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## The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals

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# THE COST OF CONFUSION: THE PARADOX OF TRADEMARKED PHARMACEUTICALS

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## ABSTRACT

*The United States spends nearly \$1,000 per person annually on drugs—forty percent more than the next highest spender, Canada, and more than twice the amount France and Germany spend. Although myriad factors contribute to high drug spending in the United States, intellectual property law plays a crucial and well-documented role in inhibiting access to cheaper, generic medications. Yet, for the most part, the discussion of the relationship between intellectual property law and drug spending has centered on patent protection. Recently, however, a few researchers have turned their attention to a different avenue of exclusivity—trademark law. New studies suggest that pharmaceutical trademarks are diminishing the ability of physicians and consumers to accurately understand the relationship between generic and brand name medications. This Article synthesizes and relies on that research to demonstrate that trademarks in the pharmaceutical industry are at odds with the theoretical foundations of trademark law. The conventional justification for trademark protection is two pronged: trademarks not only minimize consumer confusion but also ensure manufacturers maintain consistent product quality. Relying on pharmaceutical case studies and behavioral research, this Article contends that pharmaceutical trademarks and trade dress are performing the opposite functions. Instead of reducing consumer confusion and enhancing market efficiency, pharmaceutical trademarks are actually confusing patients into believing that trademarked and generic drugs are distinct medications, leading to wasteful spending and even substantial morbidity. Accordingly, this Article encourages policymakers to reexamine the utility of trademarks in the pharmaceutical industry and ultimately suggests that such trademarked names should be re-*

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\* Law Clerk to the Honorable Theodore A. McKee, Chief Judge of the United States Court of Appeals for the Third Circuit. Thanks to Amy Kapczynski, Aaron Kesselheim, David Studdert, Barton Beebe, Alfred Engelberg, and Troyen Brennan for their helpful comments.

placed with a different type of mark—one that serves to distinguish a drug’s manufacturer without differentiating the drug itself from identical generics. Such an approach has the potential to not only save millions of dollars, but also improve patient outcomes.

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#### INTRODUCTION

For decades, economists, legal scholars, and public health advocates have documented the role intellectual property laws play in inhibiting access

to cheaper, generic medications. Yet, for the most part, these studies have focused on the relationship between patent law and public health: how does patent protection impede access to generic medicines? In the last thirty years, the experts and regulators have had much to discuss. Major changes to both domestic laws—such as the Hatch-Waxman Act—and international agreements—such as the Trade-Related Aspects of Intellectual Property Rights Agreement (“TRIPS”)—have modified the scope of patent protections at the intersection of intellectual property law and public health.

But patents are not the only form of intellectual property that influence access to medications. Increasingly, policymakers and scholars are examining the potential negative impact of trademark law on public health. Trademarks are intended to provide consumers with accurate information regarding the source of a product, therein lowering consumer search costs and facilitating market efficiency. In a world replete with consumer options, trademarks enable buyers to differentiate between the Cokes® and Pepsis® to locate the particular good they desire. These marks greatly reduce the confusion that the breadth of market options could otherwise generate.

Recent research, however, reveals that pharmaceutical trademarks tend to perform the opposite function. New studies show that pharmaceutical trademarks induce consumers to artificially differentiate between bio-equivalent branded and generic medications, leading to wasteful spending and even substantial morbidity.<sup>1</sup> Instead of reducing consumer confusion, pharmaceutical trademarks create it; instead of enhancing market efficiency, they diminish it.

Cognizant of this issue, interest in the utility of pharmaceutical trademarks, or lack thereof, has grown in recent years. In 2012, the Indian Ministry of Health announced that it would prohibit the use of brand names for pharmaceutical products due to the detrimental impact such trademarks have on the demand for generic medications.<sup>2</sup> Although Indian officials have since decided against a total ban, a version of the proposal is still under consideration.<sup>3</sup> In a country where many people buy branded medications due to ignorance of brand and generics bioequivalence, such a law could change purchasing behaviors and significantly lower health care expenditures.<sup>4</sup>

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1. *See infra* Part II & III.A.

2. Kounteya Sinha, *Health Ministry Pushes for End to Sale of Branded Drugs*, THE ECON. TIMES (Oct. 16, 2012, 7:40 AM), [http://articles.economictimes.indiatimes.com/2012-10-16/news/34498956\\_1\\_generic-drugs-generic-names-generic-medicines](http://articles.economictimes.indiatimes.com/2012-10-16/news/34498956_1_generic-drugs-generic-names-generic-medicines).

3. *No New Licences for Drug Brands*, DAWN (Nov. 26, 2012, 6:25 AM), <http://www.dawn.com/news/766813/no-new-licences-for-drug-brands> (quoting the Drug Controller General of India, Dr. G.N. Singh, “[w]e want to gradually move towards a future where we will not issue any brand or trade names. We are going all out to push generic drugs solely for the benefit of the public.”).

4. Although the price differences between generic and brand name products in India are significant, there are also substantial differences in the prices of generics in India. *See*

While India's consideration of a ban on pharmaceutical trademarks may be relatively recent, the realization driving the ban is not. After analyzing the effects of trademark protection on the pharmaceutical market, a 1977 U.S. Federal Trade Commission ("FTC") report suggested that "the trademark, like the patent, might be given a limited life" due to the social costs of trademarks in perpetuity.<sup>5</sup>

Lawmakers have yet to act upon the FTC's 1977 suggestion. This Article contends that pharmaceutical trademarks and trade dress continue to induce irrational behavior in consumers, needlessly inflating health care costs and dangerously reducing patient adherence to generic drug regimens. Relying on pharmaceutical case studies and behavioral research, this Article demonstrates that pharmaceutical trademarks and trade dress lead patients to believe that branded drugs are different from and/or superior to their generic counterparts. This confusion prompts inefficient and even unhealthy prescription practices and purchasing behaviors. While trademarks may facilitate consumer knowledge and market efficiency in other arenas, they are leading to market failure in the pharmaceutical industry. In light of these findings, policymakers should eliminate pharmaceutical trademarks and trade dress and, instead, require manufacturers to label drugs with their generic names and a mark identifying the manufacturer. Such a labeling system would clarify the equivalence of brands and generics while still allowing consumers to identify a drug's source.

The remainder of this Article proceeds as follows: Part I provides an overview of trademark law and the scholarly debate surrounding the impact of trademarks. Relying on quantitative and qualitative data, Part II argues that pharmaceutical branding actually increases consumer confusion rather than reducing it. This Part also contends that consumers do not rely on pharmaceutical trademarks to ascertain a drug's source—that is, the manufacturer. Part II concludes that pharmaceutical trademarks undermine the key purpose of trademark law. Finally, Part III offers a solution—the replacement of pharmaceutical trademarks and trade dress with manufacturer marks—and explores its potential limitations.

## I. TRADEMARK THEORY

### A. *Introduction to Trademarks*

At the most basic level, a trademark is a distinctive symbol, name, or packaging that signals the origin of a particular product and distinguishes it

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generally Anita Kotwani, *Prices & Availability of Common Medicines at Six Sites in India Using a Standard Methodology*, 125 INDIAN J. MED. RES. 645 (2007) (analyzing the price differences between brand name and various generic medications for essential medicines on the Indian pharmaceutical market).

5. FED. TRADE COMM'N, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 80 (Feb. 1977).

from others.<sup>6</sup> Trademarks need not be new or previously unused to obtain protection, but they must communicate the product's true source to consumers. In doing so, trademarks ostensibly enhance the ease with which producers speak to consumers and enable consumers to differentiate between the goods available in any given market.

As a form of intellectual property, trademarks endow their owners with an exclusive right to use the distinctive name, symbol, or packaging selected. Unlike patents and copyrights,<sup>7</sup> the Constitution does not directly protect trademarks.<sup>8</sup> Instead, the federal power to grant and regulate trademarks derives from the Constitution's Commerce Clause: trademarks enhance the flow of commerce by helping consumers identify products.<sup>9</sup> This generalized objective of stimulating commerce is distinct from the particularized aim of patent and copyright law: the stimulation of specific types of economic activities, namely in the arts and sciences.<sup>10</sup> In contrast to patent and copyright law, trademark law principally functions as a form of tort law, protecting consumers from unfair competition and consumer deception.<sup>11</sup>

While trademarks have existed for "almost as long as trade itself,"<sup>12</sup> U.S. trademark law remained the dominion of the courts until Congress enacted the first trademark statute in 1870.<sup>13</sup> Today, the Lanham Act protects trademarks.<sup>14</sup> When Congress enacted the Lanham Act in 1946, the scope of trademark law was relatively narrow—advertising slogans, trade names, and product packaging were not protectable as trademarks.<sup>15</sup> These restrictions,

6. See 1 J. THOMAS MCCARTHY, *MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION* § 3:1 (4th ed. 2014) (quoting 15 U.S.C. § 1127) ("Under the modern definition of the term 'trademark,' both the common law and federal law follow the definition set forth in the federal Lanham Act: a trademark is a designation used 'to identify and distinguish' the goods of a person. Thus, the role that a designation must play to become a 'trademark' is to identify the source of one seller's goods and distinguish that source from other sources.>").

7. U.S. CONST. art. I, § 8, cl. 8. (endowing Congress with the power to enact laws for the protection of patents and copyrights, "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

8. See *The Trade-Mark Cases*, 100 U.S. 82, 94 (1879); MCCARTHY, *supra* note 6, § 6:2.

9. BARTON BEEBE ET AL., *TRADEMARKS, UNFAIR COMPETITION, AND BUSINESS TORTS* 27 (2011).

10. *Id.* at 13.

11. See *id.* at 27 (citing Mark McKenna, *The Normative Foundations of Trademark Law*, 82 NOTRE DAME L. REV. 1839 (2007)).

12. BEEBE, *supra* note 9, at 25.

13. Enacted pursuant to Congress's powers under the Patent and Copyright Clause, the first trademark statute was quickly struck down by the Supreme Court as beyond the scope of the congressional power. See *Trade-Mark Cases*, 100 U.S. at 94. In response, Congress enacted another trademark statute in 1881, this time using its Commerce Clause power. See BEEBE, *supra* note 9, at 26.

14. The Lanham Act of 1946, 15 U.S.C. § 1051, *et seq.* (2012).

15. See Glynn S. Lunney, Jr., *Trademark Monopolies*, 48 EMORY L.J. 367, 374 (1999); see also Walter J. Derenberg, *The Lanham Act of 1946: Practical Effects and Experiences*

in part, arose from the common law's requirement that a trademark be affixed to particular product in order to receive protection. But, in a larger sense, the prevailing understanding behind these restrictions was that consumers did not rely on slogans, trade names, and product packaging to identify the source of a particular product, and therefore such properties did not merit trademark protection.<sup>16</sup>

Nevertheless, the courts, the U.S. Patent and Trademark Office ("USPTO"), and, to a lesser extent, Congress have since widened the scope of trademark protection to shelter slogans, trade names, and trade dress. While the term "trademark" encompasses words, names, symbols, devices, or combinations thereof, "trade dress" means a product's packaging or design. A drug's size, shape, and color are aspects of its trade dress, and these features may also qualify for protection. Under the Lanham Act, producers may technically obtain a trademark on any distinctive word,<sup>17</sup> name,<sup>18</sup> symbol,<sup>19</sup> device,<sup>20</sup> packaging,<sup>21</sup> or design<sup>22</sup> as long as the producer uses that mark in commerce<sup>23</sup> to signal the good's source.<sup>24</sup> These marks must be used to identify and distinguish a producer's goods "from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown."<sup>25</sup> Courts have extended the scope of protectable subject matter to colors,<sup>26</sup> taste,<sup>27</sup> sound,<sup>28</sup> and smell.<sup>29</sup>

The current broad scope of trademark protection does have limits. Before a producer may obtain a trademark, she must demonstrate that her

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*After One Year's Administration*, 38 Trademark Rep. 831, 834 (1948). Nevertheless, advertising slogans and trade dress were protectable as trademarks under state unfair competition law at this time.

16. Lunney, *supra* note 15, at 374.

17. 15 U.S.C. § 1127 (2012).

18. *Id.*

19. *Id.*

20. *Id.*

21. 15 U.S.C. § 1125 (2012). Although trade dress can be registered with the Patent and Trademark Office under the Lanham Act, most trade dress and product configurations are protected without registration under Section 43(a) of the Lanham Act due to their "complex and changing nature." BEEBE, *supra* note 9, at 41.

22. 15 U.S.C. § 1125 (2012).

23. *Id.* § 1127.

24. See Barton Beebe, *Search and Persuasion in Trademark Law*, 103 MICH. L. REV. 2020, 2028-29 (2005).

25. 15 U.S.C. § 1127 (2012).

26. See *Qualitex Co. v. Jacobson Prods. Co., Inc.*, 514 U.S. 159 (1995) (holding that a green-gold color for dry cleaning press pads qualified for trademark registration).

27. See *In re N.V. Organon*, 79 U.S.P.Q.2d 1639 (T.T.A.B. 2006) (holding that taste, like color, only qualifies for registration upon a showing of secondary meaning).

28. See *In re Gen. Elec. Broad. Co., Inc.*, 199 U.S.P.Q. 560 (T.T.A.B. 1978) (holding that "Ship's Bell Clock" qualifies for registration if producer could show acquired distinctiveness).

29. See *In re Clarke*, 17 U.S.P.Q.2d 1238 (T.T.A.B. 1990) (holding that the plumeria flower fragrance on sewing thread and embroidery yarn qualifies for registration).

mark is distinctive.<sup>30</sup> Some marks, such as those that are fanciful,<sup>31</sup> arbitrary,<sup>32</sup> or suggestive,<sup>33</sup> are inherently distinctive; others, such as descriptive marks,<sup>34</sup> are only protectable if they have acquired a secondary meaning in the minds of consumers.<sup>35</sup> Importantly, generic marks are not protectable at all.<sup>36</sup> Therefore, generic names of drugs cannot be trademarked.

To qualify as inherently distinctive, trade dress must consist of the product's packaging; trade dress that centers on the product's configuration or design cannot be inherently distinctive.<sup>37</sup> Though murky, the distinction between product packaging and design rests on whether the dressing merely indicates the origin of the product (product packaging) or serves to enhance the product's appeal or usefulness (product design).<sup>38</sup> A product's useful features cannot be trademarked because a producer cannot trademark any product feature that "is essential to the use or purpose of the article or . . . affects the cost or quality of the article."<sup>39</sup>

Some academics rationalize the growth in scope of trademark protection as a necessary corollary to market expansion and product diversification in the twentieth century.<sup>40</sup> Other academics, however, note "much of this ex-

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30. 15 U.S.C. § 1052(f) (2012); *KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111, 122 (2004).

31. Fanciful trademarks are coined words or phrases that have no inherent meaning or relationship to the product they mark (for example, *Pepsi*®, *Kodak*®, or *Exxon*®). *See Zatarains, Inc. v. Oak Grove Smokehouse, Inc.*, 698 F.2d 786, 791 (5th Cir. 1983), *abrogated on other grounds by KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111 (2004).

32. Arbitrary trademarks are those that bear no semantic relationship to the products that they mark, but consist of a preexisting word or phrase, for example, *Apple*® for computers and *Camel*® for cigarettes. *See Zatarains*, 698 F.2d at 791.

33. Trademarks such as *Coppertone*® or *Amtrak*® are classified as suggestive marks because, although these trademarks do not technically describe their products, they suggest a meaning in the consumer's mind. *Id.* at 791.

34. Descriptive marks "identif[y] a characteristic or quality of an article or service." *Vision Center v. Opticks, Inc.*, 596 F.2d 111, 115 (5th Cir. 1979). For example, *American Airlines*® qualifies as a descriptive mark because it identifies the type of airline.

35. *See Abercrombie & Fitch Co. v. Hunting World, Inc.*, 537 F.2d 4, 9 (2d Cir. 1976). In *Abercrombie & Fitch Co. v. Hunting World, Inc.*, Judge Friendly created a test, now known as the *Abercrombie* Test, under which trademarks are classed as generic, descriptive, suggestive, arbitrary, or fanciful.

36. Generic marks are those that describe an entire type or category of products (for example, use of the word "escalator" to describe a particular brand of escalators). *See id.* at 9; *BEEBE*, *supra* note 9, at 59. A mark can become generic when enough of the population begins to use it not to indicate a *particular* product, but rather to describe a *type* of product. For example, the once-trademarked words *Xerox* and *Kleenex* are now arguably generic because they have become synonymous with photocopying machines and tissues, respectively. *See BEEBE*, *supra* note 9, at 70-71, 75-77.

37. *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 212, 216 (2000).

38. *Id.* at 212-13.

39. *TraFFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 32 (2001) (quoting *Qualitex Co. v. Jacobson Prods. Co., Inc.*, 514 U.S. 159, 165 (1995)).

40. *See Lunney*, *supra* note 15, at 374.



pansion has little to do with any plausible concern over consumer deception and rests squarely on the sense that someone who creates something of value ought to receive the fruits of her labors.”<sup>41</sup>

B. *Quality Insurers or Desire Manipulators? The Scholarly Debate Over the Effect of Trademark Protection*

The conventional justification for trademark protection is two pronged: Trademarks minimize consumer confusion and ensure manufacturers maintain consistent product quality.<sup>42</sup> Because trademarks enable consumers to locate specific products, these marks reduce the consumer confusion that a marketplace replete with options could otherwise generate. As Judge Easterbrook explained in *Scandia Down Corp. v. Euroquilt, Inc.*, “[b]y identifying the source of the goods, [trademarks] convey valuable information to consumers at lower costs. Easily identified trademarks reduce the costs consumers incur in searching for what they desire, and the lower the costs of search the more competitive the market.”<sup>43</sup>

In theory, trademarks also provide producers with incentives to manufacture products of consistent quality; a trademark is only valuable insofar as consumers trust that all products bearing its mark are of the same quality. As J. Thomas McCarthy explains in his canonical treatise on trademark law:

Since a trademark is not only a symbol of origin, but a symbol of a certain type of goods or services and their level of quality, a sudden and substantial change in the nature or quality of the goods sold under a mark may so change the nature of the thing symbolized that the mark becomes fraudulent and/or that the original rights are abandoned.<sup>44</sup>

The scholarly debate over the impact of trademark law and the appropriate scope of its protection centers on a normative disagreement regarding which party—the consumer or the producer—ultimately controls the value of a trademark. Are we “impossibly utilitarian consumers,”<sup>45</sup> who coolly and rationally evaluate the worth of a particular good, or are we “Pavlovian fools,”<sup>46</sup> who fall prey to corporate manipulation of our desires and opinions? The following sections explore each side of this debate via the theories of their key proponents. Informed by business and advertising literature, the final section reexamines a legal perspective on trademarks.

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41. *Id.*; see also BEEBE, *supra* note 9, at 26-27.

42. See McCARTHY, *supra* note 8, § 3:2; BEEBE, TRADEMARKS, *supra* note 9, at 30.

43. 772 F.2d 1423, 1429 (7th Cir. 1985).

44. McCARTHY, *supra* note 6, § 17:24 (internal footnote omitted).

45. Beebe, *supra* note 24, at 2023.

46. *Id.*

## i. The Economic Model of Trademark Law

Many legal scholars argue that trademark law promotes economic efficiency by encouraging firms to cater to the desires of rational consumers.<sup>47</sup> The originators of this argument—known as the economic model of trademark law—are Richard Posner and William Landes. They argue that the exclusive right to trademark protection encourages producers to improve the quality of their products.<sup>48</sup> They warn that, without strong trademark protection, imitators will free ride on the goodwill the primary producer has acquired for her mark and “eventually destroy the information capital embodied in a trademark.”<sup>49</sup> These scholars fear that the prospect of free riding may “eliminate the incentive to develop a valuable trademark in the first place.”<sup>50</sup>

One must recognize that this argument assumes consumer valuations of trademarks reflect the quality of the products they mark. As trademark scholar Barton Beebe explains, under the economic model of trademark law, the consumer “satisfies exogenously determined preferences, on which trademarks are said to have no effect.”<sup>51</sup> Thus, Landes and Posner dismiss “the power of brand advertising to bamboozle the public and thereby promote monopoly.”<sup>52</sup>

Yet, Landes and Posner are not blind to their assumption.<sup>53</sup> They acknowledge that the notion of an entirely rational consumer appears at odds with the reality of purchaser brand preferences, even when the branded and generic goods are “produced according to an identical formula, such as aspirin or household liquid bleach.”<sup>54</sup> Nevertheless, Landes and Posner argue that such preferences can still be understood as rational if they stem from concerns about manufacturing competencies:

The fact that two goods have the same chemical formula does not make them of equal quality to even the most coolly rational consumer. That consumer will be interested *not in the formulation but*

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47. See, e.g., William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & Econ. 265, 266 (1987); Peter S. Menell, *Intellectual Property: General Theories*, 2 ENCYCLOPEDIA OF LAW AND ECONOMICS 129, 149 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000); Jerre B. Swann, Sr., *Dilution Redefined for the Year 2002*, 92 TRADE-MARK REP. 585, 617 (2002).

48. Landes & Posner, *supra* note 47, at 265-66.

49. *Id.* at 270.

50. *Id.*

51. Beebe, *supra* note 24, at 2023.

52. Landes & Posner, *supra* note 47, at 274-75.

53. See *id.* at 274 (“We have assumed that a trademark induces its owner to invest in maintaining uniform product quality, but another interpretation is that it induces the owner to spend money on creating, through advertising and promotion, a spurious image of high quality that enables monopoly rents to be obtained by deflecting consumers from lower-price substitutes of equal or even higher quality.”).

54. *Id.*

*in the manufactured product and may therefore be willing to pay a premium for greater assurance that the good will actually be manufactured to the specifications of the formula.* Trademarks enable the consumer to economize on a real cost because he spends less time searching to get the quality he wants.<sup>55</sup>

Therefore, Landes and Posner rationalize the need for trademarks even among formulaically identical products based on the risk of human error in the reproduction of those formulas. Part II.D will revisit this argument, as it is critical to assessing the value of trademark protection in the pharmaceutical industry, where generic medications are bioequivalent to branded medications.

## ii. Trademarks as Artificial Product Differentiators

In contrast to Landes and Posner's inherent trust of consumer rationality, other legal scholars are skeptical of the capacity of trademarks to enhance economic efficiency. These scholars recognize that producers have both the incentive and ability to manipulate consumer goodwill through advertising and marketing. They argue that trademark protection thwarts competition and creates monopolistic returns to producers by artificially differentiating between products. Although this view of trademark law is not the dominant one, it has maintained a strong contingency of supporters since the early twentieth century.<sup>56</sup> Despite its overall decline in popularity, it has enjoyed a recent surge in recognition due to the rise of behavioral economics.<sup>57</sup>

Economist Edward Chamberlin's publication of *The Theory of Monopolistic Competition* in 1933 largely drove the scholarly community's acknowledgement of the anticompetitive effects of trademark law.<sup>58</sup> Chamberlin explained that strong trademark protection enables a producer to differentiate his product and persuade consumers that his brand, and only his brand, will satisfy the consumers' demand.<sup>59</sup> This manipulation, in turn, allows the producer to achieve a monopoly in his distinct market.<sup>60</sup> Nevertheless,

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55. *Id.* at 275 (emphasis added).

56. See BEEBE, *supra* note 9, at 32.

57. See Beebe, *supra* note 24, at 2023 (citing Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471 (1998); Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: The Problem of Market Manipulation*, 74 N.Y.U. L. REV. 630, 640-93 (1999)).

58. See BEEBE, *supra* note 9, at 32; Lunney, *supra* note 15, at 368.

59. EDWARD CHAMBERLIN, *THE THEORY OF MONOPOLISTIC COMPETITION* 56, 204 (1933).

60. *Smith v. Chanel, Inc.*, 402 F.2d 562, 567 (9th Cir. 1968) (“[T]o the extent that [brand] advertising [succeeds] . . . the trademark is endowed with sales appeal independent of the quality or price of the product to which it is attached; economically irrational elements are introduced into consumer choices; and the trademark owner is insulated from the normal pres-

Chamberlin did not argue that trademarks have no utility;<sup>61</sup> he recognized the value of product differentiation and its corresponding ability to reduce consumer search costs. But one of the primary achievements of Chamberlin's work was revealing the economic inefficiency of trademark protection. Through artificial product differentiation, trademark protection enables manufacturers to capture consumer loyalty in a detrimental manner.

Chamberlin's contemporary, Frank Schechter, also appreciated the importance of artificial product differentiation. In *The Rational Basis of Trademark Protection*, Schechter argued "the value of the modern trademark lies in its selling power."<sup>62</sup> He explained that "this selling power depends for its psychological hold upon the public, not merely upon the merit of the goods upon which it is used, but equally upon its own uniqueness and singularity."<sup>63</sup> Ultimately, Schechter recognized that consumers often pursue distinctiveness for its own sake.<sup>64</sup>

The work of Chamberlin and Schechter not only influenced the views of fellow scholars, but also swayed lawmakers and judges.<sup>65</sup> Justice Frankfurter's famous trademark opinion in *Mishawaka Rubber & Woolen Manufacturing Co. v. S.S. Kresge Co.* bears the imprint of Schechter's and Chamberlin's observations:

A trademark is a merchandising short-cut which induces a purchaser to select what he wants, *or what he has been led to believe he wants*. The owner of a mark exploits this human propensity by making every effort to impregnate the atmosphere of the market with the drawing power of a congenial symbol. Whatever the means employed, the aim is the same—to convey through the mark, in the minds of potential customers, the desirability of the commodity upon which it appears.<sup>66</sup>

In contrast to Landes and Posner, Frankfurter emphasizes the endogeneity of a particular trademark's value: a trademark acquires worth not simply through the quality of the product it marks, but also through the producer's ability to persuade consumers that the mark *itself* is valuable.

Despite their influence in the early and mid-twentieth century, Chamberlin and Schechter's arguments began to lose traction within the le-

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asures of price and quality competition. In consequence the competitive system fails to perform its function of allocating available resources efficiently.”)

61. CHAMBERLIN, *supra* note 59, at 85 (“The main point I want to make is that the welfare ideal itself (as well as the description of reality) involves a blend of monopoly and competition.”).

62. Frank I. Schechter, *The Rational Basis of Trademark Protection*, 40 HARV. L. REV. 813, 830-31 (1927).

63. *Id.*

64. Beebe, *supra* note 24, at 2043-44.

65. Lunny, *supra* note 15, at 368.

66. 316 U.S. 203, 205 (1942) (emphasis added).

gal community in the second half of the twentieth century. Some trademark scholars began to argue that trademarks were simply property, not monopolistic tools.<sup>67</sup> They ridiculed those who believed that trademarks led to monopolies as “infected with monopoly-phobia.”<sup>68</sup> Like Landes and Posner, these theorists contended that trademarks simply enable consumers to distinguish between competing goods.<sup>69</sup> Today, the courts largely subscribe to Landes and Posner’s economic analysis of trademark law.<sup>70</sup>

Chamberlin and Schechter’s arguments, however, are far from dead. In the second half of the twentieth century, the work of Ralph Brown reaffirmed Chamberlin’s core points.<sup>71</sup> An avid trademark restrictionist, Brown viewed trademark law as an instrument of consumer manipulation:

Most advertising . . . is designed not to inform, but to persuade and influence.

. . . .

. . . [D]oes the sovereign consumer have real freedom of choice? . . . National advertising is dominated by appeals to sex, fear, emulation, and patriotism, regardless of the relevance of those drives to the transaction at hand. The purchase of many advertised articles, then, has a raw emotional origin. Many others are compelled by the endless reiteration of the advertisers’ imperative: eat lemons, drink milk, wear hats. Pseudo-information fills any gaps. It takes many forms. There is the bewildering manipulation of comparatives and superlatives: “No other soap washes cleaner”; “The world’s most wanted pen.”<sup>72</sup>

Despite this cynicism, Brown, like Chamberlin, recognized that advertising could serve a useful function insofar as it provides truthful information to

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67. See Lunney, *supra* note 15, at 370.

68. See *Eastern Wine Corp. v. Winslow-Warren, Ltd.*, 137 F.2d 955, 958 (2d Cir. 1943) (“There are some persons, infected with monopoly-phobia, who shudder in the presence of any monopoly.”). See also *Standard Brands, Inc. v. Smidler*, 151 F.2d 34, 42 n.18 (2d Cir. 1945) (Frank, J., concurring); 1 RUDOLF CALLMANN, *THE LAW OF UNFAIR COMPETITION AND TRADEMARKS* § 15.5, at 225 (2d ed. 1950) (arguing that judicial monopolophobia improperly limited the scope of trademark protection); Beverly W. Pattishall, *Trademarks and the Monopoly Phobia*, 50 MICH. L. REV. 967 (1952).

69. See Lunney, *supra* note 15, at 369.

70. See BEEBE, *supra* note 9, at 28; Lunney, *supra* note 15, at 371-72 (“[C]ourts and commentators succumbed to ‘property mania’—the belief that expanded trademark protection was necessarily desirable so long as the result could be characterized as ‘property.’”).

71. See Ralph S. Brown, *Advertising and the Public Interest: Legal Protection of Trade Symbols*, 57 YALE L.J. 1165, 1171 n.29 (1948), reprinted in 108 YALE L.J. 1619, 1638 (1999) (citing CHAMBERLIN, *supra* note 59).

72. Brown, *supra* note 71, at 1169, 1182.

consumers.<sup>73</sup> Beyond this informational value, Brown believed that advertising often wastes resources<sup>74</sup> and induces irrational consumer preferences.<sup>75</sup> Brown rejected the notion that the law should protect a trademark as property in and of itself.

Legal scholars continue to analyze the occasional anticompetitive effects of trademark law.<sup>76</sup> Some of these scholars have argued that consumers are victims of the persuasive effects of well-designed trademarks,<sup>77</sup> while others are more wary of this characterization of consumer freewill.<sup>78</sup> Yet, all of these scholars acknowledge that heightened trademark protection can inefficiently impede competition through artificial product differentiation.<sup>79</sup> As one intellectual property scholar notes, “the economic case for brands and advertising is undone to the extent that trademarks are used in ways that affirmatively confuse consumers.”<sup>80</sup>

### iii. Business and Advertising: Non-Legal Perspectives on the Value of Trademarks

Lawyers are not alone in investigating the persuasive, non-informational function of trademarks.<sup>81</sup> In the fields of business, marketing, and advertis-

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73. *Id.* at 1168, 1182 (“From the point of view of the economic purist, imparting information is the only useful function of advertising” and consumers should be “willing to pay the necessary price for information”).

74. *Id.* at 1168.

75. *Id.* at 1182-83.

76. *See, e.g.*, Jeremy N. Sheff, *Biasing Brands*, 32 *CARDOZO L. REV.* 1245, 1272 (2011); Mark A. Lemley, *The Modern Lanham Act and the Death of Common Sense*, 108 *YALE L.J.* 1687, 1689 (1999); Lunney, *supra* note 15, at 420 n.212.

77. *See, e.g.*, Sheff, *supra* note 76, at 1272 (“Some of a brand’s economic value—and in some markets perhaps the largest contribution to its value—lies not in the information it conveys about the underlying product, but in the consumer’s psychological responses to the brand itself.”); Lunney, *supra* note 15, at 420 n.212 (“[T]o the extent that advertising and a trademark successfully generate an unthinking buying response—a trained reaction to the presence of a trademark where perception of the mark stimulates hand to wallet without conscious thought—does that represent a legitimate form of welfare enhancement? Were Pavlov’s dogs happier after they had been trained to salivate at the sound of a dinner bell?”).

78. Robert G. Bone, *Enforcement Costs and Trademark Puzzles*, 90 *VA. L. REV.* 2099, 2116 (2004) (“Just because advertising creates new preferences in addition to supplying information to help satisfy preferences already formed does not mean that the induced preferences are ‘irrational’ or ‘bad’ or that they should count as a social cost in considering whether to protect the mark.”); Lemley, *supra* note 76, at 1692-93 (arguing that the distinction between informational and persuasive advertising is troubling “because it impels [the conclusion] that an enormous number of consumers do not really want what they think they want; they have been duped by unscrupulous marketers.”); Jessica Litman, *Breakfast with Batman: The Public Interest in the Advertising Age*, 108 *YALE L.J.* 1717, 1727 (1999) (“Anecdotal evidence suggests that many consumers don’t feel duped, or, in any event, don’t mind being duped.”).

79. *See* Lemley, *supra* note 76, at 1695-96.

80. *Id.* at 1695-96.

81. *See, e.g.*, Roger Feldman & Félix Lobo, *Competition in Prescription Drug Markets: the Roles of Trademarks, Advertising, and Generic Names*, 14 *EUR. J. HEALTH ECON.* 667, 667 (2012). These public health academics note that “trademarks can have anticompetitive ef-

ing, specialists accept and even laud the ability of producers to use trademarks to serve non-informational roles. In the early twentieth century, branding gurus, such as Earnest Elmo Calkins, began to develop “the idea that manufacturers should strive to position their brands as concrete expressions of valued social and moral ideals.”<sup>82</sup> Calkins advocated a form of advertising that depicted products as material embodiments of people’s ideals even if these portrayals were only tenuously related to the product’s functional benefits.<sup>83</sup> Today, advertising and marketing specialists take as a given that brands have a strong psychological impact. Brands can be used to signal a certain lifestyle or set of values,<sup>84</sup> and consumers often derive psychological satisfaction from the purchase of brands that reinforce their self-image.<sup>85</sup>

Trademark law assumes branding exists solely to inform the consumer, but branding also shows important persuasive effects. Tim Ambler, a leading business and marketing scholar, notes that consumers make purchases based on their mental comfort with a particular item, rather than a rational analysis of the product’s merits. He explains:

Consumer research conducted over the last decade or so suggests strongly that consumers show very limited desire for receiving and using “objective” product information. They do not, as a rule, undertake rational, comparative evaluations of brands on the basis of their attributes or make final judgments among brands on the basis of such outputs of complex information processing as attitudes and intentions. This has long been recognised but the belief was that consumers made some analysis at some stage and kept the selected brands in a preference set thereafter. More recently, [studies] have suggested that, in many cases, consumers do not think at all. Their

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fects.” *Id.* They argue that the “[t]he culprit is advertising, which creates a ‘mental tie’ between the trademark and the physical commodity, leading to several distortions: monopoly power in the advertised goods; wasteful proliferation of brands; and a distortion in the minds of consumers regarding the desirability of the product.” *Id.* Neuroscientists have also documented the distorting effects of trademarks on consumer preferences. See Samuel M. McClure et al., *Neural Correlates of Behavioral Preference for Culturally Familiar Drinks*, 44 NEURON 379, 379-87 (2004). These researchers employed functional magnetic resonance imaging in anonymous and brand-cued taste tests of Coke® and Pepsi® to reveal how “brand knowledge” affects preferences. *Id.* at 380.

82. Douglas B. Holt, *Why Do Brands Cause Trouble? A Dialectical Theory of Consumer Culture and Branding*, 29 J. CONSUMER RES. 70, 80 (2002) (citing JACKSON LEARS, *FABLES OF ABUNDANCE: A CULTURAL HISTORY OF ADVERTISING IN AMERICA* (1995)).

83. *Id.*

84. Aron O’Cass & Emily Frost, *Status Brands: Examining the Effects of Non-Product-Related Brand Associations on Status and Conspicuous Consumption*, 11 J. PRODUCT & BRAND MGMT. 67, 67-69 (2002).

85. Tim Ambler, *Do Brands Benefit Consumers?*, 16 INT’L J. ADVERT. 167, 188-89 (2015).

findings could be interpreted as meaning that originally random choices are then maintained if consumers feel them to be right.<sup>86</sup>

Although these recent studies reveal the irrationality of consumer preference in an economic sense, Ambler defends the psychological effect of brands: “[a] consumer is entitled to spend his money in a way that maximizes his total satisfaction which is a state of his own mind, not an independent analysis of product utilities by a laboratory.”<sup>87</sup> In other words, if a consumer purchases a Gucci handbag to signal her social status or fashion savvy, the purse’s quality is irrelevant. In that scenario, the brand is important not because it informs the consumer of the purse’s source, but because it is itself a commodity; this phenomenon explains why some consumers readily seek out Gucci handbags they know to be counterfeits. Moreover, researchers also find that consumers can obtain psychological fulfillment from the familiarity of a brand. Habit often guides brand selection:<sup>88</sup> Consumers do not buy a particular brand because they like it; they like that brand because the habit of purchasing it is reassuring.<sup>89</sup>

Trademark law was not designed to protect the psychological merits of brands. As the history of trademark law makes clear, the law protects brands to ensure consumers are not deceived—trademarks were intended to play an informational role. Therefore, marketing research describing the psychological impact of branding serves to strengthen the arguments of critics of the economic theory of trademarks like Brown, Lunney, Chamberlin, and Schechter.

This research also supports the argument advanced by this Article: pharmaceutical trademarks are inefficient because their psychological influence induces consumers to behave irrationally. If trademarks lead patients to believe that branded medications—and only branded medication—can satisfy their needs, then pharmaceutical trademarks increase confusion rather than reduce it.

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86. *Id.* at 185 (internal citations omitted).

87. *Id.* at 186.

88. *Id.* at 181 (citing JOHN O’SHAUGHNESSY, *WHY PEOPLE BUY* (1987)).

89. Ambler, *supra* note 85, at 187 (“Brand loyalty may reflect, therefore, only the convenience inherent in repetitive behavior rather than commitment to the brand purchased.”) (citing S.H. Chaffee & J. M. Macleod, *Consumer Decisions and Information Use*, *Consumer Behavior: Theoretical Sources* 385 (S. Ward & T.S. Robertson eds., 1973) and Thomas S. Robertson, *Low-Commitment Consumer Behavior*, 16 *J. ADVERT. RES.* 19 (1976)).



## II. ALLERGIC TO GENERICS: CONSUMER CONFUSION ARISING FROM TRADEMARKS AND DRESS

Brand name pharmaceutical manufacturers have spent billions of dollars advertising their products<sup>90</sup> to ensure that consumers recognize drugs by their name, color, and shape.<sup>91</sup> The trademarks and dress of popular medications are etched into our cultural conscious and vocabulary. But is this branding actually useful to consumers? After providing a brief overview of pharmaceutical trademarks and nomenclature, this Part argues that pharmaceutical trademarks not only fail to reduce consumer confusion, but actually increase it. Furthermore, pharmaceutical trademarks and trade dress do not play a significant role in ensuring consistent product quality. Drawing on these conclusions, this Article demonstrates that the harms associated with pharmaceutical trademarks not only outweigh their benefits, but also cause the very inefficiencies trademarks aim to prevent.

### A. Background: Pharmaceutical Trademarks and Nomenclature

Every drug approved by the Food and Drug Administration (“FDA”) has three separate names: a chemical name, a generic (non-proprietary) name, and a brand (proprietary) name.<sup>92</sup> For example, Tylenol® is the brand name of the drug that has the chemical name N-(4-hydroxyphenyl) acetamide and the generic name acetaminophen. A drug’s chemical name describes its chemical makeup, and physicians and pharmacists rarely use this name in practice.<sup>93</sup>

A drug’s generic name is usually composed of a medically significant stem and a chemically significant root, and it directs physicians and pharmacists to a particular drug class.<sup>94</sup> Like other generic marks, generic drug names are not eligible for trademark protection.<sup>95</sup> In the United States, drugs

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90. See CONG. BUDGET OFFICE, PROMOTIONAL SPENDING FOR PRESCRIPTION DRUGS (2009); Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 673 (2007).

91. See, e.g., Dipak C. Jain & James G. Conley, *Patent Expiry and Pharmaceutical Market Opportunities at the Nexus of Pricing and Innovation Policy*, in INNOVATION AND MARKETING IN THE PHARMACEUTICAL INDUSTRY 255 (Min Ding et al. eds., 2014) (detailing the extensive advertising campaign that AstraZeneca undertook to market Prilosec®, a popular gastroesophageal reflux disease (GERD) medication).

92. See Roger Feldman & Félix Lobo, *Competition in Prescription Drug Markets: the Roles of Trademarks, Advertising, and Generic Names*, 14 EUR. J. HEALTH ECON. 668 (2012); Carol Rados, *Drug Name Confusion: Preventing Medication Errors*, 39 FDA CONSUMER 35, 36 (2005).

93. See Rados, *supra* note 92, at 37.

94. Dana M. Herberholz, *Curing Confusion: An Overview of the Regulatory Complexities of Obtaining Pharmaceutical Trademarks and A Prescription for Reform*, 8 MINN. J.L. SCI. & TECH. 97, 108 (2007) (citing Rados, *supra* note 92, at 37).

95. See Linda Gundersen, *The Complex Process of Naming Drugs*, 129 ANNALS INTERNAL MED. 677, 677-78 (1998). It is important to note that the word “generic” has a different meaning in the context of trademark law as opposed to patent law. Thus far, this paper has

obtain their generic names from the United States Adopted Names Council (“USAN Council”),<sup>96</sup> which gives generic names to all FDA approved medications.<sup>97</sup> After both the World Health Organization and USAN Council approve a generic name, the USAN Council publishes that name in the Trademark Bulletin of the Pharmaceutical Research and Manufacturers of America as well as the Pharmacopeia Forum.<sup>98</sup>

Drug companies give their medications proprietary names in order to improve consumer recognition of their products.<sup>99</sup> “Unlike a drug’s generic name, which is intended to describe its function or structure, a proprietary name is typically coined by consulting firms with expertise in prescription drug ‘naming.’”<sup>100</sup> In contrast to generic drug names, proprietary names are eligible for trademark protection.<sup>101</sup>

The FDA is primarily responsible for reviewing and approving proprietary drug names and their subsequent trademarks.<sup>102</sup> This authority is rooted in the FDA’s responsibility to regulate misleading drug labeling.<sup>103</sup> The USPTO also routinely reviews pharmaceutical trademarks.<sup>104</sup>

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used the word “branded” to refer to pioneer drugs – those that are or were once protected by a patent – and “generic” to refer to their bioequivalent counterparts. As previously discussed, in trademark law, the term “generic” simply means a name that references the class or type of product. In the pharmaceutical industry, a generic drug producer – a producer that manufactures a bioequivalent version of a pioneer drug – could choose to give its product a trademarked name. Although the drug’s actual generic name cannot be trademarked, the generic producer could give that drug another name that could be trademarked. For example, Advil®, Motrin®, and Midol®, are trademarked brands of the generic drug Ibuprofen. Although the manufactures of Advil®, Motrin®, and Midol® could not trademark the name “Ibuprofen,” because it is the drug’s generic name, these manufacturers did create different proprietary names for this drug and trademarked them accordingly. Although Advil®, Motrin®, and Midol® are all technically “branded” drugs, this paper has used the term “branded” to refer to pioneer drugs – the drugs that originally received patent protection and therefore were the first version available. To avoid confusion, this paper will continue to refer to pioneer drugs as “branded” medications, even though it is also possible for generic drugs to have a brand.

96. The USAN Council “is a private organization composed of three sponsoring organizations: the American Medical Association, United States Pharmacopeia, and the American Pharmaceutical Association.” Herberholz, *supra* note 94, at 108 (citing 21 C.F.R. § 299.4(c) (2015)).

97. Eva Vivian, *Overview of Generic Drugs and Drug Naming*, MERCK MANUAL, <http://www.merckmanuals.com/home/drugs/brand-name-and-generic-drugs/overview-of-generic-drugs-and-drug-naming> (last visited Oct. 6, 2015).

98. See Gundersen, *supra* note 95, at 677-78.

99. Herberholz, *supra* note 94, at 109.

100. *Id.*

101. See *supra* Part I.A.

102. Deirdre A. Clarke, *Proprietary Drug Name Approval: Taking the Duel Out of the Dual Agency Process*, 12 LOY. J. PUB. INT. L. 433, 442 (2011).

103. Stephen C. Clifford, *The Name Game: Creating a Trademark for a New Drug Product*, 2 DRUG DEV. & DELIVERY (2002), <http://drug-dev.com/Main/Back-Issues/The-Name-Game-Creating-a-Trademark-for-a-New-Drug-512.aspx>; see also 21 U.S.C. § 352(a) (2012); 21 C.F.R. 201.10(c)(5) (2015).

104. See Clarke, *supra* note 102, at 436-37; Clifford, *supra* note 103.

[The] FDA's focus is patient safety while the USPTO's focus is consumer confusion as to the product's source in the marketplace.<sup>49</sup> Specifically, the [FDA] must determine whether there is a potential safety or health risk based on the proprietary drug name candidate's likelihood to be confused with other drug names. . . . The FDA does not simply focus on the consumer's confusion but also focuses on the health care provider or pharmacist's ability to become confused.<sup>105</sup>

Together, the FDA and USPTO attempt to ensure that a drug's proprietary name is neither misleading nor confusing to consumers.<sup>106</sup>

For a given drug, pharmaceutical companies often obtain trademark protection on the medication's proprietary name as well as trade dress protection on the drug's design (size, shape, and color).<sup>107</sup> Although courts have sometimes invalidated a pharmaceutical firm's trade dress on the grounds that the design is functional and not merely decorative,<sup>108</sup> most firms are able to protect the colors and shapes of their medications as long as they can show that such designs have obtained a secondary meaning in the minds of consumers.<sup>109</sup>

Both a pioneer drug's proprietary name and design are critical to its competitive advantage once its patents expire and generic producers are able to enter the market. First, physicians overwhelmingly refer to medications, irrespective of the availability of generic formulations, by their brand names.<sup>110</sup> Second, because prescription drugs are repackaged at a pharmacy before they are sold to consumers,<sup>111</sup> a medication's "unique shape and color

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105. Clarke, *supra* note 102, at 442; *see also* Clifford, *supra* note 103.

106. Nevertheless, these agencies do not always perform this task perfectly. Instances of prescription name confusion due to similar product names and/or poor physician writing do occur.

107. *See generally* Julia Anne Matheson, *Trade Dress Protection: Eye Candy*, FINNEGAN (April 2009), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=6f96c9cf-3975-4729-a04d-2e8f2d271a75>.

108. *See, e.g.*, *Shire U.S. Inc. v. Barr Laboratories, Inc.*, 329 F.3d 348 (3d Cir. 2003) (holding that the trade dress of Shire's drug, Adderall, was invalid due to its functionality).

109. *See* Jeremy A. Greene & Aaron S. Kesselheim, *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health*, 365 NEW ENG. J. MED. 83, 86 (2011) ("[C]laims of trade dress remain vital in the pharmaceutical market.").

110. Michael A. Steinman, Mary-Margaret Chren & Seth Landefeld, *What's in a Name? Use of Brand Versus Generic Drug Names in United States Outpatient Practice*, 22 J. GEN. INTERNAL MED. 645, 646 (2007) (finding that physicians use the brand name of a medication 100 percent of the time when the drug does not face any generic competition and use the brand name 79 percent of the time when generic competition is present).

111. David M. Fritch, *Should "The Purple Pill" by Any Other Drug Company Still Be As Purple? The Changing Face of Trade Dress Protection for Pharmaceutical Manufacturers*, 47 IDEA 171, 181 (2006) ("Prescription drugs, however, are repackaged by the dispensing pharmacy in bottles which contain no easily identifiable designation of source, unique packaging or individual labeling trade dress to distinguish it." (internal quotation marks omitted)).

is a crucial means of . . . influencing consumer preference.”<sup>112</sup> Pharmaceutical companies carefully select the trade dress of their products so that a medication’s design becomes a “fundamental part of [the] drug[’s] personality.”<sup>113</sup>

[D]rug companies probe the consumer’s subconscious mind when they select a drug’s appearance. Glossy, two-tone capsules, for example, have a sophisticated look thought to appeal to younger buyers. Color is particularly important: Blue is masculine (Viagra is blue), red is bold and stimulating, pink is feminine, and AstraZeneca representatives describe purple as an “attractive yet dignified” shade.<sup>114</sup>

The effect of trade dress protection on consumer purchasing behavior leads pharmaceutical companies to invest heavily in the drug naming and design processes.

### B. Consumer Confusion Resulting from Product Differentiation

#### i. Are Generics and Brands Equivalent?

As discussed in the previous section, trademark theorists justify trademarks based on their ability to help consumers differentiate between similar products, therein lowering consumer search costs and reducing consumer confusion. To serve this intended purpose, the goods that trademarks distinguish must actually *be* different. If two products are identical, there is no reason for consumers to distinguish between them: any differentiation would be artificial. Therefore, to justify the use of trademarks in the pharmaceutical industry, one must be able to show that generic and brand name medications actually—or could—differ.<sup>115</sup> Yet, all available evidence suggests they do not.

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112. *Id.*; see also Jain & Conley, *supra* note 91, at 268.

113. Jill Morton, *The Color of Medications: Taking the Color of Medications Seriously*, COLOR MATTERS, [http://www.colormatters.com/body\\_pills.html](http://www.colormatters.com/body_pills.html) (last visited Jan. 26, 2013).

114. Charles W. Schmidt, *Have I Got a Drug for You!*, 4 MODERN DRUG DISCOVERY 41, 41 (2001).

115. When two drugs are similar, but not actually bioequivalent, trademark protection enables a company to signal these differences to consumers. Under these circumstances, product differentiation would not be artificial. In *SK & F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, the Third Circuit confronted such a situation. 625 F.2d 1055 (3d Cir. 1980). The case concerned two very similar diuretic drugs that contained the same active ingredient, but were not bioequivalent (the bioavailability, or rate of absorption into the blood stream, of the two drugs differed). See Greene & Kesselheim, *supra* note 109, at 84. When the manufacturer of the generic version of the diuretic medication, Premo, copied branded drug’s color scheme, the producer of the branded diuretic, SK&F, sued for trade dress infringement. See *SK & F*, 625 F.2d at 1057-58. The Third Circuit concluded that Premo’s copying of SK&F’s trade dress was actionable because:

In 1984, Congress amended the Food, Drug, and Cosmetics Act (“FDCA”), leading the FDA to issue regulations requiring bioequivalence between generic and branded drugs. These regulations ensure that all generic drugs have the same effects as their brand name counterparts. To qualify as a generic medication, the producer of such a drug must prove to the FDA that its drug has the same “dosage form, safety, strength, route of administration, quality, performance characteristics[,] and intended use”<sup>116</sup> as its branded counterpart.<sup>117</sup>

Substantial scientific research shows that generic drugs live up to this test. Many studies document the bioequivalence of generic and brand name drugs, even for medications with narrow therapeutic indices.<sup>118</sup> Studies

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SKF’s reputation would be irreparably injured by the substitution of Premo’s product for [SK&F’s product] because . . . the two products are not bioequivalents. Unknowing or willful substitution even if legally permissible would expose SKF not only to the risk of patient and physician dissatisfaction if the patient reacted to the substitute drug differently, but also to the risk of suit for the resulting consequences.

*SK & F*, 625 F.2d at 1066. Thus, the court concluded that Premo’s trade dress merited protection because it helped consumers distinguish between two products that were actually different. Similarly, in *Pennwalt v. Zenith Laboratories*, a Michigan district court enjoined a company from manufacturing a version of the diet pill phentermine that possessed similar trade dress to the brand name version of that drug because the two products were not interchangeable. 472 F. Supp. 413 (E.D. Mich. 1979). In both cases, the courts found for the pioneer brands because their trade dress actually served its intended function – preventing consumer confusion between two pills that were not equivalent.

116. *Generic Drugs: Questions and Answers*, FDA, <http://www.fda.gov/drugs/resources-for-you/consumers/questionsanswers/ucm100100.htm> (last visited Sept. 13, 2015).

117. 21 U.S.C. § 355(j)(2)(A)(iv) (2012); *see also* Fritch, *supra* note 111, at 201 (“The FDA requires that: generic drugs must have the same active ingredients and the same labeled strength as the brand-name product[,] [g]eneric drugs must have the same dosage form (for example, tablets, liquids) and must be administered in the same way[,] [g]eneric drug manufacturers must show that a generic drug is bioequivalent to the brand-name drug, which means the generic version delivers the same amount of active ingredients into a patient’s bloodstream in the same amount of time as the brand-name drug[,] [g]eneric drug labeling must be essentially the same as the labeling of the brand-name drug[,] [g]eneric drug manufacturers must fully document the generic drug’s chemistry, manufacturing steps, and quality control measures[,] [and] [f]irms must assure the FDA that the raw materials and finished product meet specifications of the U.S. Pharmacopoeia, the organization that sets standards for drug purity in the United States.”); *see also* *Generic Drugs: Questions and Answers*, FDA, <http://www.fda.gov/drugs/resourcesfor-you/consumers/questionsanswers/ucm100100.htm> (last visited Jan. 26, 2013).

118. *See* Aaron S. Kesselheim et al., *Seizure Outcomes Following Use of Generic vs. Brand name Antiepileptic Drugs: A Systematic Review and Meta-Analysis*, 70 *DRUGS* 605 (2010); Aaron S. Kesselheim et al., *Clinical Equivalence of Generic and Brand name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-Analysis*, 300 *JAMA* 2514, 2514-25 (2008); *see also* Greene & Kesselheim, *supra* note 109, at 86. A therapeutic index is a comparison between the amount of a therapeutic agent that is responsible for the therapeutic effect to the amount that causes toxicity.

on medications that treat cardiovascular disease,<sup>119</sup> epilepsy,<sup>120</sup> psychiatric disorders,<sup>121</sup> asthma,<sup>122</sup> neurologic disorders,<sup>123</sup> and dermatologic conditions<sup>124</sup> have all found that generic drugs are just as safe and effective as their branded counterparts. As one study summarized, the FDA's bioequivalence protocols "have been consistent on a pharmacologic level and translate into comparable clinical effectiveness for nearly all brand name and generic drugs."<sup>125</sup> Furthermore, "the FDA has investigated numerous reports of potential generic product inequivalence, and the Agency has claimed it cannot document a single example of therapeutic failure when an FDA-designated therapeutically equivalent product was substituted for its reference (brand name innovator) product."<sup>126</sup>

Despite substantial medical research to the contrary, some healthcare specialists still argue that there are reasons to differentiate between FDA-approved generic medications and branded drugs.<sup>127</sup> First, a few physicians dispute the bioequivalence of branded and generic drugs with narrow therapeutic indices.<sup>128</sup> The next subsection discusses these studies and their potentially flawed results at greater length.

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119. See Kesselheim, *Clinical Equivalence*, *supra* note 118, at 2524-25 (concluding that it is "reasonable for physicians and patients to rely on FDA bioequivalence rating as a proxy for clinical equivalence among a number of important cardiovascular drugs, even in higher-risk contexts such as the NTI drug warfarin").

120. Kesselheim, *Seizure Outcomes*, *supra* note 118 (finding no difference in seizure control between generic and brand name epilepsy medications).

121. C. Couprie & B. Lacarelle, *Bioequivalence and Therapeutic Equivalence in Psychiatry*, 30 *ENCEPHALE* 167 (2004) (demonstrating the bioequivalence of certain psychotropic drugs).

122. See H. Nell et al., *Therapeutic Equivalence Study of Two Formulations (Innovator v. Generic) of Beclomethasone Dipropionate in Adult Asthmatic Patients*, 91 *S. AFR. MED. J.* 51 (2001) (finding that the generic and branded versions of an important asthma medication were therapeutically equivalent).

123. P. Zapater P & J.F. Horga, *Bio-Equivalence and Generic Drugs: Reflections on Problems Which May Arise with Drugs Habitually Used in Neurology*, 30 *REVISTA DE NEUROLOGIA* 146 (2000) (explaining that although it may be difficult to prove bioequivalence for certain drugs used to treat neurological disorders, conclusions regarding bioequivalence may be valid).

124. See John R. Peters et al., *Generic Drugs – Safe, Effective, and Affordable*, 22 *DERMATOLOGIC THERAPY* 239, 239 (2009) (finding that generic dermatological products were as safe and effective as their branded counterparts).

125. Greene & Kesselheim, *supra* note 109, at 86; accord Barbara M Davit et al., *Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration*, 43 *ANNALS PHARMACOTHERAPY* 1583 (2004) (confirming the bioequivalence of FDA approved generic drugs over a twelve year period).

126. COUNCIL ON SCIENCE AND PUBLIC HEALTH, *AMER. MED. ASS'N, GENERIC SUBSTITUTION OF NARROW THERAPEUTIC INDEX DRUGS* 4 (2002) (emphasis added).

127. See *id.*

128. See C.L. Fitzgerald & M.P. Jacobson, *Generic Substitution of Levetiracetam Resulting in Increased Incidence of Breakthrough Seizures*, 45 *ANNALS PHARMACOTHERAPY* e27, at \*1 (2011); see also M.S. Duh et al., *The Risks and Costs of Multiplegeneric Substitution of Topiramate*, 72 *NEUROLOGY* 2122, 2122 (2009).

Second, some argue that the manufacturing quality of branded and generic drugs may differ.<sup>129</sup> This argument is distinct from the bioequivalence argument: it is possible that a generic drug is less effective than its branded counterpart even though it is bioequivalent because the generic was manufactured in shoddy fashion. In such a situation, the purchase of the branded drug shows more confidence in the company than the drug itself. Because the consumer presumably cares about the source of her medication, trademarks enable her to more readily discern such origins.<sup>130</sup> Indeed, as previously discussed,<sup>131</sup> Landes and Posner counter the argument that trademarks lead to artificial differentiation between formulaically identical products by pointing out that a consumer may “be willing to pay a premium for greater assurance that the good will actually be manufactured to the specifications of the formula.”<sup>132</sup>

Although there have been some reports of poor drug manufacturing quality in the past few years, these reports target both branded and generic manufacturers.<sup>133</sup> Many branded drug producers also manufacture generic medications.<sup>134</sup> In these instances, the distinction between the manufacturing quality of generic and branded drugs may not apply, since the same producer manufactures both drugs. There are no studies that substantiate the fear of poor quality generic manufacturing. Such fear is rooted in an unparticularized suspicion of generic quality, rather than real differences between the two types of drugs.

It is also important to note that the U.S. government independently regulates the quality of pharmaceutical products. Through the FDA, the government inspects pharmaceutical production facilities to ensure they are safe

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129. See Landes & Posner, *supra* note 47, at 275.

130. See Signe H. Naeve, *Heart Pills Are Red, Viagra Is Blue . . . When Does Pill Color Become Functional? An Analysis of Utilitarian and Aesthetic Functionality and Their Unintended Side Effects in the Pharmaceutical Industry*, 27 SANTA CLARA COMPUTER & HIGH TECH. L.J. 299, 325 (2011) (“Consumers have the right to know that a generic drug is actually provided by a different manufacturer and allow them to choose the lower-priced option, rather than forcing compliance by presenting them with confusing trade dress.”); see also Daniel R. Bereskin, *Brand Name and “Look-Alike” Drugs in Canada after Ciba-Geigy v. Apotex: A Proposal for Relief from Slavish Imitation*, 94 TRADEMARK REP. 1086, 1092 (2004) (“[I]t surely must also be the case that patients, who have relied upon a medication for many months or years, including patients who associate the [trade dress] with a particular medicine, believe that the medicine comes from a particular source and they have learned to trust that source.”); see also Landes & Posner, *supra* note 47, at 275 (“The fact that two goods have the same chemical formula does not make them of equal quality to even the most coolly rational consumer.”).

131. See *supra* Part I.B.i.

132. Landes & Posner, *supra* note 47, at 275.

133. See Katie Thomas, *Lapses at Big Drug Factories Add to Shortages and Danger*, N.Y. TIMES (Oct. 17, 2012), <http://www.nytimes.com/2012/10/18/business/drug-makers-stalled-in-a-cycle-of-quality-lapses-and-shortages.html>.

134. Natasha Singer, *Drug Firms Apply Brand to Generics*, N.Y. TIMES, Feb. 16, 2010, at B1, available at [http://www.nytimes.com/2010/02/16/business/16generic.html?\\_r=0](http://www.nytimes.com/2010/02/16/business/16generic.html?_r=0).

and compliant.<sup>135</sup> The FDA conducts over a thousand inspections of domestic facilities per year, inspecting approximately forty percent of domestic establishments. The Government Accountability Office has estimated that, at this rate, FDA inspects domestic manufacturers approximately once every 2.5 years.<sup>136</sup> The FDA also inspects generic drugs manufactured abroad. Although the FDA inspected these foreign sites less frequently in the past, the agency is currently ramping up its efforts to regulate overseas facilities.<sup>137</sup> For example, the FDA has opened offices in India and China and increased the number of inspections conducted at foreign pharmaceutical plants.<sup>138</sup>

This level of regulation is fairly unique: the U.S. government does not monitor the output quality in most other consumer good and service industries. Although government agencies may promulgate compliance rules and regulations for other industries, such as the automobile or power-tool industry, the government does not actively inspect the products of these industries to ensure that their outputs comport with the relevant regulations.

To be sure, the FDA is not infallible.<sup>139</sup> It does, however, provide a check on the safety and regulatory compliance of pharmaceutical manufacturers. Such regulation should ease fears that strong trademark protection is necessary to ensure product quality.

Finally, some note that generic and branded drugs can differ in their non-active ingredients, such as the dyes used to create the pill's color or filler ingredients.<sup>140</sup> But these arguments lack support.<sup>141</sup> Even if dyes affect patients differently, this possibility counsels in favor of abandoning trade dress protection altogether: if a brand name and generic drug may have slightly different effects on people due to their color, then the generic producer should be allowed to copy the trade dress of the branded drug. Moreover, if this possibility is a real concern, the FDA should require pharmaceutical manufacturers to demonstrate that the dyes they use are

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135. See U.S. GOV'T ACCOUNTABILITY OFF., GAO-10-961, DRUG SAFETY: FDA HAS CONDUCTED MORE FOREIGN INSPECTIONS AND BEGUN TO IMPROVE ITS INFORMATION ON FOREIGN ESTABLISHMENTS, BUT MORE PROGRESS IS NEEDED (2010).

136. *Id.*

137. Eric Palmer, *FDA Cuts U.S. Plant Inspections While Boosting Them Overseas*, FIERCE PHARMA MFG. (Mar. 20, 2014), <http://www.fiercepharmamanufacturing.com/story/fda-cuts-us-plant-inspections-while-boosting-them-overseas/2014-03-20>.

138. See FDA, REPORT TO CONGRESS ON THE FDA FOREIGN OFFICES (2012), available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm291803.htm#posts>; *FDA's International Posts: Improving the Safety of Imported Food and Medical Products*, FDA CONSUMER HEALTH INFO. (Mar. 2010), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM187246.pdf>.

139. See Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 92 (2008).

140. Lesley Alderman, *Tips on Generics*, N.Y. TIMES (Dec. 18, 2009), <http://www.nytimes.com/2009/12/19/health/19patientbar.html>.

141. *About Generic Medicines*, GENERIC PHARM. ASS'N, <http://www.gphaonline.org/about/generic-medicines> (last visited Oct. 6, 2015).



chemically inert. The available research examining the differences between generic and branded drugs has not found that these types of medications differ in any real way.

ii. Artificial Product Differentiation in the Pharmaceutical Market

Despite this equivalence, consumers and doctors often prefer branded medications to generic ones.<sup>142</sup> With respect to consumers, a recent AARP report found that “some adults still consider brand name drugs to be superior to generic drugs or believe that switching to a generic may compromise the quality of their medications.”<sup>143</sup>

Importantly, studies suggest that this preference is grounded in irrationality rather than misinformation. In a survey of 2,500 commercially-insured, prescription drug users, less than 10 percent of participants believed that generic drugs cause more side effects than branded drugs.<sup>144</sup> Slightly more than 10 percent of study participants disagreed with the statement, “Americans should use more generic drugs,” while almost 56 percent agreed.<sup>145</sup> When the subjects were asked if they “would rather take generics than branded medications,” however, only 37 percent agreed, while 26 percent disagreed.<sup>146</sup> Tellingly, “[r]espondents more strongly agreed with the statement that Americans, in general, should use generic drugs than with a statement that they, as individuals, preferred to use generics.”<sup>147</sup> Thus, although consumers favored greater generic drug usage for the U.S. population as a whole, they found it difficult to take their own advice. These results suggest that patient decision-making “might not be rational from an economic perspective.”<sup>148</sup>

Another study of 505 prescription drug users lends further support to this conclusion.<sup>149</sup> Twenty-two percent of respondents agreed that “generic substitution limited their ability to get what their doctor had prescribed, and about 20 percent believed that it would limit their chances of getting the best

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142. See Andrew T. Ching, *A Dynamic Oligopoly Structural Model for the Prescription Drug Market After Patent Expiration*, 51 INT'L ECON. REV. 1175, 1175 (2010); William H. Shrank et al., *Patients' Perceptions of Generic Medications*, 28 HEALTH AFFAIRS 546, 553-54 (2009); LEIGH PURVIS, AARP PUBLIC POLICY INSTITUTE, STRATEGIES TO INCREASE GENERIC DRUG UTILIZATION AND ASSOCIATED SAVINGS 7 (2008); LINDA L. BARRETT, AARP, PHYSICIANS' ATTITUDES AND PRACTICES REGARDING GENERIC DRUGS 18 (2005); Sujit S. Sansgiry, Monali Bhosle & Nathan Pope, *Consumer Perceptions Regarding Generic Drug Substitution: An Exploratory Study*, 17 J. PHARMACEUTICAL MARKETING & MGMT. 77, 82 (2005); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 332-33 (1992).

143. Purvis, *supra* note 142, at 7.

144. Shrank, *Patients' Perceptions*, *supra* note 142, at 549.

145. *Id.*

146. *Id.*

147. *Id.* at 549-50.

148. *Id.* at 555.

149. Sansgiry, Bhosle, & Pope, *supra* note 142, at 81.

medications.”<sup>150</sup> Nevertheless, a majority of these study participants (61 percent) did not believe that generic substitution increased the number of side effects they experienced.<sup>151</sup> This study confirms that consumers differentiate between generic and brand name medications for reasons they themselves recognize may not be grounded in the efficacy of the drugs.

Several studies of prescribers’ behaviors reveal that patients are not the only ones afflicted by these irrational tendencies. One study found that physician perceptions of specific drugs more closely resemble the advertising claims of the manufacturers than actual measures of the drugs’ performances.<sup>152</sup> Another study found that physicians’ interactions with drug companies influenced their requests that particular drugs be added to their hospitals’ formularies.<sup>153</sup> This result is particularly disturbing given that “more than one-half of the new drugs requested offered little or no therapeutic advantage over comparable drugs already on the formulary.”<sup>154</sup> This study, among others, supports the notion that pharmaceutical advertising and promotion induce physicians to prescribe less cost-effective drugs.<sup>155</sup> Doctor and patient irrationality may be mutually reinforcing: as doctors prescribe more branded drugs, patients are more inclined to believe that they are superior.

A final anecdote encapsulates the extent and depth of consumer differentiation between generic and branded medications. In a short article regarding the ethics of honoring patient requests for brand name medications when generic versions are available, Drs. Troyen Brennan and Thomas Lee describe the case of a woman who claims she is allergic to generic medications. Here, the patient irrationally views generic drugs as a completely distinct class of medications:

A 69-year-old woman with diabetes mellitus and supraventricular tachycardia believes that she is allergic to generic medications. . . . Her medical problems include arthritis, diabetes mellitus, hypertension, dyspepsia, and depression. She frequently comes to the office or the emergency department with symptoms that do not have an apparent physiologic basis. Over the last decade, she has undergone a wide range of diagnostic procedures that have not shown clinically significant abnormalities. A psychiatric consulta-

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150. *Id.* at 82.

151. *Id.* at 85.

152. See Jerry Avorn, Milton Chen & Robert Hartley, *Scientific versus Commercial Sources of Influence on the Prescribing Behaviors of Physicians*, 73 *AM. J. MED.* 4 (1982).

153. John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drug*, 42 *J. OF L. & ECON.* 89, 93-94 (1999) (citing Mary-Margaret Chren & C. Seth Landefeld, *Physicians’ Behavior and Their Interactions with Drug Companies*, 271 *JAMA* 684 (1994)).

154. *Id.* at 93-94.

155. See *id.* at 113.

tion 4 years ago led to the conclusion that she had somatization disorder . . . .

Three years ago, the patient received a generic preparation of glyburide and developed a rash typical of a drug allergy. *The patient concluded that she was allergic to generic medications and refused to fill prescriptions for any generic drug. She could not be convinced that allergy to all generic medications, but not to their brand name counterparts, was impossible.* She refused referral to an allergist, asserting that “I know my body.”<sup>156</sup>

This patient does not mistrust generics because she thinks they may not work as well or may be manufactured by shoddy producers; instead, she believes she has a unique, abnormal physiology reaction—an allergy—to all generic medicines, despite the impossibility of such a reaction.

### iii. The Power of Marketing: The Impetus Behind Artificial Differentiation

The above patient’s conviction likely stems from her exposure to brand advertising and trademarks. The strategic use of trademarks and advertising in the pharmaceutical industry drive artificial differentiation in exactly the way Chamberlin, Schechter, and Brown predicted it would.<sup>157</sup> Even when consumers and physicians logically understand that generic and branded drugs are equivalent, they have demonstrated an inability to apply this logic to their own drug decisions.

Pharmaceutical companies use trademarks and trade dress to define their products and imbue them with an air of uniqueness and originality. As Schechter argued, “the value of the modern trademark lies in its selling power” and “this selling power depends for its psychological hold upon the public, not merely upon the merit of the goods upon which it is used, but equally upon its own uniqueness and singularity.”<sup>158</sup> As the first-movers on the market for a particular drug, branded manufacturers are able to familiarize consumers with their trademarks and dress and build consumer loyalty to their brand for a patent period of twenty years before they face any generic competition.

Pioneer manufacturers capitalize on their first-mover advantage by heavily promoting their brand to consumers. In 2004, pharmaceutical manufacturers spent an estimated \$57.5 billion on promotional activities.<sup>159</sup> In 2008, spending on direct-to-consumer (“DTC”) advertising totaled \$4.7 bil-

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156. Troyen A. Brennan & Thomas Lee, *Allergic to Generics*, 141 ANNALS INTERNAL MED. 126, 126 (2004) (emphasis added).

157. See *supra* Part I.B.ii.

158. Schechter, *supra* note 62, at 831.

159. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLoS MED. 29, 31 (2008).

lion, nearly one-fourth of pharmaceutical manufacturers' expenditures for all promotional activities.<sup>160</sup> These DTC efforts have proved to be highly profitable: "[I]n 2001, every dollar spent on DTC advertising resulted in an additional \$4.20 in sales."<sup>161</sup> Pharmaceutical companies also spend significant sums of money promoting their products to doctors and hospitals.<sup>162</sup> In one survey, four out of five physicians reported that brand name drug representatives visit their practices weekly to advertise pharmaceutical products.<sup>163</sup> In contrast, these same physicians reported they rarely receive promotional materials from generic companies.<sup>164</sup> By saturating the markets for their medications with their brands, pioneer manufacturers succeed in depicting their brands as distinctive—the only brand that can fulfill a consumer's need. In the end, pharmaceutical advertising, like most forms of advertising, "is designed not to inform, but to persuade and influence," and this persuasion leads to irrational decision-making based on a false sense of distinctiveness.<sup>165</sup>

Branded manufacturers also benefit from the habit-forming behavior that occurs during their exclusive sales period. As discussed in Part I, habit often drives purchasing decisions.<sup>166</sup> Marketing specialists have found that consumers derive psychological satisfaction from habit. Their research suggests that patients choose to stay with more expensive, branded medications because the habit of purchasing the same brands is comforting, not because they believe the brands are safer or more effective. Information regarding the bioequivalence of two drugs is likely irrelevant when desire for brand familiarity drives drug purchasing decisions.

A well-known case study helps illustrate this point. In 1989, the pharmaceutical manufacturer, AstraZeneca, introduced a new class of gastroesophageal reflux disease ("GERD") medication known as proton-pump inhibitors ("PPIs").<sup>167</sup> After obtaining a patent on its new PPI, AstraZeneca sold the drug, omeprazole, under the proprietary name Prilosec. Many readers will recognize Prilosec as the "Purple Pill" due to its well-publicized trade dress.

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160. CONGRESSIONAL BUDGET OFFICE, *supra* note 90, at 1.

161. Herberholz, *supra* note 94, at 117.

162. The pharmaceutical industry spends more than \$7 billion per year on direct marketing to doctors. Martha Raffaele, *States Combat Drug Reps to Cut Costs*, WASH. POST (Mar. 3, 2008), [http://www.washingtonpost.com/wp-dyn/content/article/2008/03/02/AR2008030201199\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2008/03/02/AR2008030201199_pf.html).

163. BARRETT, *supra* note 142, at 8.

164. *Id.* at 12.

165. Brown, *supra* note 71, at 1169, 1181-82.

166. Ambler, *supra* note 85, at 181.

167. The FDA approved Astrazeneca's new GERD drug, Prilosec®, on Sept. 14, 1989. FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, (2015).

[P]romotions for the “Purple Pill” appeared everywhere—on TV, the Internet, and in print ads. The pill’s signature color, purple, was at the heart of this effort. When prospective patients found their way to their doctor’s office, “they didn’t even have to recall the drug’s name. All they had to do was remember its color.”<sup>168</sup>

While patented, Prilosec sold at a premium price of \$4 per pill,<sup>169</sup> and, by 2000, it was the world’s top selling drug, earning over \$6 billion per year in the United States.<sup>170</sup>

Faced with Prilosec’s patent expiration in 2001, AstraZeneca crafted a marketing campaign that allowed it to transfer the consumer goodwill associated with trademark and trade dress of Prilosec to its new patented PPI—“Nexium.” Although it was marketed as the new Prilosec, Nexium (generic name, esomeprazole) is, for all intents and purposes, the same as Prilosec: Prilosec (omeprazole) is a mixture of the active and inactive enantiomers of the chiral drug omeprazole, whereas Nexium (esomeprazole) is only the active enantiomer of the same chiral drug.<sup>171</sup> Despite this limited functional distinction, AstraZeneca obtained patent protection for Nexium.

AstraZeneca marketed Nexium as the “new purple pill,” dyeing it the same color. Unsurprisingly, this patented drug was significantly more expensive than the generic versions of omeprazole that came onto the market after Prilosec’s patent expired. Nexium® was positioned as an improved medication because, on average, it took shorter time (five days versus seven days) for GERD patients to experience relief relative to omeprazole. Esomeprazole likely shows such advantages over omeprazole,<sup>172</sup> however, purely because of its higher dosage.<sup>173</sup>

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168. Fritch, *supra* note 111, at 188 (2006) (citing Neil Swidey, *The Costly Case of the Purple Pill—The Story of One Blockbuster Heartburn Drug Tells You Everything You Need To Know About the High Cost of Prescription Medicine*, BOSTON GLOBE, Nov. 17, 2002, available at <http://articles.mercola.com/sites/articles/archive/2002/12/18/nexium.aspx>).

169. Jain & Conley, *supra* note 91, at 23.

170. Walid F. Gellad et al., *Assessing the Chiral Switch: Approval and Use of Single-Enantiomer Drugs, 2001 to 2011*, 20 AM. J. MANAGED CARE e90, e90 (2014).

171. “A chiral drug is a single molecule product that exists in 2 mirror image forms call enantiomers.” *Id.* Certain enzymatic processes can “distinguish between the R- (from Latin *rectus* for ‘right’) and S- (from the Latin *sinister* for ‘left’) enantiomers, such that 1 enantiomer may be responsible for much of pharmaceutical benefit while the other is inactive or even harmful.” *Id.* Omeprazole (Prilosec®) is a “racemic mixture of R-omeprazole and S-omeprazole, while esomeprazole, as its name implies, is isolated S-omeprazole.” *Id.* The S-omeprazole enantiomer in Prilosec® and Nexium® is responsible for both drugs’ clinical properties, while the R-omeprazole enantiomer in Prilosec® is inactive. *Id.*

172. *Id.* at e92 (“Esomeprazole 40 mg demonstrated statistically significant efficacy over omeprazole 20 mg in 2 studies, although it was not superior in 2 other studies.”).

173. Studies that found esomeprazole to be more effective than omeprazole “compared esomeprazole at a pharmacologically superior dose (40 mg) with omeprazole (usually at a dose of 20 mg).” *Id.* at e94. The single-enantiomer Nexium® contains “at least 3 times as much of the active S-isomer as 20 mg of racemic omeprazole on a per milligram basis.” *Id.* at e92.

In addition to launching Nexium, AstraZeneca began to sell an over-the-counter version of omeprazole.<sup>174</sup> Sold in the same dosage as Prilosec, AstraZeneca's over-the-counter version of omeprazole came in a salmon pink pill.<sup>175</sup> Nevertheless, AstraZeneca sold this medication in a purple packaging, "suggestive of the association with the original Prilosec purple pill."<sup>176</sup>

After a drug's patent expires, most pharmaceutical companies experience a dramatic drop in sales revenue due to the aggressive price-based competition that generic manufacturers generate.<sup>177</sup> Through its elaborate trade dress scheme, however, AstraZeneca managed to convert Prilosec sales into Nexium sales. Although Prilosec sales did fall off the post-patent cliff, Nexium picked them up. In fact, "after esomeprazole's [Nexium] approval in 2001, its use in Medicaid quickly surpassed omeprazole's [Prilosec's] and peaked at over [one] million prescriptions per quarter in the second half of 2005."<sup>178</sup> Overall, AstraZeneca's sale of proton pump inhibitor products (Nexium and over-the-counter Prilosec) remained at about \$6 billion per year *for ten years after* AstraZeneca's patent on omeprazole expired.<sup>179</sup>

AstraZeneca skillful manipulation of Prilosec's trade dress enabled it to extend its PPI-based revenue stream. When AstraZeneca reassigned Prilosec's trade dress and slogan to its newly patented medication, Nexium, the manufacturer's goal was undoubtedly to shift the consumer goodwill associated with the Prilosec brand to Nexium. By associating its new drug with the trademarks of its old medication, AstraZeneca transferred the reputation of one of its products to another. The success of AstraZeneca's marketing strategy hinged on the company's ability to convince consumers previously taking Prilosec that they should instead begin to purchase Nexium, despite the fact that their current drug was now available over-the-counter at less than one-seventh of its previous cost. Although some patients probably switched to Nexium because they actually believed it was an updated version of Prilosec, some undoubtedly switched because the trademark maneuver led them to believe that the drug they wanted—the purple pill—was Nexium. In other words, AstraZeneca used its trademarks to confuse consumers into buying a more expensive version of the same drug. Effectively inhibiting robust generic competition, this marketing scheme came at greater expense to both consumers and payors, ultimately decreasing the efficiency of the healthcare market. Although the Prilosec-Nexium case study is an extreme example of trademark manipulation, this case nevertheless reveals

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174. Jain & Conley, *supra* note 91, at 27.

175. Greene & Kesselheim, *supra* note 109, at 85 ("[C]laims of trade dress remain vital in the pharmaceutical market.").

176. Jain & Conley, *supra* note 91, at 27.

177. *Id.* at 23.

178. Gellad et al., *supra* note 170, at e92.

179. *Id.*

that trademark protection can be used to capture consumers and keep them from acting in a rational, efficient manner.

AstraZeneca's manipulative strategy has become increasingly common in the pharmaceutical industry. Brand name manufacturers now routinely rely on a medication's appearance to corner the generic market for that drug. As one commentator explains, "During the last decade, hundreds of brand name medicines have been launched as 'authorized generics.'"<sup>180</sup> An "authorized generic" is identical in appearance to its branded counterpart, except that the brand name has been replaced with the generic name and the original manufacturer's name is swapped out for the name of the generic manufacturer (which is often a subsidiary company of the brand manufacturer). For example, Johnson & Johnson created a subsidiary, Patriot Pharmaceuticals, to distribute generic versions of its products that "have the same taste, color, mouth feel, size and shape as the innovator product."<sup>181</sup> Thus, branded manufacturers are aware of the critical role that trade dress plays in conditioning consumer preferences for pharmaceutical products and have capitalized on this phenomenon in order to inhibit competition.

A number of other factors also affect consumer differentiation between branded and generic drugs. First, the price differential between generic and brand name drugs may in and of itself generate an artificial signaling effect. As one brand specialist explains, "Price is one of the first signals picked up by the market through both its level and the systematic fight against uncontrolled sales or discounts: the higher the price, the more selective the purchase seems to be, implying a positive sales-to-price elasticity."<sup>182</sup> In other words, consumers perceive price to signal quality. In most markets, this inference is not a poor one; for many goods and services price often (but not always) correlates with quality.

In the pharmaceutical market, however, generic drugs are significantly cheaper than brand name products because generic manufacturers do not incur the same outlays in marketing, research, and development that brand name companies undertake.<sup>183</sup> Therefore, consumers cannot rationally rely

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180. Alfred B. Engelberg, *The Case for Standardizing the Appearance of Bioequivalent Medications*, 17 J. MANAGED CARE PHARMACY 321, 322 (2011).

181. *About Authorized Generics*, PATRIOT PHARM. (Jan. 22, 2010), <http://www.patriotpharmaceuticals.com/patriotpharmaceuticals/faqs.html>.

182. Bernard Catry, *The Great Pretenders: The Magic of Luxury Goods*, 14 BUS. STRATEGY REV. 1, 14 (2003).

183. Generic drugs are cheaper than their branded counterparts, in part, because pioneer manufacturers incur costs associated with the research and development, testing, and FDA approval of pioneer drugs that generic manufacturers do not bear. Prior to the passage of the Hatch-Waxman Act, the FDA required generic drug companies to prove the safety and efficacy of their products independently of the brand name manufacturer, "essentially mirroring the extensive testing process followed by the drug's initial developer." See Fritch, *supra* note 111, at 176. Now, the Food, Drug and Cosmetics Act (FDCA) allows generic manufacturers to submit an abbreviated new drug application (ANDA) to obtain FDA approval for their drugs. See Ching, *supra* note 142, at 1177-78; Holly Soehnge, *The Drug Price Competition and*

on the price differential between generic and brand name products to infer a difference in quality.

Nevertheless, studies suggest they do.<sup>184</sup> A 2008 study found that when subjects were told that they were receiving a more expensive version of a pain relief medication, they experienced greater pain relief.<sup>185</sup> In this experiment, the subjects were divided into two groups: one group was told the pain medication they would be given cost \$2.50 and the other group was informed that the medication had been discounted to \$0.10. After receiving a series of electric shocks of different levels, the patients that received the “\$0.10” medication reported lower levels of pain relief than those who received the “\$2.50” medication.<sup>186</sup> These results “may help explain the popularity of high-cost medical therapies . . . over inexpensive, widely available alternatives . . . and why patients switching from branded medications may report that their generic equivalents are less effective.”<sup>187</sup> In a second study of attitudes towards generic drugs in rural Alabama, participants expressed a preference for branded medications because of their higher prices.<sup>188</sup> “One participant noted, ‘People always say you buy Domino sugar. It’s the best. Don’t buy the cheap brand. Buy Domino and you won’t have to use as much. . . . Domino’s is sweeter. Generic medicine is not as effective as, you know, the real medicine prescriptions, the strength.’”<sup>189</sup>

The difference in the prevalence of brand name versus generic drug advertising may also drive consumer differentiation of these products. As Mark Lemley explains, advertising may play a signaling role: “[W]e advertise, and therefore we must sell a good of sufficiently high quality that we can afford this high-cost expenditure.”<sup>190</sup> Therefore, the mere presence of brand name advertising may lead consumers to believe that branded drugs are of a higher quality than their generic versions. Most generic manufacturers do not ad-

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*Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L. J. 51, 53 (2003). Under the ANDA process, generic companies need only prove that their generic drugs are “bioequivalent” to their reference products. 21 U.S.C. § 355(j)(2)(A)(iv) (2006). Thus, the ANDA “permit[s] an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

184. See Shrank, *supra* note 142, at 554 (citing Rebecca L. Waber et al., *Research Letter to the Editor*, 299 JAMA 1016 (2008)) (explaining that consumer perceptions regarding generic drug safety “may be associated with the term ‘generic’ itself, which connotes lesser quality for some product categories or the belief that more-expensive products must be more effective than cheaper products”).

185. Rebecca L. Waber et al., *Research Letter to the Editor*, 299 JAMA 1016 (2008).

186. *Id.*

187. *Id.* at 1017.

188. Keri Sewell, *Perceptions of and Barriers to Use of Generic Medications in a Rural African American Population, Alabama, 2011*, 9 PREVENTING CHRONIC DISEASE 1, 2-3 (2012).

189. *Id.*

190. Lemley, *supra* note 76, at 1690.



vertise because their products are interchangeable with those of other generic manufacturers and they have no way of directing their products to consumers. This decision bears no relation to generic companies' capacity to advertise. Thus, any product differentiation that results from the fact that brand name manufacturers advertise while generic producers do not is completely artificial.

Finally, consumer rationality with respect to prescription drug purchases may be especially susceptible to manipulation due to the unique characteristics of prescription drugs. Unlike consumer decisions regarding other products such as clothing or furniture, patients must rely on the information they receive from pharmaceutical advertisements and their physicians to a much greater extent because they cannot observe or understand the functional characteristics of a particular medication before they buy it. Consumers have no choice but to over-rely upon marketing signals, like pricing and advertising, as stand-ins for efficacy or quality. Therefore, advertising and promotion in the pharmaceutical industry have a greater ability to persuade consumers and influence their decisions than does advertising in industries where a product's functional characteristics are more readily perceivable. Switching between medications can also be much more difficult and burdensome than changing between different versions of another product. Therefore, consumer preferences become "sticky," and consumer willingness to switch manufacturers is less elastic.

Widespread pharmaceutical advertising linking a particular medication to a specific proprietary name and pill design has led consumers to believe, or rather intuit, that the brand—and only the brand—delivers the needed medication. Instead of understanding Tylenol® as form of acetaminophen, many consumers perceive a CVS or Walgreen's bottle of acetaminophen as the knock-off version of Tylenol®. In effect, pharmaceutical trademarks confuse consumers into believing that brand name products are actually different from generics. Instead of clarifying the source of the medication for the consumer, pharmaceutical trademarks lead patients to perceive distinctions where none exist; instead of preventing confusion, they create it. And, just as Chamberlin and Brown suggested, this artificial product differentiation has enabled brand manufacturers to capture monopolistic returns, inhibiting generic competition and making the market for pharmaceutical products less efficient.

#### iv. The Placebo Effect: How Artificial Differentiation Drives Real Differentiation

The pernicious effects pharmaceutical trademarks have on physician and patient behavior may extend beyond the induction of unnecessary expenditures. Research shows that artificial product differentiation due to trademarks and advertising may drive real differences in drug effectiveness: it

reduces both patient adherence to medication regimens and the placebo effect that drugs often stimulate.

First, trade dress may reduce patient adherence to drug regimens when switching from a brand name to generic drug. Patients who regularly take prescription medications become deeply accustomed to the shape, size, and color of their medications. Although all pills are imprinted with an identifying code, many patients rely on the shape and color of their medications to identify them.<sup>191</sup> In fact, trusted sources of medical safety information, including the FDA, Consumers Union, and Institute of Safe Medication Practices, “encourage patients to rely on the appearance of their medication for reassurance that they are taking the right medicine at the right time and to refrain from taking any medication that looks different without getting professional reassurance.”<sup>192</sup> This reliance is especially prevalent among patients who take multiple medications, such as the elderly.<sup>193</sup> Because trade dress protection prevents generic producers from copying the designs of brand name medications even after patent protection has fallen away, changes from brand name drugs to generic products may cause patient confusion and result in prescription errors<sup>194</sup> and reduced adherence.<sup>195</sup>

Patient experiences with antiepileptic drugs (“AEDs”) provide specific examples of the type of adherence problems pharmaceutical trade dress may create. Recently, studies have reported that bioequivalent generic AEDs may not have the same clinical efficacy as their brand name counterparts.<sup>196</sup> These reports have led many physicians to believe that generic AEDs are not as effective in preventing seizures as their branded counterparts.<sup>197</sup> In fact, “some physician professional organizations and patient advocates have opposed the routine interchange of bioequivalent AEDs,”<sup>198</sup> and several states “have also entertained or passed legislation to limit substitution of generic AEDs to protect patients from breakthrough seizures.”<sup>199</sup> Nevertheless, “well-controlled studies” support the bioequivalence of generic and branded AED drugs.<sup>200</sup> One study on AEDs followed patients who, accustomed to the

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191. Engelberg, *supra* note 180, at 321; Greene & Kesselheim, *supra* note 109, at 86.

192. Engelberg, *supra* note 180, at 321.

193. *See id.*; Greene & Kesselheim, *supra* note 109, at 86.

194. *See* Greene & Kesselheim, *supra* note 109, at 86.

195. *See* Aaron S. Kesselheim et al., *Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence*, 173 JAMA INT’L MED. 202, 203 (2013); Helle Håkonsen et al., *Generic Substitution: Additional Challenge for Adherence in Hypertensive Patients?*, 25 CURRENT MED. RES. OPINION 2515, 2519 (2009).

196. *See* Christine L. Fitzgerald & Mercedes P. Jacobson, *Generic Substitution of Levetiracetam Resulting in Increased Incidence of Breakthrough Seizures*, 45 ANNALS PHARMACOTHERAPY e27 (2011); *see also* M.S. Duh et al., *The Risks and Costs of Multiplegeneric Substitution of Topiramate*, 72 NEUROLOGY 2122, 2125 (2009).

197. *See* Kesselheim, *supra* note 195, at 206.

198. *Id.*

199. *Id.*

200. *Id.*

design of a brand name AED, switched to a generic. The patients found the change in pill design to be confusing,<sup>201</sup> which led them to falter in their pill regimen adherence. These reductions in patient adherence could have driven the negative results regarding generic AED efficacy that was reported in other investigations. As the study's authors concluded, "[c]hanges in pill appearance may create a self-fulfilling prophecy in which therapeutically bioequivalent regimens actually become less clinically effective owing to induced nonpersistence."<sup>202</sup> Instead of clarifying differences between products, differences in trade dress confused consumers into reduced adherence to the same product.

A more recent study that examined the effect of changes in pill shape and color on continued patient use of cardiovascular medications confirmed these findings. This study found that patients had a 34 percent increase in the odds of change in pill color preceding an episode of non-persistent pill usage and a 66 percent increase in the odds of non-persistence after a change in pill shape.<sup>203</sup> As this study concluded, "change in the color or shape of those medications . . . may contribute to patients' stopping treatment with their medications. This factor will increase morbidity and mortality and health care spending overall because of preventable complications and disease recurrence."<sup>204</sup>

Trademarks and trade dress protection may also cause branded medications to produce beneficial placebo effects that generic drugs cannot replicate because they do not possess the same trademarks or trade dress. As previously discussed, a study of the effects of branded versus generic pain relief medications revealed that study participants experienced greater pain relief from medications the researchers told them were branded as opposed to generic.<sup>205</sup> In this study, participants received one of four types of medications: a placebo pill that contained no active ingredient but was marked with the name of a popular brand of aspirin, a placebo pill with no markings, a branded pill with an active ingredient, or an unmarked pill with an active ingredient. For both the placebo and the active ingredient pills, the study participants reported greater relief from the versions that were branded.<sup>206</sup> As the authors of this study conclude, "[b]randing appeared to supplement both the inert placebo and the active ingredients to produce more relief than either placebo or active ingredients alone."<sup>207</sup> Another study demonstrated that pa-

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201. *Id.* at 205.

202. *Id.* at 206.

203. Aaron S. Kesselheim, et al., *Burden of Changes in Pill Appearance for Patients Receiving Generic Cardiovascular Medications After Myocardial Infarction*, 161 *ANNALS INTERNAL MED.* 96, 99 (2014).

204. *Id.* at 101.

205. A. Braithwaite & P. Cooper, *Analgesic Effect of Branding in Treatment of Headaches*, 282 *BRIT. MED. J.* 1576, 1576 (1981).

206. *See id.* at 1578.

207. *Id.*

tient expectations regarding the efficacy of both placebos and pharmacologically active prescription drugs are linked to the physical attributes of their pills.<sup>208</sup> As Jeremy Greene & Aaron Kesselheim explain:

Although the classic logic of the randomized, controlled trial casts the placebo effect as a negative foil for measuring therapeutic efficacy, in practice a drug's effectiveness is still due, to some extent, to placebo effects. By not allowing a generic version to fully benefit from the functionality of such effects, differing appearances may reduce the ultimate effectiveness of certain generic drugs.<sup>209</sup>

Therefore, "changes in pill appearance may not only deprive patients of these expectations of efficacy, but potentially even have the opposite effect—a belief that the newly substituted pill will be less efficacious (the so-called nocebo effect)."<sup>210</sup> Differences in trade dress may therefore lead to worse health outcomes when a patient switches from a brand to a generic because the patient no longer receives the appearance-induced placebo effect that the brand provided.

### *C. Do Pharmaceutical Trademarks Serve a Quality Control Function?*

The second rationale for trademark protection—that brands encourage manufacturers to maintain consistent product quality because they signal the source of the product and therefore create accountability—does not fare much better. As previously discussed, in the case of the pharmaceutical industry, there is little research suggesting that the manufacturing quality of brands is superior to that of generics.<sup>211</sup> Furthermore, FDA inspection provides an additional check on generic drug quality.

Qualitative and quantitative evidence suggests that consumers rely on pharmaceutical trademarks and trade dress to identify the product itself, rather than validate the quality of the drugs they mark. The story of the patient who believed she was allergic to generics illustrates this point. The patient was not concerned with the source or quality of her generic medications. She refused to take generic drugs because she considered these medicines to be an entirely separate class of drugs. No part of her calculus hinged on a recognition of bioequivalence or a corresponding concern about the quality of generic manufacturers; instead, she made a broad generalization about generics as if they were separate products.

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208. See Greene & Kesselheim, *supra* note 109, at 87 ("For decades, studies have shown that the efficacy of placebo pills varies according to the size, shape, and color of the pills. The placebo effect is particularly evident in the treatment of patients whose disorder has potential psychosomatic components, such as anxiety, depression, dyspepsia, impotence, obesity, and pain.").

209. See *id.*

210. Kesselheim et al., *supra* note 195, at 206.

211. See *supra* Part II.B.i.

The consumer surveys regarding patient opinions of generic versus brand name medications also suggest that consumer mistrust of generic medications does not stem from legitimate concerns regarding the quality of generic drugs. Instead, these surveys intimate that such distrust stems from the irrational belief that brand name drugs are simply the BMWs, Mercedes, and Porsches of drugs. As the aforementioned study of 505 prescription drug users suggests, consumer mistrust of generic *medications* does not directly correlate with consumer mistrust of generic *manufacturers*. Therefore, the “quality control” rationale for trademark protection appears to lack grounding in genuine consumer preferences. Not only does the available data indicate that brands and generics do not differ in quality, but it also suggests that consumers are not relying on pharmaceutical trademarks as a check on the manufacturing quality of their medications.

#### D. Conclusion

The Prilosec® case study illuminates the key problem with pharmaceutical trademarks and trade dress: these forms of intellectual property protection ultimately allow pharmaceutical manufacturers to artificially differentiate their products from those of generic manufacturers so that they can extend the monopolies they enjoyed under patent protection. Consumer preferences for brand name products do not stem from their mistrust of generic manufacturers. Instead, patients feel more comfortable consuming branded medications because advertising and promotion has led them to believe that trademarked medications are superior to generic drugs. As an empirical matter, this conclusion is wrong. Consequently, pharmaceutical trademarks predominately result in the artificial and inefficient product differentiation that Chamberlin, Schechter, and Brown anticipated. Even if pharmaceutical trademarks and trade dress help some consumers identify the products they trust, the harms associated with these marks—including increased health care costs, reduced patient adherence, increased prescription errors, and the nullification of valuable placebo effects—outweigh any beneficial impact.

### III. A NEW SOLUTION: MANUFACTURER MARKS INSTEAD OF TRADEMARK AND TRADE DRESS PROTECTION

#### A. *The Need for New Strategies*

Professor Oren Bar-Gill, a leading scholar in the field of law and behavioral economics, describes the analysis policymakers should use when deciding whether to change irrational consumer behavior through legal intervention:

The question is not whether individuals make mistakes. Sure they do. The question is whether these mistakes merit legal intervention.

. . . . .  
. . . Do consumers suffer from systematic misperception of the costs and benefits associated with certain products? And, do sophisticated sellers respond strategically to consumer misperception? In particular, do sellers design their products, contracts, and pricing schemes in response to consumer misperception? . . . [I]s consumer misperception and, specifically, sellers' strategic response to consumer misperception welfare-reducing? . . . [Finally,] is legal intervention warranted and, if so, what type of legal intervention is desirable?<sup>212</sup>

This Article has shown that for pharmaceutical trademarks and trade dress, Professor Bar-Gill's first three questions should be answered affirmatively. This section sets forth a possible legal solution: the replacement of pharmaceutical trademarks and trade dress with marks that solely identify the manufacturers of medicines.

The elimination of pharmaceutical trademarks and trade dress may seem like a drastic step, especially in light of the governmental and private policies and programs put in place to encourage patients to switch to generics. On the state side, some governments have passed mandatory generic substitution laws, which require pharmacists to substitute generics for branded medications when feasible; other states have endorsed permissive generic substitution, where pharmacists are permitted, but not required, to make the substitution.<sup>213</sup> And some states obligate pharmacists to obtain patient consent prior to generic substitution, while others permit substitution without such explicit consent.<sup>214</sup> For their part, private insurers have implemented financial penalties in the form of tiered formularies and greater copayments for patients that take expensive branded medications where generics are available. Studies have demonstrated that these financial incentives increase generic drug usage.<sup>215</sup>

Despite these public and private efforts to encourage generic medication usage, patient and physician attitudes towards generic medications still result in suboptimal rates of substitution. For example, one study that analyzed state-by-state Medicaid prescription drug spending in the year 2000 found

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212. Oren Bar-Gill, *The Behavioral Economics of Consumer Contracts*, 92 MINN. L. REV. 749, 749 (2008).

213. See William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383, 1383 (2010) (describing various state laws aimed at encourage generic drug substitution).

214. See generally *id.* (finding that states requiring patient consent prior to substitution experienced the lowest rates of generic substitution after the patent for a popular cholesterol-controlling medication, Zocor, expired and a generic entered the market).

215. See Thomas S. Rector et al., *Effect of Tiered Prescription Copayments on the Use of Preferred Brand Medications*, 41 MED. CARE 398, 398 (2003); Kathleen A. Fairman et al., *Retrospective, Long-Term Follow-Up Study of the Effect of a Three-Tier Prescription Drug Copayment System on Pharmaceutical and Other Medical Utilization and Costs*, 25 CLINICAL THERAPEUTICS 3147, 3156 (2003).

that greater generic drug usage could have resulted in collective savings of \$229 million.<sup>216</sup> In fact, improved generic drug substitution would have resulted in total savings of \$450 million if the best available prices from each state had been used nationally. Medicaid spent an estimated \$329 million in 2009 to reimburse patients for twenty popular brand name medications for which therapeutically equivalent generic substitutes exist.<sup>217</sup> The study predicted that state governments would overspend between \$289 million and \$433 million on reimbursement for ten popular branded medications whose patents expired in 2011 and 2012.<sup>218</sup> It is important to bear in mind that these projected expenditures are just for Medicaid, which accounts for about 10 percent of total drug purchasing nationwide.<sup>219</sup> Improvements in generic substitution would also result in additional savings for private payors and Medicare Part D plans.<sup>220</sup> Furthermore, although financial incentives in the form of copayment differentials and tiered formularies promote generic drug substitution, healthcare specialists have concluded that “copayment differentials between generic and brand name medications may be insufficient to motivate generic drug use by some patients.”<sup>221</sup> Thus, new policies aimed at reducing physician and patient resistance to generic substitution are necessary.

Consumer distrust of generic medications is not only extremely costly, but also dangerous. Multiple studies have shown that the costs of prescription drugs to patients affect their subsequent adherence.<sup>222</sup> Because generic

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216. Michael A. Fischer & Jerry Avorn, *Economic Consequences of Underuse of Generic Drugs: Evidence from Medicaid and Implications for Prescription Drug Benefit Plans*, 38 HEALTH SERVS. RES. 1051, 1055 (2003). See also Jennifer S. Haas et al., *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997–2000*, 142 ANNALS INTERNAL MED. 891, 891 (2005) (finding that use of branded prescription drugs when identical generics were available constituted approximately 11% of over-all drug expenditures on prescriptions filled in a nationally representative sample of patients from 1997-2000).

217. Alex Brill, *Overspending on Multi-Source Drugs in Medicaid* 7 (Am. Enter. Inst. for Pub. Policy Research, Working Paper No. 2011-01, 2011) (“As total spending on these twenty multi-source products was approximately \$1.5 billion, this means Medicaid overspent by 22 percent (\$1.5 billion versus \$1.17 billion) on these products.”), <https://www.aei.org/publication/overspending-on-multi-source-drugs-in-medicaid>.

218. *Id.* at 11. See also Shrank et al., *supra* note 213, at 1389 (predicting that patient refusal of generic substitution will cost state Medicaid programs over \$100 million in the year after the patents for only three medications expire).

219. Shrank et al., *supra* note 213, at 1389.

220. *Id.*

221. William H. Shrank et al., *Improving Prescription Choices, Adherence to Therapy, and Medication Management: A Best Practice Advice from the American College of Physicians*, 11 (American College of Physicians, Working Paper, 2014) (citing Niteesh K. Choudhry et al., *Setting Prices for Generic Medications: A Survey of Patient Perception*, 2 AM. J. PHARMACY BENEFITS 33 (2010)).

222. See, e.g., Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, 298 JAMA 61, 61 (2007); William H. Shrank et al., *The Implications of Choice: Prescribing Generic or Preferred*

drugs are less expensive, patients can more readily afford generic drugs and the financial burden of medication purchase is less likely to disrupt their adherence to their long-term medication regime.<sup>223</sup> Although the elimination of trademark protection in the pharmaceutical industry is not a magic wand that would instantly convert all brand name prescriptions into generic ones, it could improve consumer comfort with generic medications, thereby increasing the rate of generic substitution. As previously discussed, easing the psychological difficulty of the switch from branded to generic drugs could improve patient adherence to their medication regimens, reduce prescription errors, and ensure that generic medications benefit from the placebo effects that branded medications currently enjoy.<sup>224</sup>

### B. *Manufacturer Marks*

As Landes and Posner explain, pharmaceutical trademarks and trade dress could serve a useful function even among identical products if these marks signal their products' sources to consumers. Arguably, pharmaceutical trademarks do not serve this function at all. But another form of property protection might. A new rule could be implemented wherein all medications must be accompanied by labels identifying the name of their manufacturers (for example, a sticker on the pill bottle), but the medication themselves could only be named, prescribed, and advertised by their generic names. If the generic names were too unwieldy, the FDA could designate shorter names for medications to be used in product advertisements.

Under such a rule, pharmaceutical trademarks, including trade dress and slogans, would be prohibited. In terms of the physical prescription, a generic drug and its branded equivalent would look and taste identical, using the same dressing and the same drug name on their pill bottles. The only difference between medications, both brands and generics, would be a small, additional label on the dispensed bottle, indicating the manufacturer of the drug.

This rule would enable generic manufacturers to use the same names and dress as branded products, therein eliminating the type of harmful differentiation trademarks have caused. It would still permit consumers to identify their medications' sources. If a consumer had a bad experience with the quality of a Pfizer drug, that consumer would be able to avoid Pfizer products by simply looking at the label on his medications. Critically, this rule would impede producer efforts to artificially distinguish between brand name and generic drugs through the names and designs of their products.

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*Pharmaceuticals Improves Medication Adherence for Chronic Conditions*, 166 ARCHIVES INTERNAL MED. 332, 335 (2006); Deborah A. Taira et al., *Copayment Level and Compliance With Antihypertensive Medication: Analysis and Policy Implications for Managed Care*, 12 AM. J. MANAGED CARE 678, 678 (2006).

223. See, e.g., Goldman et al., *supra* note 222, at 61; Shrank et al., *supra* note 222, at 332; Taira et al., *supra* note 222, at 678.

224. See *supra* Part II.B.iv.



Under such a rule, consumers would feel more comfortable and less confused when switching to generic medications.

The concern Landes and Posner identify—that even formulaically identical products can differ due to discrepancies in their manufacturing quality—though perhaps not a valid concern in today’s pharmaceutical market, must be considered. Allowing manufacturers to place their names on their products would adequately account for this potentiality. Manufacturer marks would enable consumers to locate products of the manufacturers they trust (and distrust), thereby permitting producers to capture consumer goodwill across the range of drugs they offer. These marks would accomplish this objective without suggesting that the drugs they mark differ in any respect other than their manufacturers. Thus, this rule reinforces for consumers the reality surrounding branded and generic drugs: branded and generic drugs are equivalent medications, albeit with sometimes different manufacturers.

To implement such a rule would most likely require two changes to existing law. First, a change to the Federal Food, Drug, and Cosmetic Act could require that all drugs be labeled, prescribed, and advertised by their generic names and dispensed with a label identifying the manufacturer of the medication. Such a legislative change would require the FDA to set the names and dress for all drugs and obligate pharmaceutical manufacturers to comply with the FDA’s such schemes.

In order to avert potential lawsuits, Congress should also amend the Lanham Act, so that pharmaceutical trademarks and trade dress can no longer be registered with the USPTO. More specifically, Congress could amend 15 U.S.C. § 1052, which lists trademark ineligible subject matter, to specify that trademarks on medications will be refused registration. This provision could be nested under Section 1052(e)(5), which prohibits trademarks on “any matter that, as a whole, is functional.” This change might not even be necessary, however, because 15 U.S.C. § 1051 only permits registration of a trademark when the applicant can verify that he is “entitled to use the mark in commerce”<sup>225</sup> and has a “bona fide intention to use the mark in commerce.”<sup>226</sup> If pharmaceutical companies must use the drug names authorized by the FDA, and only those names, these companies cannot verify to the USPTO that they are “entitled” or “intend” to use their own pharmaceutical trademarks in commerce.

### C. *Potential Limitations*

#### i. Constitutional Challenges

Pharmaceutical companies would undoubtedly object to such a rule, and a few legal challenges are foreseeable. Although it is beyond the scope of this Article to ponder all such lawsuits, it explores three potential causes of

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225. 15 U.S.C. § 1051(b)(3)(A) (2012).

226. *Id.* § 1051(b)(3)(B).

action—two domestic and one international. First, pharmaceutical firms might complain that this rule violates the Due Process Clause and Just Compensation Clause of the Fifth Amendment. They might argue that they have a property right to their pharmaceutical trademarks of which the government has deprived them without due process and taken without just compensation.

The Supreme Court has described trademarks as a form of property on various occasions. For example, in *College Saving Bank v. Florida Prepaid Postsecondary Education Expense Board*,<sup>227</sup> the Court stated “[t]he hallmark of a protected property interest is the right to exclude others. That is ‘one of the most essential sticks in the bundle of rights that are commonly characterized as property.’”<sup>228</sup> The Court then explained that trademarks are “the ‘property’ of the owner because he can exclude others from using them.”<sup>229</sup>

But a trademark holder’s property interest in his mark is not without limits. In his trademark treatise, McCarthy explains:

Traditional American trademark law has viewed a trademark as “property” only insofar as it is a right to prevent confusion of customers and the commercial damage that confusion creates. The American view of trademark law is that it is a form of consumer protection. This is a key feature distinguishing American trademark law from that of the Civil Law systems of most other nations. The Civil Law tradition treats a registered trademark as a form of property granted by the government, akin to that of a patent.<sup>230</sup>

Unlike patents and copyrights, trademarks “have no existence independent of the good will of the products or services in connection with which the mark is used.”<sup>231</sup> The Ninth Circuit has held that “[a] trademark owner has a property right only insofar as is necessary to prevent customer confusion as to who produced the goods and to facilitate differentiation of the trademark owner’s goods.”<sup>232</sup> Therefore, a trademark holder does not possess a property right to his mark simply because it exists and has been registered with the USPTO; instead, this property right is co-extensive with its function as an indicator of source and repository of goodwill.

Potential future pharmaceutical trademarks do not currently indicate a particular source to consumers and have yet to accrue any goodwill. Accord-

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227. 527 U.S. 666 (1999).

228. *Id.* at 673 (quoting *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979)).

229. *Id.* (“Trademark law, like contract law, confers private rights, which are themselves rights of exclusion. It grants the trademark owner a bundle of such rights.” (quoting *Kmart Corp. v. Cartier*, 485 U.S. 176, 185-86 (1988))).

230. MCCARTHY, *supra* note 6, § 2:14.

231. *Id.* § 2:15.

232. *Int’l Order of Job’s Daughters v. Lindeburg & Co.*, 633 F.2d 912, 919 (9th Cir. 1980; *see also* *Ky. Fried Chicken Corp. v. Diversified Packaging Corp.*, 549 F.2d 368 (5th Cir. 1977)).

ingly, a prospective law banning pharmaceutical trademarks would be unlikely to violate either the Due Process Clause or the Just Compensation Clause of the Fifth Amendment.

Pharmaceutical companies also hold no general right to create trademarks. As previously mentioned, the Constitution makes no provision for trademarks, unlike patents and copyrights. A company does have a right to the goodwill the company has accrued. However, that right is cognizable as a property right to a trademark only insofar as the mark captures the goodwill accrued and enables consumers to identify the product the company produces.

As companies begin to produce new, non-trademarked drugs, the manufacturer mark portion of the proposed rule will ensure that those companies are able to capture and protect the goodwill those drugs accrue. The manufacturer marks will enable consumers to locate the producers of the drugs they trust, thereby safeguarding any goodwill a company's drug has attracted.<sup>233</sup> Manufacturer marks would essentially protect and embody the same property rights that trademarks currently do. However, unlike pharmaceutical trademarks, these manufacturer marks would focus consumer goodwill on the real source of the drug, rather than an unattributed one. Switching the locus of consumer goodwill from an unattributed source to an identified one will help clarify to consumers that generic and branded producers are selling the same drug, simply produced by different companies.

It is less clear if a retrospective version of this rule would be constitutional. Because pharmaceutical companies have property rights in their current trademarks, elimination of these marks might constitute a deprivation of property without due process of the law. However, if the retrospective rule allowed branded manufacturers to continue to use their old, trademarked names in conjunction with the new generic names (for example, Atorvastatin, formerly known as Liptor, by Pfizer), it should survive a Fifth Amendment Due Process Clause challenge because such a rule would continue to protect the goodwill these brands previously accrued. Because the government would not be using the banned pharmaceutical trademarks nor permitting others to use them, a Fifth Amendment Takings cause of action would be weaker. These marks are not taken; they simply cease to exist.

Pharmaceutical manufacturers would most likely also complain that this rule violates their First Amendment right to free speech. Relying on *Friedman v. Rogers*,<sup>234</sup> these companies would contend that their trademarks con-

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233. See *Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 412 (1916) (“The redress that is accorded in trade-mark cases is based upon the party’s right to be protected in the goodwill of a trade or business . . . Courts afford redress or relief upon the ground that a party has a valuable interest in the good will-of his trade or business, and in the trade-marks adopted to maintain and extend it.”).

234. 440 U.S. 1, 11 (1979).

stitute protected commercial speech. In *Friedman*, the Supreme Court explained:

Once a trade name has been in use for some time, it may serve to identify [a particular business] and also to convey information about the type, price, and quality of services offered for sale [by that business]. In each role, the trade name is used as part of a proposal of a commercial transaction. . . . His purpose is strictly business. The use of trade names in connection with [particular business], then, is a form of commercial speech and nothing more.<sup>235</sup>

In reaching this conclusion, the Court noted that “[s]ociety . . . has a strong interest in the free flow of commercial information, both because the efficient allocation of resources depends upon informed consumer choices and because ‘even an individual advertisement, though entirely ‘commercial,’ may be of general public interest.’”<sup>236</sup> However, the Court also explained that, unlike other forms of commercial speech, trade names have “no intrinsic meaning”<sup>237</sup>:

A trade name conveys no information about the price and nature of the services offered by [a business] until it acquires meaning over a period of time by associations formed in the minds of the public between the name and some standard of price or quality. Because these ill-defined associations of trade names with price and quality information can be manipulated by the users of trade names, there is a significant possibility that trade names will be used to mislead the public.<sup>238</sup>

Like other forms of speech, commercial speech can be subjected to some forms of government regulation.<sup>239</sup> First, “[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake.”<sup>240</sup> The State may also regulate commercial speech that is misleading or deceptive.<sup>241</sup> And “when experience has proved that in fact [a particular form of] advertising is subject to abuse, the States may impose appropriate restrictions.”<sup>242</sup> The Supreme Court’s decision in *Central Hudson Gas & Electric*

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235. *Id.*

236. *Id.* at 8-9 (quoting *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 764 (1976)).

237. *Friedman*, 440 U.S. at 12.

238. *Id.* at 12-13.

239. *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) (“Some forms of commercial speech regulation are surely permissible.”); *Bates v. State Bar of Az.*, 433 U.S. 350, 383 (1977).

240. *Va. State Bd. of Pharm.*, 425 U.S. at 771.

241. *Friedman*, 440 U.S. at 14.

242. *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999).

*Corp. v. Public Service Commission of New York*<sup>243</sup> sets forth the analytical framework used to assess whether a governmental restriction on commercial speech is permissible:

At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted government interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the government interest asserted, and whether it is not more extensive than is necessary to serve that interest.<sup>244</sup>

As the Court further explained, compliance with this third requirement “may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government’s purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.”<sup>245</sup> The Supreme Court has since clarified that the “direct advancement” requirement obligates a state to demonstrate that “the harms [the state] recites are real and that its restriction will in fact alleviate them to a material degree.”<sup>246</sup>

Accordingly, if Congress passed a law prohibiting pharmaceutical trademarks and this law was challenged under the First Amendment, the government would have to show that: (1) its interest in regulating pharmaceutical trademarks is substantial; and (2) that the harms flowing from these marks are real, and this prohibition would alleviate these harms to a material degree. The research set forth earlier in this Article suggests that both of these inquiries can be answered affirmatively. First, the government has a substantial interest in lowering healthcare costs and patient morbidity.<sup>247</sup> Second, the harms resulting from pharmaceutical trademarks are real and could be alleviated to a substantial degree by a rule prohibiting their use.

In fact, the manufacturer mark rule shares similarities with the free speech restriction upheld in *Friedman*. There, the Supreme Court ruled that a Texas law banning optometrical trade names was valid because there was substantial evidence that these trade names were being used to mislead con-

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243. 447 U.S. 557, 564 (1980).

244. *Id.* at 566.

245. *Id.* at 564.

246. *Edenfield v. Fane*, 507 U.S. 761, 771 (1993).

247. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995) (stating that the government has a substantial interest in promoting the health, safety, and welfare of its citizens); *see also Pearson*, 164 F.3d at 655-56.

sumers.<sup>248</sup> In so holding, the Court noted that “the restriction on the use of trade names has only the most incidental effect on the content of the commercial speech of Texas optometrists.”<sup>249</sup> Thus, *Friedman* suggests that a ban on pharmaceutical trademarks may be permissible as long as Congress relies on the substantial evidence available that pharmaceutical trademarks are confusing consumers. Implementation of the manufacturer mark rule would further support the constitutionality of this law because such a policy would demonstrate that the government left open other avenues for pharmaceutical companies to communicate factual and useful information to the public.

## ii. International Challenges

At the international level, pharmaceutical companies will likely argue that any rule limiting the use of their trademarks and trade dress violates the trademark provisions of the TRIPS Agreement. In response to Australia’s plain packaging laws—laws that require tobacco companies to remove all trademarks from their cartons of cigarettes—several nations<sup>250</sup> as well as the tobacco industry<sup>251</sup> have advanced a number of TRIPS-based arguments.<sup>252</sup> These legal arguments preview the position the pharmaceutical industry would likely take should a nation attempt to ban pharmaceutical trademarks.

Articles 15 through 21 of the TRIPS Agreement delineate the scope of trademark protection under this treaty. First, Article 15 defines protectable subject matter and then specifically provides that “[t]he nature of the goods or services to which a trademark is to be applied shall in no case form an

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248. *Friedman v. Rogers*, 440 U.S. 1, 13-15 (1979) (“The concerns of the Texas Legislature about the deceptive and misleading uses of optometrical trade names were not speculative or hypothetical, but were based on experience in Texas with which the legislature was familiar.”).

249. *Id.* at 15-16.

250. See *Indonesia Becomes Fifth To File WTO Case Against Australia Tobacco Plain-Packaging*, INTEL. PROP. WATCH (Sept. 22, 2013, 12:28 PM), <http://www.ip-watch.org/2013/09/22/indonesia-becomes-fifth-to-file-wto-case-against-australia-tobacco-plain-packaging> (explaining that Indonesia, Ukraine, Honduras, Dominican Republic and Cuba have filed suit against Australia at the WTO).

251. Becky Freeman, Simon Chapman, & Matthew Rimmer, *The Case for the Plain Packaging of Tobacco Products*, 103 ADDICTION 580, 585 (2008) (explaining the importance of packing and trade dress to the tobacco industry).

252. On December 1, 2012, Australia passed the Tobacco Plain Packaging Act of 2011 and became the first nation to ban trade dress on cigarette packaging. Under this law, the brand name on tobacco cartons is relegated to the bottom of the box in small, plain typeface. See *Reducing the Appeal of Smoking – First Experiences with Australia’s Plain Tobacco Packaging Law*, WORLD HEALTH ORGANIZATION, [http://www.who.int/features/2013/australia\\_tobacco\\_packaging/en/](http://www.who.int/features/2013/australia_tobacco_packaging/en/) (last visited Sept. 22, 2015); Emily Allen, *Australia To Become First Country To Introduce Unbranded Cigarette Packets*, DAILY MAIL (Nov. 10, 2011 9:38 PM), <http://www.dailymail.co.uk/news/article-2060019/Australia-country-introduce-unbranded-cigarette-packets.html>.

obstacle to registration of the trademark.”<sup>253</sup> Article 20 then states that “[t]he use of a trademark in the course of trade shall not be *unjustifiably encumbered by special requirements*, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.”<sup>254</sup>

Australia’s plain packaging law has provoked heated debate over the scope and meaning of these articles. Specifically, whether a “right to use” trademarks can be implied from the trademark provisions of the TRIPS agreement. Some scholars argue that TRIPS endows trademark owners with an inherent right to use their marks.<sup>255</sup> Others contend that a “right to use” cannot be implied from the TRIPS agreement, and therefore the protections of the TRIPS agreement only come into force when a country decides to allow trademark use in the first place.<sup>256</sup>

Irrespective of this debate, there other ways to justify certain bans on trademark use. Many scholars contend that certain bans can be upheld as “justifiable” under Article 20.<sup>257</sup> As previously mentioned, Article 20 states that “[t]he use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements.”<sup>258</sup> Thus far, the World Trade Organization (“WTO”) has not considered Article 20’s concept of “justifiability” in any of its jurisprudence.<sup>259</sup> Despite this lack of precedent, many lawyers argue Article 20’s rejection of unjustifiable encumbrances should be read in light of Article 8 of the TRIPS Agreement.<sup>260</sup> Article 8 reads:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital

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253. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 15 § 4, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

254. *Id.* art. 20.

255. Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT’L L. 1149, 1149-50 (2013).

256. See Mark Davison, *Plain Packaging and the TRIPS Agreement: A Response to Professor Gervais*, 23 AUSTL. INTELL. PROP. J. 160, 160 (2013); Mark Davison, *The Legitimacy of Plain Packaging Under International Intellectual Property Law: Why There Is no Right To Use a Trademark Under Either the Paris Convention or the TRIPS Agreement*, in PUBLIC HEALTH AND PLAIN PACKAGING OF CIGARETTES: LEGAL ISSUES 81, 81 (Tania Voon et al. eds., 2012); Andrew D. Mitchell, *Australia’s Move to the Plain Packaging of Cigarettes and Its WTO Compatibility*, 5 ASIAN J. WTO & INT’L HEALTH L. & POL’Y 405, 417 (2010).

257. See Frankel & Gervais, *supra* note 255, at 1212-13.

258. TRIPS Agreement, *supra* note 253, art. 20, Marrakesh Agreement, Annex 1C, 1869 U.N.T.S. 299.

259. Mitchell, *supra* note 256, at 413.

260. See Alberto Alemanno & Enrico Bonadio, *Do you Mind My Smoking? Plain Packaging of Cigarettes Under the TRIPS Agreement*, 10 J. MARSHALL REV. INTELL. PROP. L. 450, 472-74 (2011); Freeman et al., *supra* note 251; Mitchell, *supra* note 256, at 413-15.

importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.<sup>261</sup>

Because Article 8 only allows public health measures insofar as they are “consistent with the provision of [the TRIPS] Agreement,” this article does not constitute an exception to the other obligations of the TRIPS Agreement.<sup>262</sup> “However, Article 8 can provide interpretative guidance on what would be reasonable for the purposes of Article 20.”<sup>263</sup> As paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health explains, “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health . . . .”<sup>264</sup> Reading Article 20 through the lens of Article 8 and paragraph 4 of the Doha Declaration suggests that important public health measures may well constitute justifiable encumbrances. For example, in *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, the WTO panel noted that Article 8 “inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.”<sup>265</sup>

Under this line of reasoning, one could argue that a ban on pharmaceutical trademarks is justifiable under Article 20. Because this proposal would reduce health care costs, therein increasing a government’s ability to ensure that its entire population has access to appropriate medications, such a measure is arguably justifiable under Article 20 of the TRIPS agreement.

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261. TRIPS Agreement, *supra* note 253, art. 20, Marrakesh Agreement, Annex 1C, 1869 U.N.T.S. 299.

262. See Frankel & Gervais, *supra* note 255, at 1202-03, 1206 (“In regard to plain packaging, the key relevance of Article 8 is not that it is an exception that allows public health measures that are otherwise inconsistent with the TRIPS Agreement. The key function of Article 8 is its relevance to interpreting the object and purpose of the TRIPS Agreement and applying that to an interpretation of Article 20.”).

263. Mitchell, *supra* note 256, at 419.

264. World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 4, WTO Doc. WT/MIN(01)/DEC/2 (2001).

265. Complaint by the United States, *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, ¶ 7.210, WTO Doc. WT/DS174/R (Mar. 15, 2005).



## D. Other Options

### i. The Functionality Rule

Cognizant of the adverse effects that trade dress has on patient adherence to medication regimens, courts have employed a legal doctrine known as the functionality rule to invalidate pharmaceutical trade dress.<sup>266</sup> Under this rule, “trade dress protection may not be claimed for product features that are functional.”<sup>267</sup> In 2003, the Third Circuit held that the trade dress of Adderall, a popular Attention Deficit Hyperactive Disorder (“ADHD”) medication, was functional in *Shire U.S. Inc. v. Barr Laboratories, Inc.*<sup>268</sup> Relying on the testimony of two experts, the Third Circuit (in an opinion joined by then-Judge Alito) affirmed the lower court’s determination that ADHD patients rely on the appearance of their medications for dosage information<sup>269</sup>: “[A] generic drug’s similar appearance to the branded product ‘enhance[s] patient safety and compliance with the medically prescribed dosing regimen.’”<sup>270</sup> Because the design of Adderall did not signal the source of the medication,<sup>271</sup> but rather its content and dosage type, the court found its trade dress to be impermissibly functional.

In reaching this conclusion, the Third Circuit relied on Supreme Court case law<sup>272</sup> clarifying that if a medication’s trade dress is functional, it is ineligible for trademark protection. The Supreme Court first relied on a functionality argument to rule against a trade dress infringement claim in

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266. See, e.g., *Shire U.S. Inc. v. Barr Labs., Inc.*, 329 F.3d 348 (3d Cir. 2003); *Norwich Pharm. Co. v. Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959); *Ives Labs., Inc. v. Darby Drug Co.*, 488 F. Supp. 394 (E.D.N.Y. 1980), *rev’d*, 638 F.2d 538 (2d Cir. 1981), *rev’d sub nom.* *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982), *aff’d*, 697 F.2d 291 (2d Cir. 1982).

267. *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 29 (2001).

268. *Shire*, 329 F.3d at 359.

269. *Id.* at 354 (“Dr. Bernstein’s declaration explains, *inter alia*, that because ADHD patients overuse visual cues, (1) when therapeutically equivalent ADHD products have similar visual recognition properties, adult ADHD patients will experience less confusion in correctly identifying the agent and/or its dosage strength; (2) given that almost all patients require some initial dosage titration and a subsequent substantial majority require intermittent dosage adjustment, the color coding of a particular preparation of mixed amphetamine salts tablets confers a substantial degree of clinical functionality for the patient in the titration/adjustment process; (3) many adult patients may take multiple daily dosages of different strength amphetamine salts tablets, also inferring the usefulness of similar color-coding.”).

270. *Id.* at 355 (quoting the affidavit of Cheryl D. Blume, Ph.D., expert for the defendant).

271. See *id.*

272. *Id.* at 358 (citing *Qualitex Co. v. Jacobson Products Co.*, 514 U.S. 159, 169 (1995) (“The functionality doctrine . . . protects competitors against a disadvantage (unrelated to recognition or reputation) that trademark protection might otherwise impose, namely, their inability reasonably to replicate important non-reputation-related product features. For example, this Court has written that competitors might be free to copy the color of a medical pill where that color serves to identify the kind of medication (e.g., a type of blood medicine) in addition to its source.”).

1924. In *William R. Warner & Co. v. Eli Lilly & Co.*,<sup>273</sup> Eli Lilly sued William R. Warner & Co. for copying the trade dress of its product Coco-Quinine, an antimalarial drug (quinine) mixed with chocolate syrup. The competitor product, Quin-Coco, had similar color, taste, and name to Eli Lilly's product. However, the Supreme ruled against Eli Lilly, reasoning that Coco-Quinine's chocolate flavor did "not merely serve the incidental use of identifying the respondent's preparation," but rather "supplie[d] the mixture with a quality of palatability for which there [was] no equally satisfactory substitute."<sup>274</sup>

Furthermore, in *Ives Laboratories, Inc. v. Darby Drug Co. Inc.*,<sup>275</sup> the District Court for the Eastern District of New York held that a brand name manufacturer's trade dress for the drug cyclandelate was functional because the company relied on different colors to denote distinct dosage amounts. The court cited the fact that "some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions."<sup>276</sup> Although the Supreme Court reviewed a different aspect of this case and did not touch the functionality issue, the Court noted the district court's trade dress finding and later cited it. In *Qualitex Co. v. Jacobson Products Co.*, the Court explained:

The functionality doctrine . . . protects competitors against a disadvantage (unrelated to recognition or reputation) that trademark protection might otherwise impose, namely, their inability reasonably to replicate important non-reputation-related product features. For example, this Court has written that competitors might be free to copy the color of a medical pill where that color serves to identify the kind of medication (*e.g.*, a type of blood medicine) in addition to its source.<sup>277</sup>

The functionality argument inherently recognizes the basic premise of this article: consumers do not rely on pharmaceutical trademarks to signal the source of particular medication; instead they rely on these marks to identify the type of drug generally. Although the decision to use a color-based dosage-coding scheme is undeniably "essential to the use or purpose of the article," the specific color choices in the scheme are not. A color scheme consisting of red and blue pills is just as effective as another composed of green and purple. The only reason a drug company's *specific* color choices have any bearing on a medication's functionality is because consumers be-

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273. 265 U.S. 526 (1924).

274. *Id.* at 529.

275. *Ives Labs., Inc. v. Darby Drug Co.*, 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd*, 638 F.2d 538 (2d Cir. 1981), *rev'd sub nom.* *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982), *aff'd*, 697 F.2d 291 (2d Cir. 1982).

276. *Id.* at 399.

277. 514 U.S. 159, 169 (1995).

come accustomed the company's specific color scheme over the course of the drug's patent term. Therefore, by holding that the *specific* colors in a company's coding scheme are functional, courts are essentially recognizing that "genericide"<sup>278</sup> is inevitable in the case of pharmaceutical trade dress. Over the course of a drug's patent term, patients become so familiar with its color scheme that they begin to view these colors as signaling information about the *type* of product in general rather than its specific *source*. For example, in *Shire*, patients began to understand the branded color-coding scheme for Adderall® as providing information about type of drug they were taking. Courts use the functionality doctrine to address a larger problem: due to the initial period of market exclusivity branded drugs enjoy, pharmaceutical trademarks and trade dress inevitably end up signaling type rather than source to consumers.

Practitioners and scholars have argued that the functionality doctrine can and should be used in courts to invalidate pharmaceutical trade dress.<sup>279</sup> Without disagreeing with this proposal, it should be recognized that the functionality doctrine's impact is limited. The functionality argument most likely can only be used to address trade dress protection. It would be more difficult to prove that a drug's name was "essential to the use or purpose of the device" or "affects the cost or quality of the device."<sup>280</sup>

Furthermore, the functionality argument must be asserted on a case by case basis, usually in response to an infringement suit. Should courts increasingly accept this argument, or, even better, should the Supreme Court decide pharmaceutical trade dress is functional, generic companies could begin to copy the trade dress of brand name manufacturers without fear of attracting lawsuits. Nevertheless, litigation based on the functionality argument still does not provide as complete a change to pharmaceutical trademark policy as would a new rule instituting manufacturer marks. Although the functionality doctrine is a useful tool, it does not offer a complete solution to the problem.

## ii. FDA Guidance

A second potential fix to the issue of trademarked pharmaceuticals would be FDA-issued guidance requiring generic producers to copy the

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278. Naeve, *supra* note 130, at 326 (recognizing that the functionality argument in trade dress cases blurs the concepts of secondary meaning and functionality: "The trade dress is 'functional' because it now represents a type of medication. The effort that was required to gain protection now negates that same protection. If this is a desired result, then the shape and color of a drug should be regulated by the FDA along with the generic approval process, rather than by applying circular reasoning for secondary meaning and functionality and blurring these with the parallel purpose of genericide.").

279. See Alfred B. Engelberg, *Have Prescription Drug Brand Names Become Generic?*, 20 AM. J. MANAGED CARE 867, 867 (2014); Kesselheim, et al., *supra* note 203, at 101; Engelberg, *supra* note 180, at 321.

280. *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 33 (2001).

trade dress of the brand name reference products. A recent paper studying pharmaceutical trademarks explains that “[i]n principle, the FDA could require new generic applicants to make the shape and color of their pills conform to the brand name reference listed drug.” The authors note that formal rulemaking or legislative changes to the Federal Food, Drug, and Cosmetic Act “should not be necessary” because “[f]ederal law gives the FDA the authority to reject applications for generic drugs where ‘the composition of the drug is unsafe under such conditions because of . . . the manner in which the inactive ingredients are included,’ which would cover the appearance of the pill.”<sup>281</sup> Thus, the FDA can and should encourage, if not require, generic manufacturers to adopt the same trade dress as their brand name reference products.

The appeal of this solution is its relative simplicity: it requires no new law to be passed, and no case to be won. However, like the litigation strategy, such guidance would only solve part (although not a small part) of the problem. This guidance would not deal with the issue of trademarked pharmaceutical names. Nevertheless, this option, like the litigation strategy, should be pursued. Both of these approaches have the power to significantly lessen the inefficiencies pharmaceutical trade dress generates and could be used as stopgap measures until more comprehensive reform can be achieved.

#### CONCLUSION

In the pharmaceutical industry, trademark and trade dress protection have led many patients to believe that brand name and generic drugs truly differ. This differentiation is not grounded in rational concerns regarding manufacturing quality. Instead, a more nebulous and pernicious psychological reaction accounts for consumer preferences. This Article contends that pharmaceutical trademarks and trade dress not only fail to accomplish the core goals of trademark protection, but also undermine them. In differentiating their drugs from generic products, brand name companies ultimately confuse consumers, leading them to believe that branded and generic drugs are distinct products. This confusion, in turn, impedes effective generic competition and reduces patient adherence to prescription drug regimens, ultimately increasing health care costs and morbidity. The replacement of pharmaceutical trademarks and trade dress with manufacturers’ marks would greatly reduce the negative psychological impact associated with pharmaceutical advertising while still enabling consumers to ascertain the source of their medications.

Furthermore, the concerns expressed in this Article foreshadow a potentially greater naming problem on the horizon. This past August, the FDA released its Draft Guidance for naming biosimilar products—the generic

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281. Kesselheim, *supra* note 203, at 101 (quoting 21 U.S.C. § 355(j)(4)(H)(ii)).

versions of biologic medications.<sup>282</sup> The Federal Trade Commission (“FTC”) just responded to this draft guidance, voicing strong concerns that the FDA proposal could lead to exactly the type of confusion this Article describes.<sup>283</sup> As the FTC report explains, “FTC staff is concerned that FDA’s proposal—to assign different suffixes to the drug substance names of biosimilars and their reference biologics—could result in physicians incorrectly believing that biosimilars’ drug substances differ in clinically meaningful ways from their reference biologics’ drug substances, especially since differences in drug substance names have traditionally connoted meaningful differences in drug substances. A misperception that the drug substance in a biosimilar differs in clinically meaningful ways from that in the reference biologic could deter physicians from prescribing biosimilars, thus impeding the development of biosimilar markets and competition.”<sup>284</sup> The problem described in this Article and the recent FTC report will only continue to grow in significance as biologic patents expire and biosimilars rush onto the market. As a result, it is imperative that policy makers begin to address the confusion trademarked pharmaceutical create and consider eliminating them altogether.

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282. FOOD AND DRUG ADMINISTRATION, NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS: DRAFT GUIDANCE (Aug. 2015), *available at* <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm459987.pdf>.

283. FEDERAL TRADE COMMISSION, COMMENT OF THE STAFF OF THE FEDERAL TRADE COMMISSION SUBMITTED TO THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN RESPONSE TO A REQUEST FOR COMMENTS ON ITS GUIDANCE FOR INDUSTRY ON THE “NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS; DRAFT GUIDANCE FOR INDUSTRY; AVAILABILITY” (Oct. 27, 2015), *available at* [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf).

284. *Id.* at 2.