other advertisement.”<sup>318</sup> Academic detailing would thus provide physicians with the tools to recognize drug-seeking behavior associated with disease-branding and drug-mongering strategies. By making doctors aware of these promotional

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<sup>312</sup> Susan Poser, *Unlabeled Drug Samples and the Learned Intermediary: The Case for Drug Company Liability Without Preemption*, 62 FOOD & DRUG L.J. 653, 691–92 (2007); see also *Academic Detailing and the Odds at Agincourt*, POSTSCRIPT BLOG (Apr. 22, 2010, 10:28 AM), <http://postscript.communitycatalyst.org/?p=1254> [hereinafter *Academic Detailing and the Odds at Agincourt*].

<sup>313</sup> Poser, *supra* note 312, at 692.

<sup>314</sup> Stephen B. Soumerai & Jerry Avorn, *Principles of Educational Outreach ('Academic Detailing') to Improve Clinical Decision Making*, 263 JAMA 549, 549 (1990).

<sup>315</sup> Kate Petersen, *Academic Detailing Moves Ahead at the State, Federal Level*, POSTSCRIPT BLOG (Feb. 25, 2010, 10:23 AM), <http://postscript.communitycatalyst.org/?p=1150>.

<sup>316</sup> See Poser, *supra* note 312, at 692 (“The goal of academic detailing is to counteract the influence of drug reps, improve clinical decision making by physicians, and respond to pressure to minimize healthcare costs.”).

<sup>317</sup> Shankar & Subish, *supra* note 105, at 278.

<sup>318</sup> Ishmeal Bradley, *Talk to Your Doctor: Direct-to-Consumer Advertising of Prescription Drugs, Part 3*, CLINICAL CORRELATIONS (Aug. 13, 2010, 11:30 AM), <http://www.clinicalcorrelations.org/?p=2990>.

practices, and reiterating the importance of differential diagnoses and alternative treatment options, academic detailing would be an effective tool to combat these practices. Moreover, open communication between physicians and patients, both with full knowledge of disease-branding and drug-mongering practices, would expose the manipulative effects of these practices and allow for more rational prescription drug use. In fact, research suggests that academic detailing is an effective way to counteract the influence of pharmaceutical promotional practices and reduce inappropriate prescribing.<sup>319</sup> For example, one study published in the *New England Journal of Medicine* concluded that “[a]cademically based ‘detailing’ may represent a useful and cost-effective way to improve the quality of drug-therapy decisions and reduce unnecessary expenditures.”<sup>320</sup>

Growing interest in academic detailing “is part of a growing awareness that pharmaceutical marketing has the potential to interfere with safe prescribing and patient care—and a broader effort to make sure it doesn’t.”<sup>321</sup> The problems associated with drug marketing have captured Congress’s attention and inspired it to act. The Independent Drug Education and Outreach Act (IDEA), a bill that was introduced in the House of Representatives and Senate but died in committee, would have provided “grants or contracts for prescription drug education and outreach for healthcare providers and their patients.”<sup>322</sup> The relevant section of the act would have required the Secretary of Health and Human Services to award contracts to “eligible entities for the development and implementation of programs to appropriately train and deploy healthcare professionals to educate physicians and other drug prescribers concerning the relative safety, relative effectiveness, and relative cost of prescription drugs and their alternatives.”<sup>323</sup>

The bill was premised on the notion that “[o]ffice calls work. That’s why they are the preferred sales tactic of industry. So it makes sense that governments and others who actually foot the cost of pre-

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<sup>319</sup> See, e.g., Jerry Avorn & Stephen B. Soumerai, *Improving Drug-Therapy Decisions through Educational Outreach—A Randomized Controlled Trial of Academically Based Detailing*, 308 *NEW ENG. J. MED.* 1457 (1983); M.A. O’Brien et al., *Educational Outreach Visits: Effects on Professional Practice and Health Care Outcomes*, 4 *COCHRANE DATABASE SYS. REVS.* CD000409 (2007); Soumerai & Avorn, *supra* note 314.

<sup>320</sup> Avorn & Soumerai, *supra* note 319, at 1457.

<sup>321</sup> *Academic Detailing and the Odds at Agincourt*, *supra* note 312.

<sup>322</sup> Independent Drug Education and Outreach Act of 2009 (IDEA), S. 767, 111th Cong. (2009).

<sup>323</sup> S.767 § 904(c).

scription drugs should adopt the same tactic, albeit with the goal of encouraging the use of the best, safest, most cost-effective drugs.”<sup>324</sup> Therefore, IDEA should be reintroduced, and ultimately enacted into law, as a prospective remedy for the detrimental effects of disease-branding and drug-mongering. The bill could be amended to also create advisory committees composed of sociology, marketing, and psychology experts to help construct academic-detailing protocols and public-health outreach programs. These protocols and programs would facilitate the academic detailer’s role in explaining to doctors and patients the power of medicalization—how social forces impact the definition of diseases, how disease is thus socially constructed, and how medicalization can be influenced by aggressive promotional practices. The advisory committee recommendations could clarify the sociology-of-health critique of disease-branding and drug-mongering, and the increased knowledge of these phenomena would yield a stronger defense arsenal for both prescribing physicians and patients.

Ultimately, this legislative prescription would not alter the FDA’s regulatory authority over DTC advertising and would leave the FD&C Act and associated regulations intact,<sup>325</sup> but would provide an alternative educational method of combating the deleterious effects of otherwise-legal advertising and promotional practices.

## V. CONCLUSION

The problems of disease-branding and drug-mongering have become rampant in our society, though at this juncture it is uncontested that they do not, as a general matter, violate any existing laws. These phenomena have surfaced as a result of relatively relaxed FDA regulation of DTC advertising. Drug companies have recognized the utility of socially constructing diseases and have employed this technique into effective advertising practices. It might be possible to bring a cause of action against drug companies and, somewhat derivatively, against prescribing physicians for these practices, but it seems that the most likely way to effect change in this area of law would be through legislation and education.

The likelihood of success for an IIED claim is improbable, and an NIED claim would most likely fail for a variety of reasons including

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<sup>324</sup> *The Next Big IDEA: Prescriber Education*, POSTSCRIPT BLOG (July 31, 2008, 1:16 PM), <http://postscript.communitycatalyst.org/?p=179>.

<sup>325</sup> The bill would amend the Public Health Service Act only by adding additional sections. *See* S. 767 § 2.

the lack of contemporaneousness with distress and injury and the learned intermediary doctrine defense. Furthermore, while medical malpractice claims against prescribing physicians for wrongful diagnosis might be successful on an individual basis, they would not bring about any substantial changes in drug-company advertising practices. Thus, critics of disease-branding and drug-mongering seem to be left without an effective legal remedy, and any such remedy would certainly not lead to, or result in, overhaul in a way that legislation could.

Therefore, because the promotional practices are legal and generally do not rise to the level of tortious conduct, critics of disease-branding and drug-mongering ought to consider legislative reform efforts to address pharmaceutical promotional practices and ameliorate their public health effects. Enhancing physicians' and consumers' knowledge would enable them to recognize disease-branding and drug-mongering and cope better with the torrent of such practices. Instituting academic-detailing programs would combat these practices in a systemic and non-litigious way by counteracting the effects of DTC advertising on consumer demand and physician prescribing habits.

Although these promotional practices will probably never go away, it is certainly possible for the pharmaceutical industry, the FDA, and critics alike to coexist more harmoniously. If these relevant stakeholders were aware of the existing competing economic and public-health goals, then educated doctors and consumers could select which drugs are medically necessary, rather than being persuaded by the industry's disease-branding and drug-mongering practices.