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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

ABSTRACT

The United States spends nearly $1,000 per person annually on drugs—40 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, the crucial role that intellectual property laws play in inhibiting access to cheaper, generic medications is among one of the best documented. 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 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 paper 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 paper 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 paper encourages policymakers to reexamine the utility of trademarks in the pharmaceutical industry and ultimately suggests that such names should be replaced 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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I. **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, those studying the effect these exclusionary rights have on public health have focused on the relationship between patent law and drugs—how does patent protection impede access to generic medicines? And in the last thirty years, the experts and regulators have had much to discuss, in view of 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), which have modified the scope of patent protections when addressing the intersection of intellectual property law and public health.

However, patents are not the only form of intellectual property that affect access to medications. Increasingly, policymakers and scholars alike are turning their attention to the negative impact trademark law can have 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 the Pepsis® and locate the particular good they desire. These marks greatly reduce the confusion that the breadth of market options would otherwise generate.

Yet, recent research has shown that trademarks in the pharmaceutical industry tend to perform the opposite function. Instead of clarifying the source of a particular medication, pharmaceutical trademarks may be confusing patients into believing that trademarked drug names are actually the names of the drugs themselves and, accordingly, drugs that do not possess those names, such as generic drugs, are *different* medications. New studies show that
pharmaceutical trademarks are diminishing the ability of consumers to distinguish accurately between generic and brand name medications, and this confusion is leading to wasteful spending and even substantial morbidity.\(^1\) This revelation suggests that pharmaceutical trademarks undermine the core purpose of trademark law: instead of reducing consumer confusion and enhancing market efficiency, they actually do the opposite.

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.\(^2\) Although Indian officials have since decided against this total ban, a version of the proposal is still under consideration.\(^3\) According to the Drug Controller General of India, Dr. G.N. Singh, “We 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.”\(^4\) In a country where many people buy brand name medications simply because they do not know that generic medications are bioequivalent to their brand name counterparts, such a law has the potential to change purchasing behaviors, thereby lowering health care expenditures significantly.\(^5\)

\(^1\) See *infra* Part III & IV.A.
\(^4\) *Id.*
\(^5\) 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 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
While India’s consideration of a ban on pharmaceutical trademarks may be relatively recent, the realization driving it is not: a 1977 U.S. Federal Trade Commission report on sales, promotion, and product differentiation in the pharmaceutical market found that “unlimited trademark life does exact social costs.” After analyzing the effects of trademark protection on the pharmaceutical market, the report suggested that “the trademark, like the patent, might be given a limited life.”

What has happened to this recommendation over the course of the last thirty years? Do pharmaceutical trademarks fill the role they are intended to accomplish? Do they facilitate market efficiency through the supply of accurate information to consumers? Or are they actually confusing patients and physicians into irrationally mistrusting generic products?

This paper attempts answer those questions and contribute to the growing dialogue regarding the impact of trademark law on public health. Relying on pharmaceutical case studies and behavioral research regarding physician and consumer prescription and purchasing habits, this paper contends that pharmaceutical trademarks and trade dress confuse consumers into believing that brand name medications are different from and superior to their generic counterparts. This confusion influences prescription and purchasing behaviors, needlessly inflating health care costs and dangerously reducing patient adherence to generic drug regimens. Accordingly, this paper encourages policymakers to reexamine the utility of trademarks and trade dress in the pharmaceutical industry, arguing that such protection actually runs counter to the purpose of trademark protection. While trademarks may facilitate consumer knowledge and

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6 BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATIONS IN TWO PRESCRIPTION DRUG MARKETS 80 (1977).
7 Id.
market efficiency in other arenas, they are leading to market failure in the pharmaceutical industry.

The remainder of this paper proceeds as follows: Part II provides an overview of trademark law and the scholarly debate regarding the effects trademarks have. Part III relies on quantitative and qualitative data to argue that pharmaceutical branding not only fails to serve the primary purpose of trademark law—reducing consumer confusion—but actually increases confusion. This part also contends that consumers do not rely on pharmaceutical trademarks to ascertain the sources of those drugs, i.e., which companies manufacture them. Ultimately, this part concludes that the costs associated with pharmaceutical trademarks and trade dress outweigh their benefits. Finally, Part IV offers a possible solution—the elimination of pharmaceutical trademarks and trade dress and their replacement with manufacturer marks—and explores the potential limitations of this solution.

II. 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 from others. 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 enhance the ease with which producers speak to

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8 See 1 J. THOMAS McCARTHY, TRADEMARKS AND UNFAIR COMPETITION § 3:1 (4th ed. 2014) (“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.” (quoting Lanham Act of 1946 § 45, 15 U.S.C. § 1127 (2012))).
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, trademarks are not provided for in the Constitution. Instead, the federal power to grant and regulate trademarks derives from the Commerce Clause of the Constitution: because trademarks help consumers identify the products they desire, they enhance the flow of commerce across the nation. This generalized objective of stimulating commerce is distinct from the particularized aim of patent and copyright law, which seek to stimulate specific types of economic activities, namely the arts and sciences. Thus, in contrast to patent and copyright law, trademark law principally functions as form of tort law, protecting consumers from unfair competition and consumer deception.

Although trademarks themselves have existed for “almost as long as trade itself,” U.S. trademark law remained the dominion of the courts rather than the legislature until the late nineteenth century. Trademarks were protected solely by common law until 1870, when

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9 Article I, Section 8, Clause 8 endows Congress with the power to enact laws for the protection of patents and copyrights: “To 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.” U.S. Const. art. I, § 8, cl. 8.
10 See Trade-Mark Cases, 100 U.S. 82, 94 (1879); McCarthy, supra note 8, § 6:2.
11 Barton Beebe et al., Trademarks, Unfair Competition, and Business Torts 27 (2011).
12 Id. at 13.
13 See id. at 27 (citing Mark McKenna, The Normative Foundations of Trademark Law, 82 Notre Dame L. Rev. 1839 (2007)).
14 Id. at 25.
15 Id. at 26 (citing Lawrence Friedman, A History of American Law 257 (2d ed. 1985)).
Congress enacted the first trademark statute. Today, the Lanham Act protects trademarks. At the time Congress enacted the Lanham Act in 1946, the scope of trademark law was relatively narrow: advertising slogans, trade names, and trade dress (product packaging), were not protectable as trademarks. Although these restrictions, in part, arose from the common law’s requirement that a trademark be affixed to particular product in order to receive protection, the prevailing understanding that drove these limitations was consumers did not rely on slogans, trade names, and trade dress to identify the source of a particular product, and therefore such properties did not merit trademark protection.

Since the passage of the Lanham Act, however, the courts, the Patent and Trademark Office, and, to a lesser extent, Congress have widened the scope of trademark protection so that it now shelters slogans, trade names, and trade dress from imitation. While the term “trademark” encompasses words, names, symbols, devices, or combinations thereof, a product’s packaging or design is referred to as its trade dress. For example, a drug’s size, shape, and color are aspects of its trade dress, and all of these features may qualify for protection. Under the Lanham Act, producers may technically obtain a trademark on any distinctive word, name, symbol,

16 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. 82, 94 (1879). In response, Congress enacted another trademark statute in 1881, this time using its Commerce Clause power. BEEBE, TRADEMARKS, supra note 11, at 26.
18 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 AFTER ONE YEAR’S ADMINISTRATION, 38 TRADEMARK REP. 831, 834-36 (1948). Nevertheless, advertising slogans and trade dress were protectable as trademarks under state unfair competition law at this time.
19 Lunney, supra note 18, at 374.
21 Id.
device,\textsuperscript{23} packaging,\textsuperscript{24} or design\textsuperscript{25} as long as the producer uses that mark in commerce\textsuperscript{26} to signal the good’s source.\textsuperscript{27} 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.”\textsuperscript{28} Courts have extended the scope of protectable subject matter to colors,\textsuperscript{29} taste,\textsuperscript{30} sound,\textsuperscript{31} and smell.\textsuperscript{32}

The current broad scope of trademark protection does have limits. Before a producer can obtain a trademark, she must demonstrate that her mark is distinctive. While some marks, such as those that are fanciful,\textsuperscript{33} arbitrary,\textsuperscript{34} or suggestive,\textsuperscript{35} are inherently distinctive, others, such as

\begin{itemize}
  \item Fanciful trademarks are coined words or phrases that have no inherent meaning or relationship to the product they mark (for example, Pespi®, Kodak®, or Exxon®).
  \item 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, Inc. v. Oak Grove Smokehouse, Inc., 698 F.2d 786, 791 (5th Cir. 1983), \textit{abrogated on other ground} by KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc., 543 U.S. 111 (2004).
\end{itemize}

\textsuperscript{22} Id.
\textsuperscript{23} Id.
\textsuperscript{24} Id. § 1125. 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, TRADEMARKS, supra note 11, at 41.
\textsuperscript{26} Id. § 1127.
\textsuperscript{30} See \textit{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).
\textsuperscript{32} See \textit{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).
\textsuperscript{33} Fanciful trademarks are coined words or phrases that have no inherent meaning or relationship to the product they mark (for example, Pespi®, Kodak®, or Exxon®).
\textsuperscript{34} 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, Inc. v. Oak Grove Smokehouse, Inc., 698 F.2d 786, 791 (5th Cir. 1983), \textit{abrogated on other ground} by KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc., 543 U.S. 111 (2004).
descriptive marks, are only protectable if they have acquired a secondary meaning in the minds of consumers. Furthermore, marks that are generic are not protectable at all. Trade dress can only qualify as inherently distinctive when that trade dress consists of the product’s packaging; trade dress that centers on the product’s configuration or design cannot be inherently distinctive. Although the distinction between product packaging and product design can be murky, the basic difference between these two forms of trade dress centers on whether the dressing merely indicates origin of the product (product packaging) or serves to enhance the product’s appeal or usefulness (product design). Finally, a producer cannot obtain a trademark on any product feature that “is essential to the use or purpose of the article or if it affects the cost or quality of the article.”

35 Trademarks such as Coppertone® or Amtrak® are classed 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.
36 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.
37 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.
38 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, TRADEMARKS, supra note 11, 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 arguable generic because they have become synonymous with photocopying machines and tissues, respectively. See BEEBE, TRADEMARKS, supra note 11, at 70-71, 75-77.
40 Id. at 212-13.
Some academics rationalize the growth in scope of trademark protection as a necessary corollary to market expansion and product diversification in the twentieth century.\(^{42}\) Nevertheless, other academics note that “much of this expansion 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.”\(^{43}\)

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 not only minimize consumer confusion but also ensure manufacturers maintain consistent product quality.\(^{44}\) Because trademarks enable consumers to locate products they would like to try or have enjoyed in the past, these marks reduce the consumer confusion that a marketplace replete with options would otherwise generate. Although the abundance of choices available in any given market is, in and of itself, enough to overwhelm most consumers, without trademarks, these options would become unmanageable. 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.\(^{45}\)

By clarifying the source of a particular product, so this argument goes, trademarks enhance the efficiency with which consumers make their purchases.

\(^{42}\) Lunney, *supra* note 18, at 374.

\(^{43}\) *Id.*; see also Beebe, *TRADEMARKS, supra* note 11, at 27.

\(^{44}\) *See* McCarthy, *supra* note 8, § 3:2; Beebe, *TRADEMARKS, supra* note 11, at 30.

\(^{45}\) 772 F.2d 1423, 1429-30 (7th Cir. 1985).
Trademarks also provide producers with an incentive to manufacture products of consistent quality; a trademark is only valuable insofar as consumers can trust that all products bearing its mark are of the same quality. As J. Thomas McCarthy explains in his canonical treatise on trademark law, “[s]ince 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.”

Thus, trademarks help guarantee the quality consistency of the products they mark.

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,” who coolly and rationally evaluate the worth of a particular good, or are we “Pavlovian fools,” who fall prey to corporate manipulation of our desires and opinions?

i. The Economic Model of Trademark Law

Many scholars argue that trademark law promotes economic efficiency by encouraging firms to cater to the desires of rational consumers. The originators of this argument, known as the economic model of trademark law, are Richard Posner and William Landes. Landes and

\[\text{\footnotesize McCARTHY, supra note 8, at \$ 17:24 (internal footnote omitted).}\]
\[\text{\footnotesize Id. at 2023}\]
Posner not only acknowledged that trademarks reduce search costs, but also argued that the exclusive right to trademark protection actually encourages producers to improve the quality of their products. Landes and Posner warn that, without strong trademark protection, imitators will free ride on the goodwill the primary producer has acquired for his mark and “eventually destroy the information capital embodied in a trademark.” These scholars fear that the prospect of free riding alone may “eliminate the incentive to develop a valuable trademark in the first place.”

It is important to recognize that this argument assumes consumer valuations of trademarks truly correspond to the quality of the products they mark. Landes and Posner dismiss “the power of brand advertising to bamboozle the public and thereby promote monopoly.” 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. Her psychology is understood to be predictable, administrable, and ultimately ameliorative.”

Yet, Landes and Posner are not blind to their assumption. They acknowledge that the notion of an entirely rational consumer appears at odds with the reality of purchaser preferences for brand name over generic goods when latter are “produced according to an identical formula,

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50 Landes & Posner, supra note 49, at 270 (“The value of a trademark is the saving in search costs made possible by the information or reputation that the trademark conveys or embodies about the brand (or the firm that produces the brand).”).
51 Id.
52 Id. at 274.
53 Id. at 274-75.
54 Beebe, Search and Persuasion, supra note 27, at 2023.
55 Landes & Posner, supra note 49, 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.”).
such as aspirin or household liquid bleach.” 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 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.

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 III.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 trademarks and their capacity 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, when it had greater

56 Id.
57 Id. at 274-75 (1987) (emphasis added).
58 BEEBE, TRADEMARKS, supra note 11, at 32.
influence.\textsuperscript{59} Despite its decline in popularity, it has enjoyed a recent surge in recognition due to the rise of the field of behavioral economics.\textsuperscript{60}

Economist Edward Chamberlin’s publication of \textit{The Theory of Monopolistic Competition} in 1933 largely drove the scholarly community’s acknowledgement of the potentially anticompetitive effects of trademark law.\textsuperscript{61} Chamberlain explained that strong trademark protection enables a producer to differentiate his product and persuade consumers that only his brand will satisfy the consumers’ demand.\textsuperscript{62} This manipulation, in turn, allows the producer to achieve a monopoly in his “distinct market.”\textsuperscript{63} Nevertheless, Chamberlin did not argue that trademarks have no utility\textsuperscript{64}: he recognized the value of product differentiation and its corresponding ability to reduce consumer search costs. But one of the primary achievements of Chamberlain’s work was to reveal the economic inefficiency that results from trademark

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[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 pressures of price and quality competition. In consequence the competitive system fails to perform its function of allocating available resources efficiently.
\end{flushright}

\textit{Id.}

\textsuperscript{64} \textit{Chamberlain, supra} note 62, at 93-99 (“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 . . . .”).
protection. Through artificial product differentiation, trademark protection enables manufacturers to capture consumer loyalty in a (sometimes) detrimental manner.

Chamberlain’s contemporary, Frank Schechter, also appreciated the importance of artificial product differentiation. In *The Rational Basis of Trademark Protection*, Schechter argued that “the value of the modern trademark lies in its selling power.” 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.” Ultimately, Schechter “recognized what empirical work has since demonstrated: that consumers will pursue distinctiveness, even ‘meaningless differentiation,’ for its own sake.”

The work of Chamberlain and Schechter not only influenced the views of fellow scholars, but also swayed lawmakers and judges. Justice Frankfurter’s famous trademark opinion in *Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co.* bears the imprint of Schechter’s and Chamberlain’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.

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

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66 *Id.*
68 Lunney, *supra* note 18, at 368.
69 316 U.S. 203, 205 (1942) (emphasis added).
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, Chamberlain’s and Schechter’s arguments began to lose traction in the second half of the twentieth century. Some trademark scholars began to argue that trademarks were simply property, not monopolistic tools.\(^{70}\) They ridiculed those who believed that trademarks led to monopolies as “infected with monopoly-phobia.”\(^{71}\) Like Landes and Posner, these theorists contended that trademarks simply enable consumers to distinguish between competing goods.\(^{72}\) Today, the courts and the Patent and Trademark Office (PTO) largely subscribe to Landes and Posner’s economic analysis of trademark law.\(^{73}\)

Chamberlain and Schechter’s arguments, however, are far from dead. In the second half of the twentieth century, the work of Ralph Brown reaffirmed Chamberlain’s core points.\(^{74}\) An avid trademark restrictionist, Brown viewed trademark law as an instrument of consumer manipulation:

\(^{70}\) *See* Lunney, *supra* note 18, at 486.

\(^{71}\) *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.”), *cert. denied*, 320 U.S. 758 (1943); *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 TRADE-MARKS § 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).

\(^{72}\) Lunney, *supra* note 18, at 486.

\(^{73}\) BEEBE, TRADEMARKS, *supra* note 11, at 28; Lunney, *supra* note 18, at 371-72 (“Courts 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.’”).

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.  

Despite this cynicism, Brown, like Chamberlain, recognized that advertising could serve a useful
function insofar as it provides truthful information to consumers. But beyond this informational
value, Brown believed that advertising not only wasted resources, but also induced irrational
consumer preferences. Brown rejected the notion that the law should protect trademark as
property in and of itself.

Today, many legal scholars continue to analyze the anticompetitive effects of trademark law. Some of these scholars have followed Brown and argued that consumers are victims of the
persuasive effects of well designed trademarks, while others are more wary of this

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75 Id. at 1169 and 1182.
76 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”).
77 Id. at 1168.
78 Id. at 1205-06.
79 See, e.g., Jeremy N. Sheff, Biasing Brands, 32 CARDOZO L. REV. 1245, 1272 (2011); Mark A.
(1999); Lunney, supra note 18, at 420 n.212.
80 See, e.g., Sheff, supra note 79, 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 18, 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?”).
characterization of consumer freewill.\footnote{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 79, 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.").} Yet, all of these scholars acknowledge that heightened trademark protection can inefficiently impede competition through artificial product differentiation. 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.”\footnote{Lemley, supra note 79, at 1695-96.}

Lawyers are not alone in investigating the persuasive, non-informational function of trademarks.\footnote{See, e.g., Roger Feldman & Félix Lobo, Competition in Prescription Drug Markets: the Roles of Trademarks, Advertising, and Generic Names, EUR. J. HEALTH ECON. 2 (2012). These public health academics note that “trademarks can have anticompetitive effects.” 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.” Neuroscientists have also documented the distorting effects of trademarks on consumer preferences. Samuel M. McClure, et al., Neural Correlates of Behavioral Preference for Culturally Familiar Drinks, 44 NEURON 379 (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.} In the field of business, marketing, and advertising, 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.” 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. “From Calkins’s initial leads, advertising legends like David Ogilvy and Leo Burnett ran with this idea . . . and began to methodically drive home linkages between product attributes and a package of desirable personal characteristics that together was declared to constitute the modern good life.”

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 and consumers can derive psychological satisfaction from the purchase of brands that reinforce their self-image.

The psychological effects of brands are completely distinct from the informational role trademark law assumes they play. As leading business and marketing scholar, Tim Ambler explains,

Psychological benefits differ from functional in that they lie in the mind of the consumer as distinct from lying in the product. They are an area of discomfort for those economists and consumerists who prefer a wholly rational world. . . . 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.

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85 Id.
Their findings could be interpreted as meaning that originally random choices are then maintained if consumers feel them to be right.\textsuperscript{88}

Although this research reveals 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.”\textsuperscript{89} In other words, if a consumer purchases a Gucci purse to signal her social status or fashion savvy, the purse’s quality is irrelevant. In that scenario, the brand is not important because it informs the consumer of the purse’s source; the trademark is important because it is itself a commodity—a phenomenon that explains why consumers readily seek out Gucci purses they know to be fakes.

In addition to the psychological satisfaction consumers can derive from certain brands, researchers have also found that consumers can obtain psychological fulfillment from the familiarity of a brand. Under this view, habit guides brand selection\textsuperscript{90}: Consumers do not buy a particular brand because they like it; they like that brand because the habit of purchasing it is comforting.\textsuperscript{91} “Brand loyalty may reflect, therefore, only the convenience inherent in repetitive behavior rather than commitment to the brand purchased.”\textsuperscript{92}

Whatever the psychological merits of brands may be, trademark law was not designed to protect those benefits. As the history of trademark law makes clear, we protect brands in order to

\textsuperscript{88} Id. at 24-25 (citing GORDON FOXALL, CONSUMER PSYCH. IN THE BEHAV. PERSP. (1990) & T. Robertson, Low-Commitment Consumer Behavior, 16 J. OF ADVERTISING RES. 19 (1976)).
\textsuperscript{89} Id. at 25.
\textsuperscript{90} Id. at 20 (citing JOHN O’SHAUGHNESSY, WHY PEOPLE BUY (1987)).
\textsuperscript{91} O’SHAUGHNESSY, WHY PEOPLE BUY.
\textsuperscript{92} Ambler, supra note 87, at 26 (citing S.H. Chaffee & J. M. Macleod, J. M., Consumer Decisions and Information Use, in CONSUMER BEHAVIOR: THEORETICAL SOURCES. 385 (S. Ward & T.S. Robertson eds., 1973) and T. Robertson, Low-Commitment Consumer Behavior, 16 J. ADVERTISING RES. 19 (1976)).
ensure consumers are not deceived: trademarks were intended to play an informational role. Therefore the marketing research that describes the psychological impact of branding serves to strengthen the arguments of critics like Brown, Lunney, Chamberlain, and Schechter. This research also supports the argument advanced in this paper: pharmaceutical trademarks are inefficient because their psychological impact is greater than their informational value, to the consumer’s detriment. If trademarks lead patients to believe that branded medications, and only branded medication, can satisfy their needs, then pharmaceutical trademarks are actually increasing confusion rather than reducing it.

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

Brand name pharmaceutical manufacturers have spent billions of dollars advertising their products to ensure that consumers can recognize drugs by their name, color, and shape. The trademarks and dress of popular medication are etched into our cultural conscious and vocabulary. But is this branding actually useful to consumers? This section argues that pharmaceutical trademarks not only fail to reduce consumer confusion, but actually increase it. This section also contends that pharmaceutical trademarks and trade dress do not play a significant role in ensuring consistent product quality. Drawing on these conclusions, this section suggests that the harms associated with pharmaceutical trademarks do not outweigh their benefits and are ultimately decreasing market efficiency.

A. Background: Pharmaceutical Trademarks and Nomenclature

Every drug that the FDA approves in the United States has three separate names: a chemical name, a generic (non-proprietary) name, and a brand (proprietary) name. For example, Tylenol® is the brand name of the drug which has the chemical name N-(4-hydroxyphenyl) acetamide and the generic name acetaminophen. A drug’s chemical name describes its chemical makeup, and, for the most part, physicians and pharmacists do not use this name in their practices. A drug’s generic name is usually composed of a medically significant stem and a chemically significant root and directs physicians and pharmacists to a particular drug class. Like other generic marks, generic drug names are not eligible for trademark protection.


See Rados, supra note 95, at 37.


See Linda Gundersen, The Complex Process of Naming Drugs, 129 ANNALS OF INTERNAL MED. 677, 677-78 (1998), available at http://www.annals.org/cgi/content/full/129/8/677. 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 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.
In the United States, drugs obtain their generic names from the United States Adopted Names Council (USAN Council),99 which gives generic names to all FDA approved medications.100 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.101 With respect to brand names, the FDA defines a drug’s propriety name as “the name the applicant or other entity will use for the commercial distribution of the product.”102 Drug companies give their medications proprietary names in order to improve consumer recognition of their products.103 “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.’”104 Proprietary names are eligible for trademark protection.

The FDA is primarily responsible for reviewing and approving proprietary drug names and their subsequent trademarks.105 This authority is rooted in the FDA’s responsibility to

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99 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 97, at 109 (citing 21 C.F.R. § 299.4(c) (2006)).
101 See Gundersen, supra note 98, at 677-78.
103 Herberholz, supra note 97, at 110.
104 Id.
regulate misleading drug labeling. The Patent and Trademark Office also routinely reviews pharmaceutical trademarks.

FDA’s focus is patient safety while the USPTO’s focus is consumer confusion as to the product’s source in the marketplace. 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.

Together, the FDA and PTO attempt to ensure that a drug’s proprietary name is neither misleading nor confusing to consumers.

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). Although courts have sometimes invalidated a pharmaceutical firm’s trade dress on the grounds that the design is functional and not merely decorative, 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.


107 Clarke, supra note 105, at 442; Clifford, supra note 106.

108 Clarke, supra note 105, at 442; Clifford, supra note 106.

109 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.

110 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).

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.\textsuperscript{112} Second, because prescription drugs are repackaged at a pharmacy before they are sold to consumers,\textsuperscript{113} a medication’s “unique shape and color is a crucial means of . . . influencing consumer preference.”\textsuperscript{114} Pharmaceuticals companies carefully select the trade dress of their products so that a medication’s design becomes a “fundamental part of [the] drug[‘s] personality.”\textsuperscript{115}

[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.\textsuperscript{116}

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

\textsuperscript{112} Michael A. Steinman, Mary-Margaret Chren, & Seth Landefeld, \textit{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).

\textsuperscript{113} David M. Fritch, \textit{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 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)).

\textsuperscript{114} Id.; see also Jain & Conley, \textit{supra} note 94, at 18.


\textsuperscript{116} Charles W. Schmidt, \textit{Have I Got a Drug for You!}, 4 MODERN DRUG DISCOVERY 41, 41 (2001).
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 their 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 differ.\footnote{117}

\footnote{117 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 Pharm. 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, Why Do the Same Drugs Look Different?, supra note 111, 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. The Third Circuit concluded that Premo’s copying of SK&F’s trade dress was actionable because 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.}

\textit{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 \textit{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
In 1984, Congress amended the Food, Drug, and Cosmetics Act (FDCA), which led 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. In order to qualify as a generic medication, the producer of such a drug must prove to the FDA that his drug has the same “dosage form, safety, strength, route of administration, quality, performance characteristics[,] and intended use”\(^\text{118}\) as its branded counterpart.\(^\text{119}\)

Do generic drugs live up to this test? Substantial scientific research answers this question affirmatively. Many studies document the bioequivalence of generic and brand name drugs, even for medications with narrow therapeutic indices.\(^\text{120}\) Studies on medications that treat cardiovascular disease,\(^\text{121}\) epilepsy,\(^\text{122}\) psychiatric disorders,\(^\text{123}\) asthma,\(^\text{124}\) neurologic disorders,\(^\text{125}\) pills that were not equivalent.


\(^{119}\) 21 U.S.C. § 355(j)(2)(A)(iv) (2006); see also Fritch, supra note 113, 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.”).

\(^{120}\) 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 J. AM. MED. ASS’N. 2514, 2514-25 (2008); see also Greene & Kesselheim, Why Do the Same Drugs Look Different?, supra note 111, 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.

\(^{121}\) See Kesselheim, Clinical Equivalence, supra note 120, at 2514-25 (concluding that it is “reasonable for physicians and patients to rely on FDA bioequivalence rating as a proxy for
and dermatologic conditions 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.” 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.”

Despite substantial medical research to the contrary, some still argue that there are reasons to differentiate between FDA-approved generic medications and branded drugs. First,
physicians have remarked on slight but important differences in efficacy between generic and branded drugs, usually in the context of drugs with narrow therapeutic indices. In other words, some physicians dispute the bioequivalence of branded and generic drugs with narrow therapeutic indices. This paper will discuss these studies and their potentially flawed results at greater length in the following subsection.

Second, some argue that the manufacturing quality of branded and generic drugs may differ. This argument is distinct from the bioequivalence point: 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 is more a vote of confidence in the company than the drug itself, and the consumer presumably cares about the source of her medication. Trademarks enable her to more readily discern that source. Indeed, as discussed in Part II, Landes and Posner counter the argument that trademarks lead to artificial differentiation between formulaically identical products by pointing

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131 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.”); 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, 1087 (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 49, 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.”).

132 See *supra* Part II.B.i.
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.”\textsuperscript{133}

Although there have been some reports of poor drug manufacturing quality in the past few years\textsuperscript{134} these reports do not appear exclusive to generic manufacturers. Reported problems with manufacturing quality have included both branded and generic manufacturers.\textsuperscript{135} Furthermore, many branded drug producers also manufacture generic medications.\textsuperscript{136} In these instances, the distinction between the manufacturing quality of generic and branded drugs may not apply, since the same producer is in charge of manufacturing both drugs. In general, not a single study that bears out the fear of shoddy generic manufacturing. Such a fear is rooted in no more than an un-particularized suspicion of generic quality in general, rather than real differences between the two groups 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 that they are safe and regulation compliant.\textsuperscript{137} The FDA conducts over 1000 inspections of domestic facilities per year, inspecting approximately 40 percent of domestic establishments. The Government Accountability Office has estimated that, at this rate,

\textsuperscript{133} Landes & Posner, supra note 49, at 275.


\textsuperscript{135} See Thomas, Lapses at Big Drug Factories, supra note 133.

\textsuperscript{136} Id.

\textsuperscript{137} UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, FDA HAS CONDUCTED MORE FOREIGN INSPECTIONS AND BEGUN TO IMPROVE ITS INFORMATION ON FOREIGN ESTABLISHMENTS, BUT MORE PROGRESS IS NEEDED (2010), available at http://www.gao.gov/new.items/d10961.pdf.
FDA inspects domestic manufacturers approximately once every 2.5 years.\textsuperscript{138} 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. For example, the FDA recently opened offices in India and China as well as increased the number of inspections it conducts at foreign pharmaceutical plants. Moreover, the new commissioner of the FDA, Margaret Hamburg, has stated that the inspection of pharmaceutical manufacturing facilities is a top priority for the FDA in general.\textsuperscript{139}

This level of regulation is fairly unique: the U.S. government does not monitor the output quality of most other consumer good and service industries. Although government agencies may promulgate rules and regulations with which other industries, such as the automobile or power-tool industry, must comply, 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.\textsuperscript{140} It does, however, provide an extra check on the safety and regulatory compliance of pharmaceutical manufacturers. Such regulation should ease

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\textsuperscript{139} *Staff of H.R. Comm. on Oversight & Gov’t Reform,* 112TH CONG., REP. ON FDA’S CONTRIBUTION TO THE DRUG SHORTAGE CRISIS 34 (Comm. Print 2012), available at http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-Report-FDAs-ContrIBUTION-to-the-Drug-Shortage-Crisis.pdf (“The FDA is fortunate to have received significant funding increases for the current and next fiscal year that will be devoted to additional inspection and compliance activities that will support the elements of an effective enforcement strategy . . . .”.

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the fears of those who believe that strong trademark protection is necessary to ensure product quality.

Finally, some note that generic and branded drugs often differ in their non-active ingredients, such as the dyes used to create the pill’s color or filler ingredients. The merit of this argument is dubious due to its lack of substantiation. Nevertheless, it is theoretically possible that some dyes affect patients differently. This possibility, however, 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 that dyes they use are chemically inert.

Overall, the available research examining the differences between generic and branded drugs has not found that these types of medications are different in any real way. Therefore, differentiation between them appears irrational and artificial.

ii. Artificial Product Differentiation in the Pharmaceutical Market

Despite this equivalence as well as a substantial price difference (generic drugs are often between 80 and 85 percent cheaper than their branded counterparts\textsuperscript{141}), consumers and doctors frequently prefer branded medications to generic ones\textsuperscript{142}. 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.”

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 ten percent of participants believed that generic drugs cause more side effects than branded drugs. Furthermore, only 10.9 percent of study participants disagreed with the statement, “Americans should use more generic drugs,” while almost 56 percent agreed. However, when the subjects were asked if they “would rather take generics than branded medications,” only 37.6 percent agreed, while 26.1 percent disagreed. 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.” 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. As the authors of the study conclude, these results suggest that patient decision-making “might not be rational from an economic perspective.”

A study of 505 prescription drug users in the Houston area lends further support to this conclusion. Twenty-two percent of respondents agreed that “generic substitution limited their

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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.
ability to get what their doctor had prescribed, and about twenty percent believed that it would limit their chances of getting the best medications.” 150 Nevertheless, a majority of these study participants (sixty-one percent) did not believe that generic substitution increased the number of side effects they experienced. 151 This Houston 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 their manufacturers than actual measures of the drugs’ performance. 152 Another study found that physicians’ interaction with drug companies influenced their requests that particular drugs be added to their hospitals’ formularies. 153 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.” 154 This study, among others, supports the notion that pharmaceutical advertising and promotion induce physicians to act irrationally. 155 Doctor and patient irrationality may be mutually reinforcing: as doctors prescribe more branded drugs, patients will inevitably be inclined to believe that they are superior.

150 Id. at 82.
151 Id. at 85.
153 Steinman, Chren, & Landefeld, supra note 112.
155 See also id. at 113.
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, doctors Troyen Brennan and Thomas Lee describe the case of a woman who claims she is allergic to generic 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 consultation 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.”

In this anecdote, the patient irrationally views generic drugs as a completely distinct class of medications. She 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

Why does this patient believe she is allergic to generic medications despite her doctor’s assurances that such a condition is a medical impossibility? Her conviction is not difficult to

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156 Troyen A. Brennan & Thomas Lee, Allergic to Generics, 141 ANNALS OF INTERNAL MED. 126, 126 (2004) (emphasis added).
explain. The strategic use of trademarks and advertising in the pharmaceutical industry are driving artificial differentiation between branded and generic medications in exactly the way Edward Chamberlain, Frank Schechter, and Ralph Brown predicted they would.\footnote{See supra Part II.B.ii.} Even when consumers and physicians logically understand that generic and branded drugs are equivalent—and therefore agree with the statement that the American population, as a whole, should take more generics—they have demonstrated an inability to apply this logic to their own drug decisions.

Patent-holders use trademarks and trade dress to define their products and imbue them with an air of uniqueness and originality. As Frank Schechter argued, “the value of the modern trademark lies in its selling power”\footnote{Schechter, supra note 65, at 831.} 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 distinctiveness and singularity.”\footnote{Id.} 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 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 $57.7 billion on promotional activities.\footnote{Marc-André & Joel Lexchin, The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, 5 PLoS MED. 29, 31 (2008).} Nearly a fourth of that sum ($4.7 billion) went towards direct-to-consumer advertising (DTC)—pharmaceutical promotions through television, print, and
radio that directly target consumers.\textsuperscript{161} These DTC efforts have proved to be highly profitable: “in 2001, every dollar spent on DTC advertising resulted in an additional $4.20 in sales.”\textsuperscript{162} Pharmaceutical companies also spend significant sums of money promoting their products to doctors and hospitals.\textsuperscript{163} In one survey, four out of five physicians reported that brand name drug representatives visit their practices weekly to advertise pharmaceutical products.\textsuperscript{164} In contrast, these same physicians reported that they do not receive promotional materials from generic companies.\textsuperscript{165} 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,”\textsuperscript{166} and this persuasion leads to irrational decision making based on a false sense of distinctiveness.

Branded manufacturers also benefit from the habit forming behavior that occurs during the exclusive sales period they enjoy. As discussed in Part II, habit often drives purchasing decisions, rather than reliance on relevant information.\textsuperscript{167} The work of marketing specialists who find that consumers derive psychological satisfaction from habit suggests that patients choose to stay with more expensive, branded medications not because they believe the brands are actually safer or more effective, but rather because the habit of purchasing the same brands is comforting.\textsuperscript{168} Information

\begin{footnotesize}
\textsuperscript{161} CONGRESSIONAL BUDGET OFFICE, supra note 93, at 1.
\textsuperscript{162} Herberholz, supra note 97, at 117.
\textsuperscript{163} The pharmaceutical industry spends more than $7 billion per year on direct marketing to doctors. M. Raffaele, States Combat Drug Reps to Cut Costs, WASH. POST, March 2, 2008.
\textsuperscript{164} BARRETT, supra note 142, at 8.
\textsuperscript{165} Id.
\textsuperscript{166} Brown, supra note 74, at 1169 & 1182.
\textsuperscript{167} Ambler, supra note 87.
\textsuperscript{168} JOHN O’SHAUGHNESSY, WHY PEOPLE BUY (1987).
\end{footnotesize}
regarding the bioequivalence of two drugs is irrelevant when psychological desire for brand familiarity drives drug purchases.

A well-known case study helps illustrate this point. In the fall of 1989, the pharmaceutical manufacturer, AstraZeneca, introduced a new class of gastroesophageal reflux disease (GERD) medication known as proton-pump inhibitors (PPIs). 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. Pre-patent expiration, AstraZeneca’s Prilosec® (omeprazole) sold at a premium price of $4 per pill, and, by 2000, it was the world’s top selling drug, earning over $6 billion per year in the United States.

However, AstraZeneca’s market exclusivity could not last forever. Faced with patent expiration in 2001, AstraZeneca convened a team to craft a post-expiration marketing strategy.

Formal planning for sustaining the [AstraZeneca] revenue in the category beyond patent expiry began in 1995 by an interdisciplinary group of [AstraZeneca] marketers, scientists and lawyers known as the “Shark Fin” project [.]. This group considered a host of marketing and intellectual property based options . . . . From 1997 through the end of 2000, AZ spent between $50 and $100 million/year promoting Prilosec as the “Purple Pill” . . . . This campaign successfully built the brand equity of the color purple on the pill . . . . For chronic sufferers the connection to the purple pill became emotional. Anticipating the eventual entry of generics, [AstraZeneca] launched their second generation ppi known as esomeprazole magnesium and branded as Nexium in March of 2001. From March of 2001 through 2007 [AstraZeneca] spent between US$100 and US$240 million/year advertising Nexium as “today’s purple pill”. These Nexium media messages were targeting educated professionals with GERD that could afford the treatment.

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169 The FDA approved Astrazeneca’s new GERD drug, Prilosec®, on Sept. 14 1989.
170 Jain & Conley, supra note 94, at 23.
172 Jain & Conley, supra note 94, at 23-25.
As this passage illustrates, AstraZeneca designed a marketing campaign that would enable them to transfer the consumer goodwill associated with the Prilosec® trademark and trade dress—the “purple pill”—to Nexium® once the company’s patent on omeprazole expired.

It is important to note that although the above passage refers to Nexium® (esomeprazole) as “second generation” Prilosec, Nexium®, for all intents and purposes, is 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. “A chiral drug is a single molecule product that exists in 2 mirror image forms call enantiomers.”\(^\text{173}\) 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.”\(^\text{174}\) Omeprazole (Prilosec®) is a “racemic mixture of R-omeprazole and S-omeprazole, while esomeprazole, as it name implies, is isolated S-omeprazole.”\(^\text{175}\) The S-omeprazole enantiomer in Prilosec® and Nexium® is responsible for both drugs’ clinical properties, while the R-omeprazole enantiomer in Prilosec® is inactive.\(^\text{176}\) Despite these limited functional distinctions, AstraZeneca obtained patent protection for Nexium®.

AstraZeneca marketed Nexium® as the “new purple pill” due to its copycat color. However, the pill also included two or three gold stripes “suggestive of the additional efficacy and denoting 20 and 40 milligram dosages, respectively.”\(^\text{177}\) Unsurprisingly, this drug was more expensive than the generic versions of omeprazole that entered the market after the expiration of

\(^{173}\) Gellad et al., supra note 171, at e90.
\(^{174}\) Id.
\(^{175}\) Id.
\(^{176}\) Id.
\(^{177}\) Jain & Conley, supra note 94, at 25.
the Prilosec® patent. Nexium® was positioned as an improved medication because, on average, it took shorter time (5 days vs. 7 days) for GERD patients to experience relief relative to omeprazole. Nevertheless, as a recent study of chiral drugs explains, it is likely that esomeprazole showed some advantages over omeprazole, purely because of its higher dosage. The 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).” 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.”

In addition to launching Nexium®, AstraZeneca began to sell an over-the-counter version of omeprazole. Sold in the same dosage as Prilosec®, AstraZeneca’s over-the-counter version of omeprazole came in a salmon pink pill. Nevertheless, AstraZeneca sold this medication in a purple packaging, “suggestive of the association with the original Prilosec purple pill.”

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. However, through its elaborate trade dress scheme, AstraZeneca managed to convert Prilosec® sales into Nexium® sales. Although Prilosec® sales did fall off the post-patent cliff, Nexium® picked them up right where Prilosec® left them. In fact, “after esomeprazole’s

178 Gellad et al., supra note 171, 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.”)
179 Id. at e94.
180 Id. at e92.
181 Jain & Conley, supra note 94, at 27.
182 Greene & Kesselheim, Why Do the Same Drugs Look Different?, supra note 111, at 85 (“[C]laims of trade dress remain vital in the pharmaceutical market.”).
183 Jain & Conley, supra note 94, at 27.
184 Id. at 23.
[Nexium®] approval in 2001, its use in Medicaid quickly surpassed omeprazole’s [Prilosec®’s] and peaked at over 1 million prescriptions per quarter in the second half of 2005.”\textsuperscript{185} Overall, AstraZeneca’s sale of proton pump inhibitor products (Nexium® and over-the-counter Prilosec®) remained at about $6 billion per year for 10 years after AstraZeneca’s patent on omeprazole expired.\textsuperscript{186}

Through its careful manipulation of consumer familiarity with Prilosec®’s trade dress, AstraZeneca managed to effectively extend its PPI-based revenue stream. As legal practitioner David Fritch recounts,

\begin{quote}
[i]n 1997, relaxation of FDA restrictions on direct-to-consumer prescription drug promotions led to an all-out marketing blitz, where promotions 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.”\textsuperscript{187}
\end{quote}

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 an even more expensive medication (Nexium®) despite the fact that their medication was now available over-the-counter at less than one seventh of its previous cost. Although some patients

\textsuperscript{185} Gellad et al., supra note 171, at e92.
\textsuperscript{186} Id.
probably switched to Nexium® because they actually believed the new drug was an updated and superior 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 a somewhat extreme example of trademark manipulation because AstraZeneca attempted to and succeeded in transferring the goodwill associated with a specific product to another, this case nevertheless reveals that trademark protection can be used to capture consumers and keep them from acting in a rational, efficient manner.

Furthermore, AstraZeneca’s basic strategy—manipulation of trademark protection—has become increasingly common in the pharmaceutical industry. Brand name manufacturers now routinely rely on the appearance of a medication to corner the generic drug market for that drug. As one commentator explains, “[d]uring the last decade, hundreds of brand name medicines have been launched as ‘authorized generics.’”188 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 Patriot Pharmaceuticals, a subsidiary of Johnson & Johnson, to distribute generic versions of its products that “have the same taste, color, mouth feel, size and shape as the

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innovator product.” 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 worth discussing 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, “[p]rice 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.” In other words, consumers perceive price to signal quality. In most markets, this inference is not a poor one: for many goods and services, such as hotels or lawyers, 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 (outlays that patents were partially designed to compensate) that brand name companies undertake. Therefore, consumers cannot rationally rely on the price

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191 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 112, at 176 (citing Elizabeth L. Wright, David vs. Goliath: A New Front in the Ongoing Battle Between Generic and Brand name Drug Companies, CITIZENS AGAINST GOV’T WASTE (Dec. 4, 1998), http://www.cagw.org/site/PageServer?pagename=reports_davidgoliath). Now, the Food, Drug and Cosmetics Act (FDCA) allows generic manufacturers to submit an abbreviated new drug
differential between generic and brand name products to infer a difference in quality. Nevertheless, at least one study suggests that they do.\textsuperscript{192} A 2008 study found that when subjects were told that they were receiving a more expensive version of a pain relief medication, they experience greater pain relief.\textsuperscript{193} 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 patient that received the “cheaper” medication reported lower levels of pain relief.\textsuperscript{194} As the authors of this study explain, 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.”\textsuperscript{195}

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: “we advertise, and therefore we must sell a good of sufficiently high

\begin{footnotes}
\item[193] See Shrank, \textit{Patients’ Perceptions}, \textit{ supra} note 142, at 553 (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”).
\item[194] \textit{Id.}
\item[195] \textit{Id.} at 1017.
\end{footnotes}
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 advertise 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 (the vast majority of whom have also been inundated with pharmaceutical promotional materials) 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.

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196 Lemley, supra note 79, at 1690.
197 Barrett, supra note 142, at 8.
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 Chamberlain 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.

Ralph Brown’s view of consumers as gullible sheep is, of course, less than flattering. But just because this perspective is uncomplimentary, does not make it wrong. Similarly, pharmaceutical companies would surely object to this paper’s characterization of them as skillful manipulators. To many readers, this description may seem unfair. After all, pharmaceutical companies create lifesaving products. Ultimately, however, pharmaceutical manufacturers are for-profit organizations that augment and protect their market shares through successful promotional efforts. Unfortunately, these promotional efforts often come at the price of consumer rationality and corresponding market efficiency.

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

The pernicious effects that pharmaceutical trademarks have on physician and patient behavior may extend beyond the induction of unnecessary expenditures. Some researchers have

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198 See Lemley, supra note 79, at 1692-93.
found that artificial product differentiation due to trademarks and advertising may drive real differences in drug effectiveness because such differentiation reduces patient adherence to medication regimens and negatively impacts 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, most patients cannot decipher these codes and instead rely on the shape and color of their medications to identify them.199 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.”200 This habit is especially prevalent among patients who take multiple medications, such as the elderly.201 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 errors202 and reduced adherence.203

199 Engelberg, supra note 188, at 321; Greene & Kesselheim, Why Do the Same Drugs Look Different?, supra note 111, at 86 (2011).
200 Engelberg, supra note 188, at 321.
201 Id. at 321; Greene & Kesselheim, Why Do the Same Drugs Look Different?, supra note 111, at 86 (2011).
Patient experiences with antiepileptic drugs (AEDs) provide a specific example of the type of adherence problems pharmaceutical trade dress may create. Recently, a few observational studies have reported that bioequivalent generic AEDs may not have the same clinical efficacy as their brand name counterparts. These reports have led many physicians to believe that generic AEDs are not as effective in preventing seizures as their branded counterparts. In fact, “some physician professional organizations and patient advocates have opposed the routine interchange of bioequivalent AEDs,” and several states “have also entertained or passed legislation to limit substitution of generic AEDs to ‘protect patients from breakthrough seizures.’” Nevertheless, “well-controlled studies” support the bioequivalence of generic and branded AED drugs. In their study of AEDs, Aaron Kesselheim, et al., found that when patients accustomed to the design of a brand name AED switched to a generic, these patients found the change in pill design to be confusing, which, in turn, 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 studies and suggest that “nonpersistence related to changes in color may be one unmeasured factor contributing to negative reports about bioequivalent generic AEDs.” Thus, as Kesselheim et al. conclude, “[c]hanges in pill appearance may create a self-fulfilling prophecy in which therapeutically bioequivalent regimens actually become less

205 Kesselheim, *Variations in Pill Appearance, supra* note 203, at E5.
206 Id.
207 Id.
208 Id.
209 Id. at E4.
clinically effective owing to induced nonpersistence.”\textsuperscript{210} Instead of clarifying differences between products, differences in trade dress confused consumers into reduced adherence to the same product.

These findings were confirmed in a more recent study that examined the effect of changes in pill shape and color on continued patient use of cardiovascular medications. This study found that patients had a 34\% increase in the odds of change in pill color preceding an episode of non-persistent pill usage and a 66\% increase in the odds of non-persistence after a change in pill shape.\textsuperscript{211} 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.”\textsuperscript{212}

Second, trademarks and trade dress protection may 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.\textsuperscript{213} 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.

\textsuperscript{210} Id. at E5.
\textsuperscript{211} 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).
\textsuperscript{212} Id. at 101.
For both the placebo and the active ingredient pills, the study participants reported greater relief from the versions that were branded.214 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.”215 Another study demonstrated that patients’ expectations regarding the efficacy of both placebos and pharmacologically active prescription drugs are linked to the physical attributes of their pills.216 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.217

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).”218 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. Thus, again, distinctions in trademark and trade dress bring about a self-fulfilling prophecy whereby artificial differences in name and dress cause real, measureable, discrepancies in effectiveness.

214 Id. at 1576.
215 Id. at 1578.
216 See Greene & Kesselheim, Why Do the Same Drugs Look Different?, supra note 111, 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.”); A. Hróbjartsson & P.C. Gøtzsche, Placebo interventions for All Clinical Conditions, COCHRANE DATABASE SYS. REV., Art. No.: CD003974 (2010).
217 See Greene & Kesselheim, Why Do the Same Drugs Look Different?, supra note 111, at 87.
218 Kesselheim, Variations in Pill Appearance, supra note 203, at E4-5.
Although such a consumer may rationally understand that generic medications are functionally equivalent to brand name products, they may find this reality difficult to accept due to their long-term association of the medications’ identity with particular appearances and names. As one scholar who actually supports trade dress protection for brand name drugs concedes,

[a] patient may want the generic substitution for cost reasons, but would like the psychological reassurance that the new medication is the same as the original. Allowing the same color and shape combinations may increase patient compliance in this regard. Furthermore, the patient may become familiar with a certain color or shape representing a certain type of medication or they mix medications in the same container and then rely upon visual cues to identify the medication.219

In sum, relevant research and case studies reveal that pharmaceutical trademarks and trade dress do not reduce consumer confusion, but rather cause it in favor of irrational brand loyalty. Accordingly, the first rationale for trademark protection—the prevention of consumer confusion and reduction of consumer search costs—does not hold in the case of pharmaceutical trademarks.

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.220 Furthermore, FDA inspection provides an additional check on generic drug quality.

219 Naeve, supra note 131, at 310 (footnotes omitted).
220 See supra Part III.B.i.
Moreover, and perhaps just as importantly, it also unclear that consumers are relying on pharmaceutical trademarks because they are concerned about the quality of the manufacturers. Qualitative and quantitative evidence suggests that consumers do not rely on pharmaceutical trademarks and trade dress as a check on the quality of the drugs they mark. Instead, consumers use pharmaceutical trademarks and trade dress to identify the product itself. The story of the 69-year-old patient who believed she was allergic to generics illustrates this point. The patient in this story 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 classes of drugs to which she was allergic. No part of her calculus hinged on a recognition of bioequivalence but a corresponding concern about the quality of generic manufacturers; instead she made a broad generalization about generics as if they were a separate product group.

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 Porches of drugs. In the aforementioned Houston study, twenty-two percent of respondents agreed that “generic substitution limited their ability to get what their doctor had prescribed, and about twenty percent believed that it would limit their chances of getting the best medications.”221 Yet, 58 percent of respondents believed that “generic substitution is safe because generic products are produced by reputable manufacturers”222 and 28 percent had no

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221 Sansgiry, Bhosle, & Pope, supra note 142, at 82.
222 Id. at 85.
opinion about the reputation of generic manufacturers.\textsuperscript{223} Thus, only 14 percent of study participants actually believed that generic drugs are unsafe due to the reputation of generic manufacturers.\textsuperscript{224} These data reveal that consumer mistrust of generic \textit{medications} does not directly correlate with consumer mistrust of generic \textit{manufacturers}.

Therefore, Landes and Posner second rationale for trademark protection—that brands enable consumers to ascertain the sources of products, thereby providing manufacturers with incentives to maintain consistent product quality—appears to lack any 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.

\textbf{D. Conclusion}

The Prilosec\textsuperscript{®} case study illuminates the key problem with pharmaceutical trademarks and trade dress: these forms of intellectual property protection ultimately provide pharmaceutical manufacturers with the tools they need to artificially differentiate their products from those of generic manufacturers so that they can extend the monopolies they previously enjoyed under patent protection. As this part has demonstrated, 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 consumers to believe that trademarked medications are both different from and superior to generic drugs. But, as an empirical matter, this is wrong. Consequently, pharmaceutical trademarks predominately result in the artificial and inefficient product differentiation that Chamberlain, Schechter, and Brown

\textsuperscript{223} \textit{Id.}  
\textsuperscript{224} \textit{Id.}
dreaded. Even if pharmaceutical trademarks and trade dress do help some consumers identify the products they trust, the harms associated with these markers, including increased health care costs, reduced patient adherence, increased prescription errors, and the nullification of valuable placebo effects, outweigh any beneficial impact they may have.

IV. 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, best describes the analysis policymakers should engage in 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?225

This paper has attempted to demonstrate that for pharmaceutical trademarks and trade dress, Professor Bar-Gill’s first three questions should be answered affirmatively. In this section, I set 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 policies and programs state governments and private insurers have

already put in place to encourage patients to switch to generics where possible. On the state side, some governments have passed mandatory generic substitution laws, which require pharmacists to substitute generics for branded medications when feasible, while other states have endorsed permissive generic substitution, where pharmacists are permitted, but not required, to make the substitution.\textsuperscript{226} Additionally, while some states obligate pharmacists to obtain patient consent prior to generic substitution, others permit substitution without such explicit consent.\textsuperscript{227} 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.\textsuperscript{228}

But 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 United States during 2000 found that states could have saved $229 million through greater generic drug usage.\textsuperscript{229} In fact, total savings from improved generic drug

\begin{footnotesize}
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\item \textit{Id.} Shrank, et al., found 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. \textit{Id.}
\item Michael A. Fischer & Jerry Avorn, \textit{Economic Consequences of Underuse of Generic Drug: Evidence from Medicaid and Implications for Prescription Drug Benefit Plans}, 38 HEALTH SERVS. RESEARCH 1051 (2003); Haas et al., \textit{Potential savings from substituting generic drugs for...}
\end{enumerate}
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substitution would have reached $450 million if the best available prices from each state had been used nationally. A more recent study found that the Medicaid spent an estimated $329 million in 2009 to reimburse patients for twenty popular brand name medications for which therapeutically equivalent generic substitutes exist.\textsuperscript{230} "As a 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."\textsuperscript{231} The same study predicted that state governments would overspend between $289 and $433 million on reimbursement for ten popular branded medications whose patents expired in 2011 and 2012.\textsuperscript{232} It is important to bear in mind that these projected expenditures are just for Medicaid, which accounts for about ten percent of total drug purchasing nationwide.\textsuperscript{233} Improvements in generic substitution would also result in additional savings for private payers and Medicare Part D plans.\textsuperscript{234} Furthermore, although financial incentives in the form of copayment differentials and tiered formularies do promote generic drug substitution, specialists in this field have nonetheless concluded that "copayment differentials between generic and brand name medications may be insufficient to

\textsuperscript{230} Brand name drugs: medical expenditure panel survey, 1997-2000, 142 ANNALS OF INTERNAL MED. 891 (2005) (finding that use of branded prescription drugs when identical generics were available constituted approximately 11% of overall drug expenditures on prescriptions filled in a nationally representative sample of patients from 1997-2000).
\textsuperscript{232} Id. at 1-2.
\textsuperscript{233} Id. at 2; Shrank, State Generic Substitution Laws, supra note 226, at 1389 (predicting that patient refusal of generic substitution will cost state Medicaid programs over $100 million after the patents for only three medications expire).
\textsuperscript{234} Shrank, State Generic Substitution Laws, supra note 226, at 1389.
\textsuperscript{234} Id.
motivate generic drug use by some patients.”

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. Because generic drugs are less expensive, patients can afford to continue purchasing generic drugs to a greater extent than branded ones. Thus, switching patients to cheaper generic drugs can improve patient adherence to medication regimens, in turn decreasing morbidity. 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.


237 See Goldman, Joyce, & Zheng, supra note 236; Shrank, The Implications of Choice, supra note 236; Taira, supra note 236.

238 See supra Part III.B.iv.
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. Unfortunately, pharmaceutical trademarks arguably 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. And 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. For example, when advertising a medication on television, the pharmaceutical manufacturer would only be able to use the drug’s generic name (or the shortened name designated by the FDA). In terms of the physical prescription, a generic drug and its branded equivalent would look and taste identical and the drug name on the pill bottle would be the same, but an additional sticker indicating the manufacturer of the drug would be placed on dispensed bottle.

This rule would enable generic manufacturers to use the same names and dress as branded products, therein avoiding the type of harmful differentiation trademarks have caused. Nonetheless, this rule would still allowing 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. 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. After all, the real purpose of trademark protection is to ensure that when a consumer is satisfied with a specific product, he is able to relocate it when he wants to repurchase. 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 offered. Critically, these marks would accomplish this objective without suggesting that the drugs they mark differ in any respect other than their manufacturers. This rule thus reinforces for consumers the reality surrounding branded and generic drugs: pioneer and generic drugs are the same medications, albeit with sometimes different manufacturers. Such marks, unlike today’s trademarks and trade dress, would not suggest anything more than the medications’ source.

In terms of implementation, such a rule would most likely require two changes to existing law. First, the requirement that all drugs be labeled, prescribed, and advertised by their generic names (or a shortened version thereof) and dispensed with a label identifying the manufacturer of the medication could be implemented through a change to the Federal Food, Drug, and Cosmetic Act. 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 drug naming and design schemes. In order to avert potential lawsuits, Congress should also amend the Lanham Act, so that pharmaceutical trademarks and trade dress could no longer be registered with the Patent and
Trademark Office. More specifically, Congress could amend 15 U.S.C. § 1052, which lists trademark ineligible subject matter, and specify that trademarks on medications will be refused registration. This provision could be nested under § 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” and has a “bona fide intention to use the mark in commerce.” If pharmaceutical companies must use the drug names authorized by the FDA, and only those names, these companies cannot verify to the Patent and Trademark Office 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 paper to ponder all such lawsuits, I will explore two potential causes of 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* 239

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240 Id. § 1051(3)(B).
Board, 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.’” The Court then explained that trademarks are “the ‘property’ of the owner because he can exclude others from using them.”

But a trademark holder’s property interest in his mark is not without limits. As Justice Pitney clarified a century ago, “[c]ommon law trademarks and the right to their exclusive use are of course to be classed among property rights . . . but only in the sense that a man’s right to the continued enjoyment of his trade reputation and the good-will that flows from it, free from unwarranted interference by others, is a property right, for the protection of which a trademark is an instrumentality.” McCarthy further explains in his trademark treatise:

> [t]raditional 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.

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.” As the Ninth Circuit has held, “[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

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242 Id. at 673 (quoting Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979)).
243 Id. (citing K-mart Corp. v. Cartier, Inc., 485 U.S. 176, 185-186 (1988) (“Trademark law, like contract law, confers private rights, which are themselves rights of exclusion. It grants the trademark owner a bundle of such rights”)).
244 Hanover Star Milling Co. v. Metcalf, 240 U.S. 403, 413 (1916).
245 MCCARTHY, supra note 8, § § 2:14.
246 Id. § 2:30.
Therefore, a trademark holder does not possess a property right to his mark simply because it exists and has been registered with the Patent and Trademark Office; 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. Accordingly, a prospective law banning pharmaceutical trademarks should violate neither the Due Process Clause nor 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 his company has accrued. However, that right is cognizable as a property right to a trademark only insofar as the mark captures the goodwill the company has 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. Manufacturer marks would essentially protect and embody the same property rights

247 International Order of Job’s Daughters v. Lindeburg & Co., 633 F.2d 912, 919 (9th Cir. 1980), cert. denied, 452 U.S. 941 (1981); see Kentucky Fried Chicken Corp. v. Diversified Packaging Corp., 549 F.2d 368 (5th Cir. 1977).

248 Hanover Star, 240 U.S. at 412 (“The redress that is accorded in trademark cases is based upon the party’s right to be protected in the good will 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 trademarks adopted to maintain and extend it.”).
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 anonymous one. Switching the locus of consumer goodwill from an anonymous source to a real one will help clarify to consumers that generic and branded producers are selling the same drug, simply produced by different companies.

The answer to whether a retrospective version of this rule would be constitutional is less clear. Because pharmaceutical companies have property rights to 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 name in conjunction with the new generic name (for example, Atorvastatin, formerly known as Liptor®, by Pfizer), it might survive a Fifth Amendment Due Process Clause challenge because such a rule would continue to protect the goodwill these brands previously accrued. Because, under the new rule, 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 less strong. 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*, these companies would contend that their trademarks constitute protected commercial speech. In *Friedman*, the Supreme Court explain that

> [o]nce 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

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strictly business. The use of trade names in connection with [particular business], then, is a form of commercial speech and nothing more.\textsuperscript{250}

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.’”\textsuperscript{251} However, the Court also explained that, unlike other forms of commercial speech, trade names have “no intrinsic meaning.”\textsuperscript{252}

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.\textsuperscript{253}

Like other forms of speech, commercial speech can be subjected to some forms of government regulation.\textsuperscript{254} First, “[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake.”\textsuperscript{255} The State may also regulate commercial speech that is misleading or deceptive.\textsuperscript{256} And “when experience has proved that in fact [a particular form of] advertising is subject to abuse, the States may impose appropriate restrictions.”\textsuperscript{257} The Supreme Court’s

\begin{footnotesize}
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\item \textit{Id.}
\item \textit{Id.} at 8-9 (quoting Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 764 (1976)).
\item \textit{Id.} at 12.
\item \textit{Id.} at 12-13.
\item \textit{Friedman}, 440 U.S. at 14.
\item Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999).
\end{enumerate}
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decision in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*superscript 258 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.\(^\text{259}\)

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.”\(^\text{260}\) 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.”\(^\text{261}\)

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 by this paper suggests that both of these inquiries can be answered

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\(^{258}\) 447 U.S. 557, 564 (1980).
\(^{259}\) Id. at 566.
\(^{260}\) Id. at 564.
affirmatively: the government has a substantial interest in lowering healthcare costs and patient morbidity, the harms resulting from pharmaceutical trademarks are real and could be alleviated to a substantial degree by a rule prohibiting their use.

In fact, this proposed 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 consumers. 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. . . . Since the Act does not prohibit or limit the type of informational advertising held to be protected in *Virginia Pharmacy* and *Bates*, the factual information associated with trade names may be communicated freely and explicitly to the public.

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 show that the government had 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

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

263 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 . . . .”).

264 *Id.* at 15-16.
TRIPS agreement. The TRIPS arguments that several nations have advanced in response to Australia’s new plain packaging tobacco law 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 obstacle to registration of the trademark.” Next, Articles 16 and 17 explain the exclusive rights of trademark holders and the exceptions to them. Most importantly for the purposes of this discussion, Article 20 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

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269 *Id.* art. 16 § 1.
270 *Id.* art. 17.
distinguish the goods or services of one undertaking from those of other undertakings.”

Australia’s new plain packaging law has provoked heated debate over the scope and meaning of these articles. Specifically, legal scholars debate whether a “right to use” trademarks can be implied from the trademark provisions of the TRIPS agreement. Some scholars argue that trademark owners have an inherent right to use their trademarks that can be inferred from TRIPS. Meanwhile, 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. Thus, it is debatable whether pharmaceutical companies have a right to use their trademarks under the TRIPS agreement.

Irrespective of this debate, there may be other ways to justify certain bans on trademark use. Many scholars believe that certain bans can be upheld as being “justifiable” under Article 20. 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.” Thus far, the WTO has not considered Article 20’s concept of “justifiability” in any of its jurisprudence. Despite this lack

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271 Id. art. 20.
274 Id. at 1212.
of precedent, many lawyers argue Article 20’s rejection of unjustifiable encumbrances should be read in light of Article 8 of the TRIPS Agreement.\textsuperscript{277} 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 importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.\textsuperscript{278}

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.\textsuperscript{279} “However, Article 8 can provide interpretative guidance on what would be reasonable for the purposes of Article 20.”\textsuperscript{280} 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


\textsuperscript{279} See Frankel & Gervais, \textit{supra} note 272, 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.”).

\textsuperscript{280} Mitchell, \textit{Australia’s Move, supra} note 273, at 419.
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.”

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.

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. Under this rule, “trade dress protection may not be claimed for

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product features that are functional.” In 2003, the Third Circuit held that the trade dress of Adderall®, a popular Attention Deficit Hyperactive Disorder (ADHD) medication, was functional in a case called *Shire U.S. Inc. v. Barr Laboratories, Inc.* 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. “[A] generic drug’s similar appearance to the branded product ‘enhance[s] patient safety and compliance with the medically prescribed dosing regimen.” Because the design of Adderall® did not signal the source of the medication, but rather its content and dosage type, the Third Circuit found its trade dress to be impermissibly functional.

In reaching this conclusion, the Third Circuit relied on Supreme Court case law 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

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285 329 F.3d 348.
286 Id. at 354-55 (“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.”).
287 Id. at 355 (quoting the affadavit of Cheryl D. Blume, Ph.D., expert for the defendant).
288 Id.
289 Id. at 358.
290 Qualitex Co. v. Jacobson Products Co., 514 U.S. 159, 169, 115 S. Ct. 1300, 1306, 131 L. Ed. 2d 248 (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
dress infringement claim in 1924. In William R. Warner & Co. v. Eli Lilly & Co.,\textsuperscript{291} 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. In this case, 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.”\textsuperscript{292}

Furthermore, in Ives Laboratories, Inc. v. Darby Drug Co. Inc.,\textsuperscript{293} 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.”\textsuperscript{294} 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:

\begin{quote}
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
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\begin{footnotesize}
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\item 265 U.S. 526 (1924).
\item Id. at 529.
\item Id. at 399.
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\end{footnotesize}
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.\textsuperscript{295}

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 and dress to identify the type of drug in general. 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 become 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”\textsuperscript{296} 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 \textit{Shire}, patients began to understand the branded color-coding scheme for Adderal® as providing information about type of drug they were taking, not its specific source. Courts use the functionality doctrine to address a larger problem: due to the initial period of market

\textsuperscript{295} 514 U.S. at 169.
\textsuperscript{296} See \textit{supra} note 38; Naeve, \textit{supra} note 131, 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.”).
exclusivity pioneer 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.\textsuperscript{297} 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.”\textsuperscript{298}

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 a pharmaceutical trade dress infringement lawsuit on the grounds that such dress is functional, generic companies could begin to copy the trade dress of brand name manufacturers without fear of attracting lawsuits. Even today, pharmaceutical companies are deterred from initiating such lawsuits by the Third Circuit’s decision in Shire. Nevertheless, litigation based on the functionality argument still does not provide as complete and secure of a change to pharmaceutical trademark policy as would a new rule instituting manufacturer marks. Therefore, although the functionality doctrine is a useful tool in fixing the pharmaceutical trade dress issue, it does not offer a complete solution to the problem.

\textsuperscript{297} See Alfred B. Engelberg, Have Prescription Drug Brand Names Become Generic?, 20 Am. J. MANAGED CARE 867 (2014); Aaron S. Kesselheim, et al., Burden of Changes, supra note 211, at 101; Engelberg, supra note 188.

ii. *FDA Guidance*

A second potential fix to the issue of trademarked pharmaceuticals would be FDA-issued guidance requiring generic producers to copy the trade dress of the brand name reference products. As a recent paper studying pharmaceutical trademarks explains, “[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.”

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 impact 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.

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V. CONCLUSION

In the pharmaceutical industry, trademark and trade dress protection has led many patients to believe that brand name and generic drugs are truly different products. This differentiation is not grounded in rational concerns regarding manufacturing quality. Instead, a more nebulous and pernicious psychological reaction accounts for consumer preferences. This paper has argued that pharmaceutical trademarks and trade dress not only fail to accomplish the core goals of trademark protection, but actually 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. Therefore, as policymakers look for new ways to control rising healthcare costs, this new rule should be on the table.