14-4624

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

STATE OF NEW YORK, BY AND THROUGH ERIC T. SCHNEIDERMAN, ATTORNEY GENERAL,

Plaintiff-Appellee,

v.

ACTAVIS PLC AND FOREST LABORATORIES, LLC,

Defendants-Appellants

From The United States District Court
For The Southern District Of New York
Case No. 14-CV-7473 (RWS)

BRIEF OF THE AMERICAN ANTITRUST INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES

Richard M. Brunell
Vice President & General Counsel
American Antitrust Institute
2919 Ellicott Street, NW
Washington, DC 20008
Tel: (202) 600-9640

Steve D. Shadowen
HILLIARD SHADOWEN, LLP
39 West Main Street
Mechanicsburg, PA 17055
Tel: (855) 344-3298

Attorneys for Amicus Curiae

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INTEREST OF AMICUS CURIAE

Amicus American Antitrust Institute ("AAI") is an independent and non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws.[1] AAI is managed by its Board of Directors with the guidance of an Advisory Board consisting of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders.

For many years, AAI has actively examined competition issues in prescription pharmaceutical markets, submitting amicus curiae briefs in a number of important cases involving the industry, including in the Supreme Court, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), and in this Court, *In re: DDAVP Direct Purchaser Antitrust Litig.,* 585 F.3d 677 (2d Cir. 2007); *In re Tamoxifen Citrate Antitrust Litig*., 429 F.3d 370 (2d Cir. 2007).

Just as the Supreme Court in *Actavis* rejected the pharmaceutical industry's arguments that drug manufacturers should be immune from antitrust scrutiny when they game the Hatch Waxman Act to delay generic entry by agreement, so too should this Court reject the industry's efforts to immunize brand drug

[1] Individual views of members of the Board of Directors or the Advisory Board may differ from AAI's positions. No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person or entity—other than AAI or its counsel—has contributed money that was intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a).

manufacturers from antitrust scrutiny when they engage in "product hopping" to game state drug substitution laws to thwart generic entry.

INTRODUCTION AND SUMMARY OF ARGUMENT

Defendants assert that a monopolist pharmaceutical manufacturer that redesigns its product and coerces doctors and patients to adopt it, with the purpose and effect of impairing generic substitution, is nevertheless entirely immune from antitrust scrutiny. Such a rule would be bad law and worse social policy.

Courts are, of course, properly skeptical of claims that a monopolist's redesign of its product is exclusionary conduct actionable under Section 2 of the Sherman Act. *See United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc). After all, consumers benefit not only from low prices, but also from innovation. But antitrust law must be keenly attentive and attuned to the specific characteristics of the markets in which the alleged anticompetitive conduct occurs. *See, e.g.*, M. Lemley, *Industry-Specific Antitrust Policy for Innovation*, 2011 COLUM. BUS. L. REV. 637, 648-49 (2011) (surveying case law and finding that antitrust courts "have focused on the economic characteristics of the individual industry before them"). Some markets have characteristics that increase the opportunity and incentive for a monopolist to redesign its product not to benefit consumers, but to exclude rivals. Accordingly, "[j]udicial deference to product innovation . . . does not mean that a monopolist's product design decisions are per

se lawful." *Microsoft Corp.*, 253 F.3d at 65.

The Supreme Court recently noted that prescription pharmaceutical markets have economic and regulatory characteristics that call for particular antitrust vigilance. *Actavis,* 133 S. Ct. 2223. The Court observed the "general procompetitive thrust of the [Hatch-Waxman Act]," and held that courts must thoughtfully apply antitrust law to prevent manufacturers from manipulating the "unique regulatory framework." *Id*. at 2234, 2235. The statute "unintentionally . . . created special incentives" for anticompetitive conduct, and courts applying antitrust law must take those anticompetitive incentives into account. *Id*. at 2235 (citation omitted).

A critical characteristic of prescription pharmaceutical markets is that in these markets, consumers do not make the quality/price choice that usually results in product reformulations that advance consumer welfare. Instead, the doctor chooses what product the consumer will buy, but the consumer (and/or her insurer), not the doctor, pays for the product. This "price disconnect"—the separation between product selection and payment obligation—is a substantial market defect. That market failure fully justifies antitrust scrutiny of a monopolist manufacturer's product hopping that is, on its face, an effort to impair the very mechanism (generic substitution) that the regulatory scheme has adopted to ameliorate the market failure. Where, as here, the product-hopping scheme

involves a "forced switch," liability is clear. But anticompetitive product hopping is not limited to such circumstances.

A product reformulation prevents the generic product from being substitutable at the pharmacy counter for the redesigned brand product, and thus impairs the generic's most cost-efficient (and only commercially feasible) means of competing. The reformulation may have no clinical benefits whatsoever. Or it may provide benefits to some consumers but would not be successful in a well-functioning market. Or, as the district court found in this case, the brand manufacturer may employ coercive techniques before generic entry to ensure that consumers' access to far less expensive generics does not undermine the brand manufacturer's monopoly. In each of these circumstances courts and consumers cannot rely on the market to protect consumer welfare.

Defendants and their amici apparently believe that exclusionary conduct directed at undermining generic competition enabled by generic substitution laws should be lawful because these laws, in their view, do not promote legitimate competition, but "free riding." On the contrary, undermining such *lawful* competition is anticompetitive because generic substitution laws are a key means by which the Hatch-Waxman Act ensures that brand manufacturers do not extend their economic monopolies beyond the exclusivity period provided by patents or FDA regulation.

I. THE "PRICE DISCONNECT" PREVENTS THE MARKET FROM DETERRING ANTICOMPETITIVE PRODUCT HOPPING

Empirical research regarding the annual lost consumer welfare from anticompetitive pharmaceutical redesigns suggests that the losses are on the order of some tens of billions of dollars a year. *See* S. Shadowen, K. Leffler & J. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 49 RUTGERS L.J. 1, 3 (2009) ("Shadowen, *Anticompetitive Product Changes*"). That is, as a result of these "product hops," consumers are annually paying billions more for redesigned products that bring little or no additional clinical benefit as compared to the original products they replaced.

The skeptic asks: If the high-priced redesigned product is not substantially better than the generic version of the original product, why would consumers buy the redesigned product? Won't the redesigned product fail in the market if it is not substantially better than the original product?

Understanding the economics that underlie the answer to these questions is the key to understanding why product hops are an effective way for brand manufacturers to thwart competition from generics. Understand why drug purchasers pay $2 per pill for a branded tablet when a generic capsule is available for 20¢, and you understand why product hops can be anticompetitive, even when the design change is not as trivial.

A. A "Price Disconnect" Plagues Prescription Pharmaceutical Markets

The relevant economics are straightforward and well documented in the literature. In well functioning markets, manufacturers' product design changes ordinarily lead to increased consumer welfare. When a consumer both selects and pays for the new product, she will weigh its qualities against its price and decide whether any additional cost is worth the benefit. With the price/quality trade-off in consumers' hands, manufacturers will be incentivized to make design changes that consumers are likely to value enough to pay for. New products that do not meet the "market test" will simply fail.

However, these market forces break down when the person who must pay for the product does not select it, and the person who selects it does not pay. Prescription pharmaceutical markets, in which doctors choose which product the patient will buy, are characterized by just such a "price disconnect." M. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1011 (2010) ("Carrier, *Real World*"); Drug Product Selection, Staff Report to the FTC, Bureau of Consumer Protection, at 2–3 (Jan. 1979) ("FTC Staff Report").[2] Thus, "the institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among

[2] Relevant portions of the FTC Staff Report are attached hereto as Exhibit A.

brands; it has been the physician." A. Masson & R. Steiner, FTC, *Generic Substitution And Prescription Drug Prices: Economic Effects Of State Drug Product Selection Laws, at* 5 (1985) ("FTC Generic Substitution Report").[3]

The "consumer price/quality choice" that usually disciplines markets does not exist in these markets. To buy the product, the consumer needs a prescription from her doctor. But the doctor is likely to be relatively price-insensitive, i.e., to not take price into account (or take it fully into account) when choosing which product the consumer will buy. As the FTC has concluded, "[t]he basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay." FTC Staff Report, at 2-3; *see also* Carrier, *Real World*, at 1011; M. Hurwitz & R. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J. L. & ECON. 299, 300 (1988).[4] Brand manufacturers like Forest exploit this market defect by promoting their brand products to doctors through armies of sales force "detailers"[5] on bases other than price. Carrier, *Real World*, at 1020.

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[3] Relevant portions of the FTC Generic Substitution Report are attached hereto as Exhibit B.

[4] The extensive literature on doctors' insensitivity to drug prices is gathered in Shadowen, *Anticompetitive Product Changes*, at 10-11 & n.33.

[5] A "detailer" is a sales representative who makes in-person sales calls on doctors. Detailing is generally the most effective means of marketing branded pharmaceuticals. *See* Shadowen, *Anticompetitive Product Changes*, at 11 & n.36.

B. DPS Laws Were Intended to Restore Market Forces

The Hatch-Waxman Act seeks to ensure that generics can enter the market as soon as the brand drug goes off patent, and encourages generics to challenge such patents. *See Actavis*, 133 S. Ct. at 2228-29. But generic entry would be largely ineffective in a world without state Drug Product Selection ("DPS") laws, i.e., generic-substitution laws. Those laws were specifically designed to ameliorate this price disconnect and help restore consumers' price/quality choice. Carrier, *Real World*, at 1013, 1017–18; FTC Generic Substitution Report, at 7; FTC Staff Report, at 273. The DPS laws permit or require the pharmacist to dispense a cheaper generic drug in lieu of a brand drug whenever the consumer consents. The economic insight underlying those laws is straightforward:

> Since physicians are an unlikely force behind a switch to lower-cost brands after the patent period has expired, an erosion of the patent-conferred monopoly must depend on others who have both the power and the incentive to respond to lower prices. That is the role envisioned for the drug product selection laws: to transfer some of this power to pharmacists. Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition from other pharmacies on prescription prices.

FTC Generic Substitution Report, at 7.

DPS laws "shift the choice of [product] for most prescriptions from the physician to the pharmacist." *Id*. at 1. In short, DPS laws "foster price competition by allowing the only principals who have financial incentives to make price

comparisons—the pharmacist and the patient—to select drug products on the basis of price." FTC Staff Report, at 7.

When the generic substitution system works as intended, the availability of a generic alternative effectively puts the price/quality choice back in consumers' hands. The doctor, price insensitive and conditioned by years of brand marketing, may continue to write prescriptions for the brand product. But pursuant to the DPS laws, the pharmacist (with the consumer's consent) can substitute the less expensive generic. Consumers benefit from lower drug costs and lower health insurance premiums.

C. Product Hopping Can Thwart the Generic Substitution that Would Restore Market Forces

Other aspects of the regulatory regime, however, provide an opportunity for brand manufacturers to prevent generic substitution. As a health and safety measure, the DPS laws permit generic substitution only if the FDA finds that the generic product is bioequivalent (is absorbed in the body at approximately the same rate) and therapeutically equivalent (has the same active ingredient, form, dosage, strength, and safety and efficacy profile) to the brand drug. The FDA awards an "AB-rating" to a generic drug that meets these substitution criteria, meaning that the pharmacist can substitute it when presented with a prescription for the branded product. As developed fully below, substitution at the pharmacy counter is a generic manufacturer's *only commercially feasible means of competing*

against the brand drug. This puts a premium on the generic obtaining an "AB-rating." Carrier, *Real World*, at 1018.

Brand manufacturers like Forest can prevent generic substitution—they can game the system—by changing the dosage form of the brand product before the generics enters the market. Then the generic product will not be AB-rated to the reformulated brand drug and will not be substitutable for it. Tweaking the dosage form prevents generic substitutability and thereby substantially impairs the generic's only viable means of competing. That tweaking also simultaneously erects a new set of regulatory barriers to entry—a years-long process of getting FDA approval for the new formulation[6] and possibly also an additional 30-month stay and new patent litigation. Carrier, *Real World*, at 1018–19.

Forest's insistence that its product hop preserved "consumer choice" ignores these well-known facts of the prescription pharmaceutical marketplace. Moreover, Forest's restricting the supply of Namenda IR is the antithesis of preserving consumer choice, and belied its claims that Namenda XR was materially superior to Namenda IR and was preferred by doctors and consumers. While not necessary to Plaintiff's theory, it is worth noting that even before it planned to withdraw Namenda IR, Forest's "cannibalization" of the prescription base did not reflect the

[6] In 2014 the median time to get FDA approval of an ANDA was 42 months. *See* Dept. of Health & Human Services, Federal Drug Administration, *Justification of Estimates for Appropriations Committees for Fiscal Year 2016*, at 65.

merits of the two products. Doctors received an entirely one-sided presentation as to the comparative qualities of Namenda IR versus Namenda XR. Manufacturers of other brand products had no incentive to counter Forest's message that the latter is superior to the former. Carrier, *Real World*, at 1019. And, of course, the cheaper generic Namenda IR was not yet available.

It is true, of course, that *after* generics enter the market they could try to win back some of those prescriptions. But the evidence (supported by the literature[7]) is that due to the price disconnect and other characteristics of the pharmaceutical marketplace, generics will have no viable means of regaining those prescriptions. *New York v. Actavis, PLC,* 14 Civ. 7473, 2014 WL 7015198, at *30-31 (S.D.N.Y. Dec. 11, 2014). Doctors whom Forest recently switched from prescribing Namenda IR to Namenda XR would be very reluctant to switch patients back to IR. And generic manufacturers do not (and economically cannot) use detailers to visit doctors and encourage them to switch back.[8] These are the economic realities that make it essential to Forest's anticompetitive scheme to convert the prescription base before the generics enter. *Id.* at *20 ("Once generic memantine became available, generic and branded Namenda IR would be AB substitutable at the pharmacy, and most patients with prescriptions for Namenda IR would likely

[7] *See, e.g.*, Carrier, *Real World*, at 1018, 1021; Shadowen, *Anticompetitive Product Changes*, at 54-55 (summarizing literature, reports, and other evidence).
[8] These economics are explained in detail in Shadowen, *Anticompetitive Product Changes*, at 46-48.

switch to generic memantine instead of Namenda XR."). If not enjoined, the scheme likely will succeed.

II. AMPLE AUTHORITY SUPPORTS ANTITRUST SCRUTINY OF PRODUCT HOPPING

Prescription pharmaceutical markets are not well functioning markets. Especially in these circumstances, ample authority supports subjecting product hopping in these markets to antitrust scrutiny.

Berkey Photo

The relevant case law on product redesigns starts with this Court's decision in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979). There a competitor asserted that Kodak unlawfully used its monopoly in film to make sales of cameras and film-processing services. Kodak designed its new 110 camera so that it could be used only with its new Kodacolor II film, and, for a period of eighteen months, Kodak made Kodacolor II film only for the 110 camera. The *Berkey Photo* Court rejected Plaintiff's attack on the introduction of the new film that the evidence showed that while Kodacolor II film was inferior to its predecessor, Kodacolor X, in some respects, it was superior in others. The Court held that the market was able to determine the products' relative merits "so long as the free choice of consumers is preserved." *Id*. at 287.

Berkey Photo considered a market in which consumers *did* make the price/quality choice. In such a market, said the Court, whether the price/quality

proposition offered by a reformulated product is superior to that offered by the original product is properly "inferred from the reaction of the market." *Id*. When consumers make the price/quality choice, the market will reflect "whether there is sufficient demand for a particular product to make its production worthwhile . . .." *Id*.

Importantly, the Court expressly limited its holding to those situations in which "free choice of consumers is preserved." *Id*. Thus, while the mere introduction of the new film and camera was not actionable, "the situation might be completely different if, upon introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera." *Id.* at 287 n.39. Moreover, Kodak arguably did prevent free consumer choice by restricting the use of the new Kodacolor II film to its own camera for the first eighteen months after entry. Given the 18-month "head start" for the Kodak camera, a consumer's decision to buy the Kodak camera might not reflect a decision that it was superior to competing cameras, but merely that it was the only camera that was compatible with the preferred film. Plaintiff failed, however, to produce evidence that it was injured. *Id*. at 288.

Thus, Forest is wrong when it asserts that *Berkey Photo* holds that consumers make free price/quality choices and therefore product reformulations are competitively benign. Instead, *Berkey Photo* holds that *if* consumers are

provided with and allowed to make such choices *then* a product reformulation will be benign.

Microsoft

The en banc decision in *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001), is the most prominent appellate case that analyzes a product redesign in a market that does *not* preserve the consumer's price/quality choice. The Court rejected Microsoft's argument that product redesigns should be per se lawful, and instead subjected them to rule-of-reason analysis under Section 2. *Id*. at 89-96.

Microsoft redesigned its operating system so that Netscape's rival internet browser would not be compatible with the system. The strong "network effects"[9] and installed base of existing Microsoft customers impaired free consumer choice and thereby increased the importance of compatibility between Microsoft's operating system and rivals' internet browsers. Professor Hovenkamp explains that in *Microsoft* this "premium on compatibility" allowed "a dominant firm . . . [to] exclude rivals anticompetitively by engineering incompatibilities between the dominant product and the product offered by rivals." IIIB Areeda & Hovenkamp, ANTITRUST LAW ¶776c, at 297 (3d ed. 2008). In markets with significant network externalities, compatibility may be "a key to market success." *Id*. Consequently,

[9] In essence, "network effects" exist to the extent that one person's utility from using a product depends in substantial part on how many other people also use it. For example, my telephone is more useful to me if many other people also use telephones.

the premium on compatibility "increas[ed] both the incentive and the opportunities" for anticompetitive product redesigns. *Id*. at 297. These economic realities supported antitrust scrutiny of Microsoft's product redesigns under the rule of reason. *Microsoft Corp.*, 253 F.3d at 95.[10]

Like the network effects in *Microsoft*, the price disconnect in the pharmaceutical market prevents consumers from making the relevant price/quality choice and thus heightens the importance of compatibility—AB substitutability—of generic drugs. For generic pharmaceuticals, compatibility with the branded product is essential to market success, and brand manufacturers' incentives and opportunities for welfare-reducing reformulations are consequently even greater than those in *Microsoft*. Just as in *Microsoft*, the monopolist has the means and incentive to redesign the product with anticompetitive effect, and its redesign therefore must be subject to antitrust scrutiny.[11] *See Actavis,* 133 S. Ct. at 2235

[10] A host of other cases have likewise concluded that a monopolist's product redesign can be unlawfully exclusionary under Section 2. *See, e.g.*, *C. R. Bard v. M3 Sys.,* 157 F.3d 1340, 1382 (Fed. Cir. 1998); *Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Pub., Inc.*, 63 F.3d 1540, 1551 (10th Cir. 1995); *Northeastern Tel. Co. v. AT&T*, 651 F.2d 76 (2d Cir. 1981); *Apple iPod iTunes Antitrust Litigation*, 2010 WL 2629907 (N.D. Cal. June 29, 2010); *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295 (D. Utah 1999); *Xerox Corp. v. Media Sciences Int'l, Inc*., 511 F. Supp. 2d 372, 388 (S.D.N.Y. 2007); *IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965, 1003 (N.D. Cal. 1979), *aff'd on other grounds*, 698 F.2d 1377, 1382 (9th Cir. 1983).

[11] This key fact—the presence of a price disconnect in the market here—also distinguishes other cases on which Defendants rely. *See Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1002 (9th Cir.

(regulatory framework for pharmaceuticals "unintentionally . . . created special incentives" for anticompetitive conduct).

Indeed, the product switch here not only destroyed generic substitutability but also called forth a whole new set of regulatory barriers to entry. To become substitutable for Namenda XR, the generic manufacturers must start the FDA approval process all over again, and wait out another 30-month stay under the Hatch-Waxman Act because Forest asserts that Namenda XR is protected by patents, regardless of the strength of those patents.

An Established Market Defect

To be sure, many markets are characterized by *some* defect that prevents perfect competition. For several reasons, however, the Court can be confident that the price disconnect in prescription pharmaceutical markets is a *very substantial* defect that fully warrants subjecting product hopping to antitrust scrutiny. *See Verizon v. Trinko*, 540 U.S. 398, 411 (2004) ("Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue.").

First, as demonstrated in detail above, the DPS laws in all fifty states and the District of Columbia are founded on the existence of the price disconnect. A

2010) (no price disconnect; and plaintiffs "presented no evidence to refute that" the redesigned product was superior); *Response of Carolina Inc. v. Leasco Response Inc.*, 537 F.2d 1329, 1330 (5th Cir. 1976) (no price disconnect; plaintiff's contention that its components were not compatible with defendant's new design was "completely without evidentiary support").

market defect that elicits remedial legislation in every jurisdiction in the nation is a very substantial defect that courts must take into account in deciding whether to subject conduct to antitrust scrutiny. *Cf. In re Schering-Plough Corp.*, FTC Dkt. No. 9297, 2003 WL 22989651 (Dec. 8, 2003) at *24 (the "underlying premise of these [DPS] laws … is that generic competition has the potential to lower prices" and "these regulations need to be accepted as real market factors in an antitrust analysis").[12]

Second, leading antitrust authorities have recognized that such a market defect, which directly severs the product selection from the payment obligation, must be acknowledged in the antitrust analysis. For example, as noted above in the discussion of the *Microsoft* case, Professor Hovenkamp counsels antitrust courts to be particularly vigilant in cases, such as those involving complementary products, where market circumstances "place a premium on compatibility" and thus "increase both the incentive and the opportunities for certain kinds of anticompetitive behavior." IIIB Areeda & Hovenkamp, ANTITRUST LAW ¶776c, at 297 (3d ed. 2008). And he concludes that product redesigns in the pharmaceutical industry fall into this category. Hovenkamp & Lemley, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW

[12] The FTC Commission decision was reversed on other grounds by *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), which was disapproved of by the Supreme Court in *Actavis*.

("Hovenkamp, IP AND ANTITRUST") § 15.3, at 25 (2012). (pharmaceutical product redesigns should be evaluated "[u]nder the analysis we offer in section 12.3e3," which addresses design changes intended to impair competition from complementary products); *see also* J. Jacobson, et al., *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 LOYOLA CONSUMER L. REV. 1, 8 (2010) ("There are two scenarios where an exclusionary redesign may be especially harmful: (a) in the context of network markets . . . and (b) pharmaceutical markets . . .").

Third, courts have recognized that the price disconnect requires antitrust scrutiny of prescription pharmaceutical product hopping. In *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 420–23 (D. Del. 2006), the brand manufacturer implemented two switches, one from capsules to tablets and another from one dosage strength to another. The manufacturer cannibalized the original prescription base before the generics could enter the market and withdrew the original product from the market. *Id*. at 415–18. Judge Jordan noted that courts' usual reluctance to evaluate product redesigns is founded on "the success of those products in an *open market*, and the related conclusion that the harm to [defendant's] competitors was a matter of consumer choice." *Id.* at 421 (emphasis added). Where, to the contrary, "the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate." *Id*.

The court held that the price disconnect prevents consumers from making the relevant price/quality choice, so the product switch is subject to inquiry under the rule of reason:

> The nature of the pharmaceutical market, as described in Plaintiffs' allegations, persuades me that the rule of reason approach should apply here as well. The per se standard proposed by Defendants presupposes an open market where the merits of any new product can be tested by unfettered consumer choice. But here, according to Plaintiffs, consumers were not presented with a choice between [drug] formulations.

Id. at 422.

Most recently, the court in *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litigation*, 2014 WL 6792663 (E.D. Pa. Dec. 3, 2014), applied the rule of reason to pharmaceutical product hopping, noting that the "analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind." *Id.* at *10. Specifically:

> Plaintiffs have plausibly alleged that various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals. For example, Plaintiffs assert that a disconnect exists between the person paying for the prescription and the person selecting the appropriate treatment. Due to this disconnect, the ordinary market forces that would allow consumers to consider price when selecting a product are derailed. The patient also cannot simply request to receive a generic from his or her pharmacist because the film and the generic tablets are not AB-rated and thus may not be substituted.

Id. at *12.

Given defendant's conduct and the price disconnect, the court held that "Plaintiffs have plausibly pleaded exclusionary conduct, as required for an antitrust claim." *Id*.

Fourth, the specific evidence adduced by Plaintiff New York provides a further guarantee that antitrust immunity is not warranted here. Among other things, Plaintiff proved that Forest's conduct flunked the "profit-sacrifice" test or the "no economic sense" variant. That test essentially asks whether the challenged conduct's benefits to the monopolist are greater than the costs to the monopolist, absent the effect of impairing competition.[13] Essentially, it is an economic test to determine whether the monopolist's *sole motive*—and therefore the highly likely effect—was to impair competition; if the monopolist engages in conduct that would be money-losing absent the impairment of competition, then the fact finder can infer that the monopolist was motivated solely to impair competition. *See* A. Melamed, *Exclusionary Conduct Under the Antitrust Laws: Balancing, Sacrifice, and Refusals to Deal*, 20 BERKELEY TECH. L.J. 1247, 1255 (2005) ("[T]he sacrifice test asks whether the allegedly anticompetitive conduct would be

[13] In contrast, the rule of reason, adopted by the D.C. Circuit in *Microsoft*, asks whether the benefits of the design change to consumers are greater than the losses to consumers. The profit-sacrifice test is therefore more forgiving to the monopolist. *See generally* S. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311 (2006). While the rule of reason is the normal test under Section 2 as well as Section 1 of the Sherman Act, the Court need not decide here which test is appropriate for analyzing product hopping by a monopolist.

profitable for the defendant and would make good business sense even if it did not exclude rivals and thereby create or preserve market power for the defendant.").

Plaintiff adduced evidence that the planned withdrawal and restriction of the supply of Namenda IR sacrificed profits and made no economic sense but for its impairment of generic competition. *See* Appellee Br. 15 (showing that conduct sacrificed sales to some consumers who would not switch). This is hardly surprising since one would expect that eliminating a profitable product for which there is consumer demand would be costly.

More generally, although not necessary to Plaintiff's case, there is evidence that the product redesign itself made no economic sense but for its impairment of generic competition. The district court found that "to be successful, its product switch had to be accomplished before less expensive generic versions of Namenda IR tablets became available to the market . . .. [Otherwise,] most patients with prescriptions for Namenda IR would likely switch to generic mematine instead of Namenda XR." *New York*, 2014 WL 7015198, at *20.

As applied to product redesigns, "[if] a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technological benefits." Hovenkamp, IP AND ANTITRUST, § 12.3. In other

words, if a drug reformulation would not be profitable if it were introduced *after* generic entry, then it presumably lacks significant clinical advantages and never would have been introduced in a well functioning market.

As leading commentators have concluded, "product hopping [by brand drug manufacturers] to ward off generic competition is precisely the sort of behavior the Sherman Act condemns. While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition." Hovenkamp, IP AND ANTITRUST § 15.3.

III. THE ARGUMENTS FOR ANTITRUST IMMUNITY ARE MISPLACED

Defendants and their amici offer a hodge-podge of arguments against the straightforward application of Section 2 to the unique characteristics of the pharmaceutical market. Those arguments are based on mistaken views of the law and misapprehensions of the economic characteristics of this market.

Patent Right

Defendants and their amici assert that Forest has a right under the patent law not to sell Namenda IR. Def. Br. at 36. But Plaintiff does not complain of a mere failure to sell Namenda IR. Rather, the complaint is that the withdrawal of the product is part of a product hopping scheme to transition sales from Namenda IR to Namenda XR before generic Namenda is available, the purpose and effect of which is to defeat generic substitution and maintain Forest's monopoly. This Court

must view Defendants' conduct as a whole and in its full economic context, and not, as Defendants would have it, "by dismembering it and viewing its separate parts." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962).[14]

Moreover, patent rights, like other property rights, are hardly absolute. They cannot be exercised in violation of other laws, including the antitrust laws. Indeed, the Supreme Court in *Actavis* could not have made it any clearer that "what the holder of a valid patent could do does not by itself answer the antitrust question." *Actavis*, 133 S. Ct. at 2230-31; *see id.* at 2231 ("[P]atent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."); *id.* (cases "seek to accommodate patent and antitrust policies").

Free Riding

Defendants assert that DPS laws allow generic manufacturers to "free ride" on Forest's product development and marketing efforts and Defendants are merely trying to prevent such free riding, which the antitrust laws do not protect. Def. Br. 5, 40, 43-44. Defendants' invocation of the "free riding" epithet is misplaced.

[14] Defendants contend that it makes no sense to prohibit product withdrawals while allowing "soft switches." The legality of a "soft switch" is not at issue in this case, but a soft switch may well be exclusionary if, for example, the sole purpose for introducing the reformulation is to impede generic substitution, or the new drug fails the profit-sacrifice test because it would not have been profitable if introduced after generic entry.

What Defendants claim is "free riding" (automatic generic substitution at the pharmacy) is not only a legitimate form of competition, it is the only way that competition can work in this market.[15]

To reiterate: (1) prescription pharmaceutical markets are plagued by a major defect–a price disconnect–that prevents consumers from making the fundamental price/quality choice; (2) DPS laws allow generic substitution in order to restore market forces, and do so by permitting the market participants who have incentives to get lower prices–consumers and pharmacists–to decide which product to buy; and (3) the purpose and effect of pharmaceutical product hops is to impair generic substitution and thereby prevent the restoration of these market forces. The market is broken; generic substitution helps mend it; a product hop prevents the mending and keeps the market broken.

[15] "Free riding," in the sense of taking advantage of another's investments, is ordinarily a feature, and not a bug, in a competitive economy. *See International News Service v. Associated Press*, 248 U.S. 215, 259 (1918) (Brandeis, J., dissenting) ("That competition is not unfair in a legal sense, merely because the profits gained are unearned, even if made at the expense of a rival, is shown by many cases . . .. He who follows the pioneer into a new market, or who engages in the manufacture of an article newly introduced by another, seeks profits due largely to the labor and expense of the first adventurer; but the law sanctions, indeed encourages, the pursuit."); *Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 915 (2007) (Breyer, J., dissenting). Of course, the intellectual property laws provide *limited* protection against free riding. But calling *lawful* competition "free riding" is not a legitimate justification for conduct that impairs horizontal competition, reduces demand, and harms consumers. *See, e.g., Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 486 (1992) (rejecting Kodak's argument that exclusion of ISOs was justified "to prevent ISOs from free-riding on Kodak's capital investment in equipment, parts and service").

Defendants further cite *Trinko* for the proposition that it is inappropriate to use antitrust law to enforce regulatory obligations. Def. Br. 46. That is hardly what Plaintiff's claim does. Rather, it enforces traditional monopolization principles in a particular regulatory context, just as *Trinko* provides. *See Trinko*, 540 U.S. at 411-12 ("[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." (quoting *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.)) (alterations in original); *see also Actavis*, 133 S. Ct. at 2234 (Hatch-Waxman Act, including its "general procompetitive thrust," embodies a statutory policy militating in favor of applying antitrust to reverse payment patent settlements).

Effect On Innovation

Defendants and their amici assert in broad terms, with no empirical support, that allowing antitrust scrutiny could deter innovation. *See, e.g.*, Def. Br. at 51. The Supreme Court rejected similar arguments in *Actavis*. *See Actavis*, 133 S. Ct. at 2247 (Roberts, C.J., dissenting). As the district court observed, "[p]roviding financial rewards for anticompetitive conduct is not in the public interest." Def. Brief at S.A. 135; see also *Id.* at 76. (requiring Forest to continue Namenda IR would have no impact on its incentive to innovate).

Moreover, immunizing product hopping from antitrust scrutiny could impair real innovation. Permitting pharmaceutical manufacturers to extend their

monopolies by switching the market to trivial or minor product reformulations siphons research and development funds away from riskier but medically significant, real innovations. "Brand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug." C. Hemphill & B. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMP. STUD. 613, 615 (2011). Preventing brand manufacturers from maintaining their monopolies through product hopping schemes promotes innovation rather than deterring it, because "immunity from competition is a narcotic, and rivalry a stimulant, to industrial progress; . . . the spur of constant stress is necessary to counteract an inevitable disposition to let well enough alone." *United States v. Aluminum Co. of America*, 148 F.2d 416, 427 (2d Cir. 1945) (L. Hand, J.); *see also* Federal Trade Commission's Brief as *Amicus Curiae* at 8, *Mylan Pharmaceuticals v. Warner Chilcott, PLC,* No. 2:12-cv-03824-PD (E.D. Pa. Nov. 21, 2012) 2012 WL 7649225 (threat posed by generic competition "can incentivize the brand company facing dramatic loss of sales to develop new and innovative drugs that benefit consumers" or to engage in product hopping "to impede generic substitution and thus meaningful generic competition").

Regulatory Solutions

Defendants' amicus Texas Healthcare suggests that anticompetitive product

hopping should be left to FDA regulation, citing *Trinko*. But unlike the Federal Communications Commission, which regulated the conduct at issue in *Trinko*, the FDA disclaims any statutory authority to regulate for competition. *See* S. Dogan & M. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709 (2009) (FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"). Nor does it have any ability to require that pharmaceutical product reformulations embody medically significant improvements, or that useful products are not withdrawn from the market. *See* Shadowen, *Anticompetitive Product Changes*, at 7 (quoting FDA statement that "[t]he law does not allow the FDA" to approve only reformulations that are improvements).

Generic Marketing

Lastly, Defendants and their amici assert that the generic manufacturers and third-party payors can defeat product-hopping schemes without the assistance of antitrust law. Not so.

Generic manufacturers cannot defeat an anticompetitive product switch because they cannot profitably use detailers or other doctor-oriented marketing to get doctors to switch their prescribing from the reformulated product back to the original product. *New York*, 2014 WL 7015198, at *27. A generic manufacturer that incurred the cost of getting a doctor to write the prescription for the original

product would not necessarily make the sale because, under the DPS laws, the pharmacist could fill the prescription with a competing manufacturer's product. DPS laws are *intended* to make detailing and other doctor-oriented marketing unprofitable because such marketing is the means by which manufacturers exploit the price disconnect and thereby reap supracompetitive prices. *See* Shadowen, *Anticompetitive Product Changes*, at 13-16.

Similarly, various market realities prevent most third-party payors from defeating these schemes. For example, competition among third-party payors to provided generous prescription drug coverage may make it difficult for a single payor to cover only the generic product and deny or restrict coverage for the reformulated product, particularly if it requires doctors to switch patients for a second time. Compounding this impediment, third-party payors face their own free-rider problem in convincing doctors to change their prescription habits, since all payors would benefit. *See* Shadowen, *Anticompetitive Product Changes*, at 21. Consequently, despite the billions of dollars in lost consumer welfare, payor action to defeat anticompetitive product reformulations is very much the exception rather than the rule. *Id*.

In sum, as Judge Jordan held in *Abbott Labs. v. Teva Pharms*, generic substitution is the only commercially viable means of getting generics into the hands of consumers and ending brand manufacturers' monopolies when their

patents expire:

> [W]hile [generic manufacturers] may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.

Id. at 423.

The record here likewise supports the conclusion that generic substitution is the only commercially viable means of distributing the generic product. And Defendants' restriction on the availability of Namenda IR is part of a product hopping scheme that was intended to prevent, and if not enjoined will succeed in preventing, that substitution.

CONCLUSION

For all of these reasons, and those advanced by the Attorney General, the district court's entry of a preliminary injunction should be affirmed.

Respectfully submitted,

Steve D. Shadowen
Hilliard & Shadowen LLP
39 W. Main St.
Mechanicsburg, PA 17055
(855) 344-3298

Richard M. Brunell
Vice President &
General Counsel
American Antitrust Institute

2919 Ellicott Street, NW
Washington, DC 20008
(202) 600-9640

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(d) and 32(a)(7)(B)-(C), the undersigned counsel certifies as follows:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) as modified for amici by Fed. R. App. P. 29(d) because this brief contains 6,914 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2011 in 14 point Times New Roman font. The electronic version of this brief has been scanned for viruses and is virus-free.

/s/ Steve D. Shadowen

Steve D. Shadowen
HILLIARD & SHADOWEN LLP
39 West Main Street
Mechanicsburg, PA 17055
Tel: (855) 344-3298
steve@hilliardshadowenlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of February, 2015 I filed the foregoing Brief for the American Antirust Institute as Amicus Curiae in Support of Appellees with the Clerk of the United States Court of Appeals for the Second Circuit via CM/ECF system, which will send notice of such filling to all registered CM/ECF users.

I hereby certify that six hardcopies of the foregoing brief were sent via Federal Express to:

Clerk of the Court
United States Court of Appeals for the Second Circuit
Thurgood Marshall United States Courthouse
40 Foley Square
New York, New York 10007
(212) 857-8576

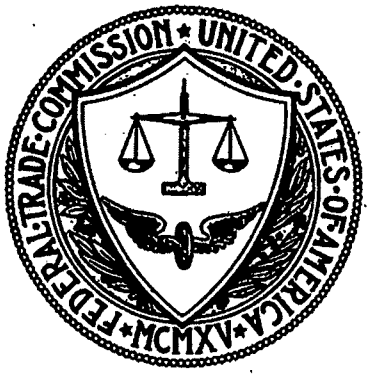
/s/ Steve D. Shadowen
Steve D. Shadowen

EXHIBIT A

DRUG PRODUCT SELECTION

Staff Report to the

Federal Trade Commission



BUREAU OF CONSUMER PROTECTION

JANUARY 1979

interchange") of drug products therapeutically equivalent to but less expensive than products prescribed by brand name, we recommend that the states adopt the Model Drug Product Selection Act discussed in Ch. X.A., infra.[6]

A. The Problem

Prescription drugs, which seldom are covered by insurance plans, cost American consumers over eight billion dollars in 1977.[7] Persons over age 65, who comprise 11 percent of the population, pay 25 percent of the national drug bill, and often must do so on limited fixed incomes.[8] A considerable portion of this expenditure could be saved if the market fostered the purchase of low-cost equivalent drug products.

The basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients

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6 This Report generally adopts the term "drug product selection" rather than "brand interchange" or "substitution." "Brand interchange" may mistakenly imply that the pharmacist is limited to selecting another branded drug product for the one prescribed, rather than an unbranded product. "Substitution" may mistakenly imply that the pharmacist is allowed to select an entirely different drug entity for the one prescribed, rather than merely a different manufacturer's formulation of the same drug, or to do so surreptitiously. (In fact, as documented in Ch. VII.A., infra, antisubstitution laws developed at a time when substitution generally did refer to deceptively dispensing a different drug entity.) "Drug" is used in this Report to indicate the active chemical ingredient or drug entity. "Drug product" means a particular manufacturer's formulation of that same drug entity. Thus, for example, "Miltown" and "Equanil" are two drug products distributed by Wallace Laboratories and Wyeth Laboratories respectively, each containing the identical drug--meprobamate. Meprobamate also may be prescribed alone or in combination under the following brand names, among others: Meprospan, Meprotabs, SK-Bamate, Tamate, Appetrol, Bamadex, Cyclex, Deprol, Equalysen, and Pathibamate. USAN and the USP Dictionary of Drug Names (M.C. Griffiths ed. 1976), at 172-173.

7 Pharmacy Times, April 1978, at 41, 48. See Ch. V.A., infra, for a discussion of drug costs.

8 Drug Topics, Sept. 1, 1977. See discussion of the special problems of the elderly at Ch. V.B., infra.

have little influence in determining which products they will buy and what prices they must pay for prescriptions.

Chemically (and therapeutically) equivalent versions of "multisource" prescription drugs (drugs available from more than one manufacturer) are frequently sold at widely disparate prices. For example, ampicillin trihydrate, a commonly-prescribed antibiotic, is available at wholesale prices ranging from $18.74 to $6.00 per hundred capsules.[9] This wide price disparity is evidence of the low priority placed on drug prices by prescribing physicians. In fact, most physicians have little knowledge of drug prices. One recent study[10] asked physicians from a diversity of practices to rank their knowledge of drug prices on a scale from one (very informed) to five (uninformed). Of the 144 physicians responding, over 32 percent replied that they had "no idea" of the prices of commonly-prescribed drugs, and over two-thirds of the remainder assessed themselves at a four or five. When the same study measured physicians' knowledge of the prices of drugs prescribed in their specialties, it found that two and a half times as many physicians underestimated as overestimated the price.

The reason for this lack of price awareness is that there is little incentive for physicians to shop around for the least expensive drug products. Patients do not choose their physicians on the basis of the cost of the drugs the physician prescribes. Indeed, probably only a small percentage of patients currently know enough about comparative drug prices or the availability of less expensive generic equivalents to ask physicians to prescribe low-cost drug products.[11] Furthermore, it is time-consuming and therefore costly for physicians to acquire comparative price information. Busy physicians understandably are concerned when choosing drugs primarily with the relative performance, benefits and risks associated with the use of a particular drug. Price considerations necessarily take on a secondary importance, if

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9 See Table 6: "HEW's MAC Savings on Ampicillin Trihydrate 250 mg. caps." in Ch. VIII., infra.

10 Fink & Kerrigan, "Physicians' Knowledge of Drug Prices," 1 Contemp. Pharmacy Prac. 18 (1978). See Ch. III.C., infra, for a discussion of this and similar studies. Except where otherwise indicated, we have not attempted in this Report to analyze the statistical validity of the various surveys cited. Where support is not available from other surveys with consistent findings, we have attempted to indicate that fact or to cite opposing studies.

11 See Ch. VII.B.4 and C.3., infra, for evidence that patients seldom ask pharmacists about the availability of low-cost products.

drug entity, but a different brand from the one prescribed.[19]

As new federal controls virtually eliminated drug counterfeiting, states began in the 1960's and 1970's to question the appropriateness of restrictive antisubstitution laws. Within the last five years or so, an ever-accelerating number of states, with major support from consumer groups and pharmacy associations, have replaced their antisubstitution laws with drug product selection laws. These laws, now enacted in 40 states and the District of Columbia (see Table of State Laws and accompanying discussion at Ch. VII.B., infra), permit the pharmacist, unless otherwise directed by the physician or the patient, to select a lower-cost generic equivalent for the brand-name prescribed. The laws recognize that the pharmacist is aware of price differences and can more efficiently select from among competing products than can physicians. The laws foster price competition by allowing the only principals who have financial incentives to make price comparisons--the pharmacist and the patient--to select drug products on the basis of price.

B. The Issues

In examining antisubstitution laws and deciding whether or not to endorse drug product selection, we considered (and discuss in this Report) several important issues. One group of issues involves drug quality -- the nature and adequacy of FDA's regulation of drug quality, the extent to which drug products with identical active ingredients also provide equivalent therapy, and the question of potential differences between the quality of brand-name and generic-name products (see Ch. VI.A. and Ch. IX.C., infra). Related to these concerns are the pharmacist's technical ability to select drug sources (Ch. IV.A., infra) and the assurance of the physician's right to specify a particular brand when medically necessary (Ch. III. and Ch. IX.B., infra).

A second group of issues involves economic concerns -- the pharmacist's incentives to select low-cost generic equivalents (Ch. II.B., infra) and the extent to which pharmacists actually do choose such products (Ch. VII.C., infra), the potential savings to consumers from drug product selection (Ch. VIII., infra) and the actual savings passed on to consumers by pharmacists (Ch. VII.C., infra). Related to these concerns are the extent to which pharmacists' anxiety about potential liability lawsuits inhibits product selection (Ch. IX.E., infra) and the potential effect of increased selection of low-cost generics on the research and development incentives of brand-name manufacturers (Ch. IX.A., infra).

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19 The role of the National Pharmaceutical Council is discussed at Ch. VII.A.1.c., infra.

CHAPTER X. THE FEDERAL TRADE COMMISSION'S ROLE

A. Model Drug Product Selection Act

Measurements of the potential benefits from drug product selection (Chapter VIII, supra) demonstrate that antisubstitution laws and regulations cost consumers hundreds of millions of dollars each year by restricting price competition in the multisource prescription drug market. And an analysis of the alleged disadvantages of drug product selection (Chapter IX, supra) demonstrates that consumer benefits can be achieved through enactment of appropriate product selection laws without compromising the quality of health care.

We recommend that the Commission offer states its assistance to facilitate pharmacists' selection of lower-cost generic equivalents whenever appropriate by encouraging states to adopt the FTC-FDA jointly-endorsed Model Drug Product Selection Act, discussed below.

We make this recommendation instead of other possible recommendations for several reasons. The states have been actively replacing their antisubstitution laws with drug product selection laws. The number of state product selection laws has more than doubled during the course of our investigation, leaving only ten states with restrictive antisubstitution laws.[1] In addition, a number of states are amending their product selection laws to make them more effective. In view of this activity, we think the most appropriate use of Commission resources is to assist states in their attempts to make product selection work.

The often-cited comment of Justice Brandeis about the value of the federal system in permitting states to serve as "laboratories" for "social and economic experiments"[2] is applicable here. We have tried in this report to analyze available evidence and identify those provisions of product selection laws that work best. In doing so, we also have tried to identify those areas in which the available evidence is not conclusive. Thus, there still seems to be justification for some experimentation by the states. We do not suggest that any state whose law is working well to produce substantial consumer savings make major modifications merely to conform to the Model Act. We do think, however, that a state law that follows the principles of the Model Act will work to save consumers money and to serve the public interest.

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1 See Table 1. State Laws, Ch. VII.B., supra.

2 New State Ice Co. v. Liebmann, 285 US. 262, 280, 311 (1932) (dissenting opinion).

EXHIBIT B

GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES:

ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS

by

Alison Masson

and

Robert L. Steiner

Staff Report

of the

Bureau of Economics
Federal Trade Commission

October 1985

CHAPTER 1

INTRODUCTION

As of mid-1984 all states have laws allowing pharmacists some choice in selecting which brand of drug to dispense in filling a prescription that names a specific brand.[1] The stated purpose of these drug product selection (DPS) laws is to lower the prices consumers pay for prescription drugs through substitution of lower-price versions of the drug for the higher-price brands typically prescribed by physicians.[2] The previous anti-substitution laws required the pharmacist to dispense whichever brand the physician named. The newer drug product selection laws under certain conditions allow the pharmacist to substitute another generically equivalent drug. Since most prescriptions are written using the proprietary name of a specific brand, rather than the established generic name of the drug product, DPS laws in effect shift the choice of brand for most prescriptions from the physician to the pharmacist. The premise underlying DPS laws is that the pharmacist has a greater incentive than the physician to identify the cheapest source of supply and to pass along at least part of the savings to the consumer.

It is the large price differences between leading brands and "generic" versions of the "same" drug that suggest that consumers could save substantially from substitution.[3] Using

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1/ By 1980 -- the year analyzed in this report -- only three states still prohibited substitution. Louisiana's law went into effect in October of 1980, Texas' at the beginnning of 1982 and Indiana's in mid-1984.

For a history of the anti-substitution laws and of their replacement with drug product selection laws see Staff Report to the Federal Trade Commission, Drug Product Selection, 1979, hereafter cited as FTC Staff Report (1979).

2/ "Generic substitution" is another term often used for drug product selection, and indeed the substitution of unbranded drug products for branded items is envisioned by the statutes in that lower-price products typically include those sold under the generic name only. The term "drug product selection" encompasses a broader range of pharmacist behavior. In filling generically written prescriptions, pharmacists must always choose a drug product. Also, a substitution may involve a second brand rather than a lower-price unbranded version.

The type of substitution analyzed in this study is limited to brand interchange within a generic entity (or drug entity), defined as the set of products which all have the same (combination of) active chemical ingredient(s).

3/ In this study, "generics" are defined as being all products other than leading brands, thereby including some products sold under a proprietary name in addition to products sold under the generic name alone. See Appendix A6 for the definitions of "leading brands" and "generics" and Chapter 3 for data on leading brand and generic prices.

persist, and in the market for prescription drugs the legal prohibitions against substitution have contributed especially to sustained price differentials.

The difference between the price of the leading brand in a prescription drug entity and the price of alternative brands in the same entity is typically large: a 1980 average across 37 leading multi-source drugs, weighted by sales in number of prescriptions, was $8.22 for the leading brand and $6.22 for the average of other brands, a difference of $2.00, or nearly 25 percent of the leading brand price.[11] Despite this broad price gap most prescriptions are filled with the leading brand. None of 12 leading drugs whose patents expired between 1970 and 1976 had in 1979 a market share of less than 90 percent in (wholesale) dollar terms, although market shares were lower (70 to 90 percent) in terms of units sold.[12] Market share erosion is moderate at best in the years following patent expiration.[13]

The institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician. A physician's prescription is a necessary precondition for the purchase of a prescription drug, and it is the physician who designates both the chemical compound and, on four-fifths of

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11/ Of the 45 drugs selected for study, in only 37 did sales of both brands and generics, by our definitions, actually appear in the 1980 data.

12/ The analysis of dollar market share is in Statman and Tyebjee (1981). The analysis of unit market share is contained in a letter from Mark B. Goodson, Associate Manager, Public Policy Planning, Hoffmann-La Roche Inc. to Robert L. Steiner, January 6, 1982. The computations were based on IMS data and covered 6 of the 12 drugs in the Statman/Tyebjee analysis. By mid-1981 the unit market shares had fallen to 58 to 84 percent in these drugs.

13/ Of course, one possible explanation of the persistence of the price differential is that leading brands are superior in quality. Despite official state formularies stating that certain brands are interchangeable, some consumers or their physicians may find that one brand is more effective or confers fewer side-effects than another. Even in the absence of laws or institutions restricting their options to purchase prescription drugs, some consumers would therefore be willing to pay a premium for certain brands of powerful drugs, just as they do now for over-the-counter drugs and other products.

notice when the physician's prescription is not the best alternative available.[17]

Since physicians are an unlikely force behind a switch to lower-cost brands after the patent period has expired, an erosion of the patent-conferred monopoly must depend on others who have both the power and the incentive to respond to lower prices. That is the role envisioned for the drug product selection laws: to transfer some of this power to pharmacists.[18] Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition with other pharmacies on prescription prices. Also, pharmacists have an immediate incentive to dispense a generic rather than a leading brand because typically the retail dollar gross margin on the generic is higher.[19] Anti-substitution laws, then, prevented pharmacists from dispensing the highest-profit products, and DPS laws can be viewed as the removal of a constraint on pharmacists' choices. Under the DPS laws, the profit-seeking drug retailer is more likely to choose a drug product with a lower (wholesale) cost and to sell it to consumers at a price below that of the leading brand. By making use of the pharmacist's interest in higher profits, DPS laws offer consumers the benefit of lower prices.

III. DATA USED IN THIS STUDY

Our primary data are from the National Prescription Audit (NPA) compiled by IMS America, Ltd. and are for 1980; we also make use of some more recent data from various sources. In the

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17/ See Chapter 3.

18/ Under all state DPS laws, the physician retains the authority explicitly to prohibit substitution on a particular prescription. In almost all states consumers also have the right to refuse substitution.

19/ See Chapter 3. Also, on publicly funded prescription drug programs, such as Medicaid, pharmacies may by the regulations be given an incentive dispense low-cost versions, as is done with the Maximum Allowable Cost (MAC) program which sets reimbursement ceilings for some drugs. Private insurers now also build into their reimbursement schedules incentives for generic dispensing.