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HEARING ON *PROFITS OVER CONSUMERS: EXPOSING HOW PHARMACEUTICAL COMPANIES GAME THE SYSTEM*

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Chairwoman Schakowsky, Ranking Member Rodgers, and distinguished members of the Subcommittee, thank you for the opportunity to testify about product hopping in the pharmaceutical industry.

My name is Joanna Shepherd. I am a Professor of Law at Emory University. I hold a Ph.D. in Economics and was formerly an Economics Professor. My research focuses on various topics in law and economics, including the healthcare industry and empirical analyses of the civil justice system. I have published broadly in law reviews, legal journals and peer-reviewed economics journals, and I am the author of two books. My research has been cited by numerous courts, including the U.S. Supreme Court. I have previously testified before the House Judiciary Committee, and before the National Academy of Sciences and several state legislative committees.

I. EXECUTIVE SUMMARY

Product hopping is a phrase used in certain quarters to describe brand drug companies' attempts to switch customers from an older version of a drug to a newer version. Typically, the newer drug has a longer patent life, thus extending the brand company's market exclusivity and profits. A product hopping switch can be either a "hard switch" or "soft switch." In a hard switch, a brand company completely withdraws an older drug from the market while introducing a new drug, whereas in a soft switch, the brand company keeps the older product on the market, but shifts marketing efforts to the new drug.

Whether product hopping is anticompetitive is highly situation dependent. Replacing older drugs for newer drugs is generally part of the normal competitive process that companies engage in as they produce innovative new products. This replacement is usually procompetitive in that it provides newer and better choices for consumers. However, when certain conditions are met, some hard and soft switches may be anticompetitive, coercing consumers to switch drugs and

depriving them of choice. This testimony will explain when brand drug company's market replacement of an older product for a newer product constitutes anticompetitive product hopping. A hard switch that eliminates consumer choice with no offsetting consumer benefit is likely an anticompetitive product hop. A soft switch that significantly interferes with consumer choice to the point that it effectively eliminates it, with no offsetting consumer benefit, is likely anticompetitive.

The next section of this testimony explains the incentives for product hopping created by legislation that applies to the drug market, patent law, and state substitution laws. The third section discusses the only two Circuit court cases that have analyzed whether product hopping claims violate federal antitrust law. In the fourth section, I describe the conditions that must be present for both a hard switch and a soft switch to be anticompetitive. The fifth and last section of this testimony explains that if enacted legislation is too broad or overly vague, instead of benefitting consumers it could harm them by reducing innovation and increasing health care spending.

II. THE LEGAL AND INDUSTRY FRAMEWORK THAT INCENTIVIZES PRODUCT SWITCHING

In this section, I describe the incentives for product hopping created by patent law and state substitution laws.

Patent law incentivizes brand-name pharmaceutical companies to make new drugs by granting an exclusive patent period during which the brand company can charge higher prices. The ability to charge higher prices during the patent period is critical because it allows the company to recoup the exorbitant costs of bringing a drug to market and provides a powerful profit incentive to innovate. Data indicate that the average brand drug takes over 10 years and $2.6 billion to make it through the arduous FDA approval process.[1] Moreover, only 10 percent of drugs that begin clinical trials are eventually approved by the FDA.[2] For the majority of brand manufacturers, this

[1] Joseph A. DiMasi, Director of Economic Analysis, Tufts Center for the Study of Drug Development, Briefing: Cost of Developing a New Drug (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf. An older study by the same authors found that it cost over $1 billion to bring a drug to market. Jospeh A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469 (2007).

[2] Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 40-41 (2014). The study used data from 2003-2011 and included both new drug applications and biologic license applications. *Id*. at 40.

means that they will never recoup their research and development costs; in fact, 80 percent of marketed brand drugs never earn enough sales to cover these costs. [3]

In contrast to the FDA approval process for new drugs, generics face a much cheaper and quicker process. The Hatch-Waxman Act in 1984[4] created the Abbreviated New Drug Application ("ANDA") process that greatly truncates the approval process for generic drugs that can demonstrate bioequivalence with the corresponding brand drug. [5] Generics that establish bioequivalence can rely on *previously submitted* brand-name safety and efficacy data, and skip the most expensive portion of the FDA approval process for brand drugs—the clinical trials.[6] As a result of the ANDA process, it only costs generics $1 to $2 million to bring a drug to market. By contrast, it costs an average of $2.6 billion to bring a new branded drug to market because of the costs of research, development and the FDA approval process.[7]

Moreover, as their patent period expires, brand companies face the likely loss of 80-90 percent of their sales to generic versions of the drug under state substitution laws. These laws allow or even require pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug. As a result, state substitution laws enable generics to "free-ride" off their brand name counterparts. Brand name manufacturers engage in extensive marketing efforts, often spending hundreds of millions of dollars to promote their drugs to physicians[8] and the general public. [9] When generic drugs are automatically substituted for brand drugs under state substitution laws, the generic companies reap the benefits of years of the brand companies' marketing efforts without bearing the costs. Generic companies typically spend very

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[3] News Release, U.S. Food & Drug Admin., FDA Approves Ofev to Treat Idiopathic Pulmonary Fibrosis (Oct. 15, 2014) http://www.fda.gov/NewsEvents/ Newsroom/PressAnnouncements/ucm418994.htm.

[4] Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(2012)).

[5] *See* Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 53 (2003).

[6] 21 U.S.C. § 355(j).

[7] OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS (Dec. 1, 2010), http://aspe.hhs.gov/basic-report/expanding-use-generic-drugs#11; Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUB. POLICY REV. 7, 13 (2003) (noting that "[g]eneric firms can file an Abbreviated New Drug Application (ANDA), a process that takes only a few years and typically costs a few million dollars.").

[8] Estimates suggests that pharmaceutical companies spend almost $100,000 in marketing efforts for every 11 practicing physicians in the United States. Abigail Zuger, *Fever Pitch: Getting Doctors To Prescribe Is Big Business*, N.Y. TIMES, Jan. 11, 1999, at A1.

[9] Brand companies spent between $103 million and $249 million on the top-10 most heavily advertised drugs in 2014 alone. *See* Beth Snyder Bulik, *The Top-10 Most Advertised Prescription Drug Brands*, FIERCEPHARMAMARKETING (2015), http://www.fiercepharmamarketing.com/special-reports/top-10-most-advertised-prescription-drug-brands

little on advertising. Instead, they free-ride on the marketing efforts of brand companies and rely on automatic substitution laws for a large chunk of their sales.

Brand companies, understanding that automatic substitution laws grant generics a regulatory windfall, often have no incentive to develop new indications for existing drugs or to continue marketing their drugs after the patent period expires and generics enter the market. To do so would essentially be handing over 80-90 percent of their sales directly to generic competitors. And a perverse consequence of the laws is that the more effective the brands are at promoting their drug to prescribers, the more money generics make when pharmacists substitute the brand for the generic.

As a result of a patchwork of multiple statutes, brand companies have the incentive to shift their marketing efforts to a new patent-protected drug which can serve as a substitute for the drug about to go off patent. To acquire a patent and FDA approval, the new drug must be different and innovative; for example, new versions may be extended-release drugs that improve patient compliance and reduce the likelihood of adverse events, scored versions of tablets that allow for increased dosing flexibility, or variations in dosage strengths that allow the drug to be used to treat new indications. The brand companies hope that if they can establish a market for their new drug, which may inevitably shift many of the consumers away from the original drug, they can preserve their profitability. While patients benefit from the development of these new drugs, critics note that they will keep at least some of the brand companies' sales out of the hands of generic entrants. Thus, incentives under patent law—incentives to innovate in order to obtain the exclusionary patent period—motivate brand companies to create new drugs instead of handing over the majority of their sales to the generic companies. As the FTC has explained, these new drugs can, in turn, benefit consumers: "The threat posed to existing brand drugs by generic competition can incentivize the brand company facing a dramatic loss of sales to develop new and innovative drugs that benefit consumers."[10]

III. PRODUCT-HOPPING DECISIONS IN CIRCUIT COURTS

Because product hopping, at least in its extreme forms, naturally frustrates generic manufacturers that can no longer free-ride off of the marketing efforts of brand companies, courts have seen some litigation in this area. The next section discusses the only two Circuit Court cases that have issued decisions on product hopping.

[10] Brief for Federal Trade Commission as Amicus Curiae, Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company, No. 12-3824, 2012 WL 7649225, (E.D. Pa. Dec. 3, 2012).

A. New York v. Actavis

In May 2015, *New York v. Actavis* became the first appellate case to address pharmaceutical product hopping.[11] In the case, the state of New York claimed that brand drug company Forest Laboratories, a subsidiary of Actavis, had initiated a hard switch to remove Alzheimer drug Namenda IR from the market and replace it with Namenda XR. The difference between the XR and IR versions was in dosage form; IR was a twice-daily drug but XR was a once-daily extended release drug. Initially the company sold both IR and XR, but tried to "soft switch" consumers to XR. Forest spent substantial sums promoting XR to doctors, caregivers, patients, and pharmacists.[12] The company also sold XR at a discounted rate, making it "considerably less expensive" than IR, and gave rebates to health plans so that patients would not have higher co-pays for XR compared to IR.[13] At the same time, Forest ceased actively marketing IR. However, as the end of the IR patent approached, the company announced plans to discontinue selling IR altogether—a hard switch.

However, before Forest could withdraw Namenda IR, the district court issued a preliminary injunction requiring Forest to continue selling the superseded IR until one month after generics entered the market. The Second Circuit upheld the injunction in *New York v. Actavis*, concluding that Forest's planned replacement of Namenda IR with Namenda XR violated Section 2 of the Sherman Act.[14] The Court decided that, while Forest's soft switch still gave consumers the ability to choose between the drugs, the planned hard switch eliminated this choice. It determined that Forest's product switch would produce anticompetitive and exclusionary effects on competition, creating a "dangerous probability" that Defendants would maintain their monopoly power after generics entered the market:[15]

> Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act . . . Here, Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically

[11] *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).
[12] *Id.* at 648.
[13] *Id.*
[14] *Id*. at 653.
[15] *Id*. at 655.

equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.[16]

B. Mylan v. Warner Chilcott

In September of 2016, *Mylan Pharmaceuticals v. Warner Chilcott* became the second and only other appellate case to analyze whether product hopping claims violate federal antitrust law.[17] In *Mylan*, the generic plaintiff argued that brand drug company Warner Chilcott engaged in a serious of product hops of acne drug Doryx by introducing reformulations that merely modified the drug's form, dosage or score.[18] With each change, Warner Chilcott eventually ceased promoting the prior formulations and ultimately withdrew them from the market, but generally not before Mylan began selling a generic version. The plaintiffs alleged that these reformulations were intended to create obstacles for generic manufacturers benefiting from automatic substitution laws because each change required generic manufacturers to re-apply for AB-rating to allow them to continue to benefit from state substitution laws. [19]

The Third Circuit concluded that Warner Chilcott had not violated Section 2 of the Sherman Act, primarily because it lacked the requisite monopoly power in the relevant market under the rule of reason test. First, the court determined that because Warner Chilcott had only an 18 percent market share in the market of interchangeable oral tetracycline drugs (a much broader market than Plaintiffs argued was relevant), it did not have monopoly power nor was it likely to achieve monopoly power with its product hops. [20] The Court further concluded that Warner Chilcott's product hops were not anticompetitive because Mylan was not entirely blocked form the market; brand Doryx had been off patent with other generic competitors for many years and Mylan continued selling generic Doryx during the relevant time period. The court ultimately concluded that although "[d]efendants were motivated by an intent to compete with generics, the evidence nonetheless demonstrates that Defendants' product modifications had no anticompetitive effects on the market."[21]

C. Points of Agreement in Circuit Decisions

Although the 2nd Circuit in *Actavis* ruled for the generic plaintiff and the 3rd Circuit in *Mylan* ruled for the brand defendant, there are several issues on which the Courts seem to agree.

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[16] *Id*. at 653-54.
[17] *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co*., 838 F.3d 421 (3d Cir. 2016)
[18] *Id.* at 430.
[19] *Id.*
[20] *Id.* at 436-438.
[21] *Id.* at 439.

First, the brand drug must have monopoly power. In *Actavis*, the defendant clearly had monopoly power, at least narrowly conceived, because the Namenda products were the only dementia drugs based on memantine. In contrast, in *Mylan*, there were several drugs on the market with the same active ingredients as Doryx that doctors, insurers, and the FDA considered to be fully interchangeable. Although both courts view monopoly power as essential, they differ in defining the market in which the power must exist. The 2nd Circuit defined the relevant market as the brand drug and its generic equivalents only, whereas the 3rd Circuit defined the market more broadly to include interchangeable products in the same therapeutic class.

Second, patent cliffs are important. In *Actavis*, the fact that the Namenda IR patent was imminently expiring when Forest announced the hard switch was critical to the 2nd Circuit's decision that the switch was for the purpose of eliminating generic competition. The 3rd Circuit agreed that an expiring patent may have resulted in a different outcome in *Mylan: "*Here, there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market."[22]

Third, brand company's reasons (or lack thereof) for engaging in the switch are important. Both courts agree that it would raise suspicions if the brand defendant has no reason for switching drugs other than impeding generic competition. The 2nd Circuit in *Namenda* concluded that "[a]ll of Defendants' procompetitive justifications for withdrawing IR are pretextual."[23] In *Mylan,* the third circuit believed that the defendants offered strong evidence of non-pretextual purposes for their various product changes, but asserted that "we do not rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases."[24]

Fourth, the nature of the switch is important, with hard switches much more likely to be deemed anticompetitive. In *Mylan,* the 3rd Circuit ruled in favor of the brand defendant because Warner Chilcott did not engage in a hard switch: "[w]hile product hopping under certain circumstances may be viewed as anticompetitive conduct, this is not one of those cases. . . Mylan was not foreclosed from the market." [25]In *Actavis,* the 2nd Circuit implied that they would have concluded differently if Forest had only engaged in a soft switch:

> Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of Berkey Photo's basic tenets: the market can determine whether one product is superior to another only 'so long as the free choice of consumers is

[22] *Id.* at 440.
[23] *New York v. Actavis PLC*, 787 F.3d 638, 658 (2d Cir. 2015).
[24] *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co*., 838 F.3d 421, 440 (3d Cir. 2016)
[25] *Id.* At 438.

preserved.' Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice.[26]

IV. WHEN IS PRODUCT HOPPING ANTICOMPETITIVE: CONSIDERATIONS FOR FUTURE LEGISLATION

Brand drug companies incrementally improve their drugs all the time. According to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.[27] Most of this activity is procompetitive in that it provides newer and better drug choices for consumers. So, when does a brand drug company's market replacement of an older product for a newer product constitute anticompetitive product hopping? Below I discuss the elements that would make both a hard switch and, in some cases, a soft switch anticompetitive.

A. Hard Switch

In *Actavis,* the 2nd Circuit stated that "[c]ertainly, neither product withdrawal nor product improvement alone is anticompetitive."[28] Indeed, removing an older drug from the market and replacing it with a newer, more effective drug is generally procompetitive. We should encourage drug companies to remove older products when there is a newer product that is clearly safer or more effective. And perhaps even more importantly, we should encourage drug companies to invest in innovating and improving their products.

However, if the hard switch eliminates consumer choice with no offsetting consumer benefit, then it is likely an anticompetitive product hop.

[26] *New York v. Actavis PLC*, 787 F.3d 638, 654-655 (2d Cir. 2015).
[27] J. Cohen, L. Cabanilla, & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 6, (2006).
[28] *New York v. Actavis PLC*, 787 F.3d 638, 653-654 (2d Cir. 2015).

1. Eliminates Consumer Choice

A hard switch eliminates consumer choice when it coerces the consumers into switching to the new product because there are no available alternatives to the original product. For example, this would occur if an older drug was pulled from the market right before its patent expired so that the generics waiting to enter the market could not use automatic substitution laws to penetrate the market of the older drug. In this situation, consumers would no longer have the choice of the older drug. They would also effectively have no choice of the generic drugs once they entered the market. As the 2nd Circuit explained in *Actavis,* because generics do little marketing on their own, "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers".[29]

In contrast, a hard switch would not eliminate consumer choice if it occurred after generics had already penetrated the market. In this situation, patients would already be accustomed to taking the generic versions of the older drug, so replacing the older drug with a newer drug would not coerce them into switching from the generic drug they had been taking. In fact, in this case, the product switch would be procompetitive because it would give consumers more choice. As the 2nd Circuit explained in *Actavis,* there is no consumer coercion if "generics had already entered the market at the time of defendants' product reformulation."[30] Similarly, a hard switch would not eliminate consumer choice if a brand company replaced a drug with plenty of patent life remaining and no generics on the horizon. This switch would not reduce the drugs that consumers could choose from; they had one drug to choose before the switch and one drug to choose after the switch.

These examples suggest that there is a window during which a hard switch can be presumed to be anticompetitive but, outside of that window, it is extremely unlikely that the product replacement eliminates consumer choice. For conventional, small-molecule drugs this window starts around the time a generic company files an acceptable ANDA containing a Paragraph IV challenge to the drug as this indicates that there is a generic competitor that could potentially enter the market. The window should end when the generic drug has penetrated the market. According to existing research, generics are able to capture over 70 percent of the brand drug's market share within only 3 months of their market entry.[31] Thus, the relevant window should end sometime around 3 months after generic entry. Outside of this window, whether before the Paragraph IV

[29] *New York v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015).
[30] *New York v. Actavis PLC*, 787 F.3d 638, at 652 n.23 (2d Cir. 2015).
[31] Henry Grabowski, Genia Long, & Richard Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED ECON. 207 (2014).

challenge or after generics have penetrated the market, a hard switch will generally not eliminate consumer choice.[32]

2. Consumer Benefit

Nevertheless, drug manufacturers that initiate a hard switch during this presumptively anticompetitive window should be able to justify the action if the new product is safer or significantly more effective. Not allowing this exception would deter drug companies from investing in and introducing clearly superior products, which would ultimately harm consumers.

Indeed, allowing defendants to justify their otherwise anticompetitive conduct is consistent with the rule-of-reason test that has generally been applied to antitrust claims by the Supreme Court over the last 100 years.[33] Under this framework, once a plaintiff establishes that the defendant's conduct is anticompetitive, the defendant may offer non-pretextual procompetitive justifications to defend its conduct.

B. Soft Switch

In general, the market introduction of a new or improved product while leaving an older product on the market is procompetitive. Consumers have access to more products, and the new product is likely to be safer or more effective in some way. We should encourage drug companies both to invest in improving their products and to bring those drugs to market when they are available. Consequently, regulation of soft switches should be done with caution.

However, if a soft switch includes conduct that significantly interferes with consumer choice so that it effectively eliminates it, with no offsetting consumer benefit, then the soft switch is likely anticompetitive.

1. Significant Interference with Consumer Choice

A soft switch significantly interferes with consumer choice to the point of effectively eliminating it when customers have no practical alternative but to switch to the new product. For

[32] It is possible that a generic could submit a Paragraph IV challenge but never come to market. In this situation, the brand company would be in limbo in this window indefinitely, even though replacing an older product with a newer product would not eliminate consumer choice. Thus, there should be an allowance that if no generics enter the market within a set amount of time, the brand company is not presumed to be in this anticompetitive window.

[33] Standard Oil Co. v. United States, 221 U.S. 1, 31 S. Ct. 502, 55 L. Ed. 619 (1911)

example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug.[34] Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers would effectively have no choice.

However, a soft switch would not significantly interfere with consumer choice to the point of effectively eliminating it if the brand company engages in standard business practices that typically accompany the introduction of a new product. These standard practices include advertising that is consistent with FDA-approved labelling, reallocating marketing efforts to the newly-released product, offering price discounts or samples so patients will try the new product, or otherwise encouraging doctors and insurers to direct patients to the new product. While these practices may shift market share to the new drug, they do nothing to eliminate the availability of the older drug or coerce patients into switching. Moreover, because the older drug remains freely available for doctors to prescribe, generics can continue to take advantage of automatic substitution laws.

Thus, a soft switch should only be presumptively anticompetitive if it so significantly interferes with consumer choice that it effectively coerces patients into switching. This degree of interference will typically require some other wrongful conduct, such as fabricating safety concerns or falsely disparaging a product, that unfairly disadvantages the original product. If it does not unfairly disadvantage the original product, then patients and their doctors can choose which drug they prefer. As the 2nd Circuit explained in *Actavis,* "the market can determine whether one product is superior to another only 'so long as the free choice of consumers is preserved.'"[35]

2. Consumer Benefit

As with a hard switch, defendants that initiate a soft switch that significantly interferes with consumer choice should be able to justify the action if the new drug is safer or more effective. Not allowing this exception would deter drug companies from introducing superior products, which would ultimately harm consumers.

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[34] See *In re:* Suboxone (Buprenorphine Hydrochloride and Naxolone) Antitrust Litigation, 64 F.Supp.3d 665, 681 (E. D. Pa. 2014).

[35] *New York v. Actavis PLC*, 787 F.3d 638, 654-655 (2d Cir. 2015) (citing to Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 287 (2d Cir. 1979)).

V. CONSEQUENCES OF OVERLY BROAD OR VAGUE LEGISLATION

Legislation defining anticompetitive product hopping should aim to facilitate generic entry and lower drug prices. However, if the enacted legislation is too broad or overly vague, it could instead harm consumers by reducing innovation and increasing health care spending.

First, overly broad legislation would deter important future innovations. Most innovation in the pharmaceutical industry involves development of next generation improvements, such as creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines.[36] According to FDA data, two-thirds of new drug approvals are for these incremental innovations.[37] And according to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.[38] Overly broad legislation would deter these important incremental innovations that are critical to improving health outcomes.

Second, legislation that is unclear about when the introduction of new products will be deemed anticompetitive product hopping will create significant uncertainty for brand innovators. This uncertainty may, in turn, lead to less innovation in the pharmaceutical industry. Brand drug companies are largely responsible for pharmaceutical innovation; in the last decade, they have spent over half a trillion dollars on R&D, and they currently account for over 90 percent of the spending on the clinical trials necessary to bring new drugs to market.[39] But if brand companies cannot reliably predict whether the introduction of new products will be considered anticompetitive, they will have less incentive to engage in costly R&D. The companies will not spend the billions of dollars[40] it typically costs to bring a new drug to market when they cannot be certain if, years down the road, the introduction of that new drug will lead to significant litigation,

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[36] *See*, INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS, 11 fig.3 (Jan. 2013), http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf.

[37] NAT'L INST. FOR HEALTH CARE MGMT. RESEARCH & EDU. FOUND., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION, 3 (2002).

[38] J. Cohen, L. Cabanilla, & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 6, (2006).

[39] PhRMA, *2019 Profile Biopharmaceutical Research Industry* 2 (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/2019-Profile-Booklet_FINAL_NoBleeds.pdf. *See generally*, Kaitin, N. Bryant & L. Lasagna, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States,* 33 J. OF CLINICAL PHARMACOLOGY 414 (1993), (92 percent of new drugs are discovered by private branded companies).

[40] Joseph A. DiMasi, Director of Economic Analysis, Tufts Center for the Study of Drug Development, Briefing: Cost of Developing a New Drug (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf.

market-stopping injunctions or penalties. If product hopping legislation increases the uncertainty around the introduction of new products, innovation will suffer.[41]

The consequences of this reduced innovation will be felt by consumers. Research shows that pharmaceutical innovation has produced significant health benefits to consumers. Empirical estimates of the benefits of pharmaceutical innovation indicate that, on average, each new drug brought to market saves 11,200 life-years *each year*. [42] Another study finds that the health improvements from each new drug can eliminate $19 billion in lost wages by preventing lost work due to illness.[43] Moreover, because new effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data show that for every incremental $1 spent on new drugs, total medical spending decreases by more than $7.[44] Brand companies are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand innovation will have long-term negative effects on consumer health and health care spending.

[41] Frank R. Lichtenberg, Columbia University & National Bureau of Economic Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999), http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf. (Empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*).

[42] Frank R. Lichtenberg, Columbia Univ, & Nat'l Bureau of Econ. Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999), http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf.

[43] Craig Garthwaite, *The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors*, 4 APPLIED ECON. 116 (2012).

[44] Frank R. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update,* 28 MANAGERIAL & DECISION ECON. 485, 485 (2007).