IGNORING DRUG TRADEMARKS

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State generic substitution laws permit, and sometimes require, a pharmacist to ignore the instructions on a prescription written by a physician. When the prescriber specifies a particular company's product, using the product's brand name, these state laws direct the pharmacist to dispense a less expensive but equivalent product made by another company. The brand name, however, is a trademark. Like other trademarks, drug trademarks distinguish goods in the market from others and signal the source of the goods. As soon as generic drugs are available, however, state law instructs the pharmacist to read the brand name—written by the doctor—as an instruction to dispense a different company's product. This is the opposite of how trademarks are supposed to operate. This Article shows that the generic drug substitution laws of the 1970s are an anomaly in our legal system. Substitution at the pharmacy was illegal, and it still is otherwise illegal. The substitution laws created an exception in pharmacy law and broke with long-standing policy in food and drug law as well as unfair competition law. These laws were intended to, and did, undermine proprietary (trademark) rights to achieve savings for payors after efforts to mandate generic prescribing failed. And they prioritized short-term cost savings over the dynamic pro-competitive benefits of a properly functioning trademark system. However, much has changed since the 1970s. The regulatory

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framework has changed, regulatory science has evolved, drug research and development has evolved, the industries have changed, the healthcare finance system is utterly different, and the relationship among parties in healthcare delivery has evolved. Policymakers should consider whether the assumptions that supported these laws remain true today.

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INTRODUCTION

If you walk into a gas station or a fast-food restaurant with a soda fountain today and ask for Coke, you will receive the carbonated soft drink made by the Coca-Cola Company. If the vendor does not stock Coke, it may ask whether you will accept a Pepsi or another alternative, and you may accept, or decline, as you wish. But the vendor will not—may not—simply dispense an alternative carbonated beverage meant to mimic the Coke you requested, even if signs on the walls say it dispenses only the alternative drink.[1] For that matter, if you walk into a pharmacy with a prescription for

1. *E.g.*, Coca-Cola Co. v. Overland, Inc., 692 F.2d 1250, 1253 (9th Cir. 1982) (enjoining restaurants' substitution of Pepsi-Cola in response to requests for Coca-Cola, without oral disclosure of the substitution, and holding that signage alone is insufficient); Coca-Cola Co. v. Dorris, 311 F. Supp. 287, 289–90 (E.D. Ark. 1970) (similar).

Merck's Zocor (which contains the active ingredient simvastatin) to lower your cholesterol, the pharmacist may not dispense Upjohn's Lipitor (which contains atorvastatin calcium) instead of the product you requested.[2]

And yet if you walk into the same pharmacy asking specifically for Zocor, made by Merck, the pharmacist will likely hand you an unbranded product containing simvastatin made by Hetero Labs, Micro Labs, Oxford Pharmaceuticals, Accord Healthcare, Lupin, Biocon Limited, Zydus Pharmaceuticals, YaoPharma, Aurobindo Pharma, or Watson Labs.[3] The pharmacist might not tell you that you are receiving a different company's product containing the same active ingredient, though if you are attentive, you might notice the substitution by reading the label of the prescription vial. The law not only permits dispensing this "generic" product, but it also often requires it. In the 1970s, payors—private insurance companies and government programs—worked with the U.S. Food and Drug Administration ("FDA"), the Federal Trade Commission ("FTC"), and consumer advocates to persuade state legislatures across the country to authorize, and in some places require, this substitution.[4]

Although generic substitution is common, and indeed expected when a consumer requests a medication, it conflicts with bedrock principles of trademark law. The brand name Coke is registered with the federal government as a trademark.[5] The Coca-Cola Company has invested in the quality of its beverage, its reputation, and its trademark for decades. It uses the name Coke to distinguish its beverages (including Diet Coke and Orange Vanilla Coke) from others in the marketplace and to identify its products as Coke's own products.[6] Consumers rely on familiarity with the company and their own preference for the company's products when they choose Coke.[7]

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2. This would violate state pharmacy law, and if the pharmacist concealed what was done, it would constitute "passing off"—a type of unfair competition. *See infra* Subpart 0.B.

3. A list of the generic simvastatin products that might be substituted for Zocor can be found by searching the FDA's Orange Book database for simvastatin. *See Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last visited Oct. 22, 2021).

4. *See infra* Part 0.

5. *See* U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/trademarks/search (select "Search our trademark database (TESS), select desired criteria, and enter "Coke" or "Coca Cola" in the searchbar) (last visited Oct. 22, 2021); *see also* JUSTIA, https://trademarks.justia.com/714/68/coke-71468708.html (last visited Oct. 22, 2021).

6. *See* Don N. Curdie, *Infringement of the Trademark "Coca-Cola*," 27 BUS. LAW. 297, 308 (1971) (stating that the trademark for Coca-Cola implies identification).

7. *See id.* at 300 ("[T]he public in using the word 'Coke' meant to indicate the drink that only The Coca-Cola Company originated.").

Dispensing a substitute cola when a consumer asks for Coke is "passing off" and "unfair competition."[8] Treating the trademark—the source indicator—as an invitation to dispense a product made by a different company nullifies the trademark-owning company's investment in the quality of its product and compromises the company's reputation.[9] Substitution allows the second company to piggyback on the first company's reputation and benefit from the goodwill the first company has developed with its customers.[10]

Substitution of purported copies for drugs specifically requested by consumers was unlawful until the 1970s.[11] Today, though, it is the lawful and usual practice. This results from a combination of the new drug approval framework implemented by the FDA, the agency's practice of publicizing that certain generic drugs are "therapeutically equivalent" to certain branded drugs,[12] and state pharmacy laws that permit or require substitution, as follows.[13]

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8. Coca-Cola Co. v. Dorris, 311 F. Supp. 287, 289 (E.D. Ark. 1970).

9. *See* Int'l Kennel Club of Chi., Inc. v. Mighty Star, Inc., 846 F.2d 1079, 1091 (7th Cir. 1988) ("[T]he most corrosive and irreparable harm attributable to trademark infringement is the inability of the victim to control the nature and quality of the defendant's goods." (quoting Processed Plastic Co. v. Warner Commc'ns, 675 F.2d 852, 858 (7th Cir. 1982))).

10. *See* Mary LaFrance, *Passing Off and Unfair Competition: Conflict and Convergence in Competition Law*, 2011 MICH. ST. L. REV. 1413, 1425 (2011) (discussing how some countries believe that companies should not be allowed to advertise in any comparative forms and piggyback on another company's already well-established reputation).

11. *See infra* Part 0.

12. *See generally* U.S. DEP'T OF HEALTH AND HUM. SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (41st ed. 2021) [hereinafter 41ST ORANGE BOOK].

13. New York *ex rel.* Scheiderman v. Actavis PLC, 787 F.3d 638, 645 (2d Cir. 2015) (stating that every state either "permit[s] or require[s] pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written"); *see also* Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant at 5, Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421 (3d Cir. 2016) (No. 15-2236) ("Since the late 1970s, state legislatures throughout the country have sought to address the prescriber-payor pricing disconnect by enacting laws that enable (and sometimes require) a pharmacist to substitute a therapeutically equivalent generic drug (known as an 'AB-rated' drug) when presented with a prescription for a brand-name drug, unless a physician directs or the patient requests otherwise."); Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 175 (2016) ("States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today . . . allow (and in some cases require) pharmacists—absent a doctor's contrary instructions—to fill prescriptions for brand-name drugs with generic versions.").

In the United States, a "new drug"—meaning a new drug *product*, a medicine in the final form to be sold in the market and administered to patients—cannot be placed on the market without FDA approval.[14] Premarket approval is required if the product is new, even if the active ingredient has been marketed in the past.[15] Products containing new, active ingredients, such as Zocor, require an approved new drug application ("NDA"),[16] while a generic copy usually requires an approved abbreviated new drug application ("ANDA").[17] This Article refers to drugs approved through the NDA process as "brand drugs" and the companies that market them as "brand companies." Drugs approved through the ANDA process are called "generic drugs" and the companies that market them are "generic companies."[18]

The differences between these applications are stark. An NDA must show the brand product is safe and effective when used as described in its labeling.[19] Developing the safety and effectiveness data needed for approval begins with laboratory and animal testing.[20] Several phases of human ("clinical") trials follow, beginning with small safety tests in healthy subjects and moving through additional phases of progressively larger trials with more ambitious goals.[21] The process usually ends with large randomized double-blind controlled clinical trials.[22] For a novel molecule, this process can take twelve

14. 21 U.S.C. § 355(a). A "drug" is, among other things, any article—other than a device—"intended for use in the cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1).

15. *See* United States v. Generix Drug Corp., 460 U.S. 453, 459 (1983) (holding that a generic drug product is a "new drug" even if the active ingredient has been marketed before).

16. If the active ingredient is biological, then the applicant instead submits a biologics license application. 42 U.S.C. § 262(a). This Article does not discuss biologics, which fall under a different federal framework.

17. *See* 21 U.S.C. § 355(j).

18. Many companies market both types of products. This Article adopts the conventions described in the text for simplicity's sake.

19. AGATA DABROWSKA & SUSAN THAUL, CONG. RSCH. SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 6 (2018).

20. *Id.* at 4.

21. *See* 21 C.F.R. § 312.21 (2021).

22. 21 U.S.C. § 355(d) (requiring substantial evidence of effectiveness from at least one adequate and well-controlled clinical trial); 21 C.F.R. § 314.126 (2021) (describing characteristics of an "adequate and well-controlled trial").

years or more.[23] It is an expensive endeavor with an uncertain outcome.[24]

An ANDA is comparatively inexpensive and quick to produce because the applicant need not prove safety and effectiveness.[25] Instead, the applicant shows that its drug is the same as, and bioequivalent to, a drug that *was* approved on the basis of safety and effectiveness, known as its "reference" drug.[26] A generic drug is the same as its reference drug if they have the same active ingredient, route of administration, dosage form, strength, and labeling.[27] The drug is "bioequivalent" to the reference drug if its active ingredient reaches the site of action in the body to the same extent, and at the same rate, as the active ingredient of the reference drug.[28] With this showing, the ANDA creates a scientific bridge to the reference drug and relies on the safety and effectiveness data in the application that supported the reference drug.[29]

The FDA lists approved new drug products in an annual publication and searchable database known as the "Orange Book."[30] Since 1980, the agency has also included a "therapeutic equivalence" assessment once it approves two products with the same active

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23. *See* Joseph A. DiMasi et al., *Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 272, 276 (2010) (finding that the development of a new drug, from target identification through approval for marketing, takes over twelve years and often much longer).

24. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 26 (2016) (estimating an average out-of-pocket cost per approved compound of about $1.4 billion and a total preapproval cost of $2.56 billion); *see also* Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1328 n.54 (2020) (discussing studies that quantify likelihood of failure).

25. *See* Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 106–08 (2016).

26. *See* 21 U.S.C. § 355(j).

27. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iii), (v); 21 C.F.R. §§ 314.94(a)(5)–(6) (2020). It is possible to change the route of administration, dosage form, or strength and still submit an ANDA with the FDA's approval of a petition. 21 U.S.C. § 355(j)(2)(C). The result is called a "petitioned ANDA." A second type of abbreviated application may propose more significant differences from the reference drug. Although the changes must be supported by new safety and effectiveness data, the application otherwise relies on the brand company's research. *See* 21 U.S.C. § 355(b)(2); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: APPLICATIONS COVERED BY SECTION 505(B)(2) 4 (1999), https://www.fda.gov/media/72419/download. Neither abbreviated application is relevant here. References to ANDAs in this Article are references to ordinary (not-petitioned) ANDAs.

28. 21 U.S.C. § 355(j)(8)(B).

29. *See* 21 U.S.C. §§ 355(j)(2)(A)(i), (iv).

30. 21 U.S.C. § 355(j)(7)(A)(i)(I); *see generally* 41ST ORANGE BOOK, *supra* note 12.

ingredient.[31] It considers two products therapeutically equivalent if they are "pharmaceutical equivalents" (same active ingredient, route of administration, dosage form, and strength) and bioequivalent.[32] This means most generic drugs approved through ANDAs are deemed therapeutically equivalent to their reference drugs. The FDA says two products deemed therapeutically equivalent can be substituted for each other "with the full expectation that the substituted product can be expected to have the same clinical effect and safety profile as the prescribed product."[33]

Once the FDA approves generic drugs based on a particular brand product, the generic drugs (as a group) tend to take over the market.[34] Many attribute this to the combination of the FDA therapeutic equivalence rating and state generic substitution laws.[35] Under these laws, if a doctor writes a prescription for a particular brand drug, state law will either require or permit the pharmacist to dispense a lower-cost generic equivalent instead. The doctor may be able to instruct otherwise by specifying that the brand drug is medically necessary (for instance, if the generic drugs contain an inactive ingredient to which the patient is allergic) or by telling the pharmacist to "dispense as written."[36] But if the doctor does not take these steps and a generic is available, the pharmacist will usually dispense the generic.[37] Depending on the state's law and the pharmacy's own policies, the pharmacist might not ask the consumer for consent to substitute and might not tell the consumer substitution

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31. 41ST ORANGE BOOK, *supra* note 12, at iv–v.

32. *Id.* at vii.

33. *Id.* at viii.

34. *E.g.*, Murray L. Aitken et al., *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales following Loss of Exclusivity*, *in* 76 MEASURING AND MODELING HEALTH CARE COSTS 243, 250 (Ana Aizcorbe et al. eds., 2018) (finding that six drugs that lost exclusivity between 2009 and 2013 also lost sixty percent of their market share within (on average) three months of generic entry); Ralf Boscheck, *Intellectual Property Rights and the Evergreening of Pharmaceuticals*, 50 INTERECONOMICS, 221, 221, 224 (2015) ("As patents expire, the first generic competitor typically enters the market with a 20 to 30 per cent discount relative to the branded product, capturing about 44 to 80 per cent of total sales within the first full year after launch.").

35. *See supra* note 13.

36. *E.g.*, COLO. REV. STAT. § 12-280-125(2)(a)(I) (2019) ("If, in the opinion of the practitioner, it is in the best interest of the patient that the pharmacist not substitute an equivalent drug or interchangeable biological product for the specific drug or biological product he or she prescribed, the practitioner may convey this information to the pharmacist . . . [by] [i]nitialing by hand or electronically a preprinted box that states 'dispense as written' or 'DAW' . . . .").

37. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

has happened.[38] The consumer might receive the drug in an amber vial with a label stating the manufacturer's name, but the consumer still might not realize substitution has occurred.[39] At other times, the consumer might receive the drug in original packaging from the brand or generic company, such as a bottle or box with the manufacturer clearly identified.

State legislatures amended their pharmacy laws to permit generic drug substitution in the 1970s when the FDA began approving generic copies of older drugs with expired patents.[40] Substitution (of *any* medicine for the one prescribed) had been illegal under state pharmacy laws as well as the law of unfair competition, which applied to both the pharmacist and the manufacturer of the substituted drug.[41] Substitution had also been illegal since the beginning of the century under FDA law, but the agency was disinclined to interfere without a risk to consumers.[42] Pharmacy law and unfair competition law had been clear since the turn of the century, and states even amended their pharmacy laws in the 1950s—during a surge in illegal substitution—to make what was implicit more explicit.[43] But by the early 1970s, public and private payors were footing the bill for prescription drugs and looking for a way to shift patients to low-cost alternatives to brand drugs. When advances in regulatory science provided better assurance of the quality of purported copies in the market, the modern substitution arrangement emerged: abbreviated applications without clinical data, publication of therapeutic equivalence advice from the FDA, and permission under state law to engage in previously illegal practices.[44]

Substitution of less expensive generic drugs for their brand counterparts saves payors money.[45] It is also the main way generic

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38. *See* Henry Grabowski et al., *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373, 380 (2012).

39. At the time of writing, the Author was holding two vials of generic drugs; one said in small print "MFR: TEVA USA," but the other simply said "LANNETT" in small print in the corner of the label without specifying the significance of the word. The Author understood that Teva and Lannett make generic drugs, but the ordinary consumer might not.

40. *See infra* Part 0.

41. Neil J. Facchinetti & W. Michael Dickson, Commentary, *Access to Generic Drugs in the 1950s: The Politics of a Social Problem*, 72 AM. J. PUB. HEALTH 468, 468, 470 (1982).

42. *See id.* at 470.

43. *See* Hossein Salehi & Stuart O. Schweitzer, *Economic Aspects of Drug Substitution*, HEALTH CARE FIN. REV., Spring 1985, at 59, 59.

44. *See* 41ST ORANGE BOOK, *supra* note 12, at iv; *infra* Subpart III.D.

45. U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 4 (2012) ("[A] series of studies estimated the total savings that have accrued to the U.S. health care system from substituting generic drugs for their brand-name counterparts, and found that from 1999 through 2010 doing so saved more than $1 trillion.").

companies get sales, because they choose not to promote their products to prescribers or patients.[46] A vast body of academic literature attacks brand companies that continue to enjoy sales after the FDA has approved generic drugs and deemed those drugs therapeutically equivalent.[47] This literature generally assumes the importance of automatic substitution, and some scholars attack the adoption and continued use of trademarks in connection with brand products.

Professors Carrier, Dogan, and Lemley, for example, criticize brand companies for introducing newer versions of their products and (sometimes) withdrawing the outdated versions.[48] The newer products lack generic equivalents, and prescriptions for the newer products will not automatically lead to dispensing generic drugs based on the older brand products. Professor Carrier also criticizes patent litigation settlements between brand companies and generic companies that require the generic company to respect a portion of the patent term, arguing that the brand company can introduce a newer version of its product in the interim, which leads to the same result.[49] These criticisms are tied to the brand company's use of a trademark. Because generic companies choose not to promote their products, a generic company depends on doctors to prescribe the particular brand product to which its product is therapeutically equivalent.[50] If doctors have moved on to a different brand product, the generic company's business strategy will fail. Professor Feldman complains that brand companies introduce newer versions of their products shortly before patents covering older versions expire and ensure a market shift to their newer products through many methods, including advertising their products and encouraging doctors to specify their brand names and decline substitution.[51] Professor

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46. *Generic Medicines*, ASS'N FOR ACCESSIBLE MED., https://accessiblemeds.org/generic-medicines (last visited Oct. 22, 2021) ("Generic manufacturers rarely spend money on advertising and marketing . . . .").

47. *See, e.g.*, William F. Haddad, *Generic Drugs–Tomorrow's Market*, 33 FOOD DRUG COSM. L.J. 488, 490 (1978).

48. *E.g.*, Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687–88, 717 (2009) (asserting that when "the branded company makes repeated changes in a drug's formulation to prevent generic substitution, rather than to improve the efficacy of the drug product," it is able to "manipulate the FDA's regulatory system" for "no purpose but to exclude competition"); Carrier & Shadowen, *supra* note 13, at 171 (describing "evergreening" as "(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and (2) encouraging doctors to write prescriptions for the reformulated rather than the original product").

49. Carrier, *supra* note 37, at 1009.

50. *See* Grabowski et al., *supra* note 38, at 377.

51. Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 499, 527 (2016).

Kesselheim argues that generic companies should be allowed to use the brand names of the products on which they are based and thus, effectively, that brand companies should have to adopt a new brand name for each product.[52]

This Article offers a deeper and more historically contextualized examination of drug substitution, drug trademarks, and the relationship between the two.[53] It makes two claims.

First, the generic drug substitution bills of the 1970s created *exceptions* to long-standing pharmacy laws that prohibited the substitution of one product for another. This claim refutes statements from supporters of generic drug substitution who suggest that instead, the antisubstitution laws enacted in the 1950s were the anomaly and that the laws of the 1970s simply repealed the anomaly.[54] Dispensing a drug other than the drug requested was

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52. Ameet Sarpatwari & Aaron S. Kesselheim, *The Case for Reforming Drug Naming: Should Brand Trademark Protections Expire upon Generic Entry?*, PLOS MED. (Feb. 9, 2016), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001955#sec005; *see also* Jonathan J. Darrow et al., *Reconsidering the Scope of US State Laws Allowing Pharmacist Substitution of Generic Drugs*, BMJ (June 23, 2020), https://www.bmj.com/content/369/bmj.m2236 (arguing lawmakers should consider authorizing pharmacists to substitute alternatives that the FDA has not deemed therapeutically equivalent).

53. The academic literature on drug trademarks is thin. Some argue that the FDA should play a more robust role in review of drug trademarks. Danielle A. Gentin, *You Say Zantac, I Say Xanax: A Critique of Drug Trademark Approval and Proposals for Reform*, 55 FOOD & DRUG L.J. 255, 267 (2000) (proposing a larger role for the FDA in review of drug trademarks because of "ever-increasing confusion generated by today's lexicon of drug names"). Others express concern about the reliability of the testing of brand names performed for FDA purposes. James A. Thomas, *The Errors of Error Testing: Potential Liability Issues for Medication Error Testing of Pharmaceutical Trademarks Under U.S. Law*, 59 FOOD & DRUG L.J. 325, 328–29 (2004) (arguing medication error testing relating to confusingly similar drug trademarks has "not been proven to provide reliably predictable results," which may create a liability risk for companies). Many express concerns about the risks to patients of drug trademark confusion. *See, e.g.*, David A. Simon, *Trademark Law and Consumer Safety*, 72 FLA. L. REV. 673, 673, 675 (2020) (arguing that when confusion presents a safety risk, courts should lower the bar for finding the mark deceptive); Sandra L. Rierson, *Pharmaceutical Counterfeiting and the Puzzle of Remedies*, 8 WAKE FOREST INTELL. PROP. L.J. 433, 434–35 (2008) (arguing that consumers who suffer from drug counterfeiting are under-compensated for their injuries, while the trademark owners may be overcompensated for activity labeled as counterfeiting under the Lanham Act); Barton Beebe & Jeanne C. Fromer, *Are We Running Out of Trademarks? An Empirical Study of Trademark Depletion and Congestion*, 131 HARV. L. REV. 945, 1027 (2018) ("For pharmaceutical products, trademark congestion can literally kill. If different drugs with distinct effects have the same name, or names that are too similar, doctors or pharmacists may inadvertently substitute one for the other with potentially lethal consequences.").

54. *E.g.*, Facchinetti & Dickson, *supra* note 41, at 468 ("[I]n the 1950s . . . an elite group of industrialists and professionals . . . were successful in defining

illegal before the 1950s and, except for generic drug substitution, remains illegal today.[55] The state pharmacy laws of the 1950s simplified enforcement, but they did not make something illegal that had been legal before. Instead, they created an *exception* to the general rule.

Second, the substitution laws were intended to, and did, undermine proprietary rights. The true purpose and actual effect of these laws was to undermine drug trademarks—in order to achieve savings for payors—by instructing that the trademarks be ignored when used in a doctor's prescription if generic drugs are available in the marketplace. In this context, then, the brand name associated with the product (a source identifier) is treated as an identifier of its active ingredient and becomes a *thing* identifier, rather than a *source* identifier. This undermines the goodwill earned by the brand company, and it conflicts with the goals of trademark law: enabling efficiency in the market and protecting property rights in goodwill.

Part I explains the long-standing bar on substitution of one drug for another prescribed. This prohibition derives from food and drug law, pharmacy law, and unfair competition law. It was the law before the 1970s and, except for generic drugs, remains the law today.[56] Part II describes the increase in illegal substitution during the middle of the century and the steps taken by brand companies to respond. Unfair competition suits against offending pharmacists generally succeeded, as did suits against the manufacturers of the illicit

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brand substitution as a health hazard and in solving the problem to their own satisfaction, with the cooperation of state officials and state legislators. . . . [There was] partial repeal of the anti-substitution laws in the 1970s . . . ."); DOMINIQUE A. TOBBELL, PILLS, POWER, AND POLICY: THE STRUGGLE FOR DRUG REFORM IN COLD WAR AMERICA AND ITS CONSEQUENCES 164 (2012) (asserting that by the end of the 1970s reformers had "succeeded in overturning the state substitution laws of the 1950s"); Thomas J. Bollyky & Aaron S. Kesselheim, *Reputation and Authority: The FDA and the Fight over U.S. Prescription Drug Importation*, 73 VAND. L. REV. 1331, 1377 (2020) ("Starting in the late 1970s, U.S. states began repealing the anti-substitution dispensing laws that had prevented pharmacists from substituting other versions of a drug for the specific brand-name version indicated on a prescription."). Supporters of the substitution laws in the 1970s said the same thing. *E.g.*, Haddad, *supra* note 47, at 489 (complaining that the brand companies were proposing changes to state generic drug substitution laws to allow consumers to specify a brand name, overriding substitution, and referring to the "successful route of the fifties when they used state legislatures to prevent substitution"); *The Pharmacist's Role in Product Selection*, 11 J. AM. PHARM. ASS'N 181, 182 (1971) ("The drug industry fought the counterfeiting problem in part by mounting its successful campaign to bring the antisubstitution laws into being.").

55. There is a parallel exception for interchangeable biologics, but as noted, this Article does not consider biologics. *See supra* note 16.

56. *See* discussion *infra* Part I.

copies.[57] State pharmacy boards also acted. Because a strategy of repeated unfair competition suits was expensive and inefficient, the brand companies turned to shoring up state pharmacy law with language confirming what the state pharmacy boards had been saying: substitution was improper. The antisubstitution laws of the 1950s reflected the merger in policymaking of two doctrinal bases for opposition to substitution: concerns about economic adulteration (economic fraud on the pharmacy's part and possible risk to patients tied to inferior products) and complaints about competitive harm (to the companies whose products were specified by the consumer).[58]

Part III explains how the exception for generic drugs came about. Concerns about the prices of new drugs—especially after drug research and development increased in complexity, risk, and expense over the 1960s—fueled hostility to drug trademarks and concerns about the brand loyalty of doctors.[59] With the spread of prescription drug coverage in insurance, the payor community developed a financial stake in selection of medicines and sought to shift patients to less expensive alternatives.[60] The exceptions enacted in the 1970s—permitting substitution with therapeutically equivalent generic drugs—responded to economic pressure from increasing drug prices after the 1962 amendments to the drug regulatory framework. These exceptions could be justified by advances in regulatory science that had reduced concerns about substitute products being inferior.[61]

Part IV reconsiders the generic drug exception in view of the purposes of trademark law and the effect of substitution on drug trademarks. It begins with a fundamental point that is regularly overlooked in scholarship and policymaking discussions: a generic product is *not the same* as the corresponding brand product. Certain *aspects*, such as the active ingredient, are the same. But sameness, here, is a regulatory concept; the word "same" does not assume its ordinary English language meaning.[62] And the *products* in the market are not the same. They are made and sold by different companies with different histories and reputations. They may be

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57. *See* discussion *infra* Subpart II.B; *see, e.g.*, Winthrop Chem. Co. v. Weinberg, 60 F.2d 461, 463 (3d Cir. 1932) (suit against pharmacist); William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526, 527–29, 533 (1924) (suit against manufacturer).

58. MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 142–43 (1974).

59. Joseph P. Reid, Note, *A Generic Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 313–14 (1999) (discussing how prices of new drugs fueled hostility to drug trademarks); *see also infra* note 250 and accompanying text (discussing the brand loyalty of doctors).

60. *See* discussion *infra* Subpart III.C.

61. *See* discussion *infra* Subparts III.B, III.D.

62. *See infra* pp. 153–55 and notes 338–50.

made using different processes and different raw ingredients.[63] This provides good reason to protect trademarks in this setting. Trademarks distinguish products in the market by their source.[64] Some argue that a brand company's trademark improperly perpetuates its patent-based exclusivity in the market. The theory is that the patent allowed the company to build brand loyalty, which is then used after patent expiry to perpetuate monopoly by luring consumers (really, doctors) away from lower-priced substitutes.[65] But we do not undermine trademarks in other product sectors on this basis, even when these products have patented features.[66] As Part IV explains, we do not because patents and trademarks pertain to different things, play different roles, and serve different purposes.

Finally, creating an exception in pharmacy law and ignoring the trademark in this setting may not be necessary anymore, if it ever was. Substitution was justified in part on a supposed market failure tied to separation between the person choosing the medicine (the doctor) and the person paying for the medicine (the patient). More recent explanations add the modern third-party payor, who (they say) neither chooses nor consumes. Permission to substitute was meant to allow pharmacists to act in their own interest, substituting a drug they had paid less for while recovering more in reimbursement. The market has changed fundamentally since the 1960s when policymakers articulated this market failure to justify generic drug substitution, and it is far from clear what would happen today without generic substitution laws in place. Payors play a powerful role now in steering doctors and patients to lower-cost alternatives.[67] They can choose to reimburse only for generic drugs, and they can require doctors to prescribe generically.[68] Doctors can, however, choose to write generic prescriptions of their own accord.

A brief conclusion follows. The antisubstitution norm of pharmacy law and the protection of drug trademarks make sense once it is clear that the brand drugs and their generic equivalents are not the same product. Although payors have a strong interest in paying less for drugs (and taxpayers have an interest in government payors doing so), payors can revise their policies to cover the least expensive products that are medically appropriate. This can be accomplished without undermining property rights and contributing to widespread conflating of brand products with their underlying active ingredients.

63. *See infra* pp. 157–58 and notes 357–61.
64. *See infra* note 377 and accompanying text.
65. *See infra* note 383 and accompanying text.
66. *See* discussion *infra* Subpart IV.C.
67. *See infra* pp. 172–73 and notes 429–33.
68. *See infra* pp. 172–73 and notes 429–33.

I. THE PROHIBITION OF SUBSTITUTION

Substitution—selling a product, including a medicine, that is not the one requested—has been disfavored under the law for centuries. Trying to encourage that practice by, for instance, making copies of a commonly requested product and encouraging their substitution has also been condemned. This disfavored status has manifested in "food and drug" law—the regulatory schemes applicable to food and drug products—state law governing the pharmacy profession, and state and federal law relating to unfair competition and trademarks.

A. Food and Drug Law

Long before the period that concerns us, governments tried to protect the public from "substitution" in food products.[69] The history of drug substitution begins with food because the line between food and drugs was blurry through the nineteenth century.[70] In food law, this act of substitution is known as "economic adulteration."[71] Depending on the nature of the substitution, economic adulteration of food may have health consequences, but initially substitution was viewed foremost as a fraud on the consumer.[72] Governments from ancient times to the present have addressed substitution and other types of economic adulteration in food. Peter Barton Hutt's exhaustive history of food adulteration and misbranding laws provides examples ranging from Roman civil laws on substitution of food ingredients[73] to medieval British proclamations prohibiting the mixing of wines and then sale under the name that commanded the higher price[74] to state laws in the 1800s and early 1900s prohibiting

69. *See generally* Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2 (1984) (providing an overview of government regulation of adulterated or misbranded food from an economic perspective).

70. Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 341 ("Throughout much of the nineteenth century, the boundary between food and drugs was porous."). It remains blurry now. *See generally* Lewis Grossman, *Foods, Drugs, and Droods: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091 (2008) (discussing that courts grant the FDA wide discretion to interpret the definitions of various terms in the Food, Drug, and Cosmetic Act).

71. Hutt & Hutt, *supra* note 69, at 63–64.

72. *See id.* at 63 ("In broad scope, [the economic adulteration provisions of the Food, Drug, and Cometic Act] prohibited economic fraud on the consumer by a manufacturer . . . .").

73. *Id.* at 5 (noting liability under Roman civil law for *stellionatus*, that is, "where anyone has substituted some article for another" (quoting 11 S.P. SCOTT, THE CIVIL LAW 8 (1932))).

74. *Id.* at 16 (describing 1419 proclamation "prohibiting the adulteration of wine or the mixing of one wine with another for sale under a name that commanded a higher price").

substitution with inferior ingredients as well as sale of "imitation" products under the name of the product imitated.[75]

So too with drugs. The concept of drug adulteration traces its lineage to the seminal work of Frederick Accum, a German chemist and author of the definitive 1820 treatise, *A Treatise on Adulteration of Food and Culinary Poisons*.[76] Although Accum focused on food, he devoted eleven pages to adulteration of medicines, including the "fraud" by which less expensive ingredients were substituted into compounds.[77]

The substitution fraud described by Accum involved drugs derived from "*materia medica*"—botanical and mineral compounds derived from "nature's pharmacy."[78] Rather than genuine Peruvian bark powder, Accum wrote, the public often received "a spurious compound of mahogany sawdust and oak wood, ground into powder, mixed with a proportion of good quinquina."[79] The price of genuine bark, he added, was "not lower than twelve shillings the pound," but the "powder bark" substitute was supplied to apothecaries at "three or four shillings a pound."[80] Similar fraud was used in the manufacture of rhubarb powder, ipecacuanha powder, and "other simple and compound medicines of great potency."[81] Accum explained that "unprincipled dealers in drugs and medicines" were concerned mainly with cheapness rather than "genuineness and excellence."[82] This substitution for economic gain was "fraud" and the drugs "counterfeited."[83]

Twenty years after Accum published his treatise, in the United States, Lewis C. Beck gave hundreds of examples of common adulteration of medicines in his treatise on the topic.[84] Some sellers

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75. *Id.* at 41 (noting Virginia statute from 1900 deeming a food adulterated if "any inferior substance or substances has or have been substituted wholly or in part for the article so that the product when sold shall deceive or tend to deceive the purchaser" and also if "it be an imitation of and sold under the specific name of another article").

76. *See generally* FREDERICK ACCUM, A TREATISE ON ADULTERATIONS OF FOOD AND CULINARY POISONS (2d ed. 1820) (providing methods to detect the fraudulent adulterations of food); *see also* Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors and Forces that Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States*, 69 FOOD & DRUG L.J. 315, 316–18 (2014) (discussing role of Accum's treatise).

77. *See* ACCUM, *supra* note 76, at 15–26.

78. Swanson, *supra* note 70, at 346–47.

79. ACCUM, *supra* note 76, at 16.

80. *Id.* at 17.

81. *Id.* at 17–18.

82. *Id.* at 18.

83. *Id.* at 19 (discussing the "adulteration of spirit of hartshorn").

84. *See generally* LEWIS C. BECK, ADULTERATION OF VARIOUS SUBSTANCES USED IN MEDICINE AND THE ARTS, WITH THE MEANS OF DETECTING THEM: INTENDED

of "cochineal," or the dried body of the female *Coccus Cacti L.*, instead provided a mix of dust and insect waste, which had been turned into a paste with water and then granulated to pieces resembling the dried insect in question.[85] Plaster of Paris was sometimes sold as "ergot."[86] Beck also noted examples of dilution: for example, iodine bottles were diluted with slate, coal, and graphite.[87]

To say that something has been "substituted" for the medicine requested (or for a component of the medicine) requires a shared understanding of what the medicine requested *is*. Pharmacopeias filled this role. In the United States, physicians launched the *United States Pharmacopeia* ("*U.S. Pharmacopeia*") in 1820, describing the composition of common medicines and providing directions for their formulation.[88] By the middle of the nineteenth century, the *U.S. Pharmacopeia* had direct competition in the United States from Beck's treatise.[89] A companion publication from the American Pharmaceutical Association ("APhA"), the *National Formulary*, emerged in 1888.[90] Eventually, Congress made the *U.S. Pharmacopeia* and the *National Formulary* the "official" compendia for purposes of federal law.[91]

Firms that made medicines listed in the *U.S. Pharmacopeia* and crafted these medicines in accordance with the publication using the ingredients specified were known as "ethical" manufacturers.[92] Over time these firms sold other medicines as well. More sophisticated—though still naturally derived—medicines emerged over the second half of the nineteenth century, including early vaccines, chemotherapies, and antibiotics.[93] By the end of the nineteenth century the Germans were synthesizing medicines in the laboratory.[94] Ethical manufacturers sold these drugs, disclosing the ingredients in the labels and to the physicians to whom they sold the

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AS A MANUAL FOR THE PHYSICIAN, THE APOTHECARY, AND THE ARTISAN (1846) (exhibiting the adulterations of different substances used in medicines and the ways to detect these adulterations).

85. *See id.* at 71.

86. *Id.* at 87.

87. *Id.* at 99–100.

88. A decade later, control of this publication shifted to pharmacists, where it would remain for the rest of the century. Swanson, *supra* note 70, at 346.

89. *Id.* at 346–47.

90. Jeremy A. Greene, *What's in a Name? Generics and the Persistence of the Pharmaceutical Brand in American Medicine*, 66 J. HIST. MED. & ALLIED SCIS. 468, 478 (2011).

91. Pure Food & Drug Act, Pub. L. No. 59-384, § 6, 34 Stat. 768, 769 (1906) (codified at 21 U.S.C. § 321(g)) (defining "drug" to include "all medicines and preparations recognized in the United States Pharmacopeia or National Formulary").

92. *See* Greene, *supra* note 90, at 475–76.

93. Swanson, *supra* note 70, at 342–43.

94. *Id.* at 347.

drugs.[95] Every active ingredient has a chemical name, based on its composition and structure.[96] Few people other than chemists are able to remember these names, however, and another name emerged for use in the labels—a name meant to be nonproprietary, a scientific name for the substance, which everyone could use.[97]

In the final quarter of the nineteenth century, lawmakers in the United States and Europe began to tackle adulteration of drugs.[98] They focused not only on the medicines sold by ethical manufacturers but also on "patent" medicines.[99] Patent medicines were not the subject of patents, and they were distinguished from ethical drugs by the secrecy of their ingredients.[100] The companies selling patent medicines affixed invented names to their products (omitting the ingredients) and marketed to consumers, often with overblown claims about panacea-like properties.[101] These companies regularly swapped out ingredients for their own convenience.[102]

In the United States, federal lawmakers introduced more than one hundred bills addressing adulteration of foods, drugs, or both, in the decades before the Pure Food and Drug Act of 1906.[103] A few

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95. *See id.* at 353–54.

96. *See, e.g.*, U.S. FOOD & DRUG ADMIN., PROZAC LABEL 19 (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/018936s075s077lbl.pdf (stating that the active ingredient of a more modern drug product made by Eli Lilly, PROZAC, "is designated (±)-N-methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-tolyl)oxy]propylamine hydrochloride and has the empirical formula of $C_{17}H_{18}F_3NO \cdot HCl$").

97. Mahsa Salsabili et al., *Naming of Chiral Drugs: Should We Revisit?*, 75 FOOD & DRUG L.J. 65, 66, 69–70 (2020) (discussing the use of nonproprietary names to benefit the prescriber, pharmacist, and others).

98. *See, e.g.*, Sale of Food and Drugs Act 1875, 45 Vict. c. 63 § 6 (Eng.) (stating no one could "sell to the prejudice of the purchaser any article of . . . drug which is not of the nature, substance, and quality of the article demanded by such purchaser").

99. *See* Swanson, *supra* note 70, at 352–53.

100. The line between companies selling USP medicines and those selling patent medicines was not rigid. *See id.* at 376.

101. Although the traditional view holds patent medicine was little more than quackery, recent archival work suggests that the makers were not duplicitous. *See generally* JOSEPH M. GABRIEL, MEDICAL MONOPOLY: INTELLECTUAL PROPERTY RIGHTS AND THE ORIGINS OF THE MODERN PHARMACEUTICAL INDUSTRY (2014).

102. Swanson, *supra* note 70, at 354 ("Doctors and pharmacists further alleged manufacturers had no compunction about changing the ingredients of a medicine to respond to fluctuations in prices of ingredients, while continuing to sell it under the same packaging, using the secrecy of their formulas to disguise shifting compositions. Businessmen bought and sold trade names rather than secret formulas, patents, or manufacturing know-how as they sought to maximize profits.").

103. *See* Charles Wesley Dunn, *Its Legislative History: Original Federal Food and Drugs Act of June 30, 1906, as Amended*, 1 FOOD DRUG COSM. L.Q. 297, 297–98 (1946).

became law.[104] Most of the enacted laws concerned food,[105] but federal legislation enacted in 1848 required examination of all medicines proposed for import into the United States and rejection of any found "so far adulterated, or in any manner deteriorated, as to render them inferior in strength and purity to the standard established" by pharmacopeias in the United States and Europe.[106] By 1888, every state and territory—except Arkansas, Mississippi, North Carolina, and the Washington Territory—had a pure food law, a pure drug law, or both, and many addressed economic adulteration of drugs.[107] In 1881, for instance, New Jersey enacted legislation deeming a drug adulterated if (1) it was sold under a name found in the *U.S. Pharmacopeia* but differed from the standard in that publication, or (2) it was sold under a name found in some other pharmacopeia or standard work on *materia medica* and differed materially from the standard in that work.[108] New York passed a law containing similar language the same year.[109]

The language of New York's law found its way into the federal Pure Food and Drug Act of 1906.[110] Under that law, a drug was considered adulterated if it was sold under a name specified in the *U.S. Pharmacopeia* and differed from the description in that book in strength, quality, or purity (unless the label clearly stated this differential characteristic).[111] It was also adulterated if its strength or purity fell below the professed standard or quality under which it was sold. Further—and this did not appear in the New York or New Jersey laws—a drug was "misbranded" under federal law if it was "an imitation of or offered for sale under the name of another article."[112] It was also misbranded if the package or label bore a false or misleading statement about its ingredients.[113]

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104. Thomas A. Bailey, *Congressional Opposition to Pure Food Legislation, 1879–1906*, 36 AM. J. SOCIO. 52, 52 (1930) (noting that from January 20, 1879, to June 30, 1906, "190 measures to protected in some way the consumer of food and drugs appeared in Congress" and "eight became law").

105. *See, e.g.*, Prohibition of the Importation of Adulterated and Spurious Teas Act, ch. 64, 22 Stat. 451, 451–52 (1883); Act of Aug. 2, 1886, ch. 840, 24 Stat. 209, 209–10 (1886) (defining butter and also imposing a tax upon and regulating the manufacture, sale, importation, and exportation of oleomargarine).

106. Act of June 26, 1848, ch. 70, 9 Stat. 237, 238 (1848) (preventing the importation of adulterated and spurious drugs and medicines).

107. U.S. DEP'T OF TREASURY, ANNUAL REPORT OF THE SECRETARY OF THE TREASURY ON THE STATE OF THE FINANCES FOR THE YEAR 1888 408–10 (1888) (listing state laws).

108. Act of Mar. 25, 1881, ch. 217, 1881 N.J. Laws 283, 283.

109. Act of May 28, 1881, ch. 407, 1881 N.Y. Laws 553, 553.

110. Pure Food & Drug Act, Pub. L. No. 59-384, § 7, 34 Stat. 768, 769–70 (1906)

111. *Id.*

112. *Id.* § 8, 34 Stat. at 770.

113. *Id.*

The modern federal drug regulatory framework, dating to 1938, contains the same basic prohibitions. The Federal Food, Drug, and Cosmetic Act ("FDCA") deems a drug "adulterated" if it purports to be a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard in that compendium.[114] A drug is "misbranded" if "its labeling is false or misleading in any particular."[115] It is also misbranded if it is "an imitation of another drug" or if it is "offered for sale under the name of another drug."[116]

The drug industry evolved, however, and has continued to do so. Earlier, chemical companies (such as Merck) made bulk chemicals for pharmacists and drug companies (such as Smith, Kline & French Laboratories), which in turn specialized in making finished products and marketing.[117] By the 1930s, ethical firms were inventing medicines in their laboratories and seeking patents—a previously disfavored practice.[118] By the middle part of the twentieth century, the chemical companies and pharmaceutical companies evolved into vertically integrated companies that handled research, production, and marketing.[119]

To the modern reader, economic adulteration and misbranding under historical food and drug laws may seem beside the point. Modern readers understand the word "substitution" as a reference to generic drug substitution—dispensing a high-quality FDA-approved product that contains the same active ingredient as, and has been deemed equivalent to, the product specified.[120] These earlier laws, the modern reader may feel, pertained to something different: dispensing something *inferior*, perhaps dispensing something

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114. Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, § 501(b), 52 Stat. 1040, 1049 (1938) (codified at 21 U.S.C. § 351(b)). The 1938 statute also deemed a drug misbranded if it was not designated by a name recognized in an official compendium unless its label bore its "common or usual name," if there was one. § 502(e), 52 Stat. at 1050–51. This provision would change in 1962. *See infra* Subpart 0. If the drug was made from more than one active ingredient, the label needed the common or usual name of each. § 502(e), 52 Stat. at 1050–51. A drug is similarly adulterated even if it does not bear a name recognized in a compendium, but its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. § 501(d), 52 Stat. at 1050; 21 U.S.C. § 351(c).

115. § 502(a), 52 Stat. at 1050; 21 U.S.C. § 352(a).

116. § 502(i), 52 Stat. at 1051; 21 U.S.C. § 352(i).

117. BUREAU OF CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 15–16, 143 (1979) [hereinafter FTC REPORT].

118. *See* Swanson, *supra* note 70, at 376.

119. *See generally* ALFRED D. CHANDLER, JR., SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES (2005) (describing evolution in the drug industry over the twentieth century).

120. *See supra* notes 31–33 and accompanying text.

containing unrelated ingredients, perhaps material misrepresentations about the nature of the product sold. But that is the point. The concept and act of "substitution" evolved as the companies and marketplace evolved, as the regulatory framework evolved, and as regulatory science improved.

Questions of identity and quality have been inherent in substitution since the beginning. At first, food and drugs were sometimes indistinct, medicines were made by pharmacists as well as proprietary firms, prescriptions were only sometimes used, and the federal government played no role. Without sophisticated scientific tools for comparison of active ingredients, and without understanding how to compare biological action in the body, even the companies (or pharmacists, as the case may be) that *meant* to make high-quality copies could not verify that they had done so.[121] Others meant to make outright shams, which they sold to pharmacists, to patients, or to both.[122] The food and drug concerns about economic adulteration and misbranding provide context for the history that follows in the next subparts. The antisubstitution pharmacy laws enacted in the 1950s reflected similar concerns about economic fraud and consumer safety, *in addition to* concerns about unfair competition and trademark infringement.[123] But then, as Part 0 explains, changes in the regulatory framework and improvements in the science stripped away these arguments against substitution—leaving unfair competition and trademark considerations in its wake.[124] These would be brushed aside with complaints about the cost of medicine.

B. Pharmacy Law

In the early decades of the twentieth century, state pharmacy laws addressed substitution by pharmacists. For example, under Illinois law at the turn of the century, a pharmacist who received a prescription for "any drug, medicine, chemical or pharmaceutical preparation" could not "substitute or cause to be substituted therefor, without notification to the purchaser, any other drug, medicine, chemical or pharmaceutical preparation."[125] New York's penal code deemed it a misdemeanor for any person filling a prescription or order

121. *See generally* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: PROCESS VALIDATION: GENERAL PRINCIPLES AND PRACTICES (2011), https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf (describing the general processes required of companies to verify quality of pharmaceuticals).

122. Amy M. Bunker, *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 493, 494–95 (2007).

123. *See supra* note 58 and accompanying text.

124. *See infra* Part III.

125. Act of May 11, 1901, ch. 91, 1901 Ill. Law 1409, 1413 (regulating the practice of pharmacy in the state of Illinois).

for medicine to substitute or dispense "a different article for or in lieu of any article prescribed, ordered, or demanded."[126]

For several years in the 1930s, the National Industrial Recovery Act ("NIRA") provided another source of authority prohibiting substitution by pharmacists.[127] Section 3 of NIRA authorized the President to approve a code of fair competition proposed by and for any trade or industrial association or group.[128] The National Recovery Administration ("NRA") administered the statute, but each code of fair competition established a "code authority," comprising individuals selected by the trade and nonvoting government representatives. This authority helped enforce the code.[129]

In August 1933, the NRA published a proposed code for the retail drug industry (pharmacies), which would have banned substitution.[130] Under the NRA, certain practices would be deemed "an act of unfair competition within the meaning of the Federal Trade Commission Act," including (1) "[s]ubstituting another article for the kind ordered without due notice to the purchaser" and (2) "[p]ackaging or selling any product or item that is an imitation or unfairly similar to another product in design, style, mark, or brand."[131] Although a stand-alone code for pharmacies was never

126. N.Y EDUC. LAW § 6816(1)(a) (McKinney 2021) ("Any person who, in . . . filling any order for drugs [or] medicines . . . substitutes or dispenses a different article for or in lieu of any article prescribed, ordered, or demanded . . . or puts up a greater or less quantity of any ingredient specified in any such prescription, order, or demand than that prescribed, ordered, or demanded . . . is guilty of a misdemeanor . . . ."); People v. Silberman, 252 A.D. 770, 770 (N.Y. App. Div. 1937) (affirming conviction of defendant for "substituting and dispensing a different article for that ordered in the prescription which he filled"); *see also* Leonard Wolfram, *Criminal Liability Without Fault—The Druggist's Dilemma in New York*, 3 FOOD DRUG COSM. L.Q. 284, 288–89 (1948) (discussing New York law).

127. *See generally* National Industrial Recovery Act, Pub. L. No. 73-67, 48 Stat. 195 (1933).

128. The President could do so after finding (1) the group imposed "no inequitable restrictions on admission to membership" and was "truly representative" of the trade or industry, and (2) the code was "not designed to promote monopolies or to eliminate or oppress small enterprises," would not "operate to discriminate against them," and would tend to effectuate the policy of the statute. *Id.* § 3(a), 48 Stat. at 196.

129. *See Records of the National Recovery Administration [NRA]*, NAT'L ARCHIVES #9.9, https://www.archives.gov/research/guide-fed-records/groups/009.html (last visited Oct. 22, 2021); *see* DONALD R. BRAND, CORPORATISM AND THE RULE OF LAW: A STUDY OF THE NATIONAL RECOVERY ADMINISTRATION 92–95 (1988).

130. *See generally* NAT'L RECOVERY ADMIN., CODE OF FAIR COMPETITION FOR THE RETAIL DRUG INDUSTRY (Aug. 26, 1933), https://www.govinfo.gov/content/pkg/GOVPUB-Y3_N21_8-b52b7f431736344baf485088ef66c581/pdf/GOVPUB-Y3_N21_8-b52b7f431736344baf485088ef66c581.pdf.

131. *Id.* art. VII, §§ 4–5, at 4.

finalized,[132] President Roosevelt approved a broader Code of Fair Competition for the Retail Trade in October 1933.[133] Supplemental provisions at the end, sometimes known as the "Retail Drug Code," stated that "[n]o drug retailer shall substitute another article or any part thereof for the kind ordered, without due notice to and consent of the customer."[134] Support for the Retail Drug Code within the pharmacy profession surely stemmed from a desire to prevent the aggressive price competition that substitution with cheaper, and often inferior, ingredients enabled. It may have also stemmed from desire to elevate the status of the profession, as suggested by the advertisements of pharmacies touting the fact *they* did not engage in substitution.[135]

In its opposition to substitution and in support for the Retail Drug Code, the pharmacy profession found an ally in ethical drug manufacturers. In the 1930s, the companies turned to the Prescription Protective Bureau ("PPB") to audit pharmacy practices around the country.[136] The PPB explained in advertising that "there exist manufacturing concerns whose business is almost entirely composed of substitute items, whose high pressure salesmen are continually bombarding the retailer to dispense cheap and unreliable products in place of the items prescribed."[137] But "[w]ith the advent of the retail drug code . . . machinery has been set up for the extermination of the substitutor."[138] PPB staff presented prescriptions to pharmacies for filling, and when PPB staff detected substitution, they complained to the local NRA compliance authority (citing the NRA Code) or state pharmacy board (citing the state's pharmacy laws or the NRA Code).[139] PPB was active throughout the

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132. *See Full List of NRA Fair Competition Codes*, LIBR. OF CONG., http://www.loc.gov/rr/business/source/nra-fair-competition-codes-full-list.xls (last visited Oct. 22, 2021).

133. *See generally* Exec. Order No. 6351, https://babel.hathitrust.org/cgi/pt?id=mdp.39015081302559&view=1up&seq=35&skin=2021 (approving the Code of Fair Competition for the Retail Trade by President Roosevelt).

134. *See id.* at 44.

135. *See, e.g.*, Feek Pharmacy, *Substitutes*, ADIRONDACK REC., Aug. 19, 1937, at 4.

136. Although the PPB is shrouded in mystery, it was based in New York and helped brand companies fight substitution. *Fighting Substitution by Code*, 166 PRINTERS' INK 62, 62 (1934) ("[PBB] is undertaking to prosecute, in the interest of several drug manufacturers, dealers who substitute on their products."); *see also NRA Control of Substitution*, 34 DRUG & COSM. INDUS. 65, 65 (1934) ("Samuel F. Friend, who has served many large drug manufacturers in the solution of their problems, is director of the Prescription Protective Bureau, which has offices in New York.").

137. *An Appeal to the Ethical Druggist*, 56 N.A.R.D. J. 953, 953 (1934).

138. *Fighting Substitution by Code*, *supra* note 136, at 62.

139. PPB also asked prescribers to report pharmacies suspected of substitution. *E.g.*, *Across the Desk: Best Doctors at Mercy of Crooked Chemists*,

country in the 1930s—filing complaints, getting pharmacists hauled before pharmacy boards, and securing convictions and fines. In 1934, for example, the *New York Times* reported the Helena Cut-Rate Drug Store had been convicted and fined $500 under the NRA Code for substituting a "crude imitation" for Smith's Ergoapiol.[140] The PPB filed nearly five dozen complaints with New York's Retail Drug Code Authority in that year alone.[141]

In May 1935, the United States Supreme Court concluded that Congress had unconstitutionally delegated its lawmaking power when enacting section 3 of the NIRA, ending the brief experiment with federal enforcement of the pharmacy profession's code.[142] State pharmacy laws precluding substitution remained in place, however, and actions before pharmacy boards continued. For instance, several dozen pharmacists were hauled before the Massachusetts pharmacy board in 1936 based on complaints filed by PPB.[143] In some places, enforcement under the NRA Code transitioned to enforcement under state pharmacy law. PPB audited Goin's Drug Store in Kansas City twice in 1935, for example, finding the store had dispensed a substitute for the Eli Lilly product prescribed.[144] The organization wrote to the Retail Drug Code Authority about a substitution occurring in March, relying on the NRA Code, and to the Board of Pharmacy about a substitution occurring in August, accusing the pharmacists of violating the "drug and pharmacy law" of Missouri.[145] The state pharmacy board has archived the complaints together, as

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37 N.Y. ST. J. MED. 1966, 1966–67 (1937) ("The Prescription Protective Bureau . . . has been waging a war on substituting druggists for several years, and [the Bureau] invites physicians to report any that need attention.").

140. *Druggist Is Fined $500: Guilty of Violating NRA Code by Filling Prescription Falsely*, N.Y. TIMES, Nov. 3, 1934, at 8.

141. *Fighting Substitution by Code*, *supra* note 136, at 62.

142. A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 541–42 (1935) (finding that statutorily authorizing the President to issue as law codes written by industry, with no constraints or guidance in place, violated the nondelegation doctrine).

143. COMMONWEALTH OF MASS. DEP'T OF CIV. SERV. & REGISTRATION, ANNUAL REPORT OF THE BOARD OF REGISTRATION IN PHARMACY (1936) (indicating a warning was given in each case, because "the method of securing the evidence in these cases was not complete enough to warrant a suspension of permit or certificate").

144. Complaint from Prescription Protective Bureau to Retail Drug Code Auth. for Kansas City, Missouri (1935) (on file with author) (indicating "1st violation" on "Mar. 12, 1935"); Complaint from Prescription Protective Bureau to Bd. of Pharmacy for Missouri (1935) (on file with author) (indicating "2nd violation" on "August 5th, 1935").

145. *See* Complaint from Prescription Protective Bureau to Retail Drug Code Auth. for Kansas City, Missouri (1935) (on file with author) (indicating "1st violation" on "Mar. 12, 1935"); Complaint from Prescription Protective Bureau to Bd. of Pharmacy for Missouri (1935) (on file with author) (indicating "2nd violation" on "August 5th, 1935").

"1st violation" and "2nd violation."[146] Through the 1930s and 1940s, pharmacists continued to illegally substitute,[147] and pharmacy boards continued to act.[148]

C. Unfair Competition Law

In prohibiting substitution and imitation, food and drug laws aim to protect consumers from both fraud and risk. The pharmacy laws address these same concerns, though the NRA Code for pharmacies also reflects concerns that honest pharmacists faced unfair price competition from those who substituted inferior products, imitation products, or even worthless products.[149] These sales also raised competitive issues for the manufacturers of the products requested, which explains their investment in enforcement under the NRA Code and state pharmacy laws.[150] These firms were harmed by both the substituting pharmacists and the maker of the substituted drug.[151] The harm was a type of unfair competition and, sometimes, trademark infringement.

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146. *See* Complaint from Prescription Protective Bureau to Retail Drug Code Auth. for Kansas City, Missouri (1935) (on file with author) (indicating "1st violation" on "Mar. 12, 1935"); Complaint from Prescription Protective Bureau to Bd. of Pharmacy for Missouri (1935) (on file with author) (indicating "2nd violation" on "August 5th, 1935").

147. *Across the Desk: Best Doctors at Mercy of Crooked Chemists*, *supra* note 139, at 1966 (reporting that fifteen percent of all pharmacists substituted when filling prescriptions, based on "actual analysis of test prescriptions checked in a recent survey of drug stores through the United States").

148. *E.g.*, Letter from Irving Zapp, Assistant Dir. of Prescription Protective Bureau, to Newt Gardner, Sec'y of the Missouri Bd. of Pharmacy (May 25, 1937) (on file with author) (enclosing "eleven formal complaints against Kansas City druggists who substituted during our recent survey"); Letter from Newt Gardner, Sec'y of the Missouri Bd. of Pharmacy, to Irving Zapp, Assistant Dir. of Prescription Protective Bureau (May 28, 1937) (on file with author) (replying three days later enclosing "a list of druggists . . . who substituted on prescriptions and who were notified to personally appear" before the board two weeks later); *see also* JEREMY A. GREENE, GENERIC: THE UNBRANDING OF MODERN MEDICINE 137–38 (2014) (describing a Michigan pharmacist who lost his license in 1949 after substituting Upjohn's prednisolone for the Schering prednisolone product—Meticorten—prescribed by the physician, even though the physician had orally consented to the substitution, and also noting court reversed the decision).

149. *See* John L. Hammer, Jr., *Substitution on Prescription*, 6 FOOD DRUG COSM. L.J. 775, 775 (1951) (referring to "the druggist who actually [engages in substitution as] the perpetrator of [an] unethical practice" that amounts to "an easy way to make money" for the manufacturers of substitutes).

150. *See id.* at 777 (discussing the extent to which substitutes "cut into the market for genuine product" and drive down profitability in light of the fact that the genuine "manufacturer's research, promotional, and administrative expenses are the same without [substitution] as with it").

151. *See id.* (describing "the loss of profits" due to substitution as "alarming").

These substitution actions have their roots in the old concept of "passing off"—roughly understood to mean selling one's own product as that of another. In England, passing off was restrained in equity before any legal cause of action was recognized by courts.[152] Over the nineteenth century, the common law of England and the United States also developed a tort action for passing off, grounded in fraud and leading to damages awards.[153] In the nineteenth and early twentieth centuries, courts sitting in equity enjoined pharmacists from passing (or "palming") off when they substituted a different drug for the one prescribed without identifying the substitution.[154] They also enjoined manufacturers of substituted drugs, finding that imitation of trade dress (essentially, the overall appearance of the product) or imitation or use of a brand name was unfair competition because it encouraged pharmacists to engage in this practice.[155]

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152. CHRISTOPHER WADLOW, THE LAW OF PASSING-OFF: UNFAIR COMPETITION BY MISREPRESENTATION 8–9 (1990).

153. *See id.* at 26–29; *see also* 4 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 25:1 (5th ed. 2021).

154. *E.g.*, Winthrop Chem. Co. v. Weinberg, 60 F.2d 461, 463 (3d Cir. 1932) (directing lower court to issue preliminary injunction against defendant pharmacist after concluding he had been "surreptitiously substituting a different phenobarbital than the one ordered by the doctor" and noting that because "Luminal commands a higher price than unbranded phenobarbital costs a druggist, the purpose of the defendant . . . is clear"); Battle & Co. v. Finlay, 45 F. 796, 796 (C.C.E.D. La. 1891) (enjoining a manufacturing chemist from supplying its own "medicinal preparation" in response to orders for the plaintiff's "Bromidia").

155. *E.g.*, Winthrop Chem. Co. v. Am. Pharm. Co., 94 F.2d 587, 588 (2d Cir. 1938) (granting preliminary injunction on a finding of unfair competition, because defendant had been forced to stop using the plaintiff's trademark with its own product but then adopted a label that featured the same pink color with the same active ingredient, identified in the same script as plaintiff's trademark, placed on a tube of the same size and shape as the plaintiff's tube, "deliberately for the purpose of enabling dealers who would do so to palm off the defendant's product for the plaintiff's"); Pinoleum Co. v. Baron, 201 N.Y.S. 44, 44–45 (N.Y. Sup. Ct. 1923) (granting injunction to plaintiff, which marketed "Pinoleum" for catarrh and which colored the product green to make it distinctive, because defendant introduced a preparation of the same materials, which he called "Baco Pinol Spray," and which he colored green as well, with "ample" evidence that "he made his preparation similar to the plaintiff's for the purpose of making it possible for druggists to use it, instead of Pinoleum, and that he sought to have the druggists use it as such substitute and thereby defraud the consumer"); Sterling Remedy Co. v. Spermine Med. Co., 112 F. 1000, 1003 (7th Cir. 1901) (finding complainant entitled to an injunction on unfair competition grounds when "defendant adopted the style and shape of the boxes, the color of the tablet, and the letterpress upon the boxes and in advertising, to palm off his goods as those of the complainant"); Sterling Remedy Co. v. Gorey, 110 F. 372, 373 (C.C.N.D. Ohio 1901) (allowing defendant to sell tablets that are compounds of cascara like plaintiff's but ordering injunction because defendant prepared his boxes and their contents so that "confusion would arise, which would result in

In the only case to reach the Court, the Court embraced this unfair competition theory.[156] Warner sold "Quin-Coco," made of quinine and chocolate, which was "incapable of being distinguished by ordinary sight or taste" from Lilly's Coco-Quinine, also containing quinine and chocolate.[157] The Court explained Warner's efforts "were directed not so much to showing the merits of [its] preparation as they were to demonstrating its practical identity with Coco-Quinine, and, since it was sold at a lower price, inducing the purchasing druggist . . . to substitute . . . the former for the latter."[158] That is, the company "sought to avail itself of the favorable repute which had been established for" Lilly's product.[159] Warner's agents "induced the substitution, either in direct terms or by suggestion or insinuation."[160] The Court held that although Lilly had no patent or trademark, it had the right to be "protected against unfair competition."[161]

Today, unfair competition law—at both the state and federal level—is a broad law of business torts that includes the tort of passing off.[162] Section 43(a) of the Lanham Act provides a cause of action for

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the purchase of a box of the defendant's medicine by one who had become favorably disposed towards the use of the remedy introduced by the complainant . . . for the purpose of taking unfair advantage of the complainant . . . [and] of the established trade of the complainant"); C.F. Simmons Med. Co. v. Mansfield Drug Co., 23 S.W. 165, 175 (Tenn. 1893) (affirming injunction on the ground of unfair competition, defined as "consisting of any device or trick whereby one manufacturer's or dealer's goods are palmed off in the market as and for the goods of another, in fraud of the public and of the persons whose goods are so displaced; the most usual of such devices being the simulation of labels, the imitation of another's style of putting up goods, and the reproduction of the form, color, and general appearance of his packages"); Brown Chem. Co. v. Frederick Stearns & Co., 37 F. 360, 363 (C.C.E.D. Mich. 1889) (finding plaintiff entitled to injunction given evidence that pharmacists "endeavored to palm off" defendant's drug as manufactured by plaintiff and explaining the rule that "no man, however honest his personal intentions, has a right to adopt and use so much of his rival's established trademark as will enable any dishonest trader into whose hands his own goods may come to sell them as the goods of his rival" (citation omitted)).

156. William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526, 531–32 (1924).

157. *Id.* at 529.

158. *Id.* at 529–30.

159. *Id.* at 530.

160. *Id.*

161. *Id.* at 532.

162. 4 MCCARTHY, *supra* note 153, § 25:1 (reporting that the rule against passing off "remains an important part of the core" of unfair competition law today); *see also* Yale Elec. Corp. v. Robertson, 26 F.2d 972, 973 (2d Cir. 1928) ("The law of unfair trade comes down very nearly to this—as judges have repeated again and again—that one merchant shall not divert customers from another by representing what he sells as emanating from the second. This has been, and perhaps even more now is, the whole Law and the Prophets on the subject, though it assumes many guises.").

unfair trade practices, including misrepresenting one's goods as those of another (passing off).[163] State common law usually permits unfair competition suits, and some states have unfair competition statutes similar to section 43(a) of the Lanham Act.[164]

Modern trademark law—which emerged over the nineteenth century at the state and then federal level—is derived in part from the laws of passing off and unfair competition.[165] Trademark law protects a trademark—a word, for instance, or a symbol used to distinguish a firm's goods in the market and to signal their source.[166] Trademarks can be registered under state or federal law (or both), and unregistered trademarks may also be protected.[167]

In the nineteenth and early twentieth centuries, reliance on trademark protection presented a risk for some drug makers. Some courts found the invented names for medicines had become associated with the *products* rather than their sources and thus concluded the names had lost eligibility for protection as trademarks; they had become "generic," which is a term of art in trademark law.[168] This

163. 15 U.S.C. § 1125(a)(1) (prohibiting false designations of origin and false descriptions); Inwood Lab'ys, Inc. v. Ives Lab'ys, Inc., 456 U.S. 844, 861 n.2 (1982) (White, J., concurring) ("[T]he purpose of the Lanham Act was to codify and unify the common law of unfair competition and trademark protection.").

164. RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 4 (AM. L. INST. 1995) ("Section 2(a) of the Uniform Deceptive Trade Practices Act . . . imposes liability upon any person or commercial entity that 'passes off goods or services as those of another' or 'causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services.' Passing off is also prohibited under the various Unfair Trade Practices and Consumer Protection Acts.").

165. 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 5:2 (5th ed. 2021) ("Early [English] decisions often used the phrase 'passing off' or 'palming off' as synonyms for a competitor's infringement of a trademark."); *id.* ("[I]n all cases where rights to the exclusive use of a trade-mark are invaded, it is invariably held that the essence of the wrong consists in the sale of the goods of one manufacturer or vendor as those of another; and that it is only when this false representation is directly or indirectly made that the party who appeals to a court of equity can have relief." (quoting Lawrence Mfg. Co. v. Tenn. Mfg. Co., 11 S. Ct. 396, 400 (1891))).

166. 15 U.S.C. § 1127.

167. Robert J. Kenney, *United States: Protecting Unregistered Trademarks Under Common Law and Unfair Competition*, WORLD TRADEMARK REV. (Sept. 1, 2017), https://www.worldtrademarkreview.com/portfolio-management/united-states-protecting-unregistered-trademarks-under-common-law-and.

168. *E.g.*, Bayer Co., Inc. v. United Drug Co., 272 F. 505, 515 (S.D.N.Y. 1921) (enjoining defendant from using "Aspirin" with manufacturing chemists, retail druggists, and physicians, who understood the term referred to the plaintiff's product and understood the generic name, acetyl salicylic acid, but permitting defendant to sell acetyl salicylic acid under the name "Aspirin" to consumers, because these customers knew the drug by the name "Aspirin" and did not associate it with a particular source); Centaur Co. v. Heinsfurter, 84 F. 955, 959

was perhaps a greater risk for makers of patent medicines, as they did not disclose their ingredients and thus provided no information other than the fanciful names they had chosen.[169] In contrast, a company selling a drug listed in the *U.S. Pharmacopeia* used ingredients specified in the compendium, and if it sold a newly synthesized compound, it disclosed the contents on the label.[170] To be sure, some used fanciful names, such as "Dramamine" for a product containing dimenhydrinate.[171] But they also identified the active ingredient by its chemical name or the shorter scientific name to keep the brand name from falling into the public domain.[172]

Some drug trademarks were protected under the 1905 federal law permitting registration of fanciful marks (made-up words) and arbitrary marks (real words unrelated to the type of good).[173] Today they are protected by the Lanham Act, which established a coherent and robust system for nationwide registration of trademarks and a basis for the substantive law of trademark infringement.[174] Many

(8th Cir. 1898) (declining to enjoin defendants from use of the word "Castoria" as a trademark, because "the word 'Castoria' has become the one name by which this medicine is generally known" and thus it is "the generic name by which the article is known to the public"); *id.* at 956–57 ("The patent gave no right to any particular name, but simply to the exclusive manufacture and sale. All such rights expired in 1885, and from that time forth any party has had a right to manufacture and sell that particular compound, and also a right to manufacture and sell it under the name by which it has become generally known to the public; and, if to that public the article has become generally known only by a single name, that name must be considered as descriptive of the thing manufactured, and not of the manufacturer.").

169. *See* Swanson, *supra* note 70, at 353.

170. U.S. PHARMACOPEIA, NOMENCLATURE GUIDELINES 1–2 (2020), https://www.usp.org/sites/default/files/usp/document/usp-nomenclature-guidelines.pdf.

171. FTC REPORT, *supra* note 117, at 27; Walter J. Derenberg, *Some Unique Features in the Selection and Protection of Pharmaceutical Trade-Marks*, 4 FOOD DRUG COSM. L.Q. 137, 141–42 (1949) (discussing the use of "house marks"); *see also* Greene, *supra* note 90, at 476 (noting that for the most part "the pharmaceutical brand in the era of ethical marketing was an institutional brand, not a product-specific brand").

172. Greene, *supra* note 90, at 484–85; *see also* 2 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 12:23 (5th ed. 2021) ("A term that is a generic name of an ingredient is not necessarily a generic name of a product containing that ingredient.").

173. Act of Feb. 20, 1905, Pub. L. No. 59-84, 34 Stat. 724, 724–26 (repealed 1946); *see also* 1 MCCARTHY, *supra* note 165, § 5:3. An amendment in 1920 permitted registration of descriptive marks. Act of Mar. 19, 1920, Pub. L. No. 66-162, 41 Stat. 533, 533–35 (repealed 1946).

174. *See generally* Trademark Act of 1946 (Lanham Act), Pub. L. No. 79-489, 60 Stat. 427. For examples of statutes in this coherent and robust system, see also 15 U.S.C. § 1052 (describing registrable trademarks); 15 U.S.C. § 1114 (describing liability of a person who infringes a registered trademark).

states have trademark registration systems similar in scope and design, and courts generally interpret the statutory provisions similarly.[175] Federal and state law permit actions for infringement of registered trademarks, in which the trademark owner must show purchasers are likely to be confused about the source, sponsorship, or origin of the goods.[176] In addition to seeking relief under trademark law, a brand company can still use unfair competition law—section 43(a) of the Lanham Act or corresponding state law; the cases are often described as infringement cases, and the underlying facts and basic idea can be the same. [177]

Trademark law also has roots in an equitable doctrine that emerged separately from the common law action for passing off: a doctrine grounded in infringement of *property* rights—tied to a firm's property interest in its trademark, its trade name, or its goodwill.[178] Professor Mossoff argues that goodwill was recognized as a type of property in the United States in the nineteenth century, citing Justice

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175. *See* 3 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 22:1.50 (5th ed. 2021) (collecting cases showing statute trademark statutes are usually construed to be consistent with trademark provisions of Lanham Act).

176. A typical case involving drugs today might involve a company with a registered trademark for its drug asserting that another company's use of a similar name infringes its trademark. *See, e.g.*, Kythera Biopharmaceuticals, Inc. v. Lithera, Inc., 998 F. Supp. 2d 890, 895–96 (C.D. Cal. 2014) (denying motion to dismiss in a trademark infringement case where plaintiff was the owner of the mark Kythera—which it associated with its lead product candidate designed to reduce human body fat—and defendant was using Lithera in connection with drugs for reducing the size and appearance of adipose deposits).

177. This was true both before and after enactment of the Lanham Act. For instance, in the 1930s, Winthrop Chemical Company had valid trademarks for five medicines, Veronal, Proargol, Theominal, Kres-lumin, and Aristol. Blackman, and various other parties used similar names (such as "Theobrominal") as well as similar bottles and sometimes similar labels. The New York Superior Court granted Winthrop a permanent injunction, writing that "comparison of the two preparations leads to the inevitable conclusion that the defendants attempted to make their article so closely resemble the plaintiff's that it could be easily palmed off on the public as the latter product." Winthrop Chem. Co. v. Blackman, 268 N.Y.S. 647, 658–59 (N.Y. Sup. Ct. 1934). "It is plain," the court added, "that the adoption of the word Theobrominal is for the purpose of deception and confusion to the public and the detriment of the plaintiff." *Id.* at 659. This was "unfair competition." *Id.* at 651. Although the defendants had not used Winthrop's actual trademarks, equity would give "the same relief" as if they had poached directly. *Id.* There had been "a studied, unfair effort on the part of the defendants to obtain the benefit of the character and reputation of the plaintiff's products, without expense on their part, and to the detriment of the public and the plaintiff alike." *Id.*

178. *See* WADLOW, *supra* note 152, at 16. Indeed, the early injunction cases reflected a property theory, as courts sitting in equity acted to protect property rights. *See* 1 MCCARTHY, *supra* note 165, § 5:2.

Story's 1841 treatise on partnerships for the proposition that goodwill is reputational value created by productive labor in the use of resources.[179] In England, passing off was explicitly reconceptualized as a strict liability trespass on property rights in the early twentieth century when courts acknowledged goodwill as a form of legal property "uniquely liable to be damaged by the type of misrepresentation which constituted passing-off."[180] Indications of the property-rights justification for protection of trademarks could be found in earlier English decisions but were not explicitly stated until the early twentieth century.[181]

Although Professor Mossoff grounds trademark law in protection of property rights, Professor Bone views trademark law's primary goal as the protection of consumers from deception and confusion.[182] He sees a more recent shift to protection of goodwill and to property theory and views it as improper.[183] In contrast, Professor McKenna argues that, like unfair competition law, trademark law was meant to protect firms from wrongs committed by their competitors.[184] He sees trademark law's historical basis as tied to property rights in the mark and concerned with illegitimate diversion of trade.[185] As a descriptive matter, Professor McCarthy finds evidence of both doctrinal bases in nineteenth century cases.[186] The drug trademark cases throughout the period covered by this Article reflect both doctrinal bases,[187] though there appears to be more emphasis on the

179. *See* Adam Mossoff, *Trademark as a Property Right*, 107 KY. L.J. 1, 4, 11, 15–16 (2018) (citing JOSEPH STORY, COMMENTARIES ON THE LAW OF PARTNERSHIPS § 99 (1841)).

180. WADLOW, *supra* note 152, at 37.

181. *See, e.g.*, *id.* at 29 n.108 (citing a "series of cases" in which Lord Westbury L.C. held that "there was a right of property in trade marks which was transmissible and enforceable even against innocent infringement").

182. Robert G. Bone, *Hunting Goodwill: A History of the Concept of Goodwill in Trademark Law*, 86 B.U. L. REV. 547, 567 (2006).

183. *See id.* at 567–72, 616–21.

184. *See* Mark P. McKenna, *The Normative Foundations of Trademark Law*, 82 NOTRE DAME L. REV. 1839, 1841, 1843–45, 1848 (2007).

185. *See id.* at 1841, 1848.

186. *See* 1 MCCARTHY, *supra* note 165, § 5:2 ("In some of the early case opinions, one finds both deception of the public and harm to the property of the plaintiff mixed together as dual goals.").

187. *See, e.g.*, Clinton E. Worden & Co. v. Calif. Fig Syrup Co., 187 U.S. 516, 528 (1903) (noting that a trademark owner seeking an injunction "to restrain the defendant from injuring his property by making false representations to the public" must not itself be guilty of false representations, in which case "no property can be claimed on it, or, in other words, the right to the exclusive use of it cannot be maintained"); Strey v. Devine's, Inc., 217 F.2d 187, 189 (7th Cir. 1954) ("It must be remembered that the trade-mark laws and the law of unfair competition are concerned not alone with the protection of a property right existing in an individual, but also with the protection of the public from fraud and deceit . . . ." (quoting Stahly, Inc. v. M. H. Jacobs Co., 183 F.2d 914, 917

property rationale.[188] Courts often remind readers that the property right flows from use of the mark and the goodwill accumulated and associated with the mark.[189] Still, both doctrinal bases appear in the cases, and this Article accepts the view that trademark law has dual goals: protection of consumers from deception and protection of the

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(1950))); Healthpoint, Ltd. v. River's Edge Pharms., LLC, No. SA-03-CV-984, 2005 WL 356839, at *3 (W.D. Tex. Feb. 14, 2005) ("Section 43(a) is designed to protect the rights of consumers to be told the truth, contrasted with the goal of trademark law in general: protecting the property rights of trademark holders against infringing competitors."); Merrell-Nat'l Lab'ys, Inc. v. Zenith Laby's, Inc., No. 76-2440, 1977 WL 22787, at *1 (D.N.J. Mar. 28, 1997) ("[T]hough the goodwill of an unpatented product or device is in the public domain . . . the goodwill, name and reputation of the producer remain his private property and may not be traded upon or exploited by his competitors." (quoting Pezon et Michele v. Ernest R. Hewin Assocs., Inc., 270 F. Supp. 423, 427 (S.D.N.Y. 1967))), *aff'd*, 579 F.2d 786 (3d Cir. 1978); Regis v. J.A. Jaynes & Co., 70 N.E. 480, 482 (1904) ("While the public are deceived, and buy the spurious production in the belief that the imitation is the original article, yet the jurisdiction to award an injunction may well rest on the ground that, where a substantial business has been built up, the output of which has become known to buyers under a designated device or name, such designation, when lawfully established, whether treated technically as a trade-mark or tradename, is property in the same sense as the instrumentalities which the owner uses in making the specific thing that he vends in the market in this form. So that the proprietor of such a trade product, if another, without authority, uses similar devices intending to represent by them that the goods are identical, is entitled to protection from this wrongful and fraudulent appropriation of his property.").

188. *See, e.g.*, Battle & Co. v. Finlay, 45 F. 796, 798 (C.C.E.D. La. 1891) ("[I]t seems to be clear that the defendants are appropriating complainants' property without their consent, and to their damage."); C.F. Simmons Med. Co. v. Mansfield Drug Co., 23 S.W. 165, 174 (Tenn. 1893) ("The right to acquire property in a trademark by use upon vendible commodities of some mark, symbol, sign, or word, susceptible of being used as such, is a common-law right, and the property so acquired is always protected by courts of equity in a proper case."); Mauger v. Dick, 55 How. Pr. 132, 135 (N.Y. Super. 1878) ("Equitable jurisdiction to restrain the use of a name or a trade-mark or letters, rests upon the ground of plaintiff's property in his name, trade-mark or letters, and of the unlawful use thereof."); Gilman v. Hunnewell, 122 Mass. 139, 147–48 (Mass. 1875) ("The right in a trade-mark, so applied, is recognized as property, which a court of chancery will protect by injunction.").

189. *See, e.g.*, Macmahan Pharmacal Co. v. Denver Chem. Mfg. Co., 113 F. 468, 471 (8th Cir. 1901) ("A word, symbol, or device, to be a valid trade-mark constituting a right of property, must have been used by the owner in connection with the sale of his goods for such length of time, and under such circumstances, as indicates to the trade that the goods in connection with which it appears are his goods, as distinguished from those of other manufacturers or dealers."); W.W.W. Pharm. Co., Inc. v. Gillette Co., 808 F. Supp. 1013, 1026 (S.D.N.Y. 1992) ("Property rights in a trademark are limited to the trademark's use in connection with a business; they are not inherent ownership rights . . . ."), *aff'd*, 984 F.2d 567 (2d Cir. 1993); Mossoff, *supra* note 179, at 4 (characterizing the trademark as a use-based property right derived from a separate property right in goodwill).

property rights of the mark owner.[190] It also treats these goals as procompetitive: the trademark facilitates informed and efficient product selection in the marketplace, and protection of the trademark encourages market participants to invest in their reputations and the quality of their products.

II. ILLEGAL SUBSTITUTION AND ITS REMEDIES IN THE MIDCENTURY

In the middle of the twentieth century, substitution by pharmacists became commonplace. The brand companies increased their use of unfair competition law and trademark law, challenging both the pharmacists who substituted and the companies whose cheaper products were dispensed. Eventually, the companies sought a more efficient solution: reinforcement of the pharmacy laws and enforcement by government instead. The new pharmacy laws reflected the marriage in policymaking of the historical bases for opposition to substitution: concerns about economic adulteration—economic fraud on the pharmacy's part and possible risk to patients tied to inferior products—and complaints about competitive harm (to the companies whose products were specified by the consumer).

A. Explosion of Illegal Substitution

At least three factors contributed to the rampant illegal substitution by pharmacists in the midcentury: the lack of a premarket approval requirement for new drugs, evolution in the role of the pharmacist (especially after a 1951 amendment to the FDCA), and the therapeutic revolution after World War II.

First, in the decades after enactment of the FDCA in 1938, many purported copies of drugs came to market without premarket FDA review.[191] The statute required submission of a new drug application for a "new drug"—meaning a drug not "generally recognized" as "safe" for the uses described in its labeling.[192] But it did not require FDA

190. 1 MCCARTHY, *supra* note 165, § 5:2; *see also* Inwood Lab'ys, Inc. v. Ives Lab'ys, Inc., 456 U.S. 844, 855 n.14 (1982) ("Such blatant trademark infringement inhibits competition and subverts both goals of the Lanham Act. By applying a trademark to goods produced by one other than the trademark's owner, the infringer deprives the owner of the goodwill which he spent energy, time, and money to obtain. . . . At the same time, the infringer deprives consumers of their ability to distinguish among the goods of competing manufacturers.").

191. Shelby Bird, Note, *Don't Try This at Home: The FDA's Restrictive Regulation of Home-Testing Devices*, 67 DUKE L.J. 383, 389–90 (2017).

192. *See* Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 87-781, §§ 102(a)(1)–(2), 52 Stat. 1040, 1041 (1962) (codified as amended at 21 U.S.C. § 321(p)) (defining "new drug"); *id.* § 104(a), 52 Stat. at 1052 (codified as amended at 21 U.S.C. § 355(a)) (requiring new drug applications). The statute required only safety data—not proof of effectiveness—in an NDA. *Id.* § 102(b), 52 Stat. at 1052 (codified as amended at 21 U.S.C. § 355(b)). A new drug could reach the

approval before market entry. Instead, the NDA took effect automatically sixty days after filing, unless denied by the agency.[193] Moreover, only new drugs required premarket applications, so any drug that was generally recognized as safe could be marketed without an application.[194] In the years that followed, once one company's NDA took effect, other companies brought copies and similar products to market *without* applications, reasoning that the effective NDA meant their product no longer constituted a "new drug."[195] Although most of these products purported to contain the same active ingredient, they were not always exact copies. For instance, some had different dosage forms or different routes of administration. The FDA called these "identical, related, or similar" drugs.[196]

Second, by the middle of the twentieth century, pharmacists had lost some autonomy and power. At first they had not only compounded medicines on receipt of a prescription but also provided medical advice and compounded treatments of their own choosing.[197] Medicines were not delivered in finished forms, ready for dispensing, until the middle of the twentieth century.[198] And, although the FDCA as originally enacted in 1938 acknowledged the existence of a class of drugs that would be dispensed only on prescription, it did not create or define the class.[199] Nor did the FDA have the power to dictate the status of any particular medicine, which meant the seller decided whether the sales should only occur by prescription. The same compound might be sold directly to patients by one company or pharmacist and only on prescription by another.[200]

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market without an application only if it was grandfathered (the same as a pre-1938 drug). *Id.* §§ 102(a)(1)–(2), 52 Stat. at 1041–42.

193. *Id.* §§ 102(c), 104(b), 52 Stat. at 1052 (codified as amended at 21 U.S.C. §§ 355(c)–(d)).

194. *Id.* §§ 102(a)(1)–(2), 52 Stat. at 1041–42.

195. Some companies reached this conclusion themselves, while others relied on written opinions from the FDA, known as "old drug opinions." Drugs for Human Use, 40 Fed. Reg. 26142, 26143 (June 20, 1975) (to be codified as 21 C.F.R. pt. 130).

196. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR FDA STAFF AND INDUSTRY: MARKETED UNAPPROVED DRUGS—COMPLIANCE POLICY GUIDE 9 (2011), https://www.fda.gov/media/71004/download.

197. *See* Dominique A. Tobbell, "*Eroding the Physician's Control of Therapy": The Postwar Politics of the Prescription*, *in* PRESCRIBED: WRITING, FILLING, USING, AND ABUSING THE PRESCRIPTION IN MODERN AMERICA 66, 66–67 (Jeremy A. Greene & Elizabeth Siegel Watkins eds., 2012).

198. *See* SILVERMAN & LEE, *supra* note 58, at 193 (noting that before World War I, ninety percent of prescription orders required a pharmacist to compound, and that by the early 1960s, companies delivered finished products to pharmacies).

199. *See* Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, § 201(g), 52 Stat. 1040, 1052 (1938).

200. *See* Nancy Tomes, *The Great American Medicine Show Revisited*, 79 BULL. HIST. MED. 627, 633 (2005) (noting drugs sold on prescriptions were also

In 1951, Congress amended the FDCA to specify circumstances under which a drug would be limited to prescription sales.[201] Without a preapproval requirement, the FDA did not yet act as a gatekeeper to the market, so companies often made the decision themselves, at least in the first instance.[202] But putting the selection of medicines in the hands of doctors—making them the gatekeepers—transformed the marketplace.[203] It made promotion directly to doctors more important, which led to greater emphasis on the brand name.[204] The FDA used its new authority to ensure that the same active ingredient was not sold both by prescription and over the counter.[205] With these changes, doctors and the FDA gained power, and pharmacists lost power.

Third, the therapeutic revolution of the midcentury challenged pharmacists, who found themselves stocking more drugs on their shelves in anticipation of prescriptions from doctors. The first modern medicines—sulfa drugs and steroids—had emerged in the 1930s.[206] Sulfanilamide led to other antibiotics, and tranquilizers emerged soon after.[207] By the 1950s, researchers were identifying an astonishing stream of new molecular entities that would change the practice of medicine and pharmacy. In the 1950s, the FDA received applications for antibiotics, steroids, blood pressure medications, anti-arrhythmic agents, cancer drugs, heart disease medications, and at the end of the decade, the first oral contraceptive.[208] And still, once one company secured an NDA, other companies launched competing versions *without* seeking premarket review by the FDA. As the FTC

available directly to consumers); *see also* Sidney H. Willig, *Ethical and Legal Implications of Drug Substitution*, 23 FOOD DRUG COSM. L.J. 284, 286 (1968) (noting that "problems in uniformity of labeling between manufacturers of the same drug" and "desire for clear statutory determination" laid the groundwork for enactment of prescription standard).

201. *See generally* Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 82-215, 65 Stat. 648 (1951).

202. *See* Tomes, *supra* note 200, at 633.

203. *See id.* at 635; *see also* Tobbell, *supra* note 197, at 66–67.

204. Tomes, *supra* note 200, at 635.

205. Section 503(b)(3) authorized the FDA to "by regulation remove drugs" from the prescription requirements in § 503(b)(1) "when such requirements are not necessary for the protection of the public health." Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 82-215, 65 Stat. 648, 649 (1951). The FDA used rulemaking to switch more than two dozen ingredients that had been marked "prescription" by some manufacturers, beginning with acetaminophen in 1955. *See generally* Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 20 Fed. Reg. 3499 (May 19, 1955).

206. Tomes, *supra* note 200, at 634.

207. FTC REPORT, *supra* note 117, at 16.

208. Suzanne White Junod, *FDA and Clinical Drug Trials: A Short History*, *in* A QUICK GUIDE TO CLINICAL TRIALS 21, 34–35 (Madhu Davies & Faiz Kermani eds., 2008).

wrote later, the market in the 1950s was flooded with products that were "resembling the popular brand-name product in color, size, shape, and sometimes packaging, but of unknown quality, content and origin."[209] Pharmacists complained about the financial and physical burden of stocking more than one drug in the same therapeutic class.[210]

These three factors worked together; even though doctors often prescribed by brand name, many pharmacists chose to substitute, providing one of the "identical, related, or similar" drugs that reached the market without FDA review.[211] The FDA expressed concern after investigations showed variations in the contents and quality of these unregulated duplicates.[212] But pharmacists paid less for these substitutes and thus benefitted financially from the practice.[213] Although organized pharmacy opposed substitution, they saw it as a natural reaction to the proliferation of choices produced by drug companies.[214] Substitution, though illegal, was widespread.[215]

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209. FTC REPORT, *supra* note 117, at 6.

210. *See* TOBBELL, *supra* note 54, at 63.

211. *See supra* note 196 and accompanying text; Facchinetti & Dickson, *supra* note 41, at 469 (calling it a generic); TOBBELL, *supra* note 54, at 64 ("[P]harmacists were engaging in the practice of substituting cheaper generic drugs for brand-name prescription drugs."); SILVERMAN & LEE, *supra* note 58, at 142–43 ("[A] number of important drugs—most still under patent—were facing competition from black-market products . . . [which] shaped, colored, and labeled exactly like the legitimate drugs [and] were generally priced far less to pharmacists . . . ."). Some evidence suggests that pharmacists substituted not only purported copies but also drugs with different active ingredients. Bruce Alan Berger, Drug Product Selection: A Study of Ohio's Law and Pharmacist's Perceptions 8 (1978) (Ph.D. dissertation, The Ohio State University) (ProQuest).

212. *See* N.E. Cook, *How the Federal Food, Drug, and Cosmetic Act Applies to the Pharmacist*, 8 FOOD DRUG COSM. L.J. 327, 331 (1953) (reporting, as an FDA inspector, that "in too many cases we have investigated, the imitation product was seriously deficient in claimed potency or otherwise adulterated—in short, it represented not just an imposition on the rights of the manufacturer of the genuine article, but could seriously affect the patient").

213. Hammer, *supra* note 149, at 777.

214. Tobbell, *supra* note 197, at 69 ("[E]ven as pharmacy leaders in the American Pharmaceutical Association, the National Association of Boards of Pharmacy, the American College of Apothecaries, and the National Conference on State Pharmaceutical Associations condemned substitution, they perceived it to be a symptom of the drug industry's economic practices . . . ."); Facchinetti & Dickson, *supra* note 41, at 471 (noting that the American Pharmaceutical Association (APhA) resolved in 1952 and again in several subsequent years to "condemn as unethical the dispensing of a pharmaceutical preparation or brand thereof other than that ordered or prescribed" and that the NABP, American College of Apothecaries, and National Conference of State Pharmaceutical Associations agreed).

215. In 1952, one firm reported that substitution on its major products was about twelve percent and as high as thirty-eight percent in New York. Facchinetti & Dickson, *supra* note 41, at 469–70. The following year more than

B. Drug Industry Response

Lawyers inside and outside the companies urged the industry to use unfair competition law to challenge illegal substitution, laying out the theory in articles and speeches.[216] Writing in 1951, for example, an attorney from drug-maker Smith, Kline & French ("SKF") identified the pharmacist as the "perpetrator" of the "unethical" practice of substitution and laid the ultimate blame at the feet of the "unscrupulous manufacturer" of the replacement product.[217] He urged others to consider unfair competition claims against competing manufacturers if the prescribed products had "distinctive nonfunctional features"—effectively, a trademark—and unfair competition claims in every case "against the retailer who actually fills a prescription calling for the original product with the substitution."[218] Another attorney explained that imitation and substitution fell within the law of passing off.[219] That is, where a competitor in dressing his goods has so imitated the goods of another with intent to deceive to the extent that the public generally cannot easily distinguish between them and retailers are placed in a position where they can readily 'palm off' the product as the goods of the other, an action will lie against the sale of such products to retailers by producers and by retailers to consumers.[220] Although substitution damaged the manufacturer's goodwill,[221] the SKF attorney viewed substitution as a business tort rather than a trespass to property, writing that passing off is "part and parcel of unfair competitive practices" which are "irrespective of a trespass upon any exclusive right of the producer."[222]

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half the brand manufacturers surveyed stated substitution was widespread or becoming so. *Id.* at 469.

216. A lawyer at Upjohn suggested another business tort: "unjustifiable inference with reasonable business expectations." Murray D. Welch, Jr., *Substitution–Another Possible String to the Bow*, 12 FOOD DRUG COSM. L.J. 289, 289 (1957). He explained, "it is a civil wrong for a person to intentionally and unjustifiably deprive another of a reasonable business expectancy even in the absence of an existing contract." *Id.*

217. Hammer, *supra* note 149, at 775 ("This manufacturer of substitute products is the real instigator of the whole fraudulent process, as his distribution of imitation products that can be passed off for well-known brands places in the hands of the druggist the instrument of fraud.").

218. *Id.* at 778–79.

219. *See* Joseph H. Stamler, *Some Legal Aspects of the Substitution Problem*, 8 FOOD DRUG COSM. L.J. 643, 645 (1953).

220. *Id.* at 646.

221. *Cf.* Sinko v. Snow-Craggs Corp., 105 F.2d 450, 453 (7th Cir. 1939) (contrasting the products at issue with a "drug preparation" as to which "the efficiency of the drug depends largely upon the capacity of the maker" and "the purchaser would care more about the personality behind the drug than the drug itself").

222. Stamler, *supra* note 219, at 646.

The defending companies sought to shift the blame to the pharmacists, arguing that they had not deceived the retailers and that they had not explicitly invited the retailers to substitute their products for any others.[223] These arguments failed because it was well settled that one "who induces another to commit a fraud and furnishes the means is equally guilty with the[] one who actually perpetrates the fraud."[224] The Third Circuit, for instance, found the features of one SKF product—including its beveled edges, scoring, and heart shape—functional, which precluded arguments grounded in trademark or trade dress infringement.[225] But the defendants had also suggested that prescriptions for the plaintiff's tablets be filled with their own tablets.[226] The court stated that SKF was "entitled to the reputation which its goods have acquired" and the public was "entitled to a means of distinguishing between" the plaintiff's tablets and those of the defendants.[227] The court explained that the "unfair competition" consisted in "the unfair and fraudulent advantage taken by the defendants . . . to pass off their product" as that of the plaintiff.[228] Brand companies routinely secured injunctions against

223. One brand industry lawyer explained: these companies "realize that the bald statement that their product X can be substituted on prescription for the well-known product Y because the physical characteristics of the two products are virtually indistinguishable gives the manufacturer of well-known Y excellent evidence against them for an unfair competition suit." Hammer, *supra* note 149, at 776. *See also, e.g.*, Upjohn Co. v. Schwartz, 246 F.2d 254, 259–62 (2d Cir. 1957) (remanding for entry of injunction because defendant distributed printed cards containing a list of its products next to the names of similar products made by Upjohn, concluding that "the cards in question when distributed to druggists and pharmacists were to be used as guides for substitution and that defendant intended such use"). The companies therefore relied on innuendo. In one unfair competition lawsuit, for instance, a judge asked the substitute manufacturer if it "ever told druggists that his product could be substituted for another." Hammer, *supra* note 149, at 776. The answer was no; "[m]y product speaks for itself." *Id.*

224. Oneida, Ltd., v. Nat'l Silver Co., 25 N.Y.S.2d 271, 276 (Sup. Ct. 1940); *see also* Smith, Kline & French Lab'ys v. Midwest Chem. Dev. Corp., 96 F. Supp. 797, 799 (N.D. Ohio 1951) (rejecting argument that the retailer was not deceived, because under theories of contributory infringement or contributory unfair competition "[a] manufacturer, who places into the hands of his immediate purchaser, goods which he knows may cause deception, is liable for unfair competition").

225. Smith, Kline & French Lab'ys v. Clark & Clark., 157 F.2d 725, 730 (3d Cir. 1946).

226. *Id.* at 731.

227. *Id.*

228. *Id.* The defendants would be enjoined from making and selling the active ingredient until SKF's patent expired, after which SKF would be entitled to a decree "enjoining the palming off of the defendants' product" as that of the plaintiff. *Id.*

manufacturers of the imitation products dispensed by pharmacists.[229] Only a minority of courts ruled the other way.[230]

Midcentury courts also found the pharmacists liable. In 1957, for instance, a federal court in Alabama enjoined pharmacist Kathlynn Fadeley from infringing A.H. Robins' trademark "Donetal" and from "substituting and passing off the product of another for the product of [Robins] when selling, offering for sale or filling prescriptions, upon calls for any product of [Robins]."[231] The next year, a federal court in

229. *E.g.*, Ross-Whitney Corp. v. Smith Kline & French Lab'ys, 207 F.2d 190, 193, 196–97, 199 (9th Cir. 1953) (affirming preliminary injunction in action for unfair competition when defendant marketed its dextroamphetamine sulfate tablet in identical size, shape, and color as plaintiff's tablet, "in an effort to develop a distinctive tablet which would point to SKF as the manufacturer without actually putting SKF's initials on the tablet," so that "no label could prevent unethical pharmacists from substituting [their] tablets for SKF's without detection and to the deceit of the prescribing doctor and his patient"); Smith Kline & French Lab'ys v. Broder, No. 12707, 1959 WL 6882, at *5 (S.D. Tex. Dec. 2, 1959) ("Defendant's conduct in advertising and furnishing retail druggists with drug products imitating the appearance and dosages of plaintiff's products, and deliberately and willfully suggesting and inviting retail druggists to palm-off and substitute said imitation products for the products of plaintiff, constitutes unfair competition, entitling plaintiff to injunctive relief."); Smith, Kline & French Lab'ys. v. Midwest Chem. Dev. Corp., 96 F. Supp. 797, 799 (N.D. Ohio 1951) (denying defendant's motion for summary judgment because a "manufacturer, who places into the hands of his immediate purchaser, goods which he knows may cause deception, is liable for unfair competition"); Smith, Kline & French Lab'ys v. Lipton, No. 28130, 1951 WL 4627, at *1 (N.D. Ohio May 24, 1951) (issuing preliminary injunction, based on plaintiff's allegation that "defendant manufactures and markets dextro-amphetamine sulfate tablets of curved edge, triangular form, and of orange color in close imitation of plaintiff's dextro-amphetamine sulfate tablets, intending thereby to enable druggists to palm off and substitute defendant's imitation tablets for those of plaintiff which are sold under plaintiff's trade name 'DEXEDRINE'"); Smith, Kline & French Lab'ys v. Heart Pharm. Corp., 90 F. Supp. 976, 978 (S.D.N.Y. 1950) (granting preliminary injunction and quoting the Supreme Court: "That no deception was practiced on the retail dealers, and that they knew exactly what they were getting, is of no consequence. The wrong was in designedly enabling the dealers to palm off the preparation as that of the . . . [plaintiff]. . . . One who induces another to commit a fraud and furnishes the means of consummating it is equally guilty and liable for the injury." (quoting William R. Warner & Co. v. Lilly & Co., 265 U.S. 526, 530–31 (1924))).

230. *E.g.*, Smith, Kline & French Lab'ys v. Waldman, 69 F. Supp. 646, 649–50 (E.D. Pa. 1946) (declining preliminary injunction in part because "sharing in the good will of another is not unfair unless the passing off of one's goods as those of another is shown" and in part because there was no evidence of intent to defraud the ultimate purchaser). This was an early case, however, and later courts would not require proof passing off had occurred. *See supra* note 229.

231. *See* A.H. Robins Co. v. Fadely, 299 F.2d 557, 558 (5th Cir. 1962) (discussing the lower court injunction in an appeal of a lower court dismissal of a

New York found that two pharmacists "willfully and intentionally competed unfairly with" the Upjohn Company, by infringing its registered trademarks "by substituting and passing off products other than" Upjohn's products when the latter were called for by the use of those trademarks.[232] Upjohn was entitled to an injunction and the pharmacists' profits.[233]

C. Reinforcement of Pharmacy Law

Although brand company unfair competition suits generally succeeded, these companies found the cases required "considerable explanation" because the situations were "usually novel to the trial courts."[234] The suits were also, according to one company lawyer, "prohibitively expensive and time consuming."[235] Moreover, even though a company could obtain an injunction against the manufacturer of the substitute, "another would quickly appear to take his place."[236] Litigation against the substituting pharmacists met with "the same unsatisfactory results."[237]

To remedy these issues, twelve brand companies joined with pharmacists to form the National Pharmaceutical Council ("NPC") in December 1953.[238] The NPC focused on addressing the manufacture and substitution of imitations of brand drugs.[239] They met with pharmacy boards, state pharmacy associations, and pharmacy students, and they also gathered evidence of substitution and asked

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petition for an order to show cause why Fadeley should not be found in contempt of the consent decree).

232. *E.g.*, Upjohn Co. v. Katz, No. CIV.A. 117-35, 1958 WL 6110, at *2 (S.D.N.Y. Mar. 6, 1958) ("Defendants [who are pharmacists] have willfully and intentionally competed unfairly with plaintiff and infringed plaintiff's registered trademarks CHERACOL, ZYMACAP, and CORTEF by substituting and passing off products other than plaintiff's products on prescriptions or calls for plaintiff's products by the use of each of said trademarks."); *see also* TOBBELL, *supra* note 54, at 65 (reporting Abbott Laboratories secured a series of injunctions against New York pharmacists in the 1950s).

233. *See Upjohn Co.*, 1958 WL 6110, at *2.

234. Hammer, *supra* note 149, at 779.

235. John J. Galbally, *Substitution as "Gross Immorality,"* 12 FOOD DRUG COSM. L.J. 758, 758 (1957).

236. *Id.*; *see also* Stamler, *supra* note 219, at 654.

237. Galbally, *supra* note 235, at 758.

238. Facchinetti & Dickson, *supra* note 41, at 470–71; *see also* TOBBELL, *supra* note 54, at 66 (quoting the first NPC president, who called for industry to "bring our combined influence to bear against those practices that are undermining the ethical principles of fair competition and fair dealing" and who committed to "squashing the practice of substitution and pharmacists' antiduplication drive").

239. TOBBELL, *supra* note 54, at 67; Facchinetti & Dickson, *supra* note 41, at 471.

pharmacy boards to act.[240] Though surely motivated mainly by competitive concerns—unfair competition and damage to their goodwill—with this audience they focused on pharmacy ethics and consumer safety.[241] Organized pharmacy was receptive: many pharmacists believed substitution "violated the ethics of the profession and community."[242] And pharmacists still had a strong commercial interest in preventing substitution.[243]

By 1956, most state boards of pharmacy opposed substitution and acted when incidents were drawn to their attention.[244] They did so whether or not state law expressly prohibited substitution.[245] But the NPC also wanted to ensure that state law expressly prohibited substitution, so it drafted model legislation to prohibit "pharmacists from dispensing not only a different drug entity, but a different *brand* from the one prescribed."[246] Thanks to the work of the NPC, most states had express prohibitions in their pharmacy laws by the end of the 1950s.[247] Brand companies invoked these laws through the 1960s to address the sale of substitute and imitation products when doctors had specified their products by name.[248]

III. AN EXCEPTION FOR MODERN GENERIC DRUGS

State and federal antisubstitution policy faced pressure in the 1960s. The 1962 amendments to the FDCA revolutionized the new

240. TOBBELL, *supra* note 54, at 67; Facchinetti & Dickson, *supra* note 41, at 471.

241. TOBBELL, *supra* note 54, at 67 (quoting an NPC speech in 1954 saying a "pharmacist is professionally, morally, and legally bound to fill that prescription precisely as the doctor wrote it").

242. GREENE, *supra* note 148, at 138; *see also* Galbally, *supra* note 235, at 758–59, 761 (arguing in 1957 that substitution constitutes "gross immorality," which is often a basis for suspension or revocation of the pharmacist's license, also arguing that it violates an obligation of fair dealing).

243. Facchinetti & Dickson, *supra* note 41, at 471.

244. TOBBELL, *supra* note 54, at 67.

245. *Id.*; Facchinetti & Dickson, *supra* note 41, at 473 (noting pharmacy literature of the 1950s indicates boards took action against substitution regardless of any explicit statutory language).

246. FTC REPORT, *supra* note 117, at 6–7; *see also* Welch, *supra* note 216, at 289 (discussing the "model antisubstituition act" put forward by the Drug, Chemical, and Allied Trade Section of the New York Board of Trade, which defined substitution as "substituting a different drug, brand of drug, or drug product of a different manufacturer or distributor for any drug, brand of drug, or drug product ordered by prescription or otherwise").

247. Silverman and Lee reported every state legislature that had not already expressly prohibited substitution had now done so, with Alaska, Missouri, and D.C. being the last holdouts. *See* SILVERMAN & LEE, *supra* note 58, at 143. Greene says that by the end of the 1950s, forty-five of fifty states expressly prohibited substitution. GREENE, *supra* note 148, at 141.

248. Willig, *supra* note 200, at 303.

drug regulatory paradigm and made premarket research and development riskier, more time consuming, and more expensive.[249] Insurance coverage for prescription drugs became more common, and payors—including public payors—developed a stake in the cost of medicines. Concern about drug prices and the brand loyalty of doctors led to suggestions that prescribers write prescriptions specifying only the active ingredient desired.[250] State pharmacy law would then allow the pharmacist to dispense any drug with that active ingredient.[251] Improvements in regulatory science eventually meant that generic drugs were reliably bioequivalent to brand drugs, and pharmacists stopped opposing substitution. Although efforts to mandate "generic prescribing" (prescribing by active ingredient) failed, the FDA and the FTC—along with payors, pharmacists, and consumer groups—instead pushed for a generic drug exception to the state law prohibition on substitution by pharmacists.[252]

A. Generic Prescribing

After enactment of the statutory prescription standard in 1951, doctors took a more visible role as intermediaries between drug companies and patients. Some argued that doctors preferred brand drugs to less expensive copies because brand advertising was clouding their judgment.[253] Reformers in the middle of the century urged federal agencies and Congress to investigate the brand industry's advertising practices, and they pushed for "generic prescribing"—that is, they wanted doctors to write prescriptions stating only an active ingredient and dose rather than a brand name (which would specify a particular company's product).[254] In their view, a "partial remedy" to the problem of high drug prices would come through "discontinuation of the common practice of relying upon brand names

249. Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 52–54 (2018); *see also* Reid, *supra* note 59, at 315 (suggesting higher prices of new drugs that had gone through the more robust post-1962 approval process influenced state legislators to reconsider anti-substitution policy).

250. *See* TOBBELL, *supra* note 54, at 163–64 (explaining that there were efforts in the 1960s and 1970s to require doctors to prescribe a generic drug if it was available).

251. *See id.*

252. *Id.* at 164 ("[C]oalition of pharmacists, consumer and patient groups, and state legislators . . . ."); *id.* at 190 (asserting that "pharmaceutical reformers achieved success at the state level . . . in part [due to] . . . the political motivation of states to reduce the economic burden of rising Medicaid costs"); Facchinetti & Dickson, *supra* note 41, at 468 (attributing laws of the 1970s to a "coalition" including consumer-advocate groups and third-party payors of prescriptions, who saw the "economic advantages" of the laws).

253. Tomes, *supra* note 200, at 653.

254. TOBBELL, *supra* note 54, at 163–64.

for identification of drugs."[255] The pharmacists who resented stocking more than one drug with the same active ingredient agreed that doctors should be encouraged, or even required, to specify the active ingredient rather than any particular company's product containing that active ingredient.[256] The brand companies perceived this as an attack on the trademark, responding that "'by plugging the use of generic names on [prescriptions],' pharmacists were verging on 'destroying the value of pharmaceutical trademarks.'"[257]

The idea caught hold, however, and various changes to the statute in 1962 were meant to encourage a shift to generic prescribing. The Senate Antitrust and Monopoly Subcommittee, chaired by Senator Estes Kefauver (D-TN), began hearings in December 1959 on "administered prices in the ethical drug industry."[258] In April 1961, Senator Kefauver introduced draft legislation to reform both the drug regulatory statute and the application of patent law and antitrust law to the brand companies.[259] The subcommittee concluded that the brand industry enjoyed "exceptionally high profits."[260] It attributed these profits to market control and blamed advertising and promotional practices that persuaded doctors to prescribe products by brand name.[261] Senator Kefauver's proposed legislation would address these issues, he said, commenting that the brand companies invest in advertising and

255. RICHARD BURACK, THE HANDBOOK OF PRESCRIPTION DRUGS: OFFICIAL NAMES, PRICES, AND SOURCES FOR PATIENT AND DOCTOR, at viii (1967); *see also* TOBBELL, *supra* note 54, at 163–64.

256. TOBBELL, *supra* note 54, at 64. Various professional pharmacy organizations adopted resolutions encouraging doctors to prescribe by generic name. Facchinetti & Dickson, *supra* note 41, at 472. Some proposed physicians add "ARB" ("any reliable brand") on their prescriptions, though others disagreed. *See, e.g.*, *"ARB" Is Threat to Fair Trade, NC Pharm Assn Declares*, 129 AM. DRUGGIST 12, 12 (1954).

257. Tobbell, *supra* note 197, at 70 (internal citation omitted).

258. 107 CONG. REC. S5638 (1961) (statement of Sen. Estes Kefauver).

259. *See generally* S. 1552, 87th Cong. (1961).

260. 107 CONG. REC. S5639 (1961) (statement of Sen. Estes Kefauver); *see also* Jeremy A. Greene & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals: The Kefauver Harris Amendments at 50*, NEW ENG. J. MED. (Oct. 18, 2012), https://www.nejm.org/doi/full/10.1056/nejmp1210007; Robert Pitofsky, Book Review, 40 N.Y.U. L. REV. 816, 817 (1965).

261. 107 CONG. REC. S5639 (1961) ("The subcommittee's studies have revealed high prices and exceptionally high profits. It appears clear that these result from control over the market and the manner in which that control is exercised. Although there are many factors involved, the principal sources of market control seem to be first, patent control; second, the extensive and costly advertising and promotion costs directed to physicians; and third, the persuasion of doctors to prescribe by brand names rather than generic names."); S. REP. NO. 87-448, at 105 (1961); *see also* Harry A. Sweeney, Jr., *The "Generic Every Time" Case: Prescription Drug Industry in Extremis*, 21 FOOD DRUG COSM. L.J. 226, 238 (1966).

promotion "for the purpose of persuading the doctors to prescribe by trade name instead of by generic name."[262] Although he would have permitted brand companies to use brand names, he noted that generic names were "too long and difficult to use" and proposed that the FDA be given power to establish nonproprietary names, "thereby providing a means of simplifying generic names which, in contrast to the short and simple tradenames, are often so long, complex, and unpronounceable that they cannot possibly be remembered or used by physicians."[263] He also proposed that the drug's label include the nonproprietary name in type "at least as large and prominent" as used for the brand name.[264] As the legislation wound its way through Congress in 1962, President Kennedy wrote in support of the proposal, explaining the goal was to "encourage physicians to prescribe drugs by nonproprietary name rather than by brand name."[265]

These proposals were controversial, and five senators signed a scathing dissent to the subcommittee report.[266] The bill also met with opposition from organized medicine and academic doctors, as well as brand companies, which defended the brand name as associated with the quality of the drug and the reputation of the manufacturer.[267] Although more radical aspects of Senator Kefauver's proposal—such as the proposal to limit drug patents to three years[268]—were

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262. 107 CONG. REC. S5638 (1961) (statement of Sen. Estes Kefauver).

263. *Id.* at 5642; S. 1552, 87th Cong. § 509(a) (1961); *see also* S. REP. NO. 87-448, at 231 (1961).

264. S. 1552, 87th Cong. § 4(a)(3) (1961).

265. 107 CONG. REC. S10105 (June 11, 1962) (letter to Sen. James O. Eastland from President John F. Kennedy).

266. *See* S. REP. NO. 87-448, at 263–369 (1961). These Senators considered the majority report a "mimeographed monstrosity which . . . appears to be nothing more than a calculated review of choice quips, statements, and exhibits presented by biased witnesses whose views were well known to the majority at the time they were called to testify." *Id.* at 263. They also pointed out the subcommittee had "no jurisdiction to review the trademark laws of the United States or to determine whether generic names should be used in lieu of brand names in prescriptions." *Id.* at 359. A small group of doctors "proposed that all brand names in the drug field be eliminated and, instead, doctors be required to write their prescriptions in generic terms." *Id.* at 360. But the U.S. economy is founded on the notion that "a job well done has its proper reward." *Id.* Moreover, if products are sold under their generic names, "all drug standards will immediately drop to the lowest" standards, because an "attempt to exceed these standards will be fruitless, as there will be no reward for those who make an extra effort to do so." *Id.*

267. Tobbell, *supra* note 197, at 74–75. Despite opposing Kefauver's proposal, the American Medical Association encouraged doctors to prescribe generic drugs for "welfare patients" for economic reasons. *Id.* at 76.

268. S. 1552, 87th Cong. § 3(d)(2) (1961) ("Every patent for a drug issued after the effective date of this paragraph shall contain a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, or selling that drug

abandoned, President Kennedy signed a final amended version of Senator Kefauver's legislation into law in October 1962.[269]

The provisions meant to encourage generic prescribing remained essentially the same. The FDA received power to designate a nonproprietary name for a drug if doing so would serve the interests of "usefulness and simplicity."[270] Further, a drug's nonproprietary name would need to be printed prominently and in type at least half as large as used for the brand name of the drug.[271] The FDA's implementing regulation, which required the nonproprietary name to accompany the brand name everywhere the latter was used, provoked an immediate lawsuit from the brand companies.[272] The companies perceived the regulation as yet another attack on drug trademarks, explaining that "brand names indicate the manufacturers' willingness to stand behind the quality and purity of their products" and that the agency's regulation undermined the value of the trademark.[273]

B. Improvements in Regulatory Science

In the decades after the 1962 amendments, the FDA developed a sophisticated regulatory framework for assessing whether two drug products with the same active ingredient are likely to have the same clinical effect in the body. Three aspects of the 1962 amendments

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for the term of three years from its effective date, and for any additional period (not exceeding fourteen years) during which the holder thereof grants to each qualified applicant an unrestricted license to make, use, and sell that drug.").

269. *See generally* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780. Interest in generic prescribing continued. *See* Greene, *supra* note 90, at 490–95 (discussing a subsequent series of bills intended to encourage generic prescribing); *see also* Tobbell, *supra* note 197, at 78.

270. Drug Amendments of 1962, Pub. L. No. 87-781, § 111(a), 76 Stat. 780, 789. Today the name is selected by the United States Adopted Name (USAN) Council, which comprises five individuals—one each from the American Medical Association, the American Pharmacists Association (formerly the American Pharmaceutical Association), and the organization publishing the *U.S. Pharmacopeia*, as well as one from the FDA and a member-at-large. *See USAN Council*, AM. MED. ASS'N, https://www.ama-assn.org/about/united-states-adopted-names/usan-council (last visited Oct. 22, 2021).

271. § 112(a), 76 Stat. at 790.

272. They argued that the regulation exceed the agency's statutory authority, but courts never resolved the issue. A justiciability issue made its way to the Supreme Court, which found the claim fit for resolution and remanded for the substantive issues to be considered by the Third Circuit. Abbott Lab'ys v. Gardner, 387 U.S. 136, 156 (1967). The parties settled before oral argument in the court of appeals. PETER BARTON HUTT ET AL., CASES AND MATERIALS: FOOD AND DRUG LAW 865 (4th ed. 2014).

273. Ronald M. Levin, *The Story of the* Abbott Labs *Trilogy: The Seeds of the Ripeness Doctrine*, *in* ADMINISTRATIVE LAW STORIES 430, 440 (Peter L. Strauss ed., 2006).

contributed to the development of this framework. First, the statute now imposed a premarket *approval* requirement: a company could not launch until the FDA affirmatively approved its product.[274] Second, the statute now required that products be proven effective as well as safe.[275] And third, Congress directed the FDA to review the effectiveness of every new drug that had reached the market under a safety-only NDA in the years before 1962.[276] The result was, eventually, premarket review of ANDAs for purported copies.[277]

To review the pre-1962 drugs, the FDA launched the Drug Efficacy Study Implementation ("DESI") program.[278] Relevant here, it decided to review not only the drugs with safety-only NDAs but also the drugs that were identical, similar, or related to them, which had reached the market without applications.[279] If the FDA found that a particular drug with an NDA was effective, then the brand company would supplement its application, conforming to the new paradigm, and companies making identical, similar, or related drugs would file ANDAs, a new mechanism that the FDA created through rulemaking in 1970.[280]

The original ANDA was nothing like today's generic drug application. The FDA required "brief statements" identifying the composition of the drug, the place it would be manufactured, processed, packed, and held, and anyone other than the applicant involved in the process.[281] The applicant certified to compliance with good manufacturing practices and outlined the methods used in (and

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274. §§ 103(a)–(b), 76 Stat. at 782–83.

275. § 102(c), 76 Stat. at 781. In addition, a drug was now a "new drug" unless it was generally recognized as safe *and effective*. § 102(a), 76 Stat. at 781.

276. §§ 107(c)(2)–(4), 76 Stat. at 788–89.

277. Applicability of DESI Notices and Notices of Opportunity for Hearing to Identical, Related, and Similar Drug Products, 37 Fed. Reg. 23185, 23187 (Oct. 31, 1972).

278. *See* Reports of Information for Drug Effectiveness, 31 Fed. Reg. 9426, 9426 (Jul. 9, 1966).

279. Applicability of DESI Notices and Notices of Opportunity for Hearing to Identical, Related, and Similar Drug Products, 37 Fed. Reg. at 23187; *see also* Abbreviated Applications, 35 Fed. Reg. 6574, 6574 (Apr. 24, 1970). The agency revoked its earlier opinions that some of these were old drugs. New-Drug Status Opinions; Statement of Policy, 33 Fed. Reg. 7758, 7758 (May 28, 1968).

280. Applicability of DESI Notices and Notices of Opportunity for Hearing to Identical, Related, and Similar Drug Products, 37 Fed. Reg. at 23187; Abbreviated Applications, 35 Fed. Reg at 6574. In 1976, the FDA announced it would take regulatory action against any generic drug marketed without an approved application, eliminating the "old drug" pathway for generics. Marketed New Drugs without Approved New Drug Application, 41 Fed. Reg. 41770, 41770–71 (Sept. 23, 1976). Many companies marketing duplicates disagreed and argued that premarket review was not required, but in 1983 the Supreme Court agreed with the agency. *See* United States v. Generix Drug Corp., 460 U.S. 453, 461 (1983).

281. Abbreviated Applications, 35 Fed. Reg. at 6575.

the controls used by facilities for) manufacture, processing, and packing the drug.[282] If applicable, the ANDA confirmed that the proposed product complied with specifications in an official compendium; otherwise, it confirmed its specifications, and testing ensured the drug's identity, strength, quality, and purity.[283] If the notice calling for ANDAs asked for bioavailability data—how much of the active ingredient (or active moiety) is absorbed from the product and becomes available at the relevant site in the body, and how quickly it does so—these would need to be provided as well.[284] At first, though, the science of bioavailability was still rudimentary,[285] and the FDA required no information or data comparing the proposed generic to the brand drug reviewed in the DESI program.

As bioavailability testing matured, it became apparent that drugs varied significantly in the human body, leading the FDA to take more aggressive steps to ensure both the bioavailability of drugs and eventually the bioequivalence of copies.[286] In the early 1970s, the agency proposed to require bioavailability data for new active ingredients, but otherwise (and for already marketed drugs), it would call for bioavailability data based on the medical importance of the drug or indications that bioavailability might be an issue.[287] By the

282. *Id.*; *see also* 21 C.F.R. § 314.3(b)(2021) (defining bioavailability as "the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action").

283. 21 C.F.R. § 130.4(f)(1)(v) (1973).

284. *Id.* § 130.4(f)(3); *see also id.* § 130.4(f)(2) (requiring labeling "in accord with the labeling conditions described in the finding that an abbreviated new-drug application is sufficient"); *id.* § 130.4(f)(4) (requiring any other information available to the applicant on adverse effects); *id.* § 130.4(f)(5) (allowing the FDA to ask for additional information); *id.* § 130.4(f)(7) (requiring a "signature of the applicant").

285. Jane Moffitt, *The Appropriateness of Bioavailability and Bioequivalence as Pre-market Clearance Considerations*, 34 FOOD DRUG COSM. L.J. 640, 645 (1979) ("At the time of the passage of the Drug Amendments of 1962, and during the years of the DESI review, it was not possible to study the bioavailability of drug products with any degree of accuracy."); Daniel Carpenter & Dominique A. Tobbell, *Bioequivalence: The Regulatory Career of a Pharmaceutical Concept*, 85 BULL. HIST. MED. 93, 98 (2011).

286. Tobbell, *supra* note 197, at 78–79 (discussing "mounting evidence and growing awareness . . . that not all versions of a pharmaceutical agent produced the same therapeutic effects").

287. New Prescription Drugs, 38 Fed. Reg. 885, 886 (proposed Jan. 5, 1973) (to be codified at 21 C.F.R. pt. 130) (noting that "it has now been established that different formulations of the same drug may produce differing concentrations of drug in body tissues or fluids when tested under standardized conditions even though the formulations may meet current standards for in vitro testing" but "[s]uitable methodology for accurately measuring the bioavailability of a drug in humans is not currently available for many products," and thus the FDA would publish "lists of drugs for which bioavailability data will be required on the basis

time it finalized this rulemaking in 1977, though, bioavailability testing methodology had evolved into sophisticated blood plasma comparisons taken over time.[288] The agency decided to require bioavailability data in all applications and bioequivalence data in some as well.[289]

Pharmacist opposition to substitution ebbed. Indeed, some in organized pharmacy sought enactment of generic substitution laws.[290] The American Pharmaceutical Association had previously been opposed but now supported generic drug substitution, explaining that companies now made generic drugs of equivalent quality to and lower cost than brand drugs.[291] Relegated to inferior professional status by the 1951 prescription standard,[292] pharmacists argued a generic drug exception would play to their strengths; they stated they understood the new bioequivalence data and could evaluate equivalence claims, asserting they should have more authority in the dispensing decision.[293] They were trained in pharmacology, and they could focus on the patient's health and counsel the patient about drug use.[294] In contrast, the doctors were

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of medical importance and/or indications that problems of bioavailability have been suggested or suspected").

288. Conditions for Marketing Human Prescription Drugs, 40 Fed. Reg. 26,142, 26,149–50 (proposed June 20, 1975) (to be codified at 21 C.F.R. pt. 130).

289. Procedures for Establishing a Bioequivalence Requirement, 42 Fed. Reg. 1,624, 1,634–38 (Jan. 7, 1977) (establishing criteria and procedures for requiring bioequivalence data relating to pharmaceutical equivalents and alternatives intended to be used interchangeably for the same therapeutic effect); Procedures for Determining the In Vivo Bioavailability of Drug Products, 42 Fed. Reg. 1,638, 1,648 (Jan. 7, 1977) (requiring every full or abbreviated application to include either evidence of in vivo availability or information to permit the FDA to waive the requirement).

290. For example, "AARP's Washington offices . . . mobilized grassroots organizers to work on state and local levels to design and pass drug substitution laws across the country." *See* GREENE, *supra* note 148, at 147–48.

291. John Jacobs, *Drug Anti-Substitution Laws Attacked*, WASH. POST (Nov. 16, 1977), https://www.washingtonpost.com/archive/politics/1977/11/16/drug-anti-substitution-laws-attacked/e0cc6a94-cc77-45fd-808d-bd8e0858bed1/ ("[U]ntil 1970 the APHA supported [anti-substitution] laws as a protection against unscrupulous firms . . . . [But] when smaller firms began manufacturing generic drugs of equivalent quality and lower cost . . . there was no longer any reason for the anti-substitution laws.").

292. *See* Edward G. Feldmann, *Drug Product Selection—Freedom with Responsibility*, 12 J. AM. PHARM. ASS'N. 368, 368 (1972) (complaining doctors view the pharmacist "primarily as a merchant" or "inferior member of the health care team who usually does what he or she is directed to do").

293. Tobbell, *supra* note 197, at 84.

294. SILVERMAN & LEE, *supra* note 58, at 199–200 ("It seems evident that dispensing physicians are dissipating much of their limited time in tasks which, in most cases, can be carried out at least as well—and possibly even better — by a *competent* pharmacist . . . ."); *see*, *e.g.*, George P. Provost, *The Pharmacist's*

slow to support generic substitution. Even in the mid-1970s, the American Medical Association ("AMA") still endorsed laws that "prohibit[ed] the unauthorized substitution of drug products."[295] In the AMA's view, these laws "encourage[d] interprofessional communications regarding drug product selection and assure[d] each profession the opportunity to exercise fully its expertise in drug usage to the advantage of patients."[296]

C. Payors Seek Savings

Like pharmacists, payors supported an exception for generic drugs. Hospitals, which purchase the drugs they administer, had long since identified the savings available from switching to the copies that proliferated in the market.[297] They developed formularies for that purpose: lists of medicines stocked in house, from which their doctors would choose, and the committees that constructed these lists focused in part on cost.[298] An institution's own formulary bypasses the substitution issue altogether; the institution employs the doctor and purchases drugs for its own dispensing pharmacy, and the formulary limits the doctor's and pharmacist's choices at the outset.[299]

In the 1960s, however, public and private insurance coverage for drugs became widespread, increasing interest in the use of formularies to shift patients to less expensive alternatives to brand

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Responsibility in the Choice of Drug Products, 27 AM. J. HOSP. PHARMACY 365, 365 (1970) (arguing for substitution laws on the basis of pharmacist competence).

295. *Joint Statement on Antisubstitution Laws and Regulations*, 225 JAMA 142, 142 (1973) (discussing a joint statement issued by American Medical Association, American Psychiatric Association, American Academy of Pediatrics, and various others).

296. *Id.*; *see also Substitution of Drugs*, 212 JAMA 1,369, 1,369 (1970) (defending prohibitions on substitution, which are "aimed at the unethical pharmacist," and pointing out ways a doctor could take steps to "delegate product selection to a trusted pharmacist" and ways a pharmacist could suggest alternative products for the doctor to consider); *Drug Antisubstitution Laws: Reprise*, 221 JAMA 711, 711 (1972) (arguing substitution could "create a spectrum of trouble ranging from minor mischief to therapeutic disaster" in part because the pharmacist rarely knows everything about the patient or why the physician picked a particular drug).

297. Government institutions (such as the Department of Defense) and public hospitals (such as Grady Memorial Hospital in Atlanta) reported in the 1960s that they had cut costs with a switch to these drugs. SILVERMAN & LEE, *supra* note 58, at 146 ("There was ample evidence to demonstrate that many governmental institutions, notably the Department of Defense, were buying generic drugs at substantial savings.").

298. *See* GREENE, *supra* note 148, at 143–45.

299. *See* Kathy A. Chase, *Medication Management*, *in* INTRODUCTION TO HOSPITAL AND HEALTH-SYSTEM PHARMACY PRACTICE 59, 66–67 (2010).

drugs.[300] These were "outpatient" formularies, meant to constrain the drugs prescribed by doctors and dispensed by pharmacists in the community.[301] As early as the 1950s, state and local public assistance programs had been constructing formularies for their participating doctors.[302] Employer-based health insurance programs and private health insurers also covered prescription drugs and developed formularies to cut their costs.[303] But it was the federal government's launch of Medicare (for persons over sixty-five) and Medicaid (for certain vulnerable populations, including those with low income) in 1965 that turned the attention of policymakers to the role that copies of brand drugs might play in saving expenses.[304]

By 1967, nearly two-thirds of states covered prescription drugs as part of their Medicaid programs, and many adopted formularies to encourage the use of early generic drugs.[305] And when Congress began considering prescription coverage for the Medicare program in the early 1970s, federal policymakers focused on three perceived impediments to achievement of savings through generic dispensing. These three perceived impediments were: the lack of any reliable list of equivalent generic drugs, the fact that doctors tended to prescribe by brand name, and state law prohibitions on substitution.[306] Even if the formularies knew which generic drugs could be substituted for particular brand drugs, state law was an impediment. If a doctor prescribed a brand product that was not listed on the formulary, the pharmacist would need to discuss with the doctor whether to dispense an alternative (unbranded equivalent) covered by the payor.[307] Federal focus on these issues started a chain of events that resulted in the FDA's creation of a substitution list and the enactment of state laws carving out a special exception for generic drugs, as explained in the next Subpart.

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300. T. Donald Rucker, *The Role of Formularies and Their Relationship to Drug Product Selection*, *in* GENERIC DRUG LAWS: A DECADE OF TRIAL—A PRESCRIPTION FOR PROGRESS 465, 469 (Theodore Goldberg et al. eds., 1986) (discussing "growth of drug insurance plans during the 1960s"). Private insurers, such as Blue Shield, began offering prepaid drug insurance as part of their plans in the 1960s. Kathleen Gondek, *Prescription Drug Payment Policy: Past, Present, and Future*, HEALTH CARE FIN. REV., Spring 1994, at 1, 4.

301. *See* Rucker, *supra* note 300, at 469.

302. *See* GREENE, *supra* note 148, at 145 ("Earlier attempts to control the cost of drug benefits associated with public welfare programs in Baltimore and New York in the 1950s asked all participating physicians to agree to an outpatient formulary of drugs for indigent patients.").

303. *See id.* at 145–46.

304. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286, 343–44, 351 (codified at 42 U.S.C. §§ 1936 *et seq.*).

305. *See* GREENE, *supra* note 148, at 146–47.

306. *See generally* TOBBELL, *supra* note 54 (discussing concerns of making generic drug prescription mandatory for Medicare patients).

307. Chase, *supra* note 299, at 70.

D. FDA Support for Substitution

The FDA had never evinced much interest in pursuing imitation products simply because of substitution.[308] The brand industry's concerns about competitive harm did not move the agency. Indeed, some agency policies jeopardized drug trademarks, but the agency was implacable even when officials from the Patent and Trademark Office raised the alarm.[309] For decades, the agency's "apparent indifference" to the protection of trademarks had concerned brand companies.[310] With the new ANDA provision in place and improvements in regulatory science, the FDA now took affirmative steps to support substitution: it prepared and released a list of substitutable drugs, and with the FTC, it drafted a model substitution law for states to enact.[311]

When Congress was considering a prescription drug benefit for Medicare in the early 1970s, its Office of Technology Assessment ("OTA") concluded that an official list of interchangeable products should be generated to guide selection of the lowest-cost products for the program.[312] The FDA developed a list for use by the Department of Defense, and in 1977 the head of the FDA's Office of Generic Drugs leaked its existence to a leading generic drug policy advocate, who in turn unveiled it in New York as part of the State's move towards a generic substitution law.[313] New York planned to adopt this list as

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308. *See* Facchinetti & Dickson, *supra* note 41, at 470 (noting that the FDA would act against an imitation product that was subpotent or otherwise adulterated, but the FDA would not act simply on account of substitution); *see also* Dan Ermann & Mike Millman, *The Role of the Federal Government in Generic Drug Substitution*, *in* GENERIC DRUG LAWS: A DECADE OF TRIAL—A PRESCRIPTION FOR PROGRESS 99, 99 (Theodore Goldberg et al. eds., 1986) ("In 1957, the Commissioner of the FDA stated that the imitation of a brand drug was not a violation of the FD&C Act if it possessed the proper ingredients in the strengths indicated on the label.").

309. The 1938 statute required that a drug not recognized in an official compendium bear a label with its common or usual name. Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, §502(e), 52 Stat. 1040, 1050–51 (1938). An attorney at PTO reported in 1949 that the FDA "insisted" on treating a drug's trademarked name as its "common or usual name." Derenberg, *supra* note 171, at 139 (quoting a letter from the FDA to the House Committee on Patents that "[o]nce it is established that a certain term has become to consumers generally the common or usual name for a given . . . drug, the intent of the [FDCA] is that all persons who manufacture and market such . . . drug identify it on its label by that name"). The "dangers" of this were readily apparent. *Id.*

310. Facchinetti & Dickson, *supra* note 41, at 470; Derenberg, *supra* note 171, at 139.

311. *See* GREENE, *supra* note 148, at 137–70 (discussing the meticulous history of substitution and the drafting of model substitution law).

312. OFF. OF TECH. ASSESSMENT, DRUG BIOEQUIVALENCE STUDY PANEL, DRUG BIOEQUIVALENCE 57 (1974) [hereinafter OTA REPORT].

313. *See* GREENE, *supra* note 148, at 154–58 (explaining Marvin Seife leaked its existence to William Haddad and guided Haddad through a series of Freedom

its official formulary.[314] When the New York Department of Health and the Governor sought assurance from the FDA that the drugs in the proposed New York list were indeed therapeutically equivalent, agency officials validated the state's list at a meeting with legislative committee staff.[315] On hearing this, Illinois officials asked the agency to do the same thing.[316] The burden of reviewing each state's list was significant, and the FDA decided instead to publish its own list.[317]

Over the same years, the FDA and FTC staff developed a model drug substitution law for the states.[318] The model law permitted a pharmacist to fill a prescription that specified a particular product by its brand name with an "equivalent drug product" listed in the state's formulary, provided the price was lower.[319] That formulary should list products the FDA had approved as safe and effective and deemed therapeutically equivalent; it should, in other words, rely on the list of substitutable products the agency was preparing.[320] Relying on the FDA's list would eliminate duplication and reduce administrative costs for the states, the FTC explained, and it would place responsibility for determining therapeutic equivalence in the hands

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of Information Act requests designed to bring its existence to the attention of the public and force the agency into its release).

314. *See* Judith Cummings, *Albany Finds Choices to Brand-Name Drugs*, N.Y. TIMES (Apr. 29, 1977), https://www.nytimes.com/1977/04/29/archives/albany-finds-choices-to-brandname-drugs-assembly-panel-will-verify.html.

315. *See id.*; Transcript of Record at 7–11, Pharm. Mfrs. Ass'n v. Whalen, 430 N.E.2d 1270 (N.Y. 1981) (No. 9556) (affidavit of Joseph Ferraro).

316. Therapeutically Equivalent Drugs, 44 Fed. Reg. 2,932, 2,934 (proposed Jan. 12, 1979) (to be codified at 21 C.F.R. pt. 20).

317. *Id.* ("Based upon these experiences, the agency concluded that continuing to provide assistance on a State-by-State basis would not be cost effective, because of the number of requests and the varying definitions and criteria among the individual statutes for evaluating therapeutic equivalence. Instead, the FDA decided it should prepare a master list to provide a guidance and information that could be utilized by each State in meeting its own responsibilities under the particulars of its drug product selection law.").

318. The FTC had opened an investigation into whether state pharmacy laws "unduly" restricted price competition for multisource prescription drugs, meaning products made by different companies but containing the same active ingredient. *See* FTC REPORT, *supra* note 117, at 1. The FTC had assumed it would recommend enactment of a federal substitution law preempting state pharmacy laws, but when it found states were already enacting generic drug exceptions, it turned to a model law for the remaining states. Michael C. McCarey, *Generic Substitution Policy*, 34 FOOD DRUG COSM. L.J. 103, 104 (1979).

319. *See* FTC REPORT, *supra* note 117, at 281 (showing Model Product Selection Act § 5 and its official commentary); *see also* Kenneth W. Shafermeyer et al., *The FDA Orange Book: Expectations Versus Realities*, 1 J. PHARMACY & L. 13, 17 n.28 (1992).

320. *See* FTC REPORT, *supra* note 117, at 281–82; *see also* Shafermeyer et al., *supra* note 319, at 13–14.

of the agency "that is the single best source of drug information and scientific expertise."[321]

Aligning with payors, pharmacists, and consumer groups, the Administration pushed for enactment of generic substitution laws. FDA officials testified before state legislatures in favor of generic substitution laws, and one brand-company lawyer said this testimony "effectively neutralized" opposition expressed by doctors, pharmacists, and the brand companies.[322] In 1979, the Secretary of Health, Education, and Welfare and the chair of the FTC asserted the model law would save consumers "$400 million a year."[323] President Carter wrote to state governors that enactment of the model law "could help save Americans millions of dollars by increasing the use of generic drug products in place of the higher price brand names."[324] By 1977, over thirty states had enacted generic drug substitution laws, although they did not all follow the FDA-FTC model.[325]

The FDA published the first *Orange Book* on October 31, 1980.[326] The preamble made the agency's goal clear: the list would help states administer their new generic substitution laws.[327] The FDA emphasized, for state policymakers, the clinical significance of its determination that two products are equivalent: "FDA believes that products considered therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same therapeutic effect as the prescribed product."[328] Four years later, Congress created a statutory pathway for ANDAs proposing copies of drugs with approved NDAs, which replaced the FDA's ANDA

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321. FTC REPORT, *supra* note 117, at 284; *see also* McCarey, *supra* note 318, at 106.

322. Nicholas L. Ruggieri, *Generic Drug Substitution and the FDA List of Approved Drug Products*, 36 FOOD DRUG COSM. L.J. 556, 559 (1981) ("From the beginning, the FDA played an active role in support of state generic substitution legislation, and even supplied witnesses who testified in favor of the proposal."); *see also* Berger, *supra* note 211, at 23–24 (noting that the FDA supported enactment of substitution laws).

323. WILLIAM C. CRAY, THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION: THE FIRST 30 YEARS 103 (1989).

324. *Id.*

325. *See* FTC REPORT, *supra* note 117, at 155, 177–80 (presenting a fifty-state survey current as of 1979); *see also* Jillena A. Warner, Note, *Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws*, 67 KY. L.J. 384, 395–96, 395 n.43 (1978) ("Between 1972 and 1979 thirty-one states and the District of Columbia abandoned their antisubstitution laws and enacted various types of laws permitting substitution.").

326. Therapeutically Equivalent Drugs; Availability of List, 45 Fed. Reg. 72582, 72582 (Oct. 31, 1980); *see generally* U.S. DEP'T OF HEALTH & HUM. SERVS., APPROVED PRESCRIPTION DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (1st ed. 1980) [hereinafter 1ST ORANGE BOOK].

327. Therapeutically Equivalent Drugs; Availability of List, 44 Fed. Reg. 2932, 2932 (proposed Jan. 12, 1979) (to be codified at 21 C.F.R. pt. 20).

328. 1ST ORANGE BOOK, *supra* note 326, at I-4.

regulation.[329] Today, a generic drug approved under this provision is usually deemed therapeutically equivalent by the FDA in the *Orange Book* and is usually considered substitutable under the state laws enacted in the 1970s.

IV. RECONSIDERATION OF THE GENERIC DRUG EXCEPTION

The generic drug exceptions are now half a century old, and they reflect a policymaking initiative that began (at least) sixty years ago with Senator Kefauver. A great deal has changed since then. The drug regulatory framework has changed profoundly. The science of drug development and drug testing is fundamentally different. The brand and drug industries have evolved. The prescription drug marketplace is different. It makes sense to reflect on these exceptions, what they mean for drug trademarks, and whether they are still important (if they ever were). Doing so requires starting with a basic drug regulatory point: even if two active ingredients (which are called "drugs") are the "same" for regulatory purposes, the products (which are also called "drugs") are not the same. The first Subpart below addresses this confusion, and the following Subparts take up the fate of trademarks and the generic drug exception.

A. Different Products and Sources

Scholars and others who write about drug brand names, including in connection with incremental innovation (and what the writers call "evergreening" by brand companies), sometimes make confused—and incorrect—assertions about the differences between brand drugs and their generic equivalents. For instance, one writer recently wrote that drug trademarks "confuse" patients into thinking a trademarked drug and a generic drug are distinct medications.[330] But she has it backwards; it is attacks on drug trademarks that confuse people into thinking a brand drug and a generic drug are the same when they are not. Reconsidering the exception for generic drugs requires first unpacking what it does and does not mean to say that two drugs are the same. Five points are key.

First, although the active ingredients are the same, the products are not. Both are called "drugs," which leads to confusion.[331] At the FDA, the term "drug" has more than one meaning. The statute defines "drug" to mean (among other things) any article "intended for use" in the treatment of disease, any article (other than food)

329. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1585.

330. Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. & TECH. L. REV. 1, 1 (2015).

331. *See* Erika Lietzan, *The "Evergreening" Metaphor in Intellectual Property Scholarship*, 53 AKRON L. REV. 805, 858–59 (2019) (explaining the different meanings of "drug" and their relevance to brand drugs and generic equivalents).

"intended to affect the structure or any function of the body," and any "component" of such an article.[332] Depending on the statutory or regulatory provision at issue, the term may refer to an active ingredient, a finished product, or both.[333] Although each "new drug" requires an approved application,[334] the FDA approves drug *products*, not active ingredients.[335] A drug product is a medicine in the finished form meant to be sold in the market and administered to patients.[336] The active ingredient is the component that furnishes the pharmacological action of the product: the fluoxetine in Prozac, for instance, and the atorvastatin in Lipitor.[337] When the FDA approves a NDA, it approves a finished product. The product is a particular formulation, made as described in the NDA (with the raw materials specified and sourced from the sellers identified, in the facility identified, using the manufacturing process described), presented at a particular strength in a particular dosage form for a particular route of administration, labeled with particular instructions and, if requested, a particular brand name.[338] The FDA approves the brand company's product (based on its full new drug application) and a generic company's product (based on its abbreviated application).

Second, although the active ingredients are the "same," this is a regulatory concept with a particularized meaning; the active ingredients may not, in fact, be chemically indistinguishable. The FDA's regulations implementing the ANDA provisions state that the phrase "same as" means, among other things, "identical."[339] But the

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332. 21 U.S.C. § 321(g)(1).

333. Lietzan, *supra* note 331, at 858.

334. 21 U.S.C. § 355(a).

335. *See* Lietzan, *supra* note 331, at 812–13.

336. 21 C.F.R. § 314.3(b) (2021) ("Drug product is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.").

337. *See* 21 C.F.R. § 210.3(b)(7) (2021) (explaining that an "[a]ctive ingredient" is "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals" and "includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect"); *see also* 21 C.F.R. § 314.3(b) (2021) (explaining that "drug substance" is "an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body" but "does not include intermediates used in the synthesis of such ingredient").

338. The company may not use a brand name unless the FDA has approved the name. *See generally* U.S. DEP'T OF HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: CONTENTS OF A COMPLETE SUBMISSION FOR THE EVALUATION OF PROPRIETARY NAMES (2016) (describing the information that is used by the FDA for the evaluation of proposed proprietary names for drugs).

339. 21 C.F.R. § 314.92(a)(1) (2021).

agency also rejected the suggestion that it adopt a requirement that active ingredients "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process; and that the stereochemistry characteristics and solid state forms of the drug have not been altered."[340] Instead, the FDA said it would "consider an active ingredient [in a generic drug product] to be the same as that of the reference listed drug if it meets the same standards for identity."[341] Six years later, in *Serono Laboratories, Inc. v. Shalala*,[342] the D.C. Circuit held that the FDA's decision to interpret "same as" to permit some variation rather than chemical identity was a permissible reading of the statute.[343]

The FDA views the *Serono* decision as establishing it has broad discretion to tailor sameness inquiries for generic drugs. For instance, when the agency approved a generic copy of Lovenox (enoxaparin sodium), it cited the *Serono* decision and said that an ANDA application for enoxaparin could prove active-ingredient sameness by meeting five criteria, each of which captures a different aspect of sameness.[344] "[W]e have broad discretion," the agency wrote, "in determining whether an ANDA applicant has submitted sufficient information upon which we can reasonably conclude that

340. Abbreviated New Drug Applications, 57 Fed. Reg. 17950, 17958–59 (Apr. 28, 1992).

341. *Id.* at 17959.

342. 158 F.3d 1313 (D.C. Cir. 1998).

343. The case involved an ANDA for Repronex (menotropins) that had cited Serono's Pergonal (menotropins). *Id.* at 1316. The active ingredient is a mixture of follicle stimulating hormone ("FSH") and luteinizing hormone ("LH") derived from the urine of post-menopausal women; the remaining ninety-five percent of the drug is composed of lactose and uncharacterized urinary proteins. *See id.* FSH is a polypeptide hormone consisting of a protein (amino acid) chain and carbohydrate side chains. *See id.* at 1317. The amino acid backbone in Repronex was the same as the backbone in Pergonal, but there were differences in the carbohydrate side chains sufficient to mean the two products had different isoforms of FSH. *Id.* The FDA concluded that the two active ingredients were the "same" because they had (1) the same protein backbone and amino acid sequence, (2) the same potency, and (3) the same degree of batch-to-batch uniformity. *See id.* at 1320–22. The D.C. Circuit permitted this. *See id.* The FDA's approach to the statutory term ("same" with respect to active ingredient) rests on the agency's evaluation of scientific data within its area of expertise. *Id.* Its interpretation was a reasonable, and hence permissible, reading of the statutory term. *Id.*

344. *See* Letter from Douglas Throckmorton, Deputy Dir., Ctr. for Drug Evaluation & Rsch., Food & Drug Admin., Dep't of Health & Hum. Servs., to Peter O. Safir & Scott L. Cunningham, Covington & Burling 26 (Jul. 23, 2010), https://www.fda.gov/media/78975/download; *see also id.* at 10 (stating that the lack of a definition for "same as" in the statute means Congress recognized the agency "must have broad discretion with respect to the information" it would "consider in making a finding on the 'sameness' of an active ingredient").

the generic drug product's active ingredient is, as a matter of law, the 'same' as that of the RLD."[345] The agency similarly rejected a brand company's argument that the generic version of Copaxone (glatiramer acetate) needed an identical active ingredient.[346] Again, it claimed broad discretion with respect to the sameness requirement.[347] Over the years, the FDA has said that while a different salt of the same active moiety is considered a different active ingredient,[348] different polymorphs of the same active moiety are considered the same active ingredient.[349] Anhydrous and hydrated entities are also considered to be the same active ingredient.[350] Also, under certain conditions, differing co-crystals—crystalline materials composed of two or more different molecules, typically active pharmaceutical ingredient and co-crystal formers in the same crystal lattice—may be the same active ingredient.[351]

Third, the FDA also does not require that the brand and generic products be identically bioavailable. The statute merely requires proof of bioequivalence, another regulatory concept. Ordinarily, after administering the proposed generic drug and the reference drug to a small group of healthy male and female adults, the generic company compares the products using two measurements: the maximum concentration of the active moiety ever achieved in the blood (known as "C_{max}") and the total amount of active moiety that reaches the blood (known as "AUC" because it reflects the area under a curve

345. Letter from Douglas Throckmorton, Deputy Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Dep't of Health & Hum. Servs., to Peter O. Safir & Scott L. Cunningham, Covington & Burling, *supra* note 344, at 10.

346. Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Dep't of Health & Hum. Servs., to Dr. J. Michael Nicholas, Vice President, Glob. Specialty Meds., Teva Pharms. 1–2 (Apr. 16, 2015), https://downloads.regulations.gov/FDA-2015-P-1050-0012/attachment_1.pdf.

347. *Id.* at 7 ("Congress recognized that [the FDA] must have broad discretion with respect to the information [the agency] may consider in making a finding on the 'sameness' of an active ingredient.").

348. *See* 41ST ORANGE BOOK, *supra* note 12, at xiv–xv; *see also* U.S. FOOD & DRUG ADMIN., MAPP 5018.2, NDA CLASSIFICATION CODES 2–3 (2015), https://www.fda.gov/media/94381/download.

349. *See* 41ST ORANGE BOOK, *supra* note 12, at xiv–xv; *see also* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69,580, 69,597 (Oct. 6, 2016) (explaining that "a polymorph"—"a different crystalline or amorphous form of the same drug substance"—is considered the "same active ingredient"); 21 C.F.R. § 314.3 (defining active moiety, the underlying molecule responsible for the pharmacological action of the drug substance).

350. *See* 41ST ORANGE BOOK, *supra* note 12, at xiv–xv.

351. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: REGULATORY CLASSIFICATION OF PHARMACEUTICAL CO-CRYSTALS 3 (2018), https://www.fda.gov/media/81824/download (stating that "a co-crystal with a pharmaceutically acceptable coformer" is analogous to a polymorph (and thus not a new active ingredient) if certain conditions are true).

representing the amount of active moiety bioavailable at points in time).[352] The agency usually requires that the 90% confidence interval for the ratio between the two products on each measurement (generic to brand) fall within 80% and 125%.[353] Some scientists and clinicians believe these standards are insufficient for certain types of drugs, such as drugs with a narrow therapeutic index (meaning a very small difference between the lowest effective dose and the highest safe dose) and drugs for treatment of epilepsy.[354] Other regulators have introduced tighter bioequivalence rules for these drugs.[355] But the point is that the brand and generic are not identically bioavailable. In 2014, for example, after the FDA received nearly two hundred complaints about insufficient therapeutic effect from Mallinckrodt's generic methylphenidate extended-release tablets, the FDA changed how it wanted generic companies to test the bioequivalence of these products and ordered the company to confirm bioequivalence the new way or withdraw its products from the

352. *See generally* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: BIOEQUIVALENCE STUDIES WITH PHARMACOKINETIC ENDPOINTS FOR DRUGS SUBMITTED UNDER AN ANDA DRAFT GUIDANCE (2013) (providing "recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs) and ANDA supplements"). Different approaches may be required for modified release products and for products that raise special issues, such as drugs with especially long half-lives and orally administered products that act locally rather than systemically. In some situations, the FDA even waives the requirement for in vivo bioequivalence studies. *See, e.g.*, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS—GENERAL CONSIDERATIONS DRAFT GUIDANCE 6, 12 (2002).

353. Barbara M. Davit et al., *Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration*, 43 ANNALS PHARMACOTHERAPY 1583, 1585 (2009).

354. *See, e.g.*, Kaja Gantar et al., *Meeting Regulatory Requirements for Drugs with a Narrow Therapeutic Index: Bioequivalence Studies of Generic Once-Daily Tacrolimus*, 12 DRUG HEALTHCARE PATIENT SAFETY 151, 153 (2020) ("Concerns about bioequivalence are especially pertinent for drugs that have a narrow therapeutic index (NTI), [i.e.], drugs in which there is only a narrow range of drug exposure between lack of efficacy and undesirable toxicity. In the case of tacrolimus, insufficient immunosuppression could lead to acute rejection and graft failure, whereas excess immunosuppression could result in infection, or effects related to extensive calcineurin inhibition such as nephrotoxicity or neurotoxicity."); Reem Odi et al., *Bioequivalence and Switchability of Generic Antiseizure Medications (ASMs): A Re-appraisal Based on Analysis of Generic ASM Products Approved in Europe*, 62 EPILEPSIA 285, 285–86 (2021) (raising questions about variability among gabapentin generics).

355. Gantar et al., *supra* note 354, at 154 (noting that the European Medicines Agency set the margin as 90.00 to 111.11% for tacrolimus and that Health Canada set the margin as 90.00 to 112.00%).

market.[356] Something similar happened with generic versions of GlaxoSmithKline's Wellbutrin XL (bupropion) in 2012.[357]

Fourth, other aspects of the products may not be the same. Federal law does not require the formulations to match, for instance, so the generic company can usually use different inactive ingredients.[358] A generic company could even use inactive ingredients that are common allergens and do not appear in the brand product. The FDA approved a generic propofol, for instance, that contained a sulfite lacking in the reference drug, Diprivan, and it even rated the drug therapeutically equivalent—paving the way for automatic substitution.[359] The impurities in the drug substances (active pharmaceutical ingredients) and drug products generally do not have to be the same.[360] The raw material suppliers will likely be different, and one company's supplier could run into quality and purity problems, while the other's does not. To give an example, after Perrigo secured approval of a generic guaifenesin tablet in 2011, based on Mucinex, it twice had to stop distributing. On the first occasion, raw material sourcing did not meet specifications (leading to a two-year wait), and on the second occasion, problems emerged with an excipient.[361] The generic and brand companies make their products at their own facilities, using their own manufacturing processes, which differ in at least the details if not in significant ways. Mylan Pharmaceuticals found itself unable to manufacture 100 mg phenytoin sodium in capsules that would be bioequivalent to Warner Lambert's Dilantin, and famously ended up stuffing a tablet inside a capsule shell—explaining to a court that it was "unsuccessful in

356. *See Methylphenidate Hydrochloride Extended Release Tablets (Generic Concerta) Made by Mallinckrodt and Kudco*, U.S. FOOD & DRUG ADMIN. (Jan. 27, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/methylphenidate-hydrochloride-extended-release-tablets-generic-concerta-made-mallinckrodt-and-kudco.

357. *See* Robert Rounder & Saul Perloff, *FDA Says Wellbutrin Generic Really Isn't Generic After All*, NORTON ROSE FULBRIGHT LLP: THE BRAND PROT. BLOG (Oct. 19, 2012), https://www.thebrandprotectionblog.com/fda-says-wellbutrin-generic-really-isnt-generic-after-all/.

358. 21 C.F.R. § 314.127(a)(8)(i)(A) (2021) (stating that the FDA will not approve an ANDA if the inactive ingredients are unsafe for use under the conditions described in the proposed product labeling); *id.* § 314.127(a)(8)(ii)(A)(3) (stating that generally, the inactive ingredients in a generic parenteral drug product must match those of the reference listed brand drug).

359. Zeneca, Inc. v. Shalala, 213 F.3d 161, 166 (4th Cir. 2000).

360. The impurities must be adequately qualified. *See, e.g.*, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ANDAS: IMPURITIES IN DRUG SUBSTANCES 7–8 (2009); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ANDAS: IMPURITIES IN DRUG PRODUCTS 5–7 (2010).

361. *Private Label* Mucinex *March Reaches Two Formulations*, PINK SHEET (May 4, 2016), https://pink.pharmaintelligence.informa.com/PS108317/Private-Label-emMucinexem-March-Reaches-Two-Formulations.

formulating an ordinary capsule that would satisfy FDA and USP requirements, and only succeeded after it had compressed the material to the point that it actually comprised a tablet."[362]

Finally, each company's compliance history is unique. For instance, both the generic company and brand company must be truthful and accurate in filings to the FDA, but one company may run into data integrity problems while the other does not. Generic manufacturer Ranbaxy pleaded guilty to data fraud in 2013, for example, and active pharmaceutical ingredient maker IPCA Laboratories engaged in backdating and falsifying laboratory data.[363] Innovator Novartis was accused in 2019 of using manipulated data to support approval of its gene therapy product, ZOLGENSMA.[364] Generic companies, like brand companies, may similarly fall out of compliance with current good manufacturing practices and fail facility inspections. For example, generic company Apotex received a series of warning letters arising out of failed inspections in the early 2000s, and the FDA eventually decided to withhold approval of new ANDAs from the company until the violations were corrected.[365] A senior agency official responsible for drug quality issues told the generic drug industry at a conference in 2019 that it needed to "take a strong look" at quality issues; roughly two-thirds of all drugs in shortage are generic durgs, and manufacturing problems were one reason.[366]

In sum, a generic drug and its reference drug are different products made by different companies. They have the "same active ingredient" in the regulatory sense, and they are "bioequivalent" in the regulatory sense. To be sure, if the FDA has found them therapeutically equivalent, then the agency has concluded that (barring manufacturing deviations) the generic product "will produce

362. Brief for Appellant at 9, Warner-Lambert Co. v. Shalala, 202 F.3d 326 (D.C. Cir. 2000) (No. 99-5048).

363. *Data Integrity Lapses Continue to Bedevil Manufacturers*, PINK SHEET (June 30, 2016), https://pink.pharmaintelligence.informa.com/PS000995/Data-Integrity-Lapses-Continue-To-Bedevil-Manufacturers.

364. Derrick Gingery, *Novartis' Zolgensma Had Manipulated Data in Application, US FDA Says*, PINK SHEET (Aug. 6, 2019), https://pink.pharmaintelligence.informa.com/PS140636/Novartis-Zolgensma-Had-Manipulated-Data-In-Application-US-FDA-Says.

365. *Apotex Manufacturing Violations Could Delay Launch of* Taxotere *Generic*, PINK SHEET (Apr. 19, 2010), https://pink.pharmaintelligence.informa.com/PS052128/Apotex-Manufacturing-Violations-Could-Delay-Launch-Of-Taxotere-Generic.

366. Joanne S. Eglovitch, *FDA's OPQ Chief Tells Generic Drug Makers It's Time to Up Their Quality Game*, PINK SHEET (Nov. 8, 2019), https://pink.pharmaintelligence.informa.com/PS141152/FDAs-OPQ-Chief-Tells-Generic-Drug-Makers-Its-Time-To-Up-Their-Quality-Game.

the same clinical effect and safety profile" as the brand product.[367] But this is clinical advice and a regulatory concept, cabined by the limitations of the supporting concepts of "same active ingredient" and "bioequivalence."[368] And it does not affect the basic point: these are different products made and sold by different companies.

With this background laid out, the Subparts that follow take up the generic drug exceptions and the fate of drug trademarks.

B. The Generic Drug Exception

The generic substitution bills of the 1970s created an exception for generic drugs from otherwise applicable law that reflects long-standing antisubstitution policy.

First, they operate as express exceptions to the rule that a pharmacist must dispense the drug (the product) specified by the prescriber. Substitution of a different drug for the one prescribed remains a violation of pharmacy law in most of the country, even if the dispensed drug is accurately labeled (thus, without deception of the consumer) and less expensive. For example, in Missouri, a pharmacist may be disciplined for the "[i]ntentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed . . . without prior written or oral approval from the prescriber for the respective change in each prescription."[369] Missouri law adds a proviso to the language just described that a pharmacist may substitute in accordance with a different provision of the statute, which in turn allows generic drug substitution if certain criteria are satisfied.[370] To give another example, Kansas pharmacy law states that every prescription "shall be filled or refilled in strict conformity with any directions of the prescriber."[371] It adds, "except that" a pharmacist may engage in generic substitution.[372] Dispensing an FDA-approved, therapeutically-equivalent, generic drug rather than a branded drug selected by the doctor for the patient would violate state pharmacy law were it not for the generic drug exception.

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367. *Drugs@FDA Glossary of Terms*, U.S. FOOD & DRUG ADMIN. (Nov. 14, 2017), https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms.

368. *Id.*

369. MO. REV. STAT. § 338.055(16) (2019).

370. *Id.*

371. KAN. STAT. ANN. § 65-1637(g) (2021); *see also* ALA. CODE § 34-23-8 (2021); ALASKA ADMIN. CODE tit. 12 § 52.460 (2021); CAL. CODE REGS. tit. 16 § 1716 (2021); LA. ADMIN. CODE tit. 46 § 2747(B)(4)(c)(iii) (2021); MICH. COMP. LAWS § 333.17751(6) (2021); MINN. STAT. § 151.21(1) (2021); N.Y. EDUC. LAW § 6816(1)(a) (McKinney 2021); N.D. CENT. CODE § 43-15-43(5) (2021); OHIO ADMIN. CODE 4729-5-30(C)(9) (2020) (repealed 2021); TENN. COMP. R. & Reg. 1140-03-.03(6)(a) (2021); VA. CODE. ANN. § 54.1-3457(16) (2021); W. VA. CODE R. § 15-2-8.5.1.d (2021); WIS. ADMIN. CODE PHAR. § 8.05(7) (2021).

372. *See* KAN. STAT. ANN. § 65-1637(g)(1)(C).

Second, the state generic substitution laws foreclose the brand company's use of unfair competition law when the pharmacist engages in this same substitution. The heart of passing off is deception of the customer, but a pharmacist who dispenses a generic drug instead of the requested brand drug does not label the generic drug as the brand drug.[373] Because pharmacy law now permits the pharmacist to substitute a generic equivalent[374] and because, as a scientific and regulatory matter, the generic company can truthfully call its product therapeutically equivalent to the brand product,[375] the pharmacist has no need to engage in deception. For similar reasons, it would be hard to frame the generic company's actions—making a copy for substitution purposes and even encouraging substitution—as unfair competition; state law and federal law and practice work together to facilitate, and in some cases require, this very substitution.

Thus, the generic substitution laws amount to an exception from—and a rejection of—antisubstitution policy. As explained, that policy had been grounded in both concerns about economic adulteration (economic fraud on the pharmacy's part and possible risk to patients tied to inferior products) and complaints about competitive harm (to the companies whose products had been specified by brand name).[376] Changes in the drug regulatory framework and improvements in science have addressed the concerns about inferior products. Concerns about competitive harm and trademarks, in contrast, were pushed aside in the name of savings.

The true purpose and actual effect of these laws was to undermine drug trademarks in order to achieve savings for payors by instructing that the trademarks be ignored when used in a prescription after generic drugs have reached the market.[377]

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373. *See, e.g.*, ALA. CODE § 34-23-8(5).

374. *See, e.g.*, KAN. STAT. ANN. § 65-1637(g)(1).

375. *See Are Generic Drugs the Same as Brand Name Drugs?*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Feb. 12, 2014), https://www.hhs.gov/answers/public-health-and-safety/are-generic-drugs-the-same-as-brand-name-drugs/index.html ("By law, generic drug products must contain the identical amounts of the same active drug ingredient as the brand name product.").

376. *See supra* note 58 and accompanying text.

377. In the 1970s, the brand companies challenged the New York substitution law, arguing that it promoted unfair competition and trademark infringement. *See generally* Pharm. Mfrs. Ass'n v. Whalen, 430 N.E.2d 1270 (N.Y. 1981). "[W]hether the law provides a technical defense to a trademark or patent infringement claim is not so important," their trade association wrote, "as the fact that the law, by its very terms, penalizes drug products which have well-known brand names." Brief of Plaintiffs-Appellants at 21–22, Pharm. Mfrs. Ass'n v. Whalen, 430 N.E.2d 1270 (N.Y. 1981) (No. 15831/78). The trial court dismissed these claims, and the appellate court said the law did not promote unfair competition or promote infringement because substitution was permissive; "in

Ordinarily, a trademark is used to distinguish a firm's goods in the market and to signal their source.[378] With the generic drug substitution exceptions in place, the brand name no longer functions this way on the prescription form. State law treats the doctor's use of the trademark as an instruction to provide a different company's product that contains the same active ingredient and is rated by the FDA as therapeutically equivalent.[379] Although efforts to mandate "generic" prescribing (by active ingredient) failed, the next best thing is state legislation that pretends as if the doctors are writing generic prescriptions, even when they are not doing so.[380] No one is hiding this objective; a leading lawyer for the generic industry argued recently that "prescription drug brand names cease to function as trademarks once the same medicine is available from more than [one] manufacturer."[381]

C. The Assault on Drug Trademarks

At least some of the time, supporters of generic substitution justify the assault on drug trademarks with the theory that the trademark improperly perpetuates the innovator's patent-based exclusivity in the market.[382] The notion seems to be that the patent creates a "monopoly" that use of the trademark perpetuates.[383] The theory is that the patent allows the manufacturer to build brand loyalty, which is used after patent expiration to perpetuate monopoly by luring consumers (here, prescribing doctors) away from lower-

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order to comply with the law, a pharmacist is not required to stock or sell an infringing generic substitute." *Pharm. Mfrs. Ass'n*, 430 N.E.2d at 1274.

378. *See* WORLD INTELL. PRO. ORG., INTRODUCTION TO TRADEMARK LAW & PRACTICE: THE BASIC CONCEPTS 9 (2d ed. 1993).

379. *See, e.g.*, ALA. CODE § 34-23-8(1) (2021).

380. *See id.* § 34-23-8(5).

381. Alfred B. Engelberg, *Have Prescription Drug Brand Names Become Generic?*, AM. J. OF MANAGED CARE (Nov. 18, 2014), https://www.ajmc.com/view/have-prescription-drug-brand-names-become-generic.

382. This argument has been around for decades. In the late 1960s, for example, Generic Formulae, Inc., argued that Pfizer's trademark, Terramycin, named the article covered by the patent, and thus, the "monopoly in the name expired with the patent." Chas. Pfizer & Co., Inc. v. Generic Formulae, Inc., 275 F. Supp. 421, 423 (E.D.N.Y. 1967). The court rejected this, saying that the "name, even if embarrassed by its complete coincidence with all lawful sales of the patented product, may still identify a specific source to a significant class of users and be entitled to protection to that extent at least." *Id.*

383. *E.g.*, W.J.R. Taylor, *The Issue of "Generic" Versus "Trade" Names,* 2 INT'L J. CLIN. PHARMACOLOGY 1, 2 (1969) ("While quality and therapeutic efficacy must be the physician's first concern, the cost of medicine being prescribed also must be considered. Little is accomplished by prescribing the correct medicine if the patient cannot afford it. This has become a burning social issue. . . . Physicians should not unwittingly create sales monopolies for certain drug companies by ordering prescription drugs by 'trade' name.").

priced substitutes.[384] But we do not undermine trademarks in other product sectors on this basis. Patents and trademarks pertain to different things, play different roles, and serve different purposes.

A patent protects a specific invention embodied in a particular drug product, such as its active ingredient, its method of use, or its method of manufacturing.[385] A brand company typically owns a patent protecting its active ingredient, and the brand product may embody other discrete inventions also protected by patents.[386] In contrast, the trademark distinguishes the entire product—the finished dosage form, with a particular amount of the active ingredient and particular inactive ingredients, in a particular dosage form, for a particular route of administration, labeled for particular uses—from others in the market, and it signals the product's source (even if it does not identify the source to consumers).[387]

Just as they pertain to different things, patents and trademarks also serve different purposes and play different roles. Protection of patents stimulates scientific and technological progress by ensuring innovators can enjoy a period of exclusivity in their inventions, meaning a period during which no others may manufacture and sell embodiments of their inventions.[388] In exchange for describing and

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384. But antitrust law does not prohibit monopoly; it only prohibits monopolization. Verizon Commc'ns, Inc. v. L. Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period — is what attracts "business acumen" in the first place; it induces risk taking that produces innovation and economic growth. To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*."). Monopolization requires unreasonably exclusionary conduct: willful maintenance of monopoly power in the market, as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. Thomas A. Lambert & Alden F. Abbott, *Recognizing the Limits of Antitrust: The Roberts Court Versus the Enforcement Agencies*, 11 J. COMPETITION L. & ECON. 791, 794–95 n.14 (2015); *see also* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 18 (4th ed. 2011).

385. 35 U.S.C. § 101 (authorizing issuance of a patent for any "new and useful process, machine, manufacture, or composition of matter," subject to the other requirements of the Patent Act).

386. *See generally* JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW (1st ed. 2005) (discussing different types of drug patent claims).

387. *Trademark, Patent, or Copyright*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/trademarks/basics/trademark-patent-copyright (last visited Oct. 22, 2021) (distinguishing trademark as identification of one's "goods . . . [which] distinguishes them from the goods . . . of others, and indicates the source of [the] goods").

388. *See* Kenneth W. Dam, *The Economic Underpinning of Patent Law*, 23 J. LEGAL STUD. 247, 247, 253 (1994) (explaining the patent system "relies on

explaining the invention in a public document, the inventor enjoys a period of exclusivity: no one may make, sell, or offer to sell the invention until the patent expires.[389] A patent on the brand company's active ingredient will preclude a generic company from selling a product with the same active ingredient during the life of the patent.[390] Once the patent expires, however, generic companies may make, use, and sell products that embody the invention—here, the active ingredient.[391] Society endures the supracompetitive pricing that patent exclusivity enables for a period, in exchange for details of the invention and in order to stimulate innovation.

In contrast, the trademark facilitates decision-making based on the goodwill associated with the source signified by the trademark, and protection of the trademark prevents appropriation of the goodwill accumulated and owned by the trademark owner through investment in its reputation and the quality of its good.[392] A trademark does not expire so long as it remains in use and under the control of the trademark owner. But it never prevents approval or sale of competing drugs, including generic drugs with the same active ingredient, route of administration, dosage form, and strength. It simply signals to the market the source of one particular product (or products) containing that active ingredient, and even after patent expiration and generic drug entry, it can continue to do so.[393]

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property concepts" and "prevents others from reaping where they have not sown and thereby promotes [research and development] investment in innovation").

389. *See generally* 35 U.S.C. § 271 (delineating a patent holder's rights to raise infringement claims). In exchange for revealing information that society can use forever (a dynamic gain), there is a welfare loss associated with monopoly power (a static cost). *See generally* Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON. 106 (1990).

390. This is because a generic drug must have the same active ingredient as its reference drug. *See* 21 U.S.C. §§ 355(j)(2)(A)(i)–(ii); *see also* Lietzan & Acri née Lybecker, *supra* note 24, at 1330–31 (discussing importance of active ingredient patent). The FDA may not approve a generic application if the product would infringe the brand company's patent. 21 U.S.C. § 355(j)(5)(B)(ii) (saying that if the generic applicant states it will wait for patent expiry to launch its product, the FDA may not issue final approval of the generic drug until patent expiry); 35 U.S.C. § 271(e)(4)(A) (saying that if the generic instead challenged the patent, resulting in litigation that the generic then lost, the court must order the effective date of FDA approval to be no earlier than patent expiry).

391. *See* John A. Pearce II, *How Companies Can Preserve Market Dominance After Patents Expire*, 39 LONG RANGE PLAN. J. 71, 71 (2006) ("When a patent expires, however, lower-priced versions of the item can be introduced by rivals.").

392. *See* Robert G. Bone, *Hunting Goodwill: A History of the Concept of Goodwill in Trademark Law*, 86 B.U. L. REV. 547, 549 (2006).

393. *Cf.* Bayer Co. v. United Drug Co., 272 F. 505, 509 (S.D.N.Y. 1921) (noting an earlier case had "decided no more than that the existence of a patent during the period when the goods became known to the public might be a controlling element in determining whether the name under which they were sold indicated a single source of origin" but adding that "since then courts have several times

This is, in fact, the reason to protect drug trademarks. The twin doctrinal bases for trademark protection are germane here.[394] Those who attack drug brand names because "the drug is the same" in a sense prove why we need to protect brand names. The products are not the same, the sources are not the same, and market participants may want to select products based on their source and the seller's reputation for product quality. Not only does the trademark distinguish the brand company's product from generic versions made by other companies,[395] but it distinguishes the brand company's product from other *brand* products in the same therapeutic class: Prozac (which contains fluoxetine) from Paxil (paroxetine), for instance. It does not distinguish "fluoxetine" (the active ingredient of Prozac) from Paxil (let alone the active ingredient of Paxil and generic versions of Paxil).[396] And when a brand company uses the trademark on related products, the mark both distinguishes the products from those of other companies *and* signals the relationship among the products. Otsuka markets six distinct products containing aripiprazole: one called the Abilify MyCite Kit (a tablet embedded with a sensor intended to track ingestion), one called the Abilify Maintena (a suspension for oral release), and four called Abilify (an oral tablet, an oral solution, an orally disintegrating tablet, and an intramuscular injection).[397] This is similar to Honda's use of the "Acura" trademark on a variety of related luxury car models: the ILX, TLX, RLX, MDX, and NSX.[398] Affixing a known mark to a product conveys useful information, allowing the purchaser to select based on familiarity with the manufacturer and the quality of the other products bearing the same brand name.

Some will argue that brand loyalty is not rational marketplace behavior in this context.[399] The argument may be that the products are close enough and will act the same way in the body, so putting aside relatively unlikely manufacturing and quality problems, neither the doctor nor the patient will notice or care about the

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said that the name of goods protected by patent might in fact indicate not only the kind of goods they were, but as well that they emanated from a single source").

394. *See supra* Subpart 0.

395. *See Trademark, Patent, or Copyright*, *supra* note 387.

396. *See* Gerardo Sison, *Paxil vs. Prozac: Differences, Similarities, and Which Is Better for You*, SINGLECARE (Jan. 3, 2020), https://www.singlecare.com/blog/paxil-vs-prozac/.

397. *Our Products*, OTSUKA, https://www.otsuka-us.com/products (last visited Oct. 22, 2021).

398. ACURA, https://www.acura.com (last visited Oct. 22, 2021).

399. *E.g.*, James T. Doluisio, *A Definition of Bioequivalence/Bioavailability and a Historical Perspective*, 32 FOOD DRUG COSM. L.J. 506, 508 (1977) (arguing that the intent of a generic substitution law is "not to alter the physician's right to specify the drug to be used for the patient but it is intended to alter his ability to select a specific manufacturer of that drug").

difference in source. And if they do not mind or even notice, this argument might be: why does trademark law even care? It cares because the trademark—or at least the underlying goodwill—is property.[400] It cares because trademarks are not patents, and keeping the concepts separate protects the coherence of both doctrines.[401] It cares because sometimes there *are* differences between the products, including quality differences, and differences among the sources (such as compliance and reputational differences).[402] It cares because the trademark continues to matter to its owner and function in the market as a source indicator.[403]

All the responses point to trademark protection's dynamic goals.[404] But what about the fact that we may have a profound interest in dispensing less expensive generic drugs rather than the brand drugs to which they are equivalent—a static objective? The answer may lie in reviewing how the market works today.[405]

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400. *See generally* Adam Mossoff, *Trademark as a Property Right*, 107 KY. L.J. 1 (2018) (discussing relationship among trademark, goodwill, and property right).

401. *See id.* at 16 (differentiating trademarks from patents by not conferring exclusive titles to trademark owners); *see also Trademark, Patent, or Copyright*, *supra* note 387 (discussing the differences between trademarks and patents and the different benefits one may gain from their protection).

402. *See Trademark, Patent, or Copyright*, *supra* note 387.

403. *See* 15 U.S.C. § 1127.

404. For a similar reason, courts did not accept the argument that mimicking trade dress in order to encourage substitution was justified because substitution would save consumers money. In 1980, for instance, Premo argued to the Third Circuit that federal policy favored competition, and it argued that the state policies underlying generic drug substitution laws "demand[ed] the conclusion that generic drug manufacturers should be free to copy the form and appearance" of popular branded products. SK&F, Co. v. Premo Pharm. Lab'ys., Inc., 625 F.2d 1055, 1067 (3d Cir. 1980). In essence, the company contended "that it would be somehow in the public interest to permit it . . . to facilitate passing off." *Id.* The court rejected this argument, focusing on the tradeoff between static and dynamic social welfare: "certain kinds of business activity, while promoting competition in the short run, are in the long run apt to be destructive of competition." *Id.* Allowing "substitutions of products over which the first manufacturer has no quality control in the long run can only discourage the effort to compete on the basis of reputation for quality." *Id.* A district court in New Jersey rejected the same argument, noting that the defendants were "trying to drape themselves in the mantle of free competition," which was "disingenuous" because their "decision to simulate plaintiffs' trade dress yields society no benefits." Boehringer Ingelheim G.m.b.H. v. Pharmadyne Lab'ys, 532 F. Supp. 1040, 1066 (D.N.J. 1980).

405. In an earlier paper, the Author explored the fact that generic drugs are substituted for medical uses that remain under patent owned by the brand company, leading to infringement. In searching for a solution to this problem, the Author assumed the need to preserve automatic substitution in non-infringing situations. On further reflection, the Author prefers to say that we have an interest in the *dispensing* of generic equivalents when appropriate—

D. Ask the Question Again: A Better Path to Generic Dispensing

Senator Kefauver wrote in 1966 that "the man who orders does not pay, and the man who pays does not order."[406] And of course, neither consumes the product. At the end of the 1970s, when the state law exceptions were locked in place, an FTC official repeated this, saying there was inadequate competition in the drug marketplace because "the consumer who pays does not choose, and the physician who chooses does not pay."[407] The notion is that the party choosing the medicine (the doctor) does not internalize the cost of the medicine and thus, when selecting among treatments in the marketplace, has no reason to consider relative cost.[408] This could, in theory, give brand loyalty undue prominence in the doctor's decision-making, disrupting forces that would ordinarily shift consumption to a less expensive alternative.[409] Even when payors adopted reimbursement strategies to give pharmacists an incentive to dispense the lowest cost drug possible, state laws prohibiting substitution tied the pharmacists' hands.[410] Hence the need for a generic drug exception.

Nearly sixty years have passed since Senator Kefauver made his remark, however, and more than forty years have passed since the states enacted exceptions for early generic drugs. Much has

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rather than in their automatic substitution. *See* Erika Lietzan, *Paper Promises for Drug Innovation*, 26 GEO. MASON L. REV. 168, 195–96 (2018).

406. ESTES KEFAUVER, IN A FEW HANDS: MONOPOLY POWER IN AMERICA 8 (1965).

407. McCarey, *supra* note 318, at 103.

408. Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 10–11 (2009) ("Not having the obligation to pay, doctors are relatively price-insensitive, i.e., they select which drugs to prescribe based on factors other than price."); *id.* at 11 n.33 (collecting various articles from 1993 to 2007 discussing the price insensitivity of doctors).

409. *See, e.g.*, *id.*, at 16 (arguing doctors are "price insensitive and conditioned by years of brand promotion" so "continue to write prescriptions for the brand product," but "[w]hen a generic is automatically substitutable at the pharmacy counter, the price/quality decision is back in the hands of economic decision makers who take account of prices: the pharmacist who makes greater margins on generics suggests them to consumers, and consumers can choose the lower-priced generic or decide that the value of the brand justifies a higher price or higher insurance co-payment"); *see also* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 437 n.7 (1986) ("Because of the enactment of antisubstitution legislation, brand-name manufacturers could insulate their market share by creating brand-name recall in physicians and pharmacists, who would tend to prescribe and dispense brand-name drug products.").

410. McCarey, *supra* note 318, at 103 ("[W]hile the wholesale price differentials between generic and brand-name drug products provides an incentive to substitute, most pharmacists are either prohibited from substituting by state anti-substitution laws or discouraged from doing so by burdensome state product selection laws.").

happened since. When Senator Kefauver wrote, there were no ANDAs and no bioequivalence findings—let alone therapeutic equivalence determinations by the FDA. Soon enough, the FDA created the ANDA and therapeutic equivalence determinations, and later Congress created a statutory generic drug approval framework requiring proof of bioequivalence. The FDA has developed deep expertise in generic drug equivalence, and it has issued nearly two thousand guidance documents with particularized bioequivalence testing instructions sorted by active ingredient.[411] The generic industry has become enormous, profitable, and powerful, with an influential trade association that did not even exist in the 1970s.[412] Patients today are also much more likely to be involved in decisions about treatment, including selection of drugs.[413] Modern patients have access to more information, in part due to the information technology explosion and the revolution in our understanding of human disease and therapeutic options.[414] Further, a series of free speech rulings affirmed the right of consumers to receive information, including information about medical treatments,[415] and in the 1980s,

411. *See generally* U.S. DEP'T OF HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: BIOEQUIVALENCE RECOMMENDATIONS FOR SPECIFIC PRODUCTS (2010) (discussing the FDA's process on designing bioequivalence studies and making FDA bioequivalence studies available to public); *Product-Specific Guidances for Generic Drug Development*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm (last visited Oct. 22, 2021) (listing 1,921 currently published product-specific guidances).

412. *See* Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53, 83 (2018) (discussing emergence of the modern generic company trade association in the early 1980s); Carpenter & Tobbell, *supra* note 285, at 122 (noting that the generic industry was not part of the political landscape in the 1970s and that their trade association at the time lacked power).

413. *See* Tobbell, *supra* note 197, at 83–84 (arguing that multiple factors led the public questioning procedures of treatment decision-making); *see generally* Lewis A. Grossman, *FDA and the Rise of the Empowered Consumer*, 66 ADMIN. L. REV. 627 (2014) (discussing modern consumers' involvement in the regulation of food and drugs).

414. *See* Erika Lietzan & Isabelle Moine-Dupuis, *Early Access to Unapproved Medicines in the United States and France*, 19 YALE J. HEALTH POL'Y L. & ETHICS 1, 14–15 ("[A] patient today has access to more personal health information than a patient fifty years ago, as well as more information about diseases and potential medical interventions.").

415. *E.g.*, Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 756 (1976) (holding that protection of speech is afforded "to the communication, to its source and to its recipients both"); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 74 (D.D.C. 1998) (holding that the FDA's restrictions on use of textbooks and journal reprints to promote unapproved uses of approved drugs violated the First Amendment), *vacated in part sub nom.* Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000) (vacating on

the FDA permitted direct-to-consumer advertising about the uses of prescription drugs.[416]

So much has changed that we might not see market failure if the generic drug exceptions were removed from state law. Even if the initial assault on drug trademarks in the 1960s and 1970s—the subordination of trademark law's dynamic goals for the static goal of cost savings for payors—could be normatively justified, the normative basis collapses if automatic substitution is no longer needed to ensure the least expensive drugs are dispensed when medically appropriate.

Consider, then, a hypothetical world: today's modern world, without generic substitution laws. In this world, substitution of drugs—dispensing a product other than the product ordered—would *always* violate pharmacy law. Taking steps to induce passing off, which includes deception of the customer, would remain unfair competition. Cases asserting as much remain successful today.[417]

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mootness grounds because government changed its interpretation of the statutory provisions).

416. Direct-to-Consumer Advertising of Prescription Drugs, 50 Fed. Reg. 36,677, 36,677 (Sept. 9, 1985).

417. *E.g.*, Par Pharm., Inc. v. Searle Pharms., Inc., No. 85C2027, 1985 WL 2353, at *4 (N.D. Ill. Aug. 20, 1985) (finding it "actionable . . . under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off" (quoting Ciba-Geigy Corp. v. Bolar Pharm. Co., 747 F.2d 844, 852 (3d Cir. 1984))); Am. Home Prods. Corp. v. Chelsea Lab'ys, Inc., 572 F. Supp. 278, 281 (D.N.J. 1982) ("Courses of conduct that make it possible or feasible for a manufacturer or pharmacist to fill a prescription with a medication other than that which the doctor ordered, and to give as little indication as possible that a substitution was made (as by copying trade dress) cannot stand very high on the scale of values. It ranks with selling imitations on the silent pretense that they are genuine. Such courses of conduct ease the passing off of goods."); Hoffman La Roche, Inc. v. Premo Pharm. Lab'ys, Inc., No. 77-1001, 1980 WL 30221, at *13, *15 (D.N.J. Sept. 3, 1980) (suggesting that a company copying the trade dress of another cannot say it is unaware of the possibility that retailers may engage in "passing off" its goods as those of another—particularly when its goal is to have its product provided as a "generic substitute" for the copied goods of others and when it is made aware that pharmacists were, in fact, mislabeling the vial or passing the drug off in some other way); Biocraft Lab'ys, Inc. v. Merck & Co., Inc., 532 F. Supp. 1068, 1074, 1082–83 (D.N.J. 1980) (finding that Biocraft deliberately copied Merck's trade dress for Elavil (amitriptyline) with its generic version, found bioequivalent by the FDA, and approved via the regulatory ANDA paradigm, and in light of evidence of "palming off," granting summary judgment declaring that Biocraft's copying of the trade dress was unfair competition); Pennwalt Corp. v. Zenith Lab'ys., Inc., 472 F. Supp. 413, 418 (E.D. Mich. 1979) ("The exact issue before this court is whether Zenith can be held responsible for a pharmacist's palming off of Phentermine Hydrochloride for Ionamin. This court is in agreement with the Eighth Circuit, Seventh Circuit and the United States District Court for the District of Massachusetts that the answer is yes, and that this result is in conformity with the generalized Michigan law on unfair

Claiming equivalence to induce substitution when the FDA has not found equivalence would be unfair competition or false advertising.[418]

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competition. Anyone who puts goods into the hands of dealers for sale to the public, which contain the means for deceiving purchasers, and which that person can reasonably anticipate may be so used, is subject to injunction against the further providing of these means, to eliminate unfair competition against the goods of another which has been or is likely to be engaged in by the dealers."); Merrell-National Lab'ys., Inc. v. Zenith Lab'ys., Inc., No. 76-2440, 1977 WL 22787, at *5 (D.N.J. Mar. 28, 1977) ("[I]t is this Court's reasoned opinion that the record available to the Court at this time sufficiently indicates that the liability for passing off extends not only to the defendant pharmacies, but also to defendants Zenith and Paramount, i.e., it is very likely that the plaintiff will prevail on the merits regarding its unfair competition claim against all defendants.").

418. These rare cases involve prescription drugs without approved applications and therapeutic equivalence assessments. The reason this happens is not important here. *See* Erika Lietzan, *Access Before Evidence and the Price of the FDA's New Drug Authorities*, 53 U. RICH. L. REV. 1243, 1272–75 (2019) (explaining the history of unapproved prescription drugs). But most courts permit false advertising cases to proceed. *E.g.*, G&W Lab'ys, Inc. v. Laser Pharms., LLC, No. 3:17-cv-3974-BRM-DEA, 2018 WL 3031943, at *13, *20 (D.N.J. June 19, 2018) (permitting Lanham Act claim, state law statutory unfair competition claim, and state unfair competition common law claim based on false claims of equivalence); Ferring Pharms., Inc. v. River's Edge Pharms., LLC, No. AW-09-02601, 2010 WL 3087419, at *3, *5 (D. Md. Aug. 6, 2010) (denying motion to dismiss Lanham Act claim of false or misleading advertising of the unapproved prescription drug "RE Methylphen," which the defendant allegedly claimed had the same amount of the same active ingredient as plaintiff's Prosed, causing private drug data publishing services to list it as a generic for Prosed); Sciele Pharma, Inc. v. Brookstone Pharms., LLC, No. 1:09-CV-3283-JEC, 2010 WL 9098290, at *6–7 (N.D. Ga. June 23, 2010) (denying motion to dismiss Lanham Act false advertising claim relating to claim that defendant's PNV and PNV-DHA prescription prenatal vitamins contain the same amount of the same ingredients as plaintiff's Prenatal Elite and Prenate DHA, causing drug databases to link them and pharmacists to improperly substitute the one for the other); HealthPoint, Ltd. v. Allen Pharm., LLC, No. SA-07-CA-0526-XR, 2008 WL 728333, at *1, *16 (W.D. Tex. Mar. 18, 2008) (denying motion to dismiss Lanham Act false advertising and unfair competition claims grounded in defendant's promotion of its unapproved drug, AllanDerm, as a "generic equivalent to and substitute for" plaintiff's unapproved drug XenaDerm); Pedinol Pharmacal, Inc. v. Rising Pharms., Inc., 512 F. Supp. 2d 137, 140–41 (E.D.N.Y. 2007) (denying defendant's motion for summary judgment on plaintiff's claims of false advertising and unfair competition in violation of the Lanham Act, in turn, grounded in defendant's allegedly false comparisons of its lactic acid product for plaintiff's Lactinol); Axcan Scandipharm Inc. v. Ethex Corp., 585 F. Supp. 2d 1067, 1082–83 (D. Minn. 2007) (denying defendant's motion for summary judgment in a false advertising and unfair competition case involving several defendants who promoted their pancreatic enzyme drugs as having an "identical formulation" to the plaintiff's pancreatic enzyme product, thus allegedly implying their drugs were its "generic equivalent substitute[s]"); Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc., 419 F. Supp. 2d 715, 729, 731 (D. Md. 2006)

But a generic company could truthfully and accurately claim that its product was an approved generic of—and therapeutically equivalent to—a particular branded product, identified by its trademark. This would *not* violate FDA law, nor would it constitute trademark infringement.[419] These claims were impossible in the 1960s and 1970s because the modern generic drug approval framework and *Orange Book* did not yet exist.[420]

Generic companies could brand their products; some already do.[421] They could promote their products directly to payors, pointing to the therapeutic equivalence and lower price, as they currently do.[422] They could promote their products as a class to prescribers:

(denying summary judgment for both parties in Lanham Act unfair competition suit brought by manufacturer of Viravan-S against manufacturer of V-Tann, which it advertised by saying "compare the active ingredient" of Viravan-S); Healthpoint, Ltd. v. River's Edge Pharms., LLC, No. SA-03-CV-984-RF, 2005 WL 356839, at *6 (W.D. Tex. Feb. 14, 2005) (finding plaintiff adequately stated Lanham Act false advertising and unfair competition claims in connection with the defendant's failure to distinguish its product from plaintiff's—in marketing to wholesalers, distributors, pharmacies, and managed care organizations—on any basis other than price, thus leading to widespread substitution); Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc., 388 F. Supp. 2d 967, 978, 980–81 (E.D. Wis. 2005) (denying summary judgment in a similar action involving a defendant that marketed Neosol, which it described as containing the same amount of the same active ingredient as its "reference" product, plaintiff's Nulev); Solvay Pharms., Inc. v. Global Pharms., 298 F. Supp. 2d 880, 886 (D. Minn. 2004) (denying motion to dismiss a company's false advertising claim in connection with a defendant's alleged advertising of its own pancreatic enzyme product as a "substitute" for plaintiff's); Solvay Pharms., Inc. v. Global Pharms., 419 F. Supp. 2d 1133, 1144–45 (D. Minn. 2006) (denying motions for summary judgment regarding plaintiff's false advertising claim in connection with defendant's alleged advertising of its pancreatic enzyme product as "equivalent," "comparable," and "generic" versions of plaintiff's pancreatic enzyme product).

419. *See* 4 MCCARTHY, *supra* note 153, § 23:11 (stating that "use of another's trademark to identify the trademark owner's goods" is "not an infringement" of trademark); *see also Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2021), https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers.

420. *Orange Book Preface: Preface to the 41st Edition*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (stating that the Orange Book was first "distributed as a proposal in January 1979").

421. *See, e.g.*, *Why Branded Generics Matter*, ABBOTT (June 27, 2017), https://www.abbott.com/corpnewsroom/strategy-and-strength/why-branded-generic-matter.html.

422. *See, e.g.*, *Sandoz Launches Ask for Generics Campaign in US, to Raise Awareness of Importance of Sustainable Access to Generic Medicines*, SANDOZ (Nov. 19, 2020), https://www.us.sandoz.com/news/media-releases/sandoz-launches-ask-generics-campaign-us-raise-awareness-importance-sustainable.

"prescribe generic sildenafil!" or even "prescribe generic!"[423] The cost of communicating with prescribers has plummeted since the 1960s and 1970s; a company can now reach prescribers in seconds using modern technology.[424] Generic companies could also promote their products—individually or in classes—directly to patients. (For example: "Generic versions of Viagra are now FDA-approved and available at pharmacies! Ask your doctor to prescribe a low-cost equivalent!")

Doctors may find it easier to write generic prescriptions now because electronic health record systems can eliminate the need to remember active ingredient names, which can be complex and even confusingly similar to the names of related active ingredients.[425] Federal legislation in 2009 authorized the Centers for Medicare and Medicaid Services ("CMS") to provide incentive payments for the adoption and meaningful use of certified electronic health record technology.[426] The ideal electronic health record platform exchanges

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423. *See, e.g.*, Ameet Sarpatwari et al., *Paying Physicians to Prescribe Generic Drugs and Follow-On Biologics in the United States*, PLOS MED. (Mar. 17, 2015), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001802#sec007 (considering various physician-centered strategies to promote generic drug prescribing).

424. *See* Elaine K. Howley, *Do Drug Company Payments to Doctors Influence Which Drugs They Prescribe?*, U.S. NEWS & WORLD REP. (Aug. 31, 2018, 9:00 AM), https://health.usnews.com/health-care/patient-advice/articles/2018-08-31/do-drug-company-payments-to-doctors-influence-which-drugs-they-prescribe.

425. This Article uses "electronic health record" ("EHR") to mean a computerized medical information system that collects, stores, and displays patient information and that is capable of exchanging information with other, interoperable, computerized medical systems elsewhere in the health information technology infrastructure. Within the literature, some would use "electronic medical record" ("EMR") for such a system, while others would reserve EMR for the electronic version of an old-fashioned paper record *within* a doctor's office and EHR for the record meant for sharing with other health organizations. On terminology, see Albert Boonstra & Manda Broekhuis, *Barriers to the Acceptance of Electronic Medical Records by Physicians from Systemic Review to Taxonomy and Interventions*, BMC HEALTH SERVS. RSCH. (Aug. 6, 2010), https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-10-231; Samuel D. Hodge, Jr. & Joanne Callahan, *Understanding Medical Records in the Twenty-First Century*, 22 BARRY L. REV. 273, 278–85 (2017) (describing the components of an EMR). For histories of EMRs, see Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know About the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7, 9–14 (2013); John Jay Kenagy, *Regulating Electronic Health Records Through the "Nuclear" Threat and Other Enforcement Options: Federal Government Actions to Compel EHR Industry Changes*, HEALTH LAW., Feb. 2021, at 5, 6–8.

426. *See* Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 467 (2009); *see also Promoting Interoperability Programs*, CTRS FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms?redirect=/herincenti

information with other provider's health information technology systems as needed.[427] Healthcare providers who have adopted these systems send electronic prescriptions to dispensing pharmacies.[428] Today, when a prescriber types a brand name (such as "Zocor") into a provider's electronic prescribing system, the program may offer the option to write, instead, a prescription for simvastatin.[429] In a world without generic drug substitution laws, electronic prescribing interfaces could default to a generic prescription, nudge the prescriber towards a generic prescription, or simply offer the prescriber a choice.

Payors will play the most important role. Since the 1960s and 1970s, payors have developed increasingly sophisticated strategies to steer doctors and patients to generic drugs.[430] For instance, a payor's formulary committee may simply decline to cover the brand drug, excluding the product from coverage and listing only the generic drugs.[431] Or it may adopt a tiered formulary to drive patients to generic copies. In a tiered formulary, preferred medications (generic equivalents) are placed in a tier that involves lower costs for the patient, while a nonpreferred medication (the brand product) is placed in a higher-cost tier.[432] In this case, patients sensitive to copayment differences could ask their doctors to prescribe generic

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veprograms (Sept. 16, 2021, 11:45 AM); *Get the Facts About Electronic Health Records: Advancing America's Health Care*, OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., https://www.healthit.gov/sites/default/files/pdf/fact-sheets/ehrs-advancing-americas-health-care.pdf (last visited Oct. 22, 2021).

427. Terry, *supra* note 425, at 27 ("EHRs should be able to exchange information with other EHRs (for example, other providers' systems), share data with patients and external stakeholders such as public health authorities, and share information across an institution's HIT ecosystem (such as with e-prescribing, CPOE, or clinical decision support (CDS) modules).").

428. *What is Electronic Prescribing?*, OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. (Sept. 10, 2019), https://www.healthit.gov/faq/what-electronic-prescribing.

429. *See, e.g.*, *Cholesterol-Lowering Drug,* CLEVELAND CLINIC (July 28, 2020), https://my.clevelandclinic.org/health/drugs/8744-cholesterol-lowering-drugs (listing simvastatin as generic name for Zocor side by side).

430. *See* Erika Lietzan, *The Uncharted Waters of Competition and Innovation in Biological Medicines*, 44 FLA. ST. U. L. REV. 883, 907–09 (2017) (explaining the power of payors to select medicines); *see also* Joanna Shepherd, *Deterring Innovation:* New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry*, 17 MINN. J.L. SCI. & TECH. 663, 688–92 (2016) (explaining the power of payors to select medicines).

431. *See, e.g.*, Alison Kodjak, *Will Your Prescription Meds Be Covered Next Year? Better Check!*, NPR (Aug. 15, 2016, 4:32 AM), https://www.npr.org/sections/health-shots/2016/08/15/489790412/will-your-prescription-meds-be-covered-next-year-better-check.

432. Cole Werble, *Formularies*, HEALTHAFFAIRS 11 (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/listitem/hpb_2017_09_14_formularies.pdf.

drugs. The payor's formulary committee might impose a "prior authorization" requirement so that the patient must obtain permission before the brand product will be covered.[433] Already today, some research suggests payor practices are more important than generic drug substitution laws in keeping healthcare expenditures down.[434] Without the laws, payor practices would presumably play the primary role.

The primary cost of eliminating the generic substitution laws would be the added burden for pharmacists and doctors. If a doctor still selects a branded product and the pharmacist discovers the payor will not cover the brand drug (or has implemented provisions that favor the generic drug), the doctor and pharmacist will need to communicate about whether an alternative covered drug is suitable. Payors and others motivated to shift patients to generic drugs—including the generic industry—could reduce this burden by promoting the availability of particular generic equivalents and encouraging doctors to engage in generic prescribing outright. Shifting the burden to payors and generic companies makes some sense because they stand to benefit; they have an incentive to invest in the process and steer doctors and patients to generic drugs.

In this hypothetical world, after approval of a generic equivalent, a prescription specifying the brand product would reflect a doctor's deliberate choice. This choice, in turn, would reflect the doctor's familiarity with the brand company and its products; it would reflect brand loyalty and the goodwill the brand company has built up. This is how a trademark is supposed to function.[435] Conversely, a prescription specifying the active ingredient would also align with the purpose of trademark law. By specifying the active ingredient instead of a particular company's approved product, the doctor signals indifference as to source, which trademark law permits.[436] Here, the brand company has accrued insufficient goodwill to maintain sales once less expensive equivalents—or less expensive drugs with the same active ingredient—are available.

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433. *See Prior Authorization*, ACAD. OF MANAGED CARE PHARMACY (July 18, 2019), https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/prior-authorization.

434. *See generally* Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, 298 JAMA 61 (2007) (describing research that suggests strategies adopted by health plans and other payors to steer doctors and patients to lower-priced drugs have reduced the role of state substitution laws in keeping expenditures down).

435. *See* Margaret Chon, *Trademark Goodwill as a Public Good: Brands and Innovations in Corporate Social Responsibility*, 21 LEWIS & CLARK L. REV. 277, 291–92 (2017).

436. *See* Alexandra J. Roberts, *Trademark Failure to Function*, 104 IOWA L. REV. 1977, 1992 (2019).

CONCLUSION

This Article argues that the generic drug substitution laws of the 1970s sacrificed the procompetitive and dynamic goals of trademark law, based on a theory of market failure that may not be accurate anymore, for short-term cost savings that could now be accomplished if generic companies assumed some responsibility for promoting their own products and pharmacists and physicians accepted the burden of engaging in conversations, when needed, about what lies in the best interest of particular patients. Under the circumstances, repeal of the generic drug exceptions makes sense, and market participants should focus on ways to encourage use of generic drugs without undermining marks.[437] A senior brand-industry lawyer, upon hearing the topic and thesis of this Article, commented that generic drug substitution is "water under the bridge." That is a fair criticism; repeal of the generic drug exception is unlikely as a political matter.[438] Moreover, it is possible generic drug substitution is diminishing in practical importance; perhaps doctors are already switching to prescribing by active ingredient, and perhaps payors are already forcing them to do so.

But the Article relates to two live and important issues. First, it responds in part to continued attacks on drug trademarks in the literature, such as a recent proposal that generic drug manufacturers be allowed to adopt the brand name of the reference drugs on which their drugs are based.[439] This is nothing new; there were similar arguments in the 1970s, including the proposal that the FTC seek cancellation of drug trademarks at patent expiration on the ground the names had become generic.[440] So long as these arguments appeal to other scholars and receive attention from policymakers, a response grounded in the role of trademarks and the essential difference between drug patents and drug trademarks remains important. Second, it points to another area of scholarship and policy writing in which sloppiness about the distinction between drugs, on the one

437. *See* Niteesh K. Choudhry et al., *Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities from the Greater Use of Generic Medications: Best Practice Advice from the Clinical Guidelines Committee of the American College of Physicians*, 164 ANNALS INTERNAL MED. 41, 46–47 (2016).

438. *See* NAT'L CONF. OF STATE LEGISLATURES, GENERIC DRUG SUBSTITUTION LAWS 1–4 (2019), https://www.ncsl.org/portals/1/documents/health/Generic_Drug_Substitution_Laws_32193.pdf (showing support from numerous states for generic drug substitution).

439. Sarpatwari & Kesselheim, *supra* note 52.

440. Michael F. Kuzow, *The FTC and the Generic Doctrine: A New Rx for Pharmaceutical Trademarks*, 15 TULSA L.J. 327, 343–46 (1979).

hand, and products, on the other hand, leads to analytical error.[441] The likely rejoinder to the thesis of this Article—that the drugs are the same—reflects this error. Sloppiness about the term "drug" in the academic literature relating to drug innovation and intellectual property[442] confuses the public and policymakers alike and can lead to reform proposals that lack a rational basis. It should be shunned, and it should be corrected whenever possible.

441. *See* Lietzan, *supra* note 331, at 811–12 (discussing how this sloppiness has led to fundamental legal and factual errors in scholarship and policymaking relating to so-called "evergreening").

442. *See id.* at 811–16.