



SCHOOL OF LAW
CASE WESTERN RESERVE
UNIVERSITY

Health Matrix: The Journal of Law-
Medicine

Volume 27 | Issue 1

2017

The Prescription for Rising Drug Prices: Competition or Price Controls?

Joanna Shepherd

Follow this and additional works at: <https://scholarlycommons.law.case.edu/healthmatrix>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Joanna Shepherd, *The Prescription for Rising Drug Prices: Competition or Price Controls?*, 27 Health Matrix 315 (2017)
Available at: <https://scholarlycommons.law.case.edu/healthmatrix/vol27/iss1/12>

This Article is brought to you for free and open access by the Student Journals at Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Health Matrix: The Journal of Law-Medicine by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

The Prescription for Rising Drug Prices: Competition or Price Controls?

Joanna Shepherd[†]

Contents

I.	Introduction	315
II.	Recent Developments in the Pharmaceutical Industry	319
	A. Demand-Side Developments: Generic Competition and Pharmacy Benefit Managers	319
	B. Supply-Side Developments: Increasing Costs and Biologic Drugs	324
	C. Changes in the Pharmaceutical Industry's Organizational Structure	330
III.	Price Controls in the Pharmaceutical Industry	331
	A. Existing Price Controls	331
	1. Medicaid	332
	2. 340B Program.....	333
	3. Departments of Defense and Veterans Affairs Drug Programs.....	334
	4. Medicare Part D	335
	5. State Price-Control Initiatives	336
	B. Likely Consequences of Further Price Controls	337
IV.	Facilitating Competition in Pharmaceuticals	340
	A. Reduce Generic Approval Backlog at the FDA.....	341
	B. Expedite Biosimilars Approval.....	342
	C. Prohibit Anticompetitive Practices	344
V.	Conclusion	346

I. Introduction

After years of modest growth, drug spending has increased dramatically. Spending in 2014 grew by over thirteen percent, the largest annual increase since 2001.¹ On average, the prices of traditional brand drugs grew by five to seven percent,² but prices on several high-profile drugs have increased by as much as 3000 percent.³ Even some generic medications—the traditionally cheaper alternative to brand drugs—have

[†] Professor of Law, Emory University School of Law.

1. IMS INST. FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SPENDING SHIFTS: A REVIEW OF THE USE OF MEDICINES IN THE U.S. IN 2014 5 (2015).

2. *Id.* at 7.

3. Aimee Picchi, *Martin Shkreli-style Drug Price Hikes are Everywhere*, CBS MONEYWATCH (Feb. 2, 2016), <http://www.cbsnews.com/news/martin-shkreli-style-drug-price-hikes-are-everywhere/>.

experienced significant price increases.⁴ This surge in drug spending has been driven by the increasing popularity of expensive specialty drugs such as biologics, higher prices on brand drugs, and fewer patent expirations that open the door for cheaper generics.⁵

In response to the sharp increase in spending and skyrocketing prices, consumers, insurance plans, medical groups, and politicians are looking for explanations and demanding change.⁶ Reforms to curb further increases have engendered rare cross-party alliances in Congress and even rarer agreement among presidential candidates.⁷ Proposed reforms include allowing more government intervention in the Medicare Part D drug program,⁸ imposing direct price controls on drugs for lower-income Medicare patients,⁹ capping consumers' out-of-pocket costs for drugs,¹⁰ promoting generic competition,¹¹ and enhancing sanctions for anticompetitive practices.¹²

-
4. See, e.g., Peter Jaret, *Prices Spike for Some Generic Drugs*, AARP BULLETIN (July, Aug. 2015), <http://www.aarp.org/health/drugs-supplements/info-2015/prices-spike-for-generic-drugs.html>; Trefis Team, *Why are Generic Drug Prices Shooting Up?*, FORBES (Feb. 27, 2015), <http://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/#25bc238a377e>.
 5. IMS INSTITUTE, *supra* note 1, at 5-8.
 6. See, e.g., Richard Mark Kirkner, *Drug Pricing Regulation Pushed from Many Sides*, MANAGED CARE (Jan. 2016), <http://www.managedcaremag.com/archives/2016/1/drug-pricing-regulation-pushed-many-sides/>; Jeanne Whalen, *Doctors Object to High Cancer-Drug Prices*, WALL ST. J. (Jul. 23, 2015), <http://www.wsj.com/articles/doctors-object-to-high-cancer-drug-prices-1437624060>.
 7. See, e.g., Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES (July 23, 2015), <http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html>; Thomas Sullivan, *Both Houses of Congress Investigating Prescription Drug Prices*, POL'Y & MED. (Nov. 06, 2015), <http://www.policymed.com/2015/11/both-houses-of-congress-investigating-prescription-drug-prices.html>.
 8. Sy Mukherjee, *Trump Joins Clinton, Sanders & Obama in Endorsing Medicare Drug Price Negotiations*, BIOPHARMADIVE (Jan. 27, 2016), <http://www.biopharmadive.com/news/trump-joins-clinton-sanders-obama-in-endorsing-medicare-drug-price-nego/412840/>.
 9. *Hillary Clinton's Plan for Lowering Prescription Drug Costs*, HILLARY FOR AM., <https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/> (last visited Feb. 13, 2016).
 10. Anne Gearan & Amy Goldstein, *Clinton Proposing \$250 Monthly Cap on Prescription Drug Costs for Patients*, WASH. POST (Sept. 22, 2015), <https://www.washingtonpost.com/news/post-politics/wp/2015/09/22/clinton-proposing-250-monthly-cap-on-prescription-drug-costs-for-patients/>.
 11. Allison Gilchrist, *Senate Scrutinizes Generic Drug Approval Backlog*, PHARMACY TIMES (Feb. 4, 2016), <http://www.pharmacytimes.com/news/senate-scrutinizes-generic-drug-approval-backlog>.
 12. See, e.g., Kirkner, *supra* note 6.

In this article, I explain why reforms promoting competition will produce better results and fewer negative consequences than reforms imposing new price controls. Price controls are government-mandated limits on prices or government-required discounts on prices. Basic economic principles, past experience, and empirical data indicate that new price controls will likely increase drug prices for some consumers, slow pharmaceutical innovation, curtail generic competition, and reduce patient access to certain medications. In contrast, reforms aimed at promoting competition or prohibiting anticompetitive practices will expand product offerings, lower drug prices for more patients, and incentivize innovation.

The article proceeds as follows: in Section II, I outline several demand-side and supply-side developments that have significantly impacted the pharmaceutical industry in recent decades. The nature of competition between brand drug companies and generic companies has changed dramatically as generics have increased their market share from nineteen percent to over eighty-eight percent of drugs sold in the United States. Brand companies now realize few sales after their patents expire and generics enter the market. At the same time that brand companies have lost market share and profits to generics, they have also seen increased power from pharmaceutical buyers—namely drug plans and pharmacy-benefit managers (“PBMs”). PBMs and drug plans now largely determine what consumers pay for drugs, what pharmacies they use, and what drugs they take, which has diminished drug companies’ influence over prices.

Drug companies have also experienced significant increases in both the costs of drug development leading to approval by the Food and Drug Administration (“FDA”) and the risks of product failures. The costs to bring a drug to market have increased from less than \$200 million to over two billion dollars,¹³ and only one in ten drugs that begin clinical trials is eventually approved by the FDA.¹⁴ As the development costs for traditional drugs have increased, drug manufacturers have shifted much of their research and development efforts toward biologic products.¹⁵ Although these complex drugs did not enter the market until the 1980s, they now comprise over a quarter of all drug spending in the United States.¹⁶ Unfortunately, because of their high costs of development and production

13. See HENRY G. GRABOWSKI & RONALD W. HANSEN., BRIEFING: COST OF DEVELOPING A NEW DRUG (2014).

14. Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 31 NATURE BIOTECHNOLOGY 40, 44 (2014).

15. See generally Shannon Gibson et al., *Why the Shift? Taking a Closer Look at the Growing Interest in Niche Markets and Personalized Medicine*, 7 WORLD MED. HEALTH POL’Y 3, 3 (2015).

16. Andrew Pollack, *Biotech Firms, Billions at Risk, Lobby States to Limit Generics*, N.Y. TIMES (Jan. 28, 2013), http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html?_r=0.

and lack of competitors to control prices, biologic drugs are prohibitively expensive for many consumers.¹⁷

In Section III, I describe existing government programs that impose price controls in the pharmaceutical industry and explain the likely consequences of further controls. As of 2005, over twenty percent of drugs sold in the U.S. were sold under government programs that mandate price controls, such as Medicaid, the 340B Program, the Department of Defense and Veterans Affairs programs, and spending in the coverage gap of Medicare Part D.¹⁸ Some programs even require drugs to be sold for a penny.¹⁹ Further price controls will create incentives for manufacturers to charge higher prices to non-covered patients to offset the discounted prices. If manufacturers are not able to offset discounts by increasing prices for non-covered consumers, all consumers may ultimately suffer. Empirical data suggest that price controls contribute to drug shortages, slow innovation, and curtail generic competition.²⁰ Ultimately, price controls meant to lower drug spending for some consumers could end up harming all consumers.

Rather than restraining prices through price controls, the government should promote competition to reduce drug prices. In Section IV, I discuss the many actions the government could take to increase competition in the pharmaceutical industry. Reducing the generic-approval backlog at the FDA will increase generic competition for drugs, expediting affordable biosimilar alternatives to biologics will lower prices for many specialty medications, and targeting anticompetitive behavior will promote competition throughout the industry. By increasing competition, these actions will expand product offerings to consumers, lower prices as suppliers compete to attain or protect valuable market share from rivals, and foster innovation as drug companies strive to create new products to stay ahead of competitors.

The recent surge in drug spending must be addressed to ensure that patients can continue to afford life-saving and life-enhancing medications.

-
17. Anthony D. So & Samuel L. Katz, *Biologics Boondoggle*, N.Y. TIMES (Mar. 7, 2010), <http://www.nytimes.com/2010/03/08/opinion/08so.html> (explaining “biologic medicines, which cost, on average, 22 times as much as ordinary drugs.”).
 18. See Jordan Rau, *Medicare reveals how much it spends on prescription drugs for Americans*, PBS NEWSHOUR (May 1, 2015, 8:32 AM), <http://www.pbs.org/newshour/rundown/medicare-reveals-much-spends-prescription-drugs-americans/>.
 19. DEP’T. HEALTH & HUM. SERV., CLARIFICATION OF PENNY PRICING POLICY (2011), *available at* <https://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf>.
 20. Patricia Earl & Phillip L. Zweig, *Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U.S. Drug Shortage*, CARE & COST (2012), <https://careandcost.com/2012/02/14/connecting-the-dots-how-anticompetitive-contracting-practices-kickbacks-and-self-dealing-by-hospital-group-purchasing-organizations-gpos-caused-the-u-s-drug-shortage/>.

However, imposing new price controls on pharmaceuticals will produce negative consequences—less innovation, drug shortages, fewer product choices, and higher prices for some consumers—that could harm consumers rather than helping them. In contrast, promoting competition will lower pharmaceutical prices and drug spending without these deleterious effects.

II. Recent Developments in the Pharmaceutical Industry

The pharmaceutical industry has steadily expanded over the last several decades. Global revenue for the industry was approximately one trillion dollars in 2015, compared to approximately \$340 billion in 1989.²¹ The United States alone spent over \$400 billion on pharmaceuticals in 2015.²²

During this period of expansion, the pharmaceutical industry has undergone significant changes that have altered the nature of competition in the industry, shifted the relative bargaining power of drug sellers and drug buyers, and increased the costs of developing and selling drugs. In this section, I outline several demand-side and supply-side developments that have significantly impacted the pharmaceutical industry in recent decades.

A. Demand-Side Developments: Generic Competition and Pharmacy Benefit Managers

The nature of competition in the pharmaceutical industry has changed dramatically over the past several decades as brand companies have lost significant market share to generics. The generic industry exploded after the Hatch-Waxman Act in 1984 created an abbreviated regulatory process that encouraged companies to produce and market cheaper, generic drugs.²³ First, to spur the introduction of low-cost generics, Hatch-Waxman created the Abbreviated New Drug Application (“ANDA”) process that allows a generic that demonstrates bioequivalence to rely on *previously submitted* brand-name safety and efficacy data.²⁴ This greatly truncated process enables generic manufacturers to quickly enter the market after

-
21. THOMSON REUTERS, *Global Pharma Sales to Reach \$1.3 Trillion* (Aug. 4, 2015), <http://thomsonreuters.com/en/articles/2015/global-pharma-sales-reach-above-1-trillion.html>; Vivian Hunt et al., *A Wake-up Call for Big Pharma*, MCKINSEY & CO. (Dec. 2011), http://www.mckinsey.com/insights/health_systems_and_services/a_wake-up_call_for_big_pharma.
 22. IMS INST. FOR HEALTHCARE INFORMATICS, *GLOBAL MEDICINES USE IN 2020: OUTLOOK AND IMPLICATIONS* 35 (2015), *available at* <http://www.imshealth.com/en/thought-leadership/ims-institute/reports/global-medicines-use-in-2020>.
 23. Pub. L. No. 98-417, 98 Stat. 1585 (1984); U.S. CONG. BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY*, ix (1998).
 24. 21 U.S.C. § 355(j) (2016).

the brand drug's patent expires. Moreover, Hatch-Waxman actively incentivizes generic companies to challenge brand patents' validity by creating a pathway for such challenges and by offering a lucrative incentive to the first generic manufacturer that files an ANDA claiming that the brand patent is either invalid or will not be infringed by the new generic. If the generic company wins or settles the patent litigation, it receives a 180-day exclusivity period during which the FDA will not approve any other generic versions of the drug, a period in which the first generic can earn substantial profits by shadow pricing the innovator's price.²⁵

Generics have been further aided by drug substitution laws in every state that allow, or even require, pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug.²⁶ These regulatory changes have allowed generics to capture significant market share from brand companies.²⁷ As shown in Figure 1, whereas generics comprised only nineteen percent of all drugs dispensed prior to 1984, they now represent over eighty-eight percent of prescriptions filled.

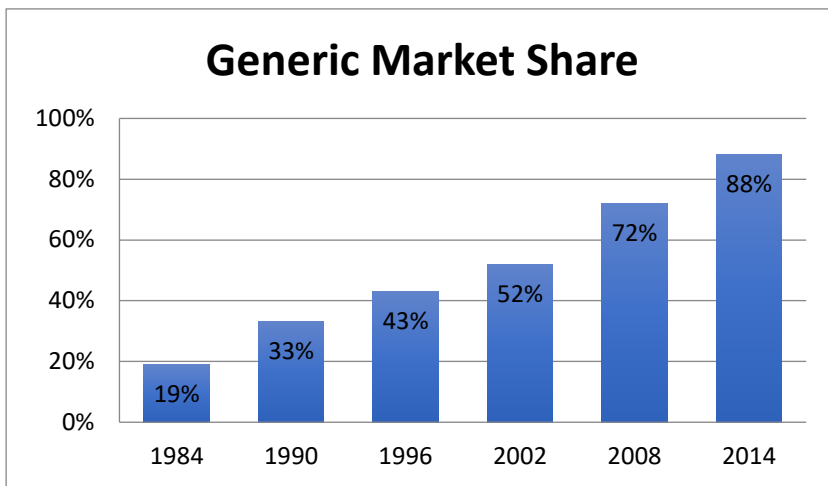


Figure 1. Growth in Generics' Share of Pharmaceutical Market²⁸

25. See, e.g., U.S. DEP'T HEALTH & HUM. SERV., GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, & COSMETIC ACT (1998).
26. BUREAU CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMM'N at 48, 150, 153 (1979).
27. U.S. CONG. BUDGET OFF., *supra* note 23, at ix.
28. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 2 (2012); IMS INST. FOR HEALTHCARE INFORMATICS, DECLINING MEDICINE USE AND COSTS: FOR BETTER OR WORSE? A REVIEW OF THE USE OF MEDICINES IN THE UNITED STATES IN 2012, at 15 (2013), *available at*

The increased competition from generics puts downward pressure on prices, generating significant cost savings for consumers. After the patent expiry of a brand drug, generics enter the market at a significantly lower price. Data show that generics enter the market at a price fifty percent less than their brand counterpart.²⁹ As more generics enter the market, the price eventually drops to eighty percent off the pre-expiry brand prices.³⁰ This lower price directly reduces spending for consumers. Indeed, the surge of cheaper generic products in recent years has produced significant savings for consumers; in the last decade alone, generic drugs have saved the healthcare system over one trillion dollars.³¹

Moreover, the speed at which customers switch from brand drugs to their generic counterparts is significantly faster than it was several decades ago. As shown in Figure 2, upon market entry, generics routinely capture over seventy percent of the brand drug's market within only three months. In contrast, as recently as 1999, generics captured less than forty percent of the market within three months. Within twelve months, generics now capture over eighty percent of the brand drug's market share, whereas in 1999, they captured slightly over fifty percent.

<http://static.correofarmaceutico.com/docs/2013/05/20/usareport.pdf>; PHRMA, CHARTPACK: BIOPHARMACEUTICALS IN PERSPECTIVE 56 (2016), *available at* <http://www.phrma.org/sites/default/files/pdf/chartpack-2015.pdf>.

29. IMS INST. FOR HEALTHCARE INFORMATICS, PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S 3 (2016).

30. *Id.*

31. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 28, at 4.

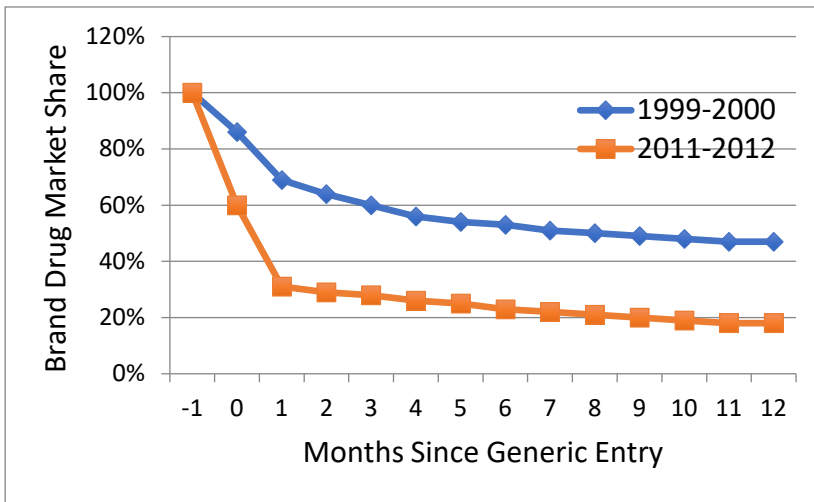


Figure 2. *Generic Erosion of Brand Drug Market Share*³²

As a result of this swift erosion of their market share, brand pharmaceutical firms realize few sales after they reach the patent cliff and generics enter the market.³³ An early study by the U.S. Congressional Budget Office found that during the first decade after the Hatch-Waxman Act, total net revenues generated by new drugs declined by twelve percent as a result of generic entry.³⁴ Between 2012 and 2018, it is estimated that pharmaceutical companies will lose almost \$150 billion in revenues because of patent expirations.³⁵

However, generic erosion of brand profits and the accompanying price reductions are somewhat cyclical because they depend on patent expirations. The first generic entrants in a market earn substantial profits as consumers immediately switch from brand drugs to the generic competitor. However, as more generics enter a market, the market share and profits of any individual generic manufacturer decline. Thus, patent expirations and the promise of significant profits for the first generic competitors incentivize generic entry. Conversely, fewer patent expirations result in less generic entry and, in turn, less price reduction. For example, reduced brand innovation in the mid-1990s resulted in fewer patent

32. Henry Grabowski et al., *Recent Trends in Brand Name and Generic Drug Competition*, 17 J. MED ECON. 207, 207 (2013).

33. VanEck, *Drug Patent Expirations: \$190 Billion in Sales Up for Grabs*, MARKET REALIST (Mar. 3, 2016, 1:58PM), <http://marketrealist.com/2016/03/drug-patent-expirations-190-billion-sales-grabs/>.

34. U.S. CONG. BUDGET OFFICE, *supra* note 23, at 38.

35. PRICEWATERHOUSECOOPERS, FROM VISION TO DECISION: PHARMA 2020, at 6 (2012), available at <http://www.pwc.com/gx/en/pharma-life-sciences/pharma2020/assets/pwc-pharma-success-strategies.pdf>.

expirations of brand drugs between 2013 and 2015,³⁶ and in turn, less generic entry.³⁷

At the same time that brand companies have lost market share to generics, they have also faced increased power from pharmaceutical buyers. PBMs, which administer the prescription drug coverage for over ninety-five percent of insured Americans,³⁸ have adopted various benefit changes and tools to reduce pharmaceutical prices and steer patients to less-expensive alternatives.³⁹ For example, PBMs have successfully reduced drug spending by requiring substitution of generic drugs for brand name drugs when clinically appropriate.⁴⁰ Many PBMs also offer mail-order pharmacy services that lower drug prices by ensuring that consumers are dispensed the cheapest drug within a therapeutic class, which is often a generic.⁴¹

PBMs also employ tiered formularies—a list of approved or preferred drugs for the health plan—and direct consumers to the formulary drugs with incentives, such as lower copayments. Because formulary status can greatly influence the sales of a drug, PBMs are able to negotiate significant discounts from drug manufacturers in exchange for a formulary listing.⁴² Once on the formulary, drugs are assigned to one of several tiers based on their cost to the health plan.⁴³ For example, whereas a non-formulary drug may cost a beneficiary one hundred dollars, drugs in the generic tier of the formulary could cost ten dollars and drugs in the brand tier of the formulary could cost thirty dollars. The tiered copayments and coinsurance give beneficiaries a powerful incentive to use generic or low-cost brand-name medications.

36. See IMS INST., *supra* note 28, at 16.

37. Katie Thomas, *Generic Drug Makers See a Drought Ahead*, N.Y. TIMES (Dec. 3, 2012), http://www.nytimes.com/2012/12/04/business/generic-drug-makers-facing-squeeze-on-revenue.html?_r=0.

38. Federal Trade Commission, Letter to Senator Richard L. Brown, North Dakota Senate, 4 (March 8, 2005), *available at* <http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf>.

39. See Dan Goldman et al., *Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health*, 298 J. AM. MED. 61, 61 (2007).

40. See U.S. GOV'T ACCOUNTABILITY OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 28 (2003).

41. FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 23-40 (2005).

42. Federal Trade Commission, Letter to Assembly Member Greg Aghazarian, California General Assembly, 6-7 (September 7, 2004), *available at* <http://www.ftc.gov/be/V040027.pdf>.

43. FED. TRADE COMM'N, *supra* note 41, at 6-7.

These and other innovative tools have saved Americans billions of dollars each year.⁴⁴ However, they have also dramatically changed the landscape of the pharmaceutical market by lessening drug companies' influence over prices. In the 1970s, most prescription drugs were prescribed by doctors that were largely insensitive to price, methodically filled by pharmacists, and paid for by consumers or, less frequently, by third-party payors that had little influence over the drug chosen or the price paid.⁴⁵ As a consequence, drug manufacturers had enormous control over price. In contrast, the market for prescription drugs in 2016 is one in which the PBMs and drug plans have harnessed the buying clout of millions of consumers to negotiate discounted prescription drug prices.⁴⁶ PBMs and drug plans now largely determine what consumers pay for drugs, which pharmacies they use, and which drugs they take.⁴⁷ As a result, PBMs and drug plans have replaced drug manufacturers in the driver's seat when it comes to determining prices.

B. Supply-Side Developments: Increasing Costs and Biologic Drugs

At the same time that generics and PBMs have decreased the demand for brand drugs, drug companies have also experienced significant increases in the costs of drug development leading to FDA approval and the risks of product failures. Since the 1962 amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA has continued to increase the requirements for new-drug approvals. For example, whereas clinical trials in the 1970s typically only enrolled 2000 patients, trials in the 1990s regularly enrolled over 5000 patients.⁴⁸ Similarly, the costs of recruiting patients, the length of the clinical-trial period, and the number and complexity of clinical tests used in clinical trials have increased over time.⁴⁹ These more-stringent requirements, along with the more-complex science associated with specialized medications, have significantly increased the

-
44. U.S. CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE 40 (2002) (Estimating of the magnitude of PBMs' cost-savings range from 30 percent to 35 percent of total prescription drug spending); *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, VISANTE 5 (2011), <http://thatswhatpbmsdo.com/wp-content/uploads/2016/02/visante-pbm-savings-study-Feb-2016.pdf>.
45. See Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1011, 1077-1120 (2010).
46. Thomas Gryta, *What is a 'Pharmacy Benefit Manager?'*, WALL ST. J. (July 21, 2011), <http://online.wsj.com/article/SB10001424053111903554904576460322664055328.html>.
47. *Id.*
48. Henry Grabowski, *The Evolution of the Pharmaceutical Industry Over the Past 50 Years: A Personal Reflection*, 18 INT. J. ECON. BUS. 161, 169 (2011).
49. *Id.*; Kenneth A. Getz et al., *Variability in Protocol Design Complexity by Phase and Therapeutic Area*, 45 DRUG INFORM. J. 413 (2011).

costs of drug development and FDA approval. The most current estimates indicate that it now costs approximately \$2.6 billion to develop and bring each new drug to market.⁵⁰ However, as shown in Figure 3, those costs were estimated to be \$179 million in the 1970s;⁵¹ \$413 million in the 1980s,⁵² and \$1.04 billion in the 1990s and early 2000s.⁵³ In contrast, it costs generic manufacturers only one to two million dollars to bring a drug to market.⁵⁴

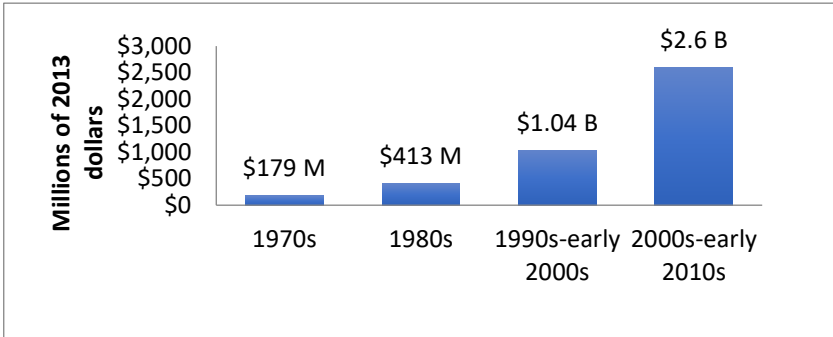


Figure 3. *The Cost of Bringing a New Drug to Market*

Moreover, only about ten percent of brand drugs that begin clinical trials are eventually approved by the FDA. The most recent study to track FDA approval rates found that the approval rate varied by trial phase: phase I had a 64.5 percent success rate, phase II had a 32.4 percent success rate, phase III had a 60.1 percent success rate, and the FDA approved 83.2 percent of applications that passed phase III.⁵⁵ Ultimately, of one hundred

50. GRABOWSKI & HANSEN, *supra* note 13.

51. Ronald W. Hansen, *The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes*, in ISSUES IN PHARMACEUTICAL ECONOMICS, 151 (R. I. Chien, ed., 1979).

52. GRABOWSKI & HANSEN, *supra* note 13 (as shown in graph titled “Growth in Capitalized R&D Costs per Approved New Compound”).

53. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 181 (2003).

54. See Brief for Federal Trade Commission as Amicus Curiae, Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company, 2012 WL 7649225 (2012) No. 12-3824.

55. Hay et al., *supra* note 14, at 41 (Stating phase I trials—usually including 20-80 healthy subjects and lasting 1-3 months—focus on the safety of the drug and determine the metabolic and pharmacologic actions of drugs, side effects of increasing doses, and early evidence of effectiveness. Phase II trials—usually including 100-300 subjects and lasting 1-2 years—focus on the drug’s effectiveness. Phase III verifies the drug’s efficacy and safety with 1,000-3,000 subjects suffering from the disease and lasts 1-4 years). The study used data from 2003-2011 and included both new drug applications and biologic license applications. *Id.* at 40.

drugs that begin Phase I trials, only ten drugs will eventually be approved.⁵⁶ As a result, drug-approval rates have increased little in recent decades, despite dramatic increases in research and development (“R&D”) spending. Figure 4 illustrates these disparate trends.

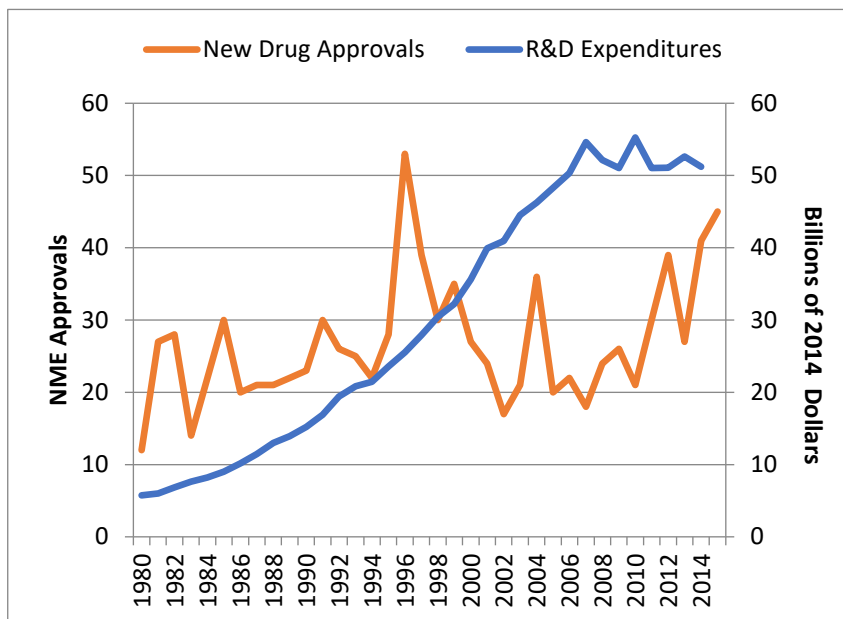


Figure 4: New Drug Approvals and R&D Spending⁵⁷

Even after FDA approval, pharmaceutical manufacturers increasingly face patent challenges that reduce the likelihood that drugs will achieve commercial success. Hatch-Waxman actively incentivizes generic companies to challenge the validity of brand-name patents by creating a pathway for such challenges and by offering a lucrative incentive to the first generic manufacturer that files a challenge—known as a Paragraph IV challenge—claiming that the brand patent is either invalid or will not be

56. *Id.* at 41.

57. *Annual Membership Survey*, PHRMA 4 (2015), http://www.phrma.org/sites/default/files/pdf/2015-phrma_profile_membership_results.pdf (showing industry R&D spending in 2014 dollars and based on members of the PhRMA trade association); FOOD & DRUG ADMIN., *Summary of NDA Approvals & Receipts, 1938 to the Present*, FDA.gov, <http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm> (noting that drug approvals from 1980-2011 include new molecular entities, including both chemicals and biologics) (last updated Jan. 18, 2013); FOOD & DRUG ADMIN. CTR. DRUG EVAL. & RESEARCH, *NOVEL DRUGS 2015 3* (2016) (noting that data from 2012-2014 is from the U.S. Food and Drug Administration).

infringed by the new generic.⁵⁸ If the generic company wins or settles the patent litigation, it receives a 180-day exclusivity period during which the FDA will not approve any other generic versions of the drug, a period in which the first generic can earn substantial profits.⁵⁹ As a result of these incentives, Paragraph IV challenges have exploded in recent years; whereas only nine percent of drugs facing generic entry in 1995 were challenged, eighty-one percent of drugs facing generic entry in 2012 were challenged.⁶⁰ Moreover, Paragraph IV challenges are occurring earlier in the life of brand drugs. Drugs entering the market as generics in 1995 faced their first challenge 18.7 years after original launch.⁶¹ By comparison, drugs entering the market as generics in 2012 saw only 6.9 years between market launch and the first Paragraph IV challenge.⁶² These challenges threaten a drug's commercial success and cost pharmaceutical companies significant legal fees.

Moreover, in 2012 the Leahy-Smith America Invents Act gave generics a new administrative venue to challenge patents, the *inter partes* review ("IPR").⁶³ IPR challenges replaced *inter partes* re-examinations to facilitate patent challenges by offering a quicker, more-efficient, and less-expensive procedure.⁶⁴ Indeed, data show that generics and other parties are taking advantage of the new pathway; the number of IPR challenges to pharmaceutical patents continues to increase, with twice as many challenges filed in 2015 compared to 2014.⁶⁵

The competition from generics, increasing power of PBMs, increasing R&D costs, and risk of patent challenges mean that many pharmaceuticals will never attain commercial success. Even for the ten percent of drugs that receive FDA approval, only twenty percent will ever earn enough revenue

58. Margo Bagley, *Patent Term Restoration and Non-Patent Exclusivity in the U.S.*, in PHARMACEUTICAL INNOVATION, COMPETITION, AND PATENT LAW 111, 116-117 (Josef Drexler & Nari Lee eds., 2013).

59. See, e.g., U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 25, at 4.

60. Grabowski et al., *supra* note 32, at 106.

61. *Id.*

62. *Id.*

63. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat at 299-305 (2011) (setting forth procedures for IPR).

64. See Joanna Shepherd, *Disrupting the Balance: The Conflict between Hatch-Waxman and Inter Partes Review*, N.Y.U. J. INTELL. PROP. & ENTMT'L (forthcoming 2016), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2838236 (giving a full explanation of IPR and the administrative proceedings it replaced).

65. See Stephen Maebius, *Bio/Pharma IPR Challenges Nearly Double in 2015*, PTAB TRIAL INSIGHTS (July 28, 2015), <https://www.ptabtrialinsights.com/2015/07/biopharma-ipr-challenges-nearly-double-in-2015-cabilly-415-patent-challenged/>.

to cover the growing R&D costs.⁶⁶ Moreover, the likelihood that a drug will become profitable has decreased over time as the risk of failure and development costs have increased.⁶⁷ The average lifetime revenues for new drugs are lower now than at any point in the last twenty-five years.⁶⁸

As the development costs for traditional drugs have increased, drug manufacturers have shifted much of their research and development efforts toward biologic products. Biologics primarily distinguish themselves from traditional drugs by their origins: they derive from living organisms, typically proteins, though occasionally including toxins, blood, viruses, or allergens.⁶⁹ These medications are far more complex than traditional medicines. Whereas a traditional drug might contain between a few dozen to one hundred atoms per molecule, a biologic's complicated proteins can include from several thousand to tens of thousands of atoms per molecule.⁷⁰

Biologics are comparatively new, relative to traditional drugs; the FDA cleared the first biologic for human use, human insulin, in 1982.⁷¹ However, by 2013, spending on biologic drugs comprised a quarter of all drug spending in the U.S.⁷² This spending is expected to grow at an annual rate of over ten percent, eventually reaching over \$386 billion in 2019.⁷³

Biologic drugs are currently prohibitively expensive for many consumers. The average cost of a biologic drug is twenty-two times greater than a traditional drug.⁷⁴ The average annual cost of a biologic drug is estimated to be \$34,550,⁷⁵ but annual costs for many biologic drugs exceed

-
66. John A. Vernon et al., *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 HEALTH ECON. 1002, 1004 (2010).
67. Ernst Berndt et al., *Decline in Economic Returns from New Drugs Raises Questions about Sustaining Innovations*, 34 HEALTH AFFAIRS 245, 251-2 (2015).
68. See generally PhRMA, *supra* note 57, at 3.
69. Jason Kanter & Robin Feldman, *Understanding & Incentivizing Biosimilars*, 58 HASTINGS L.J. 57, 59 (2012) (citing 42 U.S.C. § 262(i)(1) (2006)).
70. See, e.g., Joan Kerber-Walker, *Small Molecules, Large Biologics, and the Biosimilar Debate*, ARIZ. BIOINDUSTRY ASS'N. (Feb. 18, 2013), <http://www.azbio.org/small-molecules-large-biologics-and-the-biosimilar-debate>.
71. See JUDITH A. JOHNSON, CONGRESSIONAL RESEARCH SERVICE, FDA REGULATION OF FOLLOW-ON BIOLOGICS 1 (2010) [hereinafter CRS FDA REPORT].
72. Andrew Pollack, *Biotech Firms, Billions at Risk, Lobby States to Limit Generics*, N.Y. TIMES (Jan. 28, 2013), <http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html>; see also IMS INST. FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE: A REVIEW OF THE USE OF MEDICINES IN THE UNITED STATES IN 2013, at 30 (2014).
73. BCC RESEARCH, REPORT OVERVIEW: BIOLOGIC THERAPEUTIC DRUGS: TECHNOLOGIES AND GLOBAL MARKETS, No. BIO079C (2015).
74. So & Katz, *supra* note 17.
75. Erwin A. Blackstone & Joseph P. Fuhr, Jr., *Innovation and Competition: Will Biosimilars Succeed?* 9 BIOTECHNOLOGY HEALTHCARE 24, 26 (2012).

\$200,000.⁷⁶ Moreover, by requiring large patient coinsurance for specialty drugs, such as biologics, most consumers' prescription-drug insurance coverage fails to fully defray these massive costs.⁷⁷ As a result, many consumers cannot afford to obtain these life-saving or life-enhancing drugs.

Fortunately, Congress has recognized the need for cheaper, biosimilar versions of biologic drugs. Similar to generic versions of traditional drugs, biosimilars are close substitutes for brand biologic drugs that can be sold at a lower price after the brand biologic's patent expires.⁷⁸ As part of the Affordable Care Act ("ACA"), Congress created a biosimilar-approval pathway that would enable these cheaper biologic drugs to obtain FDA approval and reach patients more quickly.⁷⁹ Consumers stand to benefit significantly from the new market competition from lower-cost, but similarly effective, biosimilars; in fact, estimates suggest this competition could save consumers \$250 billion over the next decade.⁸⁰

However, the FDA has, thus far, been slow to approve biosimilars, approving only three biosimilar drugs to date.⁸¹ Furthermore, the FDA has yet to issue guidance on how biosimilars should prove they are interchangeable with biologics.⁸² Burdensome requirements for interchangeability will increase the difficulty and cost of biosimilar

-
76. Francis Megerlin et al., *Biosimilars and The European Experience: Implications For The United States*, 32 HEALTH AFF. 1803 (2013).
77. See, e.g., Leigh Purvis, Senior Strategic Policy Advisor, AARP, Presentation for FTC Biosimilars Workshop on Naming Proposals and Impact on Competition at 8-12 (Feb. 4, 2014), available at http://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/purvis.pdf.
78. *HRI's Top Ten Health Industry Issues of 2016, Issue 9: Biosimilars*, PRICEWATERHOUSECOOPERS (2016), <http://www.pwc.com/us/en/health-industries/top-health-industry-issues/biosimilars.html>.
79. *Id.*
80. See, e.g., Steve Miller, Senior Vice President, Express Scripts, Presentation for FTC Biosimilars Workshop on Naming Proposals and Impact on Competition, at 7 (Feb. 4, 2014), available at http://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/miller.pdf.
81. See Zachary Brennan, *FDA Approves Third Biosimilar in US, First for Amgen's Blockbuster Enbrel*, REGULATORY AFF. PROF'L SOC'Y (Aug. 30, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/08/30/25739/FDA-Approves-Third-Biosimilar-in-US-First-for-Amgens-Blockbuster-Enbrel/>.
82. Zachary Brennan, *FDA Likely to Require Substantial Clinical Data for Interchangeable Biosimilars, Lawyers Say*, REGULATORY AFFAIRS PROF'L SOC'Y (Jan. 12, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/01/12/23887/FDA-Likely-to-Require-Substantial-Clinical-Data-for-Interchangeable-Biosimilars-Lawyers-Say/>.

approval, restricting the savings possible from biosimilar competition. Moreover, even when the FDA approves a biosimilar, there may be protracted patent challenges that significantly delay its availability to patients.⁸³

C. Changes in the Pharmaceutical Industry's Organizational Structure

With the intensifying competition from generics, expanding power from PBMs, increasing costs of R&D, and growing risk of commercial failure, the pharmaceutical industry has undergone significant structural change. Several large pharmaceutical companies have merged to offset losses in market share and achieve cost savings from greater economies of scale.⁸⁴ Indeed, the number of pharmaceutical companies earning more than five billion dollars in annual profits has shrunk in the last two decades.⁸⁵ This consolidation has achieved some efficiencies and increased short-term earnings.⁸⁶

Similarly, the generic industry has experienced recent consolidation in response to the reduction in patent expirations and exclusivity periods. Many generic companies have merged, while others have acquired brand companies to diversify their risk and reliance on generic drugs.⁸⁷

But at the same time the pharmaceutical industry has experienced greater horizontal consolidation, it has also seen more vertical disintegration. Until the mid-1970s, the industry was dominated by large firms that generally kept most divisions in house; from R&D, production, and regulatory affairs to marketing, they were fully vertically integrated.⁸⁸ Moreover, the firms generally financed their own R&D expenditures, using primarily internal finance and, sometimes, bank loans.⁸⁹ However, in the 1980s, the importance of biotechnology startups and development-stage firms with venture-capital financing expanded.⁹⁰ These firms positioned themselves as a specialized layer between academic-research institutions

83. See Peter Loftus, *Panel Recommends FDA Approval of Remicade Knockoff*, WALL ST. J. (Feb. 10, 2016), <http://www.wsj.com/articles/panel-recommends-fda-approval-of-remicade-knockoff-1455057993>.

84. Grabowski, *supra* note 48, at 173.

85. Hunt et al., *supra* note 21.

86. Grabowski, *supra* note 48, at 173.

87. Cynthia Koons, *Teva's Just the Start as More Generic Drugmakers Poised to Merge*, BLOOMBERG (Aug. 5, 2015), <http://www.bloomberg.com/news/articles/2015-08-05/teva-s-just-the-start-as-more-generic-drugmakers-poised-to-merge>.

88. Grabowski, *supra* note 48, at 162.

89. See *id.* at 170.

90. Iain M. Cockburn, *The Changing Structure Of The Pharmaceutical Industry*, 23 HEALTH AFFAIRS 10, 15-16 (2004).

and pharmaceutical companies, and slowly evolved into important suppliers of cutting-edge technology to pharmaceutical companies.⁹¹

Now, instead of developing new products in their own R&D facilities, large pharmaceutical firms increasingly seek alliances with biotechnology and development-stage firms for new technologies and a broader R&D pipeline.⁹² The advantages of these smaller firms—proximity to academic research, a less bureaucratic structure, and a higher tolerance for risk—gives them a comparative advantage in drug research.⁹³ In contrast, the large pharmaceutical firms specialize in large-scale clinical trial design, manufacturing, marketing, and coordination with regulatory authorities.⁹⁴ Pharmaceutical companies increasingly rely on the research conducted by biotechnology companies, with as much of forty percent of pharmaceutical sales now coming from drugs that originated in biotechnology companies.⁹⁵ This outsourcing of drug development to biotechnology companies over the last several decades has contributed to biotechnology’s significantly higher growth rates compared to traditional pharmaceutical companies.⁹⁶

III. Price Controls in the Pharmaceutical Industry

Politicians have recently called for price controls on pharmaceutical prices. Price controls are government-mandated limits on prices or government-required discounts on prices.⁹⁷ Hillary Clinton has called for price controls for lower-income Medicare patients⁹⁸ and President Trump joined Clinton, Bernie Sanders, and President Obama in calling for more government intervention in the Medicare Part D program.⁹⁹ This section will describe existing government programs that utilize price controls in the pharmaceutical industry and explain the likely consequences of further controls.

A. Existing Price Controls

In this section, I discuss the largest public drug programs that utilize price controls—Medicaid, the 340B program, Department of Defense (“DOD”) and Veterans Affairs (“VA”) programs, and spending in the

91. *Id.* at 16.

92. Grabowski, *supra* note 48, at 165-66.

93. *Id.* at 165.

94. *Id.*

95. Cockburn, *supra* note 90, at 16.

96. Hunt et al., *supra* note 21.

97. See *Price Controls*, LIBRARY ECON. & LIBERTY, <http://www.econlib.org/library/Topics/College/pricecontrols.html> (last visited Apr. 1, 2017).

98. See, e.g., HILLARY FOR AM., *supra* note 9.

99. Mukherjee, *supra* note 8.

coverage gap of Medicare Part D. These public programs accounted for over forty percent of the drug spending in non-hospital settings in 2014.¹⁰⁰ As a result of their wide coverage, manufacturers have little choice but to participate in the public programs. Moreover, it is difficult for manufacturers to pick and choose among programs; the Department of Health and Human Services (“HHS”) requires participants in Medicaid to also make drugs available under the 340B, DOD, and VA programs.¹⁰¹

In order to sell drugs to consumers covered by these public programs, manufacturers must agree to offer certain rebates or discounts on drug prices. The calculations are generally based on the average manufacturer price (“AMP”)—the average price wholesalers pay manufacturers for drugs that are sold to retail pharmacies—or the best price (“BP”)—the lowest price at which the manufacturer offers the drug to any purchaser, including all rebates and discounts.

1. Medicaid

Created in 1965, the Medicaid program provides health insurance for low- income and medically needy individuals.¹⁰² The specific methodology used to determine the required rebate depends upon whether the drug is a brand drug, generic drug, a clotting-factor drug, or an exclusively pediatric drug.¹⁰³ For example, for brand-name drugs, the required rebate is the greater of 23.1 percent of the AMP or the difference between the AMP and the BP.¹⁰⁴ That is, brand manufacturers are required to sell drugs for 23.1 percent off the AMP, or, if they offer the drug for an even lower price to any other purchaser, they must match that price for Medicaid. The effect of this best price requirement is to penalize manufacturers who discount their products in private negotiations.

The Affordable Care Act significantly expanded Medicaid eligibility.¹⁰⁵ Whereas 34.2 million people were covered by Medicaid in 1995, by 2014,

100. See, e.g., U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *Nat’l Health Expenditures Data*, CMS.GOV, at Table 4 (2015), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

101. See U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *MEDICAID DRUG REBATE PROGRAM (2015)* [hereinafter *DRUG REBATE PROGRAM*], available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html>.

102. See generally, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicaid Eligibility*, MEDICAID.GOV (last updated Feb. 15, 2017), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html>.

103. See *DRUG REBATE PROGRAM*, *supra* note 102.

104. *Id.*

105. See *Obamacare Medicaid Expansion*, OBAMACARE FACTS, <http://obamacarefacts.com/obamacares-medicaid-expansion> (last visited Feb. 14, 2016).

this number had grown to 64.9 million individuals, or twenty percent of the U.S. population.¹⁰⁶ State Medicaid data indicates that manufacturers paid in excess of \$16.7 billion in Medicaid rebates in 2012.¹⁰⁷

2. 340B Program

The 340B program, created by Congress in 1992, requires drug manufacturers to provide outpatient drugs at significantly reduced prices to 340B-qualified buyers.¹⁰⁸ Qualified buyers generally include public-health clinics serving uninsured and low-income patients and disproportionate-share hospitals whose patient populations include a high proportion of low-income patients.¹⁰⁹ However, since the 340B program's inception, the eligibility requirements have greatly expanded.¹¹⁰ Specifically, the ACA broadened the definition of eligible entities to include many additional types of hospitals.¹¹¹ Moreover, mergers between 340B providers and non-340B providers have further expanded the list of qualified buyers.¹¹² As a result, both the number of 340B-eligible hospitals and the money spent on 340B drugs tripled between 2005 and 2014.¹¹³ By 2014, there were over 14,000 hospitals and affiliated sites in the 340B program, representing about one-third of all U.S. hospitals.¹¹⁴

As previously discussed, drug manufacturers that participate in Medicaid must enter into an agreement to sell drugs at a discount under the 340B program.¹¹⁵ Like the Medicaid discount, the 340B discounted price

106. See U.S. DEP'T OF HEALTH & HUMAN SERV., 2014 CMS STATISTICS (2014), available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2014_final.pdf.

107. DANIEL R. LEVINSON, OFFICE OF INSPECTOR GENERAL, OEI-03-13-00659, MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN, at 6 (2015).

108. Veteran's Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. § 602 (amended Public Health Servs. Act to include § 340B).

109. MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: OVERVIEW OF THE 340B DRUG PRICING PROGRAM, at vii (2015).

110. John McManus, *The 340B Program is in Dire Need of Reform*, LIFE SCI. LEADER (Apr. 26, 2013), <http://www.lifescienceleader.com/docpreview/the-b-discount-program-is-in-dire-need-of-reform-0001/d42503b6-2543-4dce-a789-a1ac008dd9b6>.

111. Affordable Care Act, Pub. L. No. 111-148, §7101, 124 Stat. 259 (2010).

112. Aaron Vandervelde, Director, Berkeley Research Group, Presentation: 340B Covered Entity Acquisitions of Physician-based Oncology Practices, at 3 (Apr. 22, 2014), available at http://www.thinkbrg.com/media/publication/449_340B%20Physician-based%20Oncology%20Practice%20Acquisitions.pdf.

113. MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 109, at 10-12.

114. *Id.* at 4.

115. U.S. DEP'T OF HEALTH & HUMAN SERVS., *Medicaid Drug Rebate Program*, MEDICAID.GOV (last updated Feb. 15, 2017), <https://www.medicaid.gov/medicaid-chip-program->

is set relative to the AMP, and must be at least a 23.1 percent discount.¹¹⁶ However, the statutory formula calculates different discounts for different products and is estimated to produce discounts that average forty-five percent off the AMP.¹¹⁷ Moreover, the formulas can result in a negative 340B selling price for a drug, in which case the Health Resources and Services Administration (“HRSA”) instructs manufacturers to set the drug price at a penny.¹¹⁸

HRSA estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year 2013.¹¹⁹ Unfortunately, many of these savings are not reaching low-income patients. The 340B statute does not require that providers only dispense 340B drugs to needy patients.¹²⁰ Instead, providers may purchase 340B drugs at a steep discount, sell them to non-qualified patients, and pocket the difference between the 340B discounted price and the reimbursement from the non-qualified patients’ private insurance companies.¹²¹ Indeed, a recent study by the U.S. Government Accountability Office found that about half of the 340B entities in the study generated revenue from private insurer reimbursements that exceeded 340B prices.¹²² As an example, Duke University Hospital, a 340B hospital, generated \$48.3 million in 2012 by selling 340B discounted drugs to its patients, two-thirds of whom are privately insured.¹²³

3. Departments of Defense and Veterans Affairs Drug Programs

The DOD and VA are also major purchasers of prescription drugs. In 2012, the DOD and VA spent \$11.8 billion to purchase drugs on behalf of

information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html.

116. David H. Howard et al., *Pricing in the Market for Anticancer Drugs*, 29 J. ECON. PERSPECTIVES 139, 156 (2015).

117. McManus, *supra* note 110.

118. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-836, DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT, at 11 n.31 (2011); *id.* at 21 (Stating, “one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA’s penny pricing policy, it received an order from a covered entity that exceeded the manufacturer’s current national supply by 50 percent.”).

119. MEDICARE PAYMENT ADVISORY COMM’N, *supra* note 109, at vii.

120. See Lauren Flynn Kelly, *340B Program Shirks Charitable Care, Undermines Formularies, Argue PBMs*, AIS HEALTH (Apr. 4, 2014), <https://aishealth.com/archive/ndbn040414-02>.

121. *See id.*

122. GAO-11-836, *supra* note 119, at 13.

123. McManus, *supra* note 111.

approximately 18.5 million active-duty and retired military personnel, their dependents, and eligible veterans.¹²⁴

In order to sell drugs through Medicaid, drug manufacturers must also provide drugs to four government agencies—the VA, DOD, Public Health Service, and Coast Guard—at statutorily-imposed discounts.¹²⁵ Drug manufacturers must provide certain drugs to these agencies at the lesser of (1) a twenty-four percent discount off the AMP offered to non-federal sources or (2) the lowest price manufacturers charge their most-favored nonfederal customers under comparable terms.¹²⁶ Both the DOD and the VA also use prescription drug formularies to lower prices even further below the statutorily-required discounts.¹²⁷ Moreover, the agencies enter into national contracts to provide additional pricing concessions from specific vendors.¹²⁸ The most recent estimate of the price savings from the combination of these efforts indicates that VA and DOD pricing for brand pharmaceuticals was approximately forty-one to forty-two percent of the average wholesale price (“AWP”).¹²⁹

4. Medicare Part D

The Medicare Modernization Act of 2003 added an optional Medicare prescription drug benefit, Medicare Part D, to offer coverage to many of the nation’s retirees and disabled persons.¹³⁰ In 2015, more than thirty-nine million beneficiaries were enrolled in Medicare Part D plans.¹³¹ The Part D plans are actually private plans that receive payments from the government to provide Medicare-subsidized drug coverage for enrollees.

Unlike Medicaid and the 340B program, there is no statutory rebate level on prescription drugs covered under the program. Instead, the private Medicare Part D plans, acting on behalf of the Medicare program, negotiate prices with pharmaceutical manufacturers and may obtain price

124. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-13-358, PRESCRIPTION DRUGS: COMPARISON OF DOD AND VA DIRECT PURCHASE PRICES 1 (Apr. 2013).

125. Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4971, §603(a)(1), (4 Nov. 1992).

126. PHARMA, CHART PACK: BIOPHARMACEUTICALS IN MEDICARE, MEDICAID & DEPARTMENT OF VETERAN AFFAIRS 68 (2012).

127. *See id.*

128. GAO-13-358, *supra* note 118, at 4.

129. U.S. CONG. BUDGET OFF., PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS 9 (2005).

130. *See* Medicare Prescription Drug, Improvement, and Modernization Act, 42 U.S.C. § 1305 (2003).

131. Jack Hoadley et al., *Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends 2006-2015*, HENRY KAISER FAMILY FOUND. 6 (Oct. 5, 2015), <http://files.kff.org/attachment/report-medicare-part-d-at-ten-years-the-2015-marketplace-and-key-trends-2006-2015>.

concessions in the form of rebates.¹³² Manufacturers are willing to offer significant rebates and discounts in order to provide drugs to the millions of covered participants. According to Medicare Trustees, a board that reports annually to Congress on the financial operations of Medicare, the rebates often amount to as much as a twenty- to thirty-percent discount on brand medicines.¹³³ Manufacturers paid in excess of \$10.3 billion in Part D rebates in 2012.¹³⁴

In addition to the significant discounts negotiated by the private plans, the Medicare Part D program does include direct price controls on drugs sold in the coverage gap. The coverage gap (or “donut hole”) is a spending level at which enrollees are responsible for a larger share of their total drug costs than they are at below or above this level. For 2016, the coverage gap begins when the individual and the plan have spent \$3310 on covered drugs and ends when they have spent \$7515.¹³⁵ Medicare Part D requires brand drug manufacturers to offer fifty-percent discounts on drugs sold during the coverage gap.¹³⁶ These discounts will cost drug manufacturers approximately forty-one billion dollars between 2012 and 2021.¹³⁷

5. State Price-Control Initiatives

In addition to the federal regulations and programs discussed above, states are currently considering their own price controls. The California Drug Price Relief Act, which appeared on the state’s November 2016 ballot, would have prohibited state agencies from paying more for a drug than the price at which the drug is sold under the federal VA drug program.¹³⁸ A

132. BOARD OF TR. OF FED. HOSP. INS. & FED. SUPPLEMENTARY MED. TR. FUNDS, ANNUAL REPORT 166 (2012).

133. *Id.* at 165, n.72.

134. LEVINSON, *supra* note 107, at 6.

135. See CTRS. FOR MEDICARE & MEDICAID SERV., *Costs in the Coverage Gap*, MEDICARE.GOV, <https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html> (last visited Apr. 1, 2017).

136. See *id.*; CTRS. FOR MEDICARE & MEDICAID SERV., *Part D Information for Pharmaceutical Manufacturers*, CMS.GOV, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Pharma.html>.

137. PRICEWATERHOUSECOOPERS HEALTH RESEARCH INST., *Implications of the US Supreme Court Ruling on Healthcare*, PWC 6 (June 2012), <http://pwhealth.com/cgi-local/hregister.cgi/reg/implications-of-the-US-Supreme-Court-ruling-on-healthcare.pdf>.

138. Letter from Michael Weinstein, to Ashley Johansson, Initiative Coordinator, Office of the Attorney General (Apr. 3, 2015), *available at* [https://oag.ca.gov/system/files/initiatives/pdfs/15-0009%20\(Prescription%20Drug%20Costs\).pdf](https://oag.ca.gov/system/files/initiatives/pdfs/15-0009%20(Prescription%20Drug%20Costs).pdf).

similar measure in Ohio, the Ohio Drug Price Relief Act,¹³⁹ will appear on the November 2017 ballot.¹⁴⁰

B. Likely Consequences of Further Price Controls

Although the existing price controls lower prices for some consumers, they likely result in increased prices for others. Many of the required rebates under Medicaid, the 340B program, and VA and DOD programs are based on drugs' AMP. Calculating rebates from average drug prices gives manufacturers an incentive to set higher prices to wholesalers and pharmacies in order to offset discounts.¹⁴¹ Moreover, with at least forty percent of drugs sold under price controls, and some programs even requiring drugs to be sold for a penny,¹⁴² manufacturers are forced to sell many drugs at significant discounts. This creates incentives to charge higher prices to other, non-covered patients to offset the discounts. Indeed, numerous academic studies and government analyses have concluded that required discounts under Medicaid and Medicare have resulted in increased prices for other consumers as manufacturers offset the revenue lost under price controls.¹⁴³ Further price controls will only amplify these incentives.

If manufacturers are not able to offset discounts by increasing prices for non-covered consumers, all consumers may ultimately suffer. Basic economic principles predict that price controls result in drug shortages; at a below-market price, the demand for drugs exceeds the amount of drugs that manufacturers are willing to sell. Indeed, recent research suggests that

139. See petition from Donald J. McTigue, Attorney, McTigue McGinnis & Colombo LLC, to Mike DeWine, Attorney General, Ohio (Jul. 22, 2015), available at <http://www.ohioattorneygeneral.gov/getattachment/8592c88b-fa92-4c66-a92a-383c8862b53b/Ohio-Drug-Price-Relief-Act.aspx>.

140. Letter from Jon Husted, Sec'y State, Ohio, to Donald J. McTigue, Partner, McTigue & McGinnis LLC (Sept. 30, 2016), available at <https://www.aidshealth.org/wp-content/uploads/2016/10/Supplementary-Petition-SOS-Certification.pdf>.

141. Howard et al., *supra* note 116, at 156.

142. See U.S. DEP'T HEALTH & HUMAN SERV. HEALTH RESOURCES & SERV. ADMIN, NO. 2011-2, CLARIFICATION OF PENNY PRICING POLICY (2011).

143. See, e.g. Mark Duggan & Fiona M. Scott Morton, *The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing*, 121 Q. J. ECON. 1, 1 (2006); Howard et al., *supra* note 117, at 140; CONG. BUDGET OFFICE, HOW THE MEDICAID REBATE ON PRESCRIPTION DRUGS AFFECTS PRICING IN THE PHARMACEUTICAL INDUSTRY 2 (1996); GOV'T ACCOUNTABILITY OFFICE, GAO/HEHS-94-194FS, CHANGES IN BEST PRICE FOR OUTPATIENT DRUGS PURCHASED BY HMOs AND HOSPITALS 2 (1994); Jim Hahn, *Federal Drug Price Negotiation: Implications for Medicare Part D*, CONG. RES. SERV. (Apr. 19, 2007), <http://congressionalresearch.com/RL33782/document.php?study=Federal+Drug+Price+Negotiation+Implications+for+Medicare+Part+D>.

price controls in the U.S. pharmaceutical industry have created drug shortages.¹⁴⁴

In addition, price controls may prevent many companies from earning profits sufficient to offset their R&D costs or the risk of failure. This could slow innovation, negatively impacting long-term health outcomes. Moreover, if other countries' experiences are any indication, lower profits will likely curtail generic competition.¹⁴⁵ A less-competitive pharmaceutical industry will, in turn, reduce choices, innovation, and, ironically, increase drug spending.

As previously discussed, brand companies incur an average of \$2.6 billion in costs to bring each drug to market with FDA approval.¹⁴⁶ They must offset these significant costs before generic competition destroys brand profits; within three months of the first generic entry, generics have already captured over seventy percent of the brand drugs' market, and within twelve months, brand companies retain less than twenty percent of their original market share.¹⁴⁷ As a result, brand companies have a very limited window during which they can earn revenues sufficient to offset the significant costs of R&D, not to mention the production, operating, marketing, and distributional costs of selling a drug. In fact, research indicates that the average window of exclusivity during which companies can earn significant revenues is less than thirteen years.¹⁴⁸ Selling drugs at too low a price during this window will result in significant losses for drug companies.

Furthermore, brand companies must price a drug not only to recoup the drug's own costs; they must also consider the costs of all the product failures in their pricing decisions. Only about ten percent of drugs that begin clinical trials are eventually approved by the FDA.¹⁴⁹ Moreover, even the ten percent of drugs that receive FDA approval are not all commercial successes. Data indicate that only twenty percent of marketed brand drugs will ever earn enough sales to cover their development costs.¹⁵⁰ The other eighty percent of approved drugs generate losses for drug makers.

Thus, if only ten percent of drugs are approved and twenty percent of those are able to recoup costs, then only one in fifty drugs developed by

144. See David B. Ridley et al., *No Shot: US Vaccine Prices And Shortages*, 35 HEALTH AFF. 235, Abstract (2016); Brian Rye, *Medicare Price Controls Worsen Drug Shortages, Boost Gray Market*, BLOOMBERG GOV'T STUDY (Oct. 1, 2012), [http://glacialblog.com/userfiles/76/BGov_Drug_Shortage_Report\(2\).pdf](http://glacialblog.com/userfiles/76/BGov_Drug_Shortage_Report(2).pdf).

145. See INT'L TRADE ASS'N, U.S. DEP'T COM., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES 21 (2004); Grabowski et al., *supra* note 32, at 7.

146. GRABOWSKI & HANSEN, *supra* note 13, at 5.

147. Grabowski et al., *supra* note 32, at 7.

148. *Id.*

149. Hay et al., *supra* note 14, at 40-41. (using data from 2003-2011 and including both new drug applications and biologic license applications).

150. Vernon et al., *supra* note 66, at 1004.

brand companies is a winner that earns positive profits. The price of these winners must not just recoup their own costs, they must also help recoup the costs of the forty-nine out of fifty drugs that never earn a profit. Failure to cover the losers' costs will slow investment in R&D; drug companies will not spend millions and billions of dollars developing drugs if they cannot recoup the costs of that development.

Less R&D spending will, in turn, result in less innovation throughout the industry. A substantial body of empirical literature establishes a direct relationship between pharmaceutical firms' profitability, research and development efforts, and innovation. Numerous studies have found that policies that increase pharmaceutical profitability lead to increases in new clinical trials, new molecular entities, and new drug offerings.¹⁵¹ Other studies have found that policies that reduce expected profitability lead to decreases in R&D spending.¹⁵² Indeed, the U.S. Department of Commerce confirms a "close correlation between revenues, cash flow, and profit margins on the one hand and R&D expenditures on the other."¹⁵³ Thus, if price controls force brand companies to operate in a way that reduces profitability over the long term, the result will be less innovation in the pharmaceutical market.

Consumers will suffer from reductions in innovation. Research shows that pharmaceutical innovation has produced significant health benefits to consumers. Empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*.¹⁵⁴ Another study finds that the health improvements from each new drug can eliminate nineteen billion dollars in lost wages by preventing lost work due to illness.¹⁵⁵ Additionally, because new effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data show that for every incremental dollar spent on new drugs, total medical spending decreases by more than seven dollars.¹⁵⁶

151. See Duggan & Morton, *supra* note 143, at 7; Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q. J. ECON. 527, 527 (2004); Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q. J. ECON. 1049, 1049 (2004).

152. Joseph Golec et al., *Pharmaceutical R&D Spending and Threats of Price Regulation*, 45 J. FIN. & QUANTITATIVE ANALYSIS 239, 239 (2010); Frank R. Lichtenberg, *Public Policy and Innovation in the U.S. Pharmaceutical Industry*, in PUBLIC POLICY AND THE ECONOMICS OF ENTREPRENEURSHIP 83, 102, 105-106 (D. Holtz-Eakin & H. S. Rosen eds., 2004).

153. INT'L TRADE ASS'N, U.S. DEP'T COM., *supra* note 145, at 25.

154. See *generally* FRANK R. LICHTENBERG & NAT'L BUREAU ECON. RESEARCH, PHARMACEUTICAL INNOVATION, MORTALITY REDUCTION, AND ECONOMIC GROWTH (1998), available at <http://www.nber.org/papers/w6569>.

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

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

Brand companies, and the profit incentives that motivate them, are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand innovation will have long-term negative effects on consumer health and healthcare spending.

Finally, lower profitability will likely reduce competition in the pharmaceutical industry. Generic entry, like the market entry of suppliers in any industry, depends on potential profits. Indeed, several examples illustrate the relationship between profits and generic entry. First, the substantial profit potential under the Hatch-Waxman 180-day exclusivity period has led to a significant increase in generic challenges.¹⁵⁷ Second, generics race to enter the market upon brand-patent expiry to claim a share of brand drugs' market share and profits before the market is saturated with generic competitors.¹⁵⁸ Conversely, in periods when few patents are expiring, the existing profits available in the market are much lower and fewer generics enter.¹⁵⁹ Finally, foreign countries that utilize price controls to control drug prices have significantly less generic competition; without the profit potential, fewer generics enter the international markets.¹⁶⁰

Currently, the U.S. market has more generic competition than any other market, largely because of the significant profit potential for these firms.¹⁶¹ However, additional price controls will lead to reductions in generic entry. This reduction in generic competition will reduce consumers' choices of drugs and increase drug prices. Although price controls will require set discounts from average prices, without generic competition, these average prices will be much higher than they would be with more competition. Similarly, intensely competitive markets spur innovation as firms innovate to gain market share and outdo competitors. If price controls lead to a less-competitive market, incentives to innovate will also decline.

IV. Facilitating Competition in Pharmaceuticals

Instead of imposing price controls, there are many actions the government could take to increase competition in the pharmaceutical industry. By increasing competition, these actions will expand product offerings, giving consumers more choice in the drugs they take. They will also lower prices as suppliers compete to attain or protect valuable market share from rivals. Finally, increased competition will lead to more innovation as drug companies strive to create new products to stay ahead

157. Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J. L. & ECON. 331 (1992).

158. *Id.* at 334.

159. Thomas, *supra* note 37.

160. U.S. DEP'T COMMERCE, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES 21 (2004).

161. *Id.* at ix.

of competitors. Below, I discuss several actions the government could take relatively quickly to increase competition in the pharmaceutical industry.

A. *Reduce Generic Approval Backlog at the FDA*

The single most important factor in controlling drug spending in recent decades has been the dramatic increase in generic-drug usage. Generic drugs saved consumers \$254 billion in 2014 and \$1.68 trillion over the past decade.¹⁶² The degree to which generics reduce drug prices depends on the number of generic competitors in the market; the more competitors, the more prices face downward pressure. Unfortunately, a backlog of generic drug approvals at the FDA has restricted generic competition in many important market segments.

In 2012, Congress enacted the Generic Drug User Fee Act to provide the FDA with funds from generic-drug makers to ensure a speedy FDA approval process for generic drugs.¹⁶³ Despite this, in January 2016, there were over 3500 generic applications pending approval.¹⁶⁴ Moreover, according to the chairman of the Senate health committee, the approval process is taking longer for generic drugs; the median approval time was thirty months in 2012, compared to forty-eight months in 2016.¹⁶⁵

Both the backlog of generics awaiting approval and the lengthy approval times are hindering generic entry and restricting the price drops that typically occur with increased competition. The price drop after generic entry depends on the number of generics entering the market; more generics mean a more significant decline in prices. Indeed, estimates suggest that by the time there are six or more competitors for a generic drug, the generic price has dropped to about ten percent of the brand price.¹⁶⁶ Yet many drugs have only a few generic competitors and, as a result, consumers do not enjoy the savings that would be possible with more generic entry.¹⁶⁷

162. GENERIC PHARMACEUTICAL ASSOC., *GENERIC DRUG SAVINGS IN THE U.S. 1* (2015), available at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

163. Generic Drug User Fee Amendments of 2012, Pub. L. No. 112-144, 126 Stat. 993, Title III.

164. *Alexander: Despite Extra \$1 Billion to Speed Generic Drug Approvals, FDA Process Still Too Slow*, U.S. SENATE COMM. ON HEALTH, ED., LABOR & PENSIONS (Jan. 28, 2016), <http://www.help.senate.gov/chair/newsroom/press/alexander-despite-extra-1-billion-to-speed-generic-drug-approvals-fda-process-still-too-slow>.

165. *Id.*

166. *Id.*

167. Zachary Brennan, *FDA's Woodcock: Generic Drug Application Backlog will be Eliminated before GDUFA II*, REGULATORY AFFAIRS PROF'L SOC'Y (Jan. 28, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/01/28/24195/FDA%E2%80%99s-Woodcock-Generic-Drug-Application-Backlog-Will-be-Eliminated-Before-GDUFA-II/>.

Congress is currently pressuring the FDA to reduce this backlog and promote generic entry.¹⁶⁸ Enhanced efforts will facilitate generic competition and, in turn, reduce drug prices and lower consumers' spending on medications.

B. Expedite Biosimilars Approval

Recognizing the expansion in biologic drugs and the growing importance of affordable biosimilar alternatives, Congress provided an expedited FDA approval pathway for biosimilars under the Biologics Price Competition and Innovation Act ("BPCIA") of the ACA.¹⁶⁹ Under BPCIA, a proposed biologic substitute does not have to demonstrate bioequivalence, but merely biosimilarity, to a reference product.¹⁷⁰ A product approved as biosimilar may further be deemed interchangeable with another biologic if its manufacturer can demonstrate that switching between the reference biologic and the proposed substitute presents no additional risk in safety or efficacy for consumers.¹⁷¹ Importantly, under federal law, interchangeable products may be substituted for reference biologics without a prescribing doctor's intervention.¹⁷² However, BPCIA vests with the FDA broad discretion in determining biosimilarity; the FDA may rely on various studies—or waive these requirements¹⁷³—make rules,¹⁷⁴ issue guidance, or even categorically ban biosimilar applications for classes of biologics.¹⁷⁵

Despite BPCIA's charge to the FDA, the FDA has proven surprisingly tentative in promoting biosimilar approval. As of January 2016, it had approved only three biosimilars for use in the U.S. despite several pending biosimilar applications.¹⁷⁶ The FDA has also yet to provide any meaningful guidance as to what standards the agency will employ in determining whether a biosimilar is interchangeable with a biologic.¹⁷⁷ Burdensome requirements for interchangeability will increase the difficulty and cost of biosimilar approval. Moreover, many states require biosimilars to be deemed interchangeable before they can be automatically substituted for their biologic counterpart at pharmacies.¹⁷⁸ A high hurdle for what constitutes interchangeability will limit automatic substitution of affordable

168. Gilchrist, *supra* note 11.

169. 42 U.S.C. § 262(i)(2)(B) (2016).

170. *Id.*

171. 42 U.S.C. § 262(i)(3) (2016).

172. *Id.*

173. 42 U.S.C. § 262(k) (2016).

174. *Id.*

175. 42 U.S.C. § 262(k)(8)(E) (2016).

176. Brennan, *supra* note 81.

177. Brennan, *supra* note 82.

178. *Id.*

biosimilars and, in turn, greatly reduce the savings possible from biosimilar competition.

American consumers stand to benefit significantly from BPCIA's biosimilar-approval pathway. Consumers currently spend over sixty-six billion dollars a year on high-priced biologic drugs.¹⁷⁹ In 2014, ten biologics with over three billion dollars in annual sales were on the list of the top-twenty-five selling drugs, and seven of the top eight best-selling drugs were biologics.¹⁸⁰ Many biologic drugs are currently prohibitively expensive for consumers. The average cost of a biologic drug is twenty-two times greater than a traditional drug.¹⁸¹ Moreover, by requiring large patient coinsurance for specialty drugs, such as biologics, most consumers' prescription-drug insurance coverage fails to fully defray these massive costs.¹⁸² As a result, many consumers cannot afford to obtain these life-saving or life-enhancing drugs.

Expediting the approval of biosimilars will increase competition in the market for biologic drugs, reducing prices and allowing more patients access to these treatments. Evidence from Europe reveals that biosimilars have stimulated market competition, reducing prices and saving consumers between fifteen billion dollars and forty-five billion dollars from 2007 to 2020.¹⁸³ Many expensive biologics stand to soon go off-patent in the U.S., opening the door for competition from cheaper biosimilars.¹⁸⁴ As a result, estimates suggest that a biosimilar-approval pathway at the FDA will save U.S. consumers between forty-four billion dollars¹⁸⁵ and \$250 billion¹⁸⁶ over the next decade.

179. Andrew W. Mulcahy et al., *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND CORP. 7 (2014), http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

180. B. Sargent, *10 Biologics on Best Selling Drugs List for 2014*, CELL CULTURE DISH (Mar. 19, 2015), <http://cellculturedish.com/2015/03/10-biologics-on-best-selling-drugs-list-for-2014/>.

181. So & Katz, *supra* note 17.

182. Purvis, *supra* note 77, at slides 8-12.

183. Sumant Ramachandra, *Lessons for the United States: Biosimilar Market Development Worldwide*, at slide 13 (Feb. 4, 2014), http://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/ramachandra.pdf.

184. FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 4 (2009), <http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

185. Mulcahy et al., *supra* note 179, at 13.

186. Miller, *supra* note 80, at slide 7.

C. Prohibit Anticompetitive Practices

In addition to promoting more competition, courts and lawmakers can do more to prohibit anticompetitive behaviors. Like promoting generic and biosimilar entry, preventing anticompetitive practices will increase competition in the pharmaceutical industry and lower prices. Although an in-depth discussion of anticompetitive practices in the pharmaceutical industry is beyond the scope of this article, recent investigations and regulatory actions suggest that a few new practices may be low-hanging fruit that could be easily targeted. Below I provide a few examples.

First, some product-switching cases may be targets for increased enforcement. These cases arise when brand companies decide to shift their marketing efforts away from drugs about to go off-patent and toward a new drug that can serve as a substitute for the expiring drug. Much of this behavior is the predictable business response to the incentives created by patent law and state substitution laws. As previously discussed, developing a drug and obtaining FDA approval costs an average of \$2.6 billion and the patent period provides a very limited window during which companies can charge higher prices to recoup these exorbitant costs. As the patent period expires, brand companies typically lose eighty to ninety percent of their sales to generic versions of the drug under state substitution laws that allow or even require pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug.¹⁸⁷ Instead of continuing to market drugs after the patent period expires and handing over eighty to ninety percent of their sales to generic competitors, brand companies often decide to shift their marketing efforts to a new drug that can serve as a substitute for the drug about to go off-patent.

As I have argued in prior work,¹⁸⁸ many product-switching cases are not anticompetitive because it is within patent holders' rights to stop marketing a drug during its patent period, and removing an obsolete product from market when there is a new and improved version is not consumer coercion. Furthermore, marketing a new product that is still under patent does not prevent consumers from switching to generic versions of the prior drug and does not bar generics from several existing cost-efficient means of distribution. However, certain product-switching behavior may give rise to valid anticompetitive claims. Sometimes, the shift in marketing effort from a drug facing patent expiry to a substitute is accompanied by other wrongful and fraudulent behavior intended to coerce consumers. Examples include cases where the manufacturers fabricate safety concerns or falsely disparage the original drug to drive consumers to the new substitute.¹⁸⁹

187. *New York v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir. 2015).

188. Joanna Shepherd, *Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors' Market Entry*, 17 MINN. J. L. SCI. & TECH. 2 (2016).

189. *In re: Suboxone (Buprenorphine Hydrochloride and Naxalone) Antitrust Litigation*, 64 F.Supp.3d 665, 681 (E.D. Pa. 2014) (plaintiffs also alleged that defendants falsely disparaged the tablet through fabricated safety concerns); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F.Supp.2d 408 (D. Del. 2006) (denying defendant's

Other examples include cases where the manufacturer's new drug is nothing but a sham innovation that does not justify shifts in marketing effort or redirecting consumers.¹⁹⁰ Enforcing actions against these and similar anticompetitive practices in product-switching cases will facilitate generic entry and, in turn, lower drug prices.

Abuse of the FDA's Risk Evaluation and Mitigation Strategies ("REMS") program is another area in which enhanced enforcement could increase competition. The FDA introduced REMS in 2007 to augment the agency's post-approval authority over drugs and ensure that a drug's benefits exceed its risks.¹⁹¹ The FDA requires REMS for drugs that need additional communication with prescribers, pharmacists, or patients to manage any risks or safety concerns associated with a drug.¹⁹² For many drugs, REMS restrict distribution and prescribing practices and require additional recordkeeping by prescribers and pharmacists. Nearly forty percent of new drugs are subject to REMS restrictions.¹⁹³

Unfortunately, generic manufacturers now claim that some brand manufacturers are using REMS to thwart generic entry. They argue that brand companies point to REMS' restrictive distribution requirements to deny generic manufacturers access to the product samples they need to receive FDA approval. For example, the now-notorious Martin Shkreli and Turing Pharmaceuticals allegedly restricted the distribution of pyrimethamine to a single source to make it more difficult for generic competitors to obtain samples needed for bioequivalence testing.¹⁹⁴ Both the Federal Trade Commission and Congress launched investigations into Turing for possible antitrust violations when the

motion to dismiss. Plaintiffs alleged that defendant twice tweaked the drug formulation to prevent automatic generic substitution and removed the prior formulations from the National Drug Data File to prevent pharmacies from filling prescriptions for the older versions and their generic counterparts).

190. JOSHUA D. WRIGHT & DOUGLAS H. GINSBURG, *THE CANADIAN COMPETITION BUREAU'S DRAFT UPDATED INTELLECTUAL PROPERTY ENFORCEMENT GUIDELINES 1* (2015), available at https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf ("We respectfully recommend against imposing a competition law sanction on product switching absent clear and convincing objective evidence that Product B represents a sham innovation with zero or negative consumer welfare benefits.").
191. Jordan Paradise, *REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 *HOUS. J. HEALTH L. & POL'Y* 43, 57 (2015).
192. *Id.* at 57.
193. Darren S. Tucker et al., *REMS: The Next Pharmaceutical Enforcement Priority?*, 28 *ANTITRUST* 74, 74 (2014).
194. Michael Carrier & Aaron Kesselheim, *The Daraprim Price Hike and a Role for Antitrust*, HEALTH AFF. BLOG (Oct., 21, 2015), <http://healthaffairs.org/blog/2015/10/21/the-daraprim-price-hike-and-a-role-for-antitrust/>.

restricted distribution of pyrimethamine was accompanied by a 5000 percent price increase.¹⁹⁵

Courts have yet to rule on whether restrictive distribution under REMS can constitute anticompetitive conduct.¹⁹⁶ However, Congress is currently considering proposals to prevent any abuses.¹⁹⁷ While limiting distribution to ensure that risky products are sold and used safely is what the FDA intended with the REMS program, using the program to limit generic entry harms competition and increases prices for pharmaceuticals. Courts and lawmakers should be cautious in striking the right balance between ensuring drug safety on the one hand and facilitating competition on the other.

V. Conclusion

Recent surges in drug spending have provoked anger and prompted calls for reform. However, policy makers should understand the full consequences of intervention in the pharmaceutical industry before acting. Reforms calling for new price controls could impose harms on consumers that outweigh any benefits that they provide through lower prices. Basic economic principles, past experience, and empirical data indicate that new price controls will likely increase drug prices for some consumers, slow pharmaceutical innovation, curtail generic competition, and reduce consumer choice. In contrast, reforms aimed at promoting competition or prohibiting anticompetitive practices will lower pharmaceutical prices and drug spending without these deleterious effects.

195. Brett Norman & Sarah Karlin, *Martin Shkreli Gets Temporary Reprieve from Hill Scrutiny*, POLITICO (Jan. 25, 2016), <http://www.politico.com/tipsheets/prescription-pulse/2016/01/the-martin-shkreli-show-comes-to-the-hill-212335>.

196. Melissa Lipman, *Price Hike Scrutiny May Land Drug Cos. In Antitrust Hot Water*, LAW 360 (Oct. 8, 2015), <http://www.law360.com/articles/712636/price-hike-scrutiny-may-land-drug-cos-in-antitrust-hot-water>.

197. John Kennedy, *Generic-Drug Cos. Urge Senate To Fight FDA Approval Delays*, LAW 360 (Jan. 5, 2016), <http://www.law360.com/articles/742740/generic-drug-cos-urge-senate-to-fight-fda-approval-delays>.