HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health

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Generic drugs are widely considered to be cost-efficient substitutes for brand-name medications. They make up about 70% of the total number of U.S. prescriptions but less than 20% of the total prescription-drug costs.[1] Although brand-name drugs and generic drugs are both approved by the Food and Drug Administration (FDA) and may be interchangeable with respect to their clinical effects, they can differ substantially in their appearance. Consumers of brand-name medications receive identical-appearing batches of pills with each refill, whereas consumers of generic drugs must be prepared to receive pills of a different size, color, and shape, depending on which manufacturer is supplying their pharmacies.[2] For example, at least 10 generic versions of fluoxetine exist (4 of which are shown in Fig. 1) that are pharmacologically equivalent to the innovator drug but vary in their color patterns. This variation in the appearance of generic drugs has its roots in U.S. intellectual-property law. In the past, drug manufacturers successfully claimed exclusive ownership of the physical aspects of their products — including the size, shape, color, texture, aroma, and flavor — as private property under a subset of trademark law called "trade dress."[3,4] Such a practice constrained the ability of generic-drug manufacturers to design follow-on products that reproduced the physical appearance of the innovator brands.

In this article, we review the legal basis of trade dress as it has applied to pharmaceutical products and consider the public health implications of variations in pill appearance. We then discuss how a system of more uniform drug appearance could be designed to reduce medical error and promote patient adherence to treatment regimens that involve generic drugs.

PRINCIPLES OF TRADE DRESS

A trademark is a name, logo, or imprint that designates a particular company or product in the minds of consumers. Trade dress describes any material quality of a product's packaging or physical appearance that serves a branding function.[5] Although the name "Coca-Cola" is a word mark, the design of the iconic Coca-Cola bottle is an example of trade dress. Trade dress supports a manufacturer's investment in establishing a product as distinct from other, similar products. Legal recognition of trade dress is economically efficient for the marketplace because it allows consumers to identify a product's unique source and therefore recognize its established quality and reliability. Unlike the 20-year term of a patent, the term of protection for trade dress can be indefinite.

To qualify as trade dress an attribute must meet three criteria: it must be nonfunctional, it must lead to confusion (or deception) if imitated, and it must have a secondary association with the product for the consumer. A product's functional attributes are essential to the use or purpose of the product or must affect the cost or quality of the product.[6,7] Functionality is key in pharmaceutical-related trade dress, because if a company with a brand-name drug owned exclusive rights over a functional attribute of that drug, a competitor could not offer a truly equivalent generic version.

For pharmaceutical products, the most obvious functional attributes include their efficacy, safety, and quality. In the 1920s, the Supreme Court ruled on a trade-dress case that involved Eli Lilly's Coco-Quinine, a formulation of the unpatented antimalarial drug quinine mixed

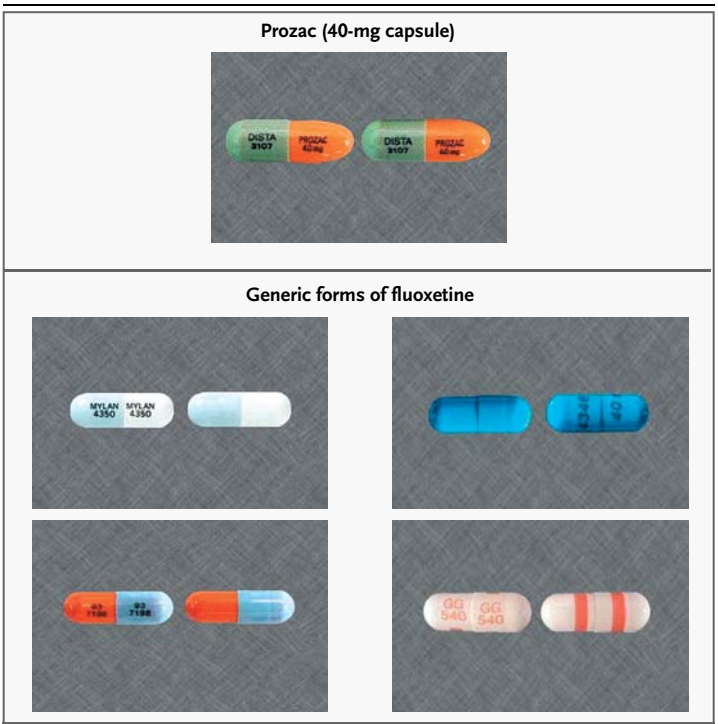

Figure 1. Differences in the Appearance of the Innovator Drug (Prozac, Lilly) and Four Generic Versions of Fluoxetine (40-mg capsules).
Images courtesy of Cerner Multum.

with chocolate syrup, and a subsequent product with a similar color, taste, and name (Quin-Coco) marketed by a competitor. The Court ruled that in spite of these similarities, Quin-Coco did not represent trade-dress infringement and could remain on the market because the 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."[8] Similarly, in the 1950s, the Second Circuit Court of Appeals held that the "soothing" pink color of Pepto-Bismol provided "therapeutic value" in treating upset stomachs and was therefore not protectable as trade dress.[9]

PHARMACEUTICAL TRADE DRESS

Legal protection for pharmaceutical trade dress expanded in the mid-20th century amid increasing concerns about counterfeit drugs, which copied the appearance, packaging, and name of a brand-name drug. Corrupt pharmacists deceptively substituted ("palmed off") poor-quality counterfeit drugs in place of brand-name prescriptions, charging the consumer for the brand-name drug while pocketing the price difference.[10] During this era, antisubstitution laws in over 40 states made it illegal for a pharmacist to fill a prescription for a brand-name drug with a product from a different manufacturer.[11]

Protection of intellectual property covering the physical attributes of pills therefore served two primary purposes. One purpose of trade-dress protection was to reduce the practice of palming off. Premo Pharmaceuticals was sued for trade-dress infringement when it marketed its generic version of the diuretic hydrochlorothiazide/triamterene with a maroon-and-white capsule identical to that of brand-name drug Dyazide, produced by Smith, Kline and French. In *SK&F v. Premo*, the Third Circuit Court of Appeals upheld trade-dress protection because near-identical pills would facilitate the practice of "unscrupulous pharmacists" in "substituting less expensive generic drugs for the brand name drugs prescribed without informing their customers and without passing along the benefit of the lower price."[12] The court also found that the color scheme was nonfunctional because it did not help patients identify the drug, pointing to other maroon-and-white capsules that were not diuretics.

A second purpose, the courts rationalized, was to allow trade-dress protection to serve a public health function by preventing the substitution of a drug that was similar but not identical to another.[13] In *SK&F v. Premo*, the two diuretic products were chemically equivalent, but their rate of absorption into the bloodstream (bioavailability) differed. In another case, a federal district court in Michigan enjoined a competitor from producing a version of the diet pill phentermine that was similar in appearance to a brand-name version because the efficacy of the hydrochloride salt of phentermine in the generic manufacturer's version did not necessarily match the efficacy of the brand-name manufacturer's phentermine resin complex, so the two drugs were not interchangeable.[14] Notably, both these arguments upholding pharmaceutical trade-dress rights were meant to protect consumers from deception by the producers of look-alike drugs.

An alternative view was offered by a New York federal district court in *Ives v. Darby*, a case that involved the peripherally acting vasodilator cyclan-

delate (Cyclospasmol). After the patent for cyclandelate expired, competing products mimicked the brand-name drug's color schemes: blue for the 200-mg capsule, and blue and red for the 400-mg capsule. The district court ruled that the competing cyclandelate products could remain on the market because the colors were functional to patients and their physicians. One example of such functionality was 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."[15] In addition, the cyclandelate competitors could demonstrate biologic equivalence of their products to Cyclospasmol. When the case rose to the Supreme Court, the decision was upheld on a different basis, although the Court noted "the petitioners offered a legitimate reason for producing an imitative product."[16]

Despite the outcome in *Ives*, trade dress remained integral to the sales strategies of some manufacturers of brand-name drugs. For example, AstraZeneca's omeprazole (Prilosec) was widely promoted as "the purple pill" after its launch in 1989. As Prilosec's market exclusivity was ending, AstraZeneca launched the prescription-only follow-on product esomeprazole (Nexium) as "the *new* purple pill" in 2001 to encourage patients accustomed to taking Prilosec to switch to Nexium. Notably, when AstraZeneca began to sell omeprazole without a prescription as Prilosec OTC, the company changed the color of its product to salmon pink. Conversely, as Lilly's green-and-cream capsule fluoxetine (Prozac, 20 mg) faced generic-drug competition in 2001, the company repackaged fluoxetine in pink-and-purple capsules and marketed it as a new drug, Sarafem (20 mg), which was approved by the FDA in 2000 for the treatment of a new indication — perimenstrual dysphoric disorder.[17] In this case, the change in color was designed to discourage physicians from prescribing the less expensive generic fluoxetine in place of Sarafem.

The 1997 FDA guidelines for expanding direct-to-consumer (DTC) advertising of prescription drugs further enhanced the power of pharmaceutical trade dress as broadcast campaigns began to include images of the pills themselves.[18,19] One of the first drugs to be promoted heavily to consumers after its approval in 1998 was Viagra (sildenafil), Pfizer's drug for treating erectile dysfunction. The company included a picture of the drug in nearly all the advertisements for it, which served to identify the brand of Viagra with both the color (pale blue) and the shape (diamond) of the tablets.

Concurrent Supreme Court rulings in other industries promised even broader pathways for trade dress. In one ruling that protected the festive décor of a Mexican restaurant, the Court suggested that some trade dress could be inherently distinctive, despite the lack of evidence that consumers associated the décor with the restaurant.[20] Soon after, in the case of *Qualitex v. Jacobson*, the Court held that color alone could constitute a defensible trademark if it had acquired a secondary meaning.[21] Nonetheless, even under the ruling in *Qualitex*, the color of a pill might not be protectable if the attribute served "a significant nontrademark function."

THE RISE OF GENERIC DRUGS

Meanwhile, new developments in the pharmaceutical marketplace began to undercut the legal foundations previously used to support trade dress in products such as the purple pill and the blue, diamond-shaped tablet. First, in the 1960s and 1970s, a wave of patent expirations for widely used drugs expanded the potential for generic-drug sales among hospitals, pharmacies, and government purchasing agencies. Generic-drug manufacturers evolved from a shadowy group of firms pressing tablets in small, nondescript warehouses into a set of legitimate pharmaceutical firms regulated by the FDA.[22]

Second, as state and federal government insurance programs took on a larger burden of drug costs, the value of cost containment through substitution of therapeutically equivalent generic-drug products led to a reexamination of the antisubstitution laws. During the 1970s, state laws prohibiting generic substitution were largely reversed and were replaced by laws mandating the interchangeability of brand-name drugs and approved generic drugs. This was aided by the 1978 publication of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the Orange Book) by the FDA, a compendium of all products approved by the FDA that were found to be bioequivalent and available for generic interchange. Finally, the federal Hatch–Waxman Act of 1984 established an Abbreviated New Drug Application (ANDA) pathway for FDA approval of generic drugs based on bioequivalence to the

brand-name version. In the aftermath of this legislation, the number of prescriptions for generic drugs began to rise quickly in the United States.[23,24]

These alterations had substantial implications for the legal status of pharmaceutical trade dress. Concerns about palming off were mitigated after FDA protocols ensuring bioequivalence of generic drugs undercut the public health risk that courts had used to justify trade dress for pill attributes. The new landscape was formally recognized in 2003 by the Third Circuit Court of Appeals in *Shire v. Barr*, a case involving the prescription stimulant mixture of dextroamphetamine and amphetamine (Adderall), marketed principally for the treatment of attention deficit–hyperactivity disorder (ADHD). When Shire Pharmaceuticals brought this drug to market in 1996, its promotional materials highlighted how differences in the color, size, and shape of the various doses of Adderall promoted the ability of children with ADHD to adhere to their regimens. Shire sued Barr, the first generic competitor, when it copied Adderall's distinctive dose–color scheme. At trial, Barr argued that Shire's own claims established the functionality of the purported trade dress. The court agreed, finding that because of their functionality, the color, size, and shape of Adderall were nonprotectable.[25]

TRADE DRESS AND PUBLIC HEALTH

The *Shire v. Barr* case unraveled the legal protection that previously supported pharmaceutical trade dress.[18] Since then, certain Supreme Court cases have further demarcated its boundaries.[26] For example, the Court held that trade dress did not apply to functional aspects of temporary road signs even when alternative designs existed that could perform a similar function.[6] Thus, the Court clarified that competitors were indeed free to copy features that increased the utility of a product.

However, claims of trade dress remain vital in the pharmaceutical market.[19] With increasing generic competition, trade-dress strategies are described in industry publications as ways for innovator firms to retain market share for their products after their patents and market exclusivity expire.[18] During at least the past 5 years, brand-name pharmaceutical companies have begun to license their trade dress to manufacturers of so-called authorized generics, which advertise the characteristic of similar appearance as a reason for consumers to use these products.

Proponents of trade-dress protection argue that consumers need to be able to identify the brand by the appearance of the pills because the drugs are dispensed in a standard prescription bottle.[19] Yet this argument is undercut by the success of the FDA's bioequivalence protocols, which have been consistent on a pharmacologic level[27] and translate into comparable clinical effectiveness for nearly all brand-name and generic drugs.[28] Instead, the existence of generic drugs that look different from the brand-name version can have important negative effects on patient outcomes in three key areas — prescription error, medication adherence, and the contribution of the placebo effect — as described below.

It is well known that prescription error can result from confusion regarding the appearance of a drug. Much of the research into this problem emerges from the inpatient setting,[29] but confusion borne by outpatients involving pills with different attributes has been reported as well.[30,31] Although all pills are imprinted with an identifying code, these codes are indecipherable by most patients, as well as by many physicians.[32] Confusion about pills may be exacerbated as a result of regimen complexity or among patients with limited health literacy.[33] Patients who take multiple medications are often elderly, with higher rates of visual or cognitive impairment, which increases the risk of errors.[34-36] Recently, color and shape differentiation have been shown to be important factors in patients' correct identification of over-the-counter drugs.[37]

The World Health Organization has estimated that as few as half of all drug regimens for the treatment of chronic diseases are optimally adhered to.[38] As the public health problem of nonadherence became increasingly recognized,[39] the use of DTC advertisements that included images of pills were defended as increasing adherence to medication regimens for chronic diseases.[40] Although no direct research has been carried out on this issue, claims linking pill color and shape to adherence by patients with ADHD were central to the case of *Shire v. Barr.* Particularly during the transition period after brand-name drugs lose their market exclusivity, consistency in appearance between brand-name drugs and generic drugs could help promote patient adherence.

Finally, a resurgence of research on the placebo effect suggests that drug appearance can have a distinct functionality. For decades, studies have shown that the efficacy of placebo pills varies according to the size, shape, and color of the pills.[41-44] 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.[45,46] Newer research suggests that placebo efficacy varies with external packaging and the perceived dollar value of the treatment being applied.[47] 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.

Literature that measures the magnitude of prescription error, medication adherence, and placebo effects attributable to generic or brand pill appearance is limited; explicit outcomes research in this area is still lacking. No one knows how many medication errors are due to problems related to visual cues. Nonetheless, it is clear that the external attributes of pills can have benefits separate from the therapeutic effect of their active ingredients. It follows that maintaining some consistency of these effects is important to ensure the overall equivalency of brand-name drugs and generic drugs.

POLICY RECOMMENDATIONS

If brand-name pharmaceutical manufacturers are no longer able to rely on trade dress to protect the attributes of their products, federal policies affecting this field need to be sharply reconsidered. A first step toward reform would be to include FDA certification of pharmaceutical size, shape, and color in the drug-approval process. For example, a pill's attributes could be proposed by the manufacturer during the original New Drug Application. Currently, such a process occurs for the brand name of the medication[48]; extending it to pill appearance should not require additional legislation. This would create a clear path for generic manufacturers to declare during the ANDA process that their products have similar appearances. Where these drugs do differ (e.g., as in dyes, fillers, or excipients), physicians or pharmacists could still locate manufacturer data from unique identifier codes embossed on pills. Further public health benefits could emerge if the reduction in trade dress helps to combat the physician's persistent use of, and the patient's preference for, costly brands when generic equivalents are available.[49]

The obvious limitation of this approach is that it would apply only to newly introduced pharmaceutical products, leaving most of the existing therapeutic armamentarium unaffected. Therefore, we suggest that a rational scheme be created for pharmaceuticals that have already been approved whereby each distinct agent could be identified by a combination of its size, shape, and color. An example of such a scheme is the successful introduction in the United Kingdom of color-coding for metered-dose inhalers. Patients with asthma had frequently confused bronchodilators with steroid inhalers,[50] leading the National Health Service to systematize inhaler appearance: all short-acting inhalers (bronchodilators) became blue and all preventive agents (steroids) became brown, orange, or burgundy.[51] A similar color-coding scheme was piloted in the United States for ophthalmologic products, in which the caps on generic preparations of atropine, pilocarpine, and other drug products having multiple strengths were color-coded to match those of the innovator-drug products.[52]

Introducing a color-coding scheme for the entire pharmacopoeia may require additional legislation to ensure full compliance and would place an additional cost on generic-drug manufacturers to retool production of oral forms of their drugs. However, to begin the process of policymaking, the FDA could formally recognize the importance of pill appearance to the therapeutic equivalence of generic drugs. Such a statement could help clear the way for generic-drug manufacturers to adjust their products to conform with the original appearance of the innovator products.

CONCLUSIONS

The legal protection of pharmaceutical-pill attributes emerged in part to prevent the sale of counterfeit goods and to prevent the practice of palming off. But the rise of the modern generic-

drug industry, the products of which are subject to FDA inspection and bioequivalence standards, has largely obviated these concerns. With few exceptions, consumers should be able to expect that a generic drug will treat their condition as well as the brand-name version. The benefit of having similar brand-name and generic-drug products that range widely in appearance now seems negligible. Instituting a more consistent and organized system of pill appearance would increase patient adherence, reduce the complexity of medical regimens, reduce medication error, and encourage the rational use of bioequivalent generic drugs.

Dr. Greene reports receiving a Junior Faculty Fellowship from the Ewing Marion Kauffman Foundation for Entrepreneurship Research. Dr. Kesselheim reports receiving a career development award (K08HS18465-01) from the Agency for Healthcare Research and Quality and a Robert Wood Johnson Foundation Investigator Award in Health Policy Research.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Jerry Avorn, Alfred Engelberg, Kevin Outterson, and Stacey Dogan for their comments on earlier drafts of the manuscript.

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