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Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs

*Paula Tironi**

INTRODUCTION

Pharmaceutical innovation has generated tremendous benefits for human health.¹ Prescription drugs can reduce suffering, prevent surgeries and hospitalization, save lives, and permit individuals to live more productive and fulfilling lives.² Prescription drugs have also been shown to decrease the cost of hospitalization.³ Those who need but cannot afford prescription medication risk the continuation or worsening of symptoms, development of complications, and loss of productivity including missed work days and potential dismissal, as well as preventable pain, disability, and death.

Federal legislation to improve the affordability of pharmaceuticals includes the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,⁴ which launched the Medicare Part D prescription drug

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1. Scott Gottlieb, Deputy Comm'r for Med. & Scientific Affairs, Food & Drug Admin., Speech at the Thirtieth International Good Manufacturing Practices Conference (Mar. 14, 2006) (transcript available at <http://www.fda.gov/oc/speeches/2006/gmp0314.html>).

2. *Id.*

3. Robert I. Field, *Handbook of Pharmaceutical Public Policy*, 29 J. LEGAL MED. 255, 255 (2008) (book review); Bruce C. Stuart et al., *Assessing the Impact of Drug Use on Hospital Costs*, 44 HEALTH SERVICES RESOURCES 128, 137 (2009).

4. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L.

program to help elderly and disabled Americans afford prescription drugs.⁵ The Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Act”)⁶ facilitated market entry by manufacturers of generic pharmaceuticals while incenting research-based (“innovator”) pharmaceutical companies to develop new innovative brand-name drugs.⁷ State legislation to improve access to prescription drugs includes initiatives that lower drug prices for elderly and low-income individuals, purchasing pools that drive volume discounts from pharmaceutical manufacturers, and drug importation programs that enable state residents to purchase drugs from abroad.⁸

Despite existing initiatives, a significant number of American consumers do not or can not access the prescription drugs they require. In 2007, a reported 36.1 million working-age adults and children went without medication due to concerns over cost, an 11.7 million increase from 2003.⁹ Many of these individuals lack insurance, while others are underinsured with health plans that either does not cover the outpatient prescription drugs they need or impose cost-sharing at levels they cannot afford.¹⁰ Affordability problems may also stem from higher prescribing rates and increasing drug prices, particularly for new medications.¹¹

Part I of this article discusses advances in prescription medication and its importance in the health care system. In the past one hundred years, pharmaceuticals have revolutionized medical care. Prescription drugs are now available to alleviate symptoms and to help cure or manage diseases that in the recent past were disabling or fatal.

Part II analyzes access to pharmaceuticals in the United States. Individuals covered by various health plans and programs, and those who have no prescription drug coverage, pay significantly different prices for the same medications. Factors influencing access include public and private assistance programs and discounted prices for certain generic

No. 108-173, 117 Stat. 2066 (2003).

5. See Medicare.gov, Prescription Drug Coverage, <http://www.medicare.gov/pdphone.asp> (last visited Sept. 9, 2009).

6. See generally Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994)).

7. Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 0018, ¶ 2 (2003).

8. Nat'l Conference of State Legislatures, 2008 Prescription Drug State Legislation, <http://www.ncsl.org/IssuesResearch/Health/2008PrescriptionDrugStateLegislationNCSL/tabid/14418/Default.aspx#Map> (last visited Nov. 15, 2009).

9. LAURIE E. FELLAND & JAMES D. RESCHOVSKY, CTR. FOR STUDYING HEALTH SYS. CHANGE, MORE NONELDERLY AMERICANS FACE PROBLEMS AFFORDING PRESCRIPTION DRUGS 1 (2009), <http://www.hschange.com/CONTENT/1039/1039.pdf>.

10. *Id.*

11. *Id.*

pharmaceuticals by discount stores and chain pharmacies.

Part III describes the pharmaceutical industry and its role in the health care system. Innovator pharmaceutical manufacturers research, develop and test new drugs, obtain patent protection, secure approval from the Food and Drug Administration (FDA), and then market and promote their product to physicians, pharmacists, and consumers. These manufacturers strategically price and seek reimbursement status to maximize returns on their investment. The Hatch-Waxman Act encourages generics manufacturers to develop products that are equivalent to brand-name drugs, to rely on the innovator's research to secure FDA approval through a less burdensome procedure, and to challenge the innovator's patents with the goal of marketing generic versions of patented drugs prior to the patent expiration date.¹²

Part IV explores industry trends that affect access. Trends affecting pharmaceutical manufacturers include the numerous drug patents that will expire before 2016 (the "patent cliff") and the paucity of new drugs in the developmental "pipeline." Other trends influencing manufacturers include a slowdown in the growth of demand for prescription drugs; financial problems due to the current economic crisis, a potential increase in liability for pharmaceutical products that harm consumers, and an increase in mergers and acquisitions, particularly involving biotechnology companies and products. Drug manufacturers are threatened by developments in personalized medicine because genetic testing for drug effectiveness could lead to smaller market share for their products. A similar threat is posed by comparative effectiveness analysis,¹³ which could have a negative impact on prescribing rates of drugs and drug therapies that are found less effective than their alternatives.

Payor trends that affect drug prices include increased measures to control utilization and reimbursement, such as cost-sharing, tiered formularies, prior authorization, and utilization review. Consumers have been affected by trends including increased unemployment causing workers to lose employee health benefits and economic problems that prompt employers to cut back coverage to retained employees. Out-of-pocket drug expenditures increase as plans impose cost-sharing measures and higher numbers enter

12. FDA, Abbreviated New Drug Application (ANDA): Generics, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (last visited Oct. 24, 2009) [hereinafter ANDA]; Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 176 (2008).

13. Comparative effectiveness research compares the relative effectiveness of various medical treatments. See U.S. Dep't of Health & Human Servs., Comparative Effectiveness Research Funding, <http://www.hhs.gov/recovery/programs/cer/> (last visited Nov. 15 2009).

the ranks of the unemployed and underemployed. Certain trends, however, promote access. For example, the approaching patent cliff could increase the availability of generics. Similarly, chain drug stores promote discounted generics and some offer free antibiotics.

Part V discusses industry strategies that can affect pricing. Pharmaceutical manufacturers are publicly-held corporations that employ strategies to maximize profits and return on investment in order to benefit their shareholders. As such, they have devised a number of strategies to compete in the health care marketplace and to thwart competition by generics manufacturers and other pharmaceutical innovators. These strategies include product migration pricing, switching drugs to over-the-counter status, and promotional activities such as direct-to-consumer advertising to increase market share.

Part VI reviews a number of proposals to reform the pharmaceutical component of the health care system. Proposed federal legislation would amend the antitrust laws to discourage innovators and generics manufacturers from negotiating “reverse payment” agreements whereby the innovator pays the generics challenger and the generics company consents not to enter the market until an agreed-upon date. Legislation has been put forward to permit the development and marketing of generic biotechnology products, as well as promotion of generics through consumer education campaigns. Several proposals would allow importation of drugs from countries whose direct or indirect price control strategies result in lower prices. To make prescription drugs more affordable to Medicare beneficiaries, a proposed reform would enable the Medicare prescription drug program (Part D) to negotiate directly with pharmaceutical manufacturers to obtain volume discounts. Prescription drug expenditures could also be decreased by using the results of comparative-effectiveness research and cost-benefit analysis to select drugs to treat patients more effectively, efficiently, and economically. Proposed regulations on promotional expenditures by pharmaceutical companies could impact demand and market share, and reduce major drug company costs that contribute to high prices. Several proposals address the compulsory licensing or auctioning of pharmaceutical patents. Finally, access and affordability are examined in light of proposals for universal coverage.

I. THE IMPORTANCE OF PRESCRIPTION MEDICATION

Pharmaceuticals and biologicals¹⁴ are an indispensable part of modern

14. A pharmaceutical is a chemistry-based drug based on a small molecule. A biological is a drug based on a protein manufactured from a living organism, such as a vaccine. See Robert Pear, *Congress Seeks Compromise to Approve Generic Biotechnology Drugs*, N.Y. TIMES, Apr. 8, 2007, § 1, at 22 [hereinafter Pear, *Congress Seeks Compromise*].

health care. The history of pharmaceutical innovation describes a gradual alleviation of human sickness and suffering that has resulted in a status of health and longevity unimaginable a century ago. The discovery of a method to isolate insulin in 1922 helped prevent diabetics from dying of slow starvation.¹⁵ The “therapeutic revolution” of the 1940s,¹⁶ which was accelerated during World War II, protected millions against infection through the synthesis of penicillin.¹⁷ New medicines decreased U.S. deaths from HIV/AIDS from the 1995 rate of 16.2 per 100,000 to 4.9 deaths in 2002.¹⁸ Prescription drugs help prevent cancer recurrence¹⁹ and can treat and reduce the risk of heart disease,²⁰ accounting for 40 percent of the increase in life expectancy.²¹

One example of the importance of prescription medications is antihypertensive medicines, which reduce deaths and hospitalizations. Without such medications, an estimated 86,000 deaths and 833,000 hospitalizations would have occurred in the U.S. between 1999 and 2000.²² Treating hypertension with pharmaceuticals can result in an annual 38 percent decrease in the number of hospitalizations for stroke, and a 25 percent reduction in the number of hospitalizations for heart attack.²³ Following treatment guidelines for hypertension could avoid 420,000 hospitalizations and 89,000 deaths.²⁴

Pharmaceuticals allow individuals to manage the symptoms of physical and mental illnesses including epilepsy,²⁵ depression,²⁶ multiple sclerosis,²⁷

15. RICHARD A. EPSTEIN, *OVERDOSE* 6 (2006).

16. ALFRED D. CHANDLER, JR., *SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES* 179 (2005).

17. EPSTEIN, *supra* note 15, at 3.

18. PHARM. RESEARCH & MFRS. OF AMERICA, *VALUE OF MEDICINES: FACTS AND FIGURES 2006* 11 (2006), <http://www.phrma.org/files/Value%20of%20Medicine%202006.pdf>.

19. *Id.* at 12, 16.

20. *Id.* at 13.

21. *Id.* at 10.

22. *Id.* at 19.

23. PHARM. RESEARCH & MFRS. OF AMERICA, *SHARP DECLINE IN PRESCRIPTION DRUG SPENDING GROWTH* 6 (2008), <http://www.phrma.org/files/Drug%20Spending%20Brochure%20FINAL.pdf> [hereinafter *SHARP DECLINE*].

24. *Id.*

25. Epilepsy Found., *Treatment*, <http://www.epilepsyfoundation.org/about/treatment/> (last visited Sept. 8, 2009).

26. Mayo Clinic, *Depression (Major Depression): Treatments and Drugs*, <http://www.mayoclinic.com/health/depression/DS00175/DSECTION=treatments-and-drugs> (last visited Sept. 8, 2009).

27. Mayo Clinic, *Multiple Sclerosis: Treatments and Drugs*, <http://www.mayoclinic.com/health/multiple-sclerosis/DS00188/DSECTION=treatments-and-drugs> (last visited Sept. 8, 2009).

obsessive compulsive disorder,²⁸ and scores of other painful and debilitating illnesses. Fifty-four percent of American adults report that they currently take prescription drugs, and nineteen percent of adults say they take four or more medicines each day.²⁹ Sixty-four percent of U.S. households have a member who regularly uses prescription drugs.³⁰

II. ACCESS TO PRESCRIPTION PHARMACEUTICALS

Obtaining an outpatient prescription medication depends on a variety of factors. A consumer must have access to a provider with prescribing privileges and must be able to obtain any test necessary to determine the need for or appropriateness of a given drug. He or she must have either health coverage (along with the means to pay any premium, deductible, co-insurance or co-pay) or funds to pay for the product out-of-pocket, as well as the ability to travel to a retail pharmacy to purchase the product or to obtain it from a mail-order pharmacy using either the postal system or the Internet. Access also depends on the information available to the consumer regarding diseases, treatment options, possible side effects, contraindications, and pharmaceutical alternatives including the availability of generics.

Physicians use the term “treatment gap” to refer to individuals who are at-risk but do not receive therapy. For example, over sixty percent of those at intermediate risk for a cardiovascular event do not receive treatment either because they do not have physicians or because their physicians have not offered treatment.³¹ Patients’ failure to adhere to medication therapy costs the United States an estimated \$100-300 billion in lost productivity and unnecessary health care spending every year.³²

Focusing on health insurance coverage and pharmaceutical pricing, therefore, addresses only part of the access problem, albeit a significant part: 79 percent of American adults believe drug prices are unreasonable, and 41 percent report problems, with 16 percent reporting serious problems

28. Mayo Clinic, Obsessive-Compulsive Disorder (OCD): Treatments and Drugs, <http://www.mayoclinic.com/health/obsessive-compulsive-disorder/DS00189/DSECTION=treatments-and-drugs> (last visited Sept. 8, 2009).

29. KAISER FAMILY FOUND., KAISER PUBLIC OPINION SPOTLIGHT: VIEWS ON PRESCRIPTION DRUGS AND THE PHARMACEUTICAL INDUSTRY 1 (2008), http://www.kff.org/spotlight/rxdrugs/upload/Rx_Drugs.pdf [hereinafter KAISER SPOTLIGHT].

30. Press Release, Pew Internet & Am. Life Project, One-Quarter of American Adults Have Used the Internet to Find Prescription Drug Information (Oct. 10, 2004), <http://www.pewinternet.org/Press-Releases/2004/Onequarter-of-American-adults-have-used-the-internet-to-find-prescription-drug-information.aspx>.

31. Mary E. Tinetti, *Over-the-Counter Sales of Statins and Other Drugs for Asymptomatic Conditions*, 358 NEW ENG. J. MED. 2728, 2728 (2008).

32. SHARP DECLINE, *supra* note 23, at 5.

affording medication.³³ According to the Kaiser Family Foundation:

Three in ten adults (29%) say they have not filled a prescription because of the cost in the last two years, and nearly a quarter (23%) say they have cut pills in half or skipped doses in order to make a medication last longer. . . . Problems paying for prescription drugs are even more common among those who take larger numbers of medications or are in lower income brackets.³⁴

The Center for Studying Health System Change reports that:

After remaining steady in the early part of the decade, the proportion of Americans under age 65 reporting problems affording prescription drugs increased from 10.3 percent in 2003 to 13.9 percent in 2007—a 35 percent increase . . . Approximately 36.1 million working-age (19-64) adults and children went without prescription drugs because of cost concerns in 2007, an increase of 11.7 million people from 2003.³⁵

Among working age adults, unmet drug needs increased from 13.8 percent in 2003 to 17.8 percent in 2007 (an increase of 29 percent).³⁶ Among children, unmet need for prescription medication rose from 3.1 percent in 2003 to 5 percent in 2007 (children tend to require fewer prescription drugs than adults).³⁷ According to the Center for Studying Health System Change, the increase is likely the result of higher prescribing rates, increased drug prices, higher patient cost sharing under private health plans, and market entry of expensive new pharmaceuticals.³⁸

A March 2009 poll indicated that in 2008, 22 percent of American adults did not fill a prescription because of cost, 17 percent took a medication less frequently than directed, and 51 percent of the uninsured did not see a physician when needed (compared to 24 percent among those with insurance).³⁹

The uninsured, individuals who lack private or governmental health coverage, pay out-of-pocket for prescription medications as well as for the physician visit to obtain a prescription. According to the U.S. Census Bureau, 45.7 million Americans were uninsured in 2007.⁴⁰ One study

33. KAISER SPOTLIGHT, *supra* note 29, at 12.

34. *Id.* at 12.

35. FELLAND & RESCHOVSKY, *supra* note 9, at 1.

36. *Id.*

37. *Id.*

38. *Id.*

39. HARRIS INTERACTIVE, MAJORITY OF U.S. ADULTS WORRIED ABOUT COST OF MEDICAL CARE AND INSURANCE: MANY FAIL TO GET NECESSARY CARE DUE TO COST 1 (2009), http://www.harrisinteractive.com/news/pubs/harris_healthday_poll_2009_03_09.pdf.

40. U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2007 20 fig. 6 (2008), <http://www.census.gov/prod/2008pubs/p60-235.pdf>.

estimates 86.7 million (one in three U.S. residents under the age of 65) went without insurance at some point during 2007 and 2008.⁴¹ Individuals with health insurance may be considered “underinsured” because their out-of-pocket medical expenses are high relative to their income.⁴² According to the Commonwealth Fund, 25 million insured adults were underinsured in 2007 (a 60 percent increase from the 16 million underinsured in 2003).⁴³ Underinsured adults are less likely to have prescription drug coverage and are more likely to forego care.⁴⁴ An underinsured individual may lack coverage for treatment of a pre-existing condition or may have difficulty paying for treatment due to a high deductible. He or she may be required to pay a portion of the retail prescription price due to cost sharing requirements including co-pays and co-insurance. If a given prescription medication is not covered under a health insurance policy, an insured individual may be required to pay the entire cost out of pocket. This can happen if the drug is not listed in the plan formulary or if the insurance company declines coverage of a drug that it deems experimental.⁴⁵ Medicare beneficiaries who decline to elect outpatient prescription drug coverage under Part D⁴⁶ and who lack supplemental sources of health insurance may be underinsured. Similarly, Medicare beneficiaries who are covered by a Part D prescription drug plan are often uninsured for prescription drugs during the coverage gap commonly referred to as the doughnut hole.⁴⁷ Patients with private insurance paid for approximately

41. *Analysis: 86.7M in U.S. Without Insurance*, UNITED PRESS INT’L, March 14, 2009, http://www.upi.com/Top_News/2009/03/04/Analysis_867M_in_US_without_insurance/UPI-15511236186872/.

42. THE COMMONWEALTH FUND, *INSURED BUT POORLY PROTECTED: HOW MANY ARE UNDERINSURED? U.S. ADULTS TRENDS, 2003 TO 2007 2* (2008), http://www.commonwealthfund.org/~media/Files/Publications/In%20the%20Literature/2008/Jun/How%20Many%20Are%20Underinsured%20%20Trends%20Among%20U%20S%20%20Adults%20%202003%20and%202007/Schoen_howmanyareunderinsured_chartpack%20pdf.pdf.

43. *Id.*

44. Cathy Schoen et al., *Insured But Not Protected: How Many Adults Underinsured?*, HEALTH AFF. W5-289, 295, 297 (2005), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.289v1?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&title=Insured+but+not+protected&andorexactitle=and&andorexactitleabs=and&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>.

45. Vanessa Fuhrmans, *A Family Illness, and Fewer Friends Who Can Help*, WALL ST. J., Mar. 5, 2009, at A14.

46. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare beneficiaries could enroll in outpatient prescription drug coverage under Medicare starting on Jan. 1, 2006. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, 117 Stat. 2066 (2003).

47. DEP’T. OF HEALTH & HUMAN SERVS., *HOW THE COVERAGE GAP WORKS IN MEDICARE DRUG PLANS 1* (2008), <http://www.cms.hhs.gov/partnerships/downloads/11240-P.pdf>. When a Part D beneficiary and his or her plan has spent \$2,700 (2009) for covered drugs, the beneficiary is in the coverage gap or “doughnut hole” and must pay 100% of the cost of their

one-third of their prescription drug costs out-of-pocket in 2004.⁴⁸

Rising health care costs and the current economic crisis affect the health care choices and behavior of insured individuals and the coverage decisions of health plans and employers. For the first time in more than a decade, the number of prescriptions dispensed in the United States decreased in the first eight months of 2007, an indication that people may be skimping on prescription drugs to save money.⁴⁹ The research firm IMS Health reported that the decline occurred in June, July, and August, suggesting a link with the time period when Medicare Part D beneficiaries tend to enter the doughnut hole.⁵⁰ According to a survey by the employee benefits management firm Watson Wyatt Worldwide, 17 percent of the 2,487 surveyed employees at large U.S. companies either did not fill a prescription or skipped doses of prescribed medicine in 2008, an increase from 13 percent in 2007.⁵¹ But the news is not all bad: more employees chose a lower-cost drug option (46 percent, compared to 42 percent in 2007) and more spoke with their doctors about seeking more affordable medical treatments (14 percent, compared to 9 percent in 2007). An increased number of the surveyed employees made efforts to improve their personal care (66 percent as compared to 61 percent in 2007).⁵²

Employee health coverage has grown increasingly expensive: employers have raised premiums⁵³ and the trend in health insurance plans is to require higher deductibles, greater cost sharing, and to restrict the scope of benefits which shifts more of the financial risk to employees.⁵⁴ According to benefits firm Hewitt Associates, out of 340 large firms employing a total of more than 5 million workers, two out of three employers seek to reduce health-care subsidies in 2010, which will likely increase employees' out-of-pocket costs.⁵⁵ Employers are also considering mandating generic drug use and requiring employees to purchase maintenance drugs from mail-order

prescriptions, in addition to their Part D plan premiums, until he or she has paid the \$4,350 (2009) out-of-pocket drug costs that qualify him or her for catastrophic coverage.

48. SHARP DECLINE, *supra* note 23, at 4.

49. Stephanie Saul, *In Sour Economy, Some Scale Back on Medications*, N.Y. TIMES, Oct. 22, 2008, at A1. The article mentions that patients may be splitting pills or taking them less often rather than foregoing medication altogether or declining to purchase medication for symptomless conditions such as statins for cholesterol. The cause of the downturn may also be due to safety concerns about certain pharmaceuticals.

50. *Id.*

51. Press Release, Watson Wyatt Worldwide, U.S. Workers Taking Steps To Lower Medical Costs, Watson Wyatt Survey Finds (Dec. 10, 2008), <http://www.watsonwyatt.com/us/news/press.asp?ID=20212>.

52. *Id.*

53. Furhman, *supra* note 45, at A14.

54. Schoen et al., *supra* note 44, at W5-289.

55. Bruce Japsen, *Employers to Shrink Insurance Benefits*, CHI. TRIB., Mar. 5, 2009, News, at 20.

pharmacies.⁵⁶ Four percent of employers studied are taking steps to discontinue providing health benefits altogether.⁵⁷ In 2009, workers are expected to average out-of-pocket monthly health care costs of \$156 (a 10.1 percent increase from 2008).⁵⁸

It is estimated that 75 million Americans were either underinsured or uninsured in 2007 (an estimated 42 percent of all adults, compared to 35 percent in 2003),⁵⁹ and every member of that population is vulnerable to the potential inability to afford a required prescription medication.

The Institute of Medicine recently released a study entitled “America’s Uninsured Crisis: Consequences for Health and Health Care” that states, “for children with special health care needs, being uninsured can have disastrous consequences”⁶⁰ and provides the following example:

Ginny was born with a congenital cardiac anomaly that was repaired successfully when she was 5 years old and funded through her Medicaid insurance. She had steadily followed up with her pediatric cardiologists, and, as soon as she developed an arrhythmia at 11 years old, it was discovered and her regimen of anti-arrhythmic medication was titrated to perfectly control her heart’s rhythm.

As the end of her Medicaid eligibility approached, Ginny scoured her small town for jobs, but none of the small businesses there would hire her. At the time of her 19th birthday, Ginny’s Medicaid drug coverage stopped, and she was left without the means to buy her anti-arrhythmic medications and went without. Ginny died of a fatal arrhythmia 5 months later.⁶¹

The Cox family in North Carolina has health insurance but coverage gaps (sometimes totaling \$40,000 per year) require that they rely on family members, friends, and their church to help them afford medical treatment for their three children who have Schwachmann Diamond Syndrome.⁶² Economic difficulties made donations shrink and the family is making a

56. *Id.*

57. *Id.*

58. *Id.*

59. SARA R. COLLINS ET AL., THE COMMONWEALTH FUND, LOSING GROUND: HOW THE LOSS OF ADEQUATE HEALTH INSURANCE IS BURDENING WORKING FAMILIES 8 (2008), http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2008/Aug/Losing%20Ground%20How%20the%20Loss%20of%20Adequate%20Health%20Insurance%20Is%20Burdening%20Working%20Families%20208212%20Finding/Collins_losinggroundbiennialsurvey2007_1163%20pdf.pdf.

60. INST. OF MED. OF THE NAT’L ACADS., AMERICA’S UNINSURED CRISIS: CONSEQUENCES FOR HEALTH AND HEALTH CARE 63 (2009), http://books.nap.edu/openbook.php?record_id=12511&page=13.pdf [hereinafter UNINSURED CRISIS].

61. *Id.*

62. Fuhrmans, *supra* note 45, at A14.

contingency plan to move into their vacant trailer and live on relatives' property in order to afford their children's treatment.⁶³

The elderly, disabled, and adults with chronic health problems are significantly more likely to skimp on medication because of cost:

When faced with high out-of-pocket costs for prescription drugs, many patients, particularly the elderly and disabled, skip or take smaller doses of their medications, or stop filling prescriptions. . . As many as 29 percent of disabled Medicare beneficiaries and 13 percent of elderly Medicare beneficiaries have reported such cost-related underuse, and the rates are even higher among individuals with low incomes and/or multiple chronic conditions. . . Nonadherence to medication therapy has been shown to lead to negative health outcomes, and greater use of emergency department and inpatient hospital services.⁶⁴

More than 60 percent of the uninsured chronically ill, and 46 percent of the underinsured chronically ill, report skipping medication due to cost (compared with 15 percent of the chronically ill with adequate health insurance).⁶⁵ If the co-payment doubles for a prescription medication prescribed for a chronic condition, adherence is reduced by 25 to 45 percent, hospitalizations increase by 10 percent, and visits to the emergency room increase by 17 percent.⁶⁶

The Institute of Medicine (IOM) reports that qualifying for Medicare coverage can significantly improve the cardiovascular health status of previously uninsured adults,⁶⁷ although it is unclear whether the improvement is due to prescription drugs or another form of medical treatment. Another study discussed by the IOM involved two groups of diabetic adults.⁶⁸ The glycemic control in the uninsured group was significantly worse than that of the group covered by Medicare.⁶⁹ However, after age sixty-five both groups had similar outcomes.⁷⁰ The IOM report states that Medicare coverage improves the health of uninsured adults with chronic disease in several ways, but that “[a]ccess to prescription drugs appears to be especially important – previously uninsured adults who gained prescription drug coverage experienced the greatest health

63. *Id.*

64. Julie M. Donohue et al., *Potential Savings from an Evidence-Based Consumer-Oriented Public Education Campaign on Prescription Drugs*, 43 HEALTH SERVICES RESOURCES 1558, 1558 (2008).

65. COLLINS ET AL., *supra* note 59, at x.

66. SHARP DECLINE, *supra* note 23, at 5.

67. UNINSURED CRISIS, *supra* note 60, at 8.

68. *Id.* at 77.

69. *Id.*

70. *Id.*

improvement.”⁷¹

Prescription drug prices can lead to non-adherence among the poor:

Prescription drug prices are a significant barrier to appropriate medication use. Cost-related underuse in the uninsured is common, and even small increases in drug prices can dramatically affect medication adherence among the poor . . . There are clear adverse health effects associated with decreased medication adherence, including poorer control of chronic disease and higher rates of hospitalization and emergency room visits. . .

While many low-income individuals obtain prescription coverage through government programs and may receive relatively generous drug benefits, those who have no prescription coverage are required to pay the full retail price charged at their pharmacies. More than half of uninsured adults younger than 65 come from low-income families. . . Because of discounts negotiated by insurance companies, cash-paying customers are charged higher prices for their drugs than their insured counterparts. . .⁷²

Approximately 75 million uninsured and underinsured⁷³ risk inability to access needed prescription medications.⁷⁴ The risk is greatest for the chronically ill who require maintenance medication. Inability to acquire pharmaceuticals can result in a worsening of symptoms or failure to improve, which can cause preventable pain and premature death as well as economic consequences to the individual, his or her family, and society as a whole.

The structure and dynamics of the pharmaceutical industry directly impacts the availability and pricing of prescription drugs, as well as the nature and feasibility of efforts to make drugs more accessible through reform. An individual’s access to pharmaceuticals depends on the pharmaceutical industry that develops, obtains approvals, manufactures, markets, and sells prescription medications.

III. THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry grew out of the chemical industries of Germany and the United States in the late nineteenth century.⁷⁵ A buyer in 1885 could purchase medicinal preparations from manufacturers whose names are familiar today: Merck, SmithKline, Eli Lilly, and John Wyeth,

71. *Id.*

72. Walid F. Gellad et al., *Variation in Drug Prices at Pharmacies: Are Prices Higher in Poor Areas?*, 44 HEALTH SERVICES RESOURCES 606, 606-07 (2009).

73. COLLINS ET AL., *supra* note 59.

74. *See text accompanying* notes 40-48.

75. CHANDLER, *supra* note 16, at 178-79.

among others.⁷⁶

Traditional “innovator” pharmaceutical manufacturers research, develop, and patent a drug, obtain approval that the drug is safe and effective from the Food and Drug Administration,⁷⁷ market and promote the drug,⁷⁸ and are entitled to charge monopoly profits and exclude competition for the duration of the patent.⁷⁹ Generics manufacturers produce drugs that are the therapeutic equivalents of drugs developed by innovators⁸⁰ and market them at a lower cost.⁸¹

Traditionally, drug wholesalers purchased pharmaceuticals at a discount from manufacturers and sold them to retail and institutional pharmacies.⁸² Today, a more complicated supply chain includes a variety of public and private payors and negotiators, including: private and employee-sponsored health plans, government programs such as Medicare and the U.S. Department of Veterans Affairs (the “VA”), pharmacy benefits managers, and prescription assistance organizations.⁸³ The industry structure and stakeholders create the basis for pharmaceutical pricing dynamics, which ultimately affects consumer access and the affordability of prescription medications.

A. Innovator Pharmaceutical Manufacturers

Pharmaceutical innovators are manufacturers that research and develop new products, obtain FDA approval through testing and clinical trials, secure patent protection, and promote a “brand-name” product to physicians, pharmacists, and consumers.⁸⁴ Patent protection allows

76. *Id.* at 177.

77. *See generally* PHARM. RESEARCH & MFRS. OF AM., DELIVERING ON THE PROMISE OF PHARMACEUTICAL INNOVATION: THE NEED TO MAINTAIN STRONG AND PREDICTABLE INTELLECTUAL PROPERTY RIGHTS (2002), <http://www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf>.

78. *See generally* MEREDITH B. ROSENTHAL ET AL., KAISER FAMILY FOUND., DEMAND EFFECTS OF RECENT CHANGES IN PRESCRIPTION DRUG PROMOTION (2003), <http://www.kff.org/rxdrugs/upload/Demand-Effects-of-Recent-Changes-in-Prescription-Drug-Promotion-Report.pdf>.

79. EPSTEIN, *supra* note 15, at 9.

80. FDA, *Drugs@FDA Glossary of Terms*, <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm> (last visited Oct. 6, 2009).

81. Generic Pharmaceutical Assoc., *About Generics*, <http://www.gphaonline.org/about-gpha/about-generics> (last visited Oct. 6, 2009).

82. KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 1 (2005), <http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf>.

83. *See generally id.*

84. *See* Michelle Meadows, FDA, New FDA Initiatives to Improve Drug Reviews and Reduce Legal Loopholes, <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134448.htm> (last visited Oct. 24, 2009); FDA, The Impact of Direct-to-Consumer Advertising, <http://www.fda.gov/Drugs/ResourcesForYou/>

innovators to demand monopoly prices for the life of the patent.⁸⁵

Higher drug prices fund research and the development (R&D) of new drugs, but public policy may have to choose between the development of new drugs and lower prices that increase access to drugs.⁸⁶ There is evidence that R&D spending increases with drug prices.⁸⁷ Innovator pharmaceutical manufacturers attempt to develop “blockbuster” drugs with annual sales of at least \$1 billion in order to offset the high cost of R&D and to fund the development of subsequent products.⁸⁸

The Food, Drug and Cosmetic Act requires an innovator pharmaceutical manufacturer to submit a New Drug Application (NDA) and prove the product safe and effective before marketing it to the public.⁸⁹ Researching and developing a new prescription medication can take ten to fifteen years and the efforts of thousands of researchers and regulators.⁹⁰ Average R&D costs for a single drug can exceed \$1 billion.⁹¹ Millions of dollars are spent on potential drugs that fail in clinical trials.⁹² It is estimated that only one out of 5,000 to 10,000 potential new pharmaceuticals makes it to human trials,⁹³ and many drugs that succeed in animal trials fail when tested on humans.⁹⁴

By contrast, generic drugs sell for much lower prices than brand-name equivalents.⁹⁵ Generics avoid the cost of R&D and the expenses associated with NDA approval from the FDA.⁹⁶

Consumers/ucm143562.htm (last visited Oct. 24, 2009).

85. EPSTEIN, *supra* note 15, at 9.

86. Alan M. Garber & Victor Fuchs, Brookings Institution, Medical Innovation: Promises and Pitfalls, http://www.brookings.edu/articles/2003/winter_technology_fuchs.aspx (last visited Oct. 24, 2009).

87. Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 212 (2005) (suggesting that an increase of ten percent in the growth of real drug prices is linked to an increase of almost six percent in R&D intensity).

88. Field, *supra* note 3, at 258.

89. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2006).

90. Billy Tauzin, The Next 50 Years of Medical Innovation Has Already Started (Nov. 1, 2008), http://www.phrma.org/about_phrma/straight_talk_from_billy_tauzin/the_next_50_years_of_medical_innovatin_has_already_started/.

91. *Id.*

92. Gregory A Petsko, *Pharmacogenomics Arrives*, 5 GENOME BIOLOGY 108, 108 (2004).

93. Barbara Martinez & Jacob Goldstein, *Big Pharma Faces Grim Prognosis*, WALL ST. J., Dec. 6, 2007, at A1.

94. *Id.*

95. ANDA, *supra* note 12.

96. *Id.*

B. Generics Manufacturers

Generics manufacturers duplicate the active ingredient in a brand-name pharmaceutical and are free to market the generic drug if it does not infringe on the brand name drug's patent, or when the brand-name drug's patent has expired.⁹⁷ On average, generics cost 30 to 80 percent less than their brand-name equivalents.⁹⁸

States, health plans, and employers often require pharmacists to fill prescriptions with a generic, if available. In 2008, 63.7 percent of U.S. prescriptions were filled by generics,⁹⁹ a slight decrease from 67 percent in 1997 but higher than the 2006 and 2005 figures of 63 and 60 percent, respectively.¹⁰⁰ According to IMS, U.S. retail sales of generic pharmaceuticals totaled approximately \$33 billion in 2008.¹⁰¹

The FDA requires that a generic contain the same active ingredient as the brand-name drug, although its colorants, binders, and fillers may differ.¹⁰² The generic must deliver 80 to 125 percent of the amount of active ingredient in the brand-name drug, but the Generic Pharmaceutical Association states that on average, a generic does not vary significantly from the corresponding brand-name drug.¹⁰³ In 1997, researchers found an average of less than 4 percent difference in blood levels between generics and originals.¹⁰⁴

In spite of the close resemblance between generics and their brand-name counterparts, there have been incidents of patients claiming generics lack the original's efficacy, most notably with epilepsy drugs. Patient advocacy groups, including the Epilepsy Foundation of America, encourage states to prohibit "drug product substitution," a process by which a pharmacist can substitute a generic for a brand name drug without permission from the prescribing physician.¹⁰⁵

Many states promote the use of generic drugs through drug product substitution laws that allow a pharmacist to fill a prescription with a generic

97. Avery, *supra* note 12.

98. Micah Hartman et al., *National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998*, 28 HEALTH AFF. 246, 250 (2009).

99. Intercont'l Marketing Servs., *IMS Health Reports Annual Global Generics Prescription Sales Growth of 3.6 Percent, to \$78 Billion*, <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=2943d52288d1e110VgnVCM100000ed152ca2RCRD&vgnnextfmt=default> (last visited Oct. 6, 2009).

100. Hartman et al., *supra* note 98, at 250.

101. Intercont'l Marketing Servs., *supra* note 99.

102. Shannon Pettypiece, *Seizure Threat Tied to Drug-Swap Laws May Hurt Teva, Mylan*, BLOOMBERG, Feb. 11, 2009, <http://www.bloomberg.com/apps/news?pid=20601103&sid=a9k3iDl4bTHo&refer=us>.

103. *Id.*

104. *Id.*

105. *Id.*

if the prescribing physician does not specifically disallow generic substitution.¹⁰⁶ Thirty states mandate substitution if a generic is available.¹⁰⁷ However, several states, including North Carolina, Tennessee, Utah, and Hawaii, have passed measures that stop drug product substitution, according to the Generic Pharmaceutical Association.¹⁰⁸ Druggists in those states must now obtain patient or doctor consent, or sometimes both, for switches involving certain classes of medicine.¹⁰⁹

Congress promoted generics pharmaceutical marketing with the passage of the Drug Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act.¹¹⁰ The Hatch-Waxman Act allows a generics manufacturer to submit to the FDA an Abbreviated New Drug Application (ANDA), which is a less expensive approval process than the NDA process and does not require clinical trials.¹¹¹ As a result, between 1984 and mid-2007, the use of generic drugs in the U.S. increased from nineteen to sixty-seven percent of all prescriptions.¹¹²

Blurring the distinction between innovator pharmaceutical manufacturers and generics manufacturers, some innovators have entered the generics industry. Novartis, an innovator, owns Sandoz, a generics manufacturer,¹¹³ and Pfizer manufactures generics through its Greenstone unit.¹¹⁴ Other innovators negotiate arrangements with independent generics manufacturers under which the generics concern is licensed to sell "authorized generics" that are identical to the original brand-name drug.¹¹⁵ Authorized generics can also refer to a generics version of a brand-name drug that is manufactured and sold by the innovator drug company that sells the brand-name equivalent (or by a division of that company).¹¹⁶

A number of large chain pharmacies and discount stores, including Wal-

106. Richard Cauchi, *Substituting Drugs: State Roles*, LEGISBRIEF (Nat'l Conf. of St. Legislatures, Denver, Colo.), June-July 2009.

107. Evan H. Langdon, Comment, *Switching to Generic: The Need for Physician and Patient Consent When Substituting Antiepileptic Medication*, 25 J. CONTEMP. HEALTH L. & POL'Y 166, 179 (2008).

108. Pettypiece, *supra* note 102.

109. *Id.*

110. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 *et seq.* (1994)).

111. Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 309 (2005).

112. SHARP DECLINE, *supra* note 23.

113. Heather Timmons & Tom Wright, *Novartis to Buy Two Makers of Generics*, N.Y. TIMES, Feb. 22, 2005, at C1.

114. Pfizer, Established Products Fact Sheet, http://www.pfizer.com/news/press_kits/established_products_fact_sheet.jsp (last visited Oct. 18, 2009).

115. Martinez & Goldstein, *supra* note 93.

116. FTC, AUTHORIZED GENERICS: AN INTERIM REPORT (2009), <http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf>.

Mart, CVS Caremark, Walgreen Co., and Rite Aid Corp., have implemented aggressive drug discount programs that enable consumers to purchase certain generic drugs at prices that can be as low as \$4 for a one-month supply.¹¹⁷ Wal-Mart announced that its program saved its customers over \$610 million in its first year.¹¹⁸ Several pharmacies offer free antibiotics as well, including Meijer, ShopRite, Giant Food Stores, Stop & Shop, and Wegmans.¹¹⁹ Some of these pharmacies have been criticized for refusing to extend the discount prices to Medicaid and Medicare beneficiaries, including those who have entered the doughnut hole and must pay the full prescription drug cost out-of-pocket until they reach the catastrophic coverage threshold.¹²⁰

Low-income individuals may not have full access to these programs because chain pharmacies tend not to be located in low income areas, which are more likely to be served by independent pharmacies with higher prices.¹²¹ A recent study concluded that mean prices on pharmaceuticals are sometimes highest in the poorest zip codes, thereby putting at a disadvantage those who lack transportation to purchase medication at chain stores.¹²²

There is a risk that these discount programs may be challenged under laws prohibiting unfair trade practices and predatory pricing.¹²³ Predatory pricing laws were originally enacted in various states to protect small retailers from large retail chains. A legal challenge based on predatory pricing laws could argue that large chain pharmacies could use discount programs to drive competitors out of business then recoup their losses by raising prices.¹²⁴ Discount programs have excluded certain drugs in individual states due to state laws prohibiting retailers from selling items below cost.¹²⁵

C. Biotechnology Manufacturers

Whereas traditional pharmaceutical manufacturers develop new drugs

117. Dinah Wisenberg Brin, *Corporate News: Pharmacies Fight Tough Battle on Generic Prices*, WALL ST. J., Dec. 22, 2008, at B3.

118. NAT'L CONFERENCE OF STATE LEGISLATURES, *GENERIC DRUG PRICING AND STATES*, 2009 EDITION, [http://www.ncsl.org/programs/health/generic\\$.htm](http://www.ncsl.org/programs/health/generic$.htm).

119. Tara Parker-Pope, *U.S. Warns of Danger in Giveaways of Antibiotics*, N.Y. TIMES, Mar. 5, 2009, at A22.

120. David Shaffer, *Whistleblower: 'Low-Cost' Generic Drugs Not Cheap For All - Walgreens and Some Other Pharmacies Charge More If the Government Is Buying*, MINN. STAR TRIB., Mar. 26, 2009, at 1A.

121. Gellad et al., *supra* note 72, at 6.

122. *Id.* at 4.

123. NAT'L CONFERENCE OF STATE LEGISLATURES, *supra* note 118.

124. *Id.*

125. *Id.*

using chemistry, biotechnology pharmaceutical companies use biological processes to develop new drugs from living organisms.¹²⁶ Biotechnology drugs include vaccines, treatments for cancer, diabetes, and cardiovascular illness.¹²⁷ Although biotechnology is a relatively new addition to the pharmaceutical industry, biotechnology companies that are members of the Biotechnology Industry Organization (BIO) have thus far brought 254 new drugs to market.¹²⁸

Ernst & Young estimates the American market for biotechnology drugs exceeds \$60 billion annually,¹²⁹ the generics drug industry expects that figure to exceed \$100 billion in 2011.¹³⁰ Some biotech drugs are highly profitable. For example, Genentech Inc. charges \$4,400 per month for Avastin, a cancer drug.¹³¹ Patients with Gaucher disease sometimes pay \$200,000 for treatment with Cerezyme, a biotechnology drug from Genzyme.¹³² However, the biotechnology industry as a whole is risky because many biotech companies fail to achieve profitability after investing millions of dollars in research.¹³³ The United States has no process for the approval of generic biological drugs.

D. Purchasers and Payors

1. Private Health Plans

In 2007, 202 million Americans were covered by private health insurance.¹³⁴ Although most Americans with private health insurance obtain their coverage through an employer, the number of employees covered by employer-sponsored insurance is decreasing.¹³⁵ In 2005, sixty-four percent

126. Andrew Pollack, *Costly Drugs Known as Biologics Prompt Exclusivity Debate*, N.Y. TIMES, July 22, 2009, at B1.

127. BIOTECHNOLOGY INDUS. ORG., HEALTH BROCHURE 1 (2009), http://bio.org/aboutbio/Health_Brochure_2009.pdf.

128. Biotechnology Indus. Org., BIO Health Overview, <http://bio.org/healthcare/> (last visited Oct. 18, 2009).

129. Catherine Larkin, *Waxman Limits Protections for Amgen, Genentech Drugs (Update1)*, BLOOMBERG, March 11, 2009, <http://www.bloomberg.com/apps/news?pid=20670001&refer=&sid=aG3mcgOKpd4E>.

130. Alicia Mundy, *Corporate News: Firms Prepare for a Fight Over Generic Drugs*, WALL ST. J., Mar. 12, 2009, at B4.

131. Martinez & Goldstein, *supra* note 93.

132. Larkin, *supra* note 129.

133. Andrew Pollack, *For Biotech, A Tax Break Spells Hope*, N.Y. TIMES, Dec. 10, 2008, at B1; *see also* Andrew Pollack, *Drug Investors Lose Patience*, N.Y. TIMES, Mar. 9, 2009, at B1.

134. U.S. Census Bureau, Health Insurance Coverage: 2007 - Highlights, <http://www.census.gov/hhes/www/hlthins/hlthin07/hlth07asc.html> (last visited Oct. 18, 2009).

135. *See* PETER CUNNINGHAM ET AL., KAISER FAM. FOUND., THE FRAYING LINK BETWEEN WORK AND HEALTH INSURANCE: TRENDS IN EMPLOYER-SPONSORED INSURANCE FOR

of U.S. workers had access to outpatient prescription drug coverage through an employer-provided health care plan, and fewer than fifty percent participated in the prescription drug coverage.¹³⁶

Private health plans employ a number of techniques to control the cost of outpatient pharmaceuticals. Cost sharing, in the form of co-pays or co-insurance, is the most familiar to consumers. A co-pay is a flat payment per prescription or refill.¹³⁷ Co-insurance requires the consumer to pay a percentage of the cost of the drug.¹³⁸ A health plan with a tiered formulary frequently assigns graduated cost sharing to the various tiers to encourage selection of generics and other lower cost drugs.¹³⁹

Four-tier formularies started with Medicare drug plans (86 percent of plans had Tier 4 in 2008)¹⁴⁰ and have spread quickly to the private insurance market. By 2008, 10 percent of private and employer sponsored plans had Tier 4.¹⁴¹ Unlike a co-pay, which requires consumers to pay a flat amount per prescription, Tier 4 designation requires a payment of 20 to 33 percent of the drug's cost, which can be burdensome because the monthly cost of certain drugs can be in the thousands of dollars.¹⁴²

In the 1990s, it was not uncommon for consumers to expect to make a small co-payment for any kind of medicine.¹⁴³ Today, incentive-based formularies commonly assign co-payment amounts depending on the drug prescribed, the price differential between a brand-name drug and lower cost substitutes, and the various agreements negotiated among the insurer, the manufacturer, and the pharmacy.¹⁴⁴ In some cases, consumers are required to pay up to one-half the price of a drug.¹⁴⁵

Other cost containment strategies commonly used by health plans

EMPLOYEES, 2000-2007 (2008), <http://www.kff.org/uninsured/upload/7840.pdf>.

136. PAUL A. WELCHER, BUREAU OF LAB. STATISTICS, ACCESS TO AND PARTICIPATION IN EMPLOYER-PROVIDED HEALTH CARE PLANS, PRIVATE INDUSTRY, 2005 (2006), <http://www.bls.gov/opub/cwc/cm20060120ch01.htm>.

137. JOHN P. SOMMERS & BETH LEVIN CRIMMEL, MED. EXPENDITURE PANEL SURV., STATISTICAL BRIEF #209, CO-PAYS, DEDUCTIBLES, AND COINSURANCE PERCENTAGES FOR EMPLOYER-SPONSORED HEALTH INSURANCE IN THE PRIVATE SECTOR, BY FIRM SIZE CLASSIFICATION, 2006 2 (2008), http://meps.ahrq.gov/mepsweb/data_files/publications/st209/stat209.pdf.

138. *Id.*

139. Lesley Alderman, *Strategies for Saving on Prescription Drugs*, N.Y. TIMES, Feb 6, 2009, <http://www.nytimes.com/2009/02/07/health/06patient.html>.

140. Gina Kolata, *Co-Payments Go Way Up For Drugs with High Prices*, N.Y. TIMES Apr. 14, 2008, at A1.

141. *Id.*

142. *Id.*

143. Cindy Parks Thomas, *Incentive-Based Formularies*, 349 NEW ENG. J. MED. 2186, 2186 (2003).

144. *Id.*

145. *Id.*

include: formularies that exclude certain drugs from coverage, dispensing limits, caps on the quantity of drugs covered, utilization review, prior authorization, step therapy,¹⁴⁶ mandatory generic substitution, reference pricing, education strategies for consumers and physicians,¹⁴⁷ restrictions on the pharmacy network, mail-order incentives, and disease management.¹⁴⁸

2. Government Programs

a. Medicare

Medicare is a government health insurance program for individuals age sixty-five or older, certain disabled persons, and those with kidney failure who require dialysis (End-Stage Renal Disease, or ESRD).¹⁴⁹ Medicare Part A reimburses certain costs for hospital inpatients, skilled nursing facilities, hospice, and some home health care.¹⁵⁰ Medicare originally reimbursed hospitals on a cost-based system, but hospital costs rose dramatically under this payment system.¹⁵¹ Between 1965 and 1983, hospital costs increased from \$3 billion to \$37 billion per year.¹⁵² Today, Part A pays most hospitals a flat rate per case to reward hospitals for efficiency.¹⁵³ Medicare Part A therefore covers, but does not separately reimburse for, prescription drugs administered to Medicare beneficiaries as inpatients. Part A influences pricing only indirectly by giving hospitals additional incentive to acquire pharmaceuticals at the greatest possible discount.

By contrast, Medicare Part B influences pharmaceutical pricing directly, but only with respect to a limited number of pharmaceutical products. Part B reimburses outpatient physician fees for certain beneficiaries and covers a

146. Step therapy, also referred to as step protocol, requires a prescriber to begin treatment with the most cost-effective, safest available drug. More expensive or risky drugs are made available only to those patients who do not respond well to the earlier treatment. Medterms Online Med. Dictionary, Definition of Step Therapy, <http://www.medterms.com/script/main/art.asp?articlekey=40302> (last visited Oct. 18, 2009).

147. JACK HOADLEY, KAISER FAM. FOUND., COST CONTAINMENT STRATEGIES FOR PRESCRIPTION DRUGS: ASSESSING THE EVIDENCE IN THE LITERATURE 32, 72 (2005), <http://www.kff.org/rxdrugs/upload/Cost-Containment-Strategies-for-Precription-Drugs-Assessing-The-Evidence-in-the-Literature-Report.pdf>.

148. Thomas, *supra* note 143, at 2188.

149. Ctr. for Medicare & Medicaid Servs., Medicare Program - General Information, <http://www.cms.hhs.gov/MedicareGenInfo/> (last visited Oct 18, 2009).

150. Ctr. for Medicare & Medicaid Servs., Medicare Part A - General Information, http://www.cms.hhs.gov/MedicareGenInfo/02_Part%20A.asp (last visited Oct 18, 2009).

151. OFFICE OF EVALUATION AND INSPECTIONS, REGION IX, OFFICE OF THE INSPECTOR GEN., OEI-09-00-00200, MEDICARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM HOW DRG RATES ARE CALCULATED AND UPDATED 1 (2001), <http://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf>.

152. *Id.*

153. *Id.*

limited number of drugs that tend to be administered in a physician's office.¹⁵⁴ Prior to 2004, Part B reimbursed prescription drugs at either the amount billed by the physician or ninety-five percent of the Average Wholesale Price (AWP), whichever was lower.¹⁵⁵ The AWP is the pharmacy industry's "sticker price," published by pharmaceutical manufacturers in national price compendia (it is not an actual average of prices paid by wholesalers). The prices reimbursed under Part B were higher than the prices charged to physicians by their suppliers and the Medicare program was overpaying millions of dollars annually under this system.¹⁵⁶

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)¹⁵⁷ reformed Part B prescription drug reimbursement by reimbursing most Part B drugs at 85 percent of AWP in 2004.¹⁵⁸ In 2005 Part B began reimbursing drugs at 106 percent of the Average Sale Price (ASP), a pricing benchmark that is defined by statute and based on reports of actual transactions.¹⁵⁹ The reform substantially lowered the reimbursement cost of many drugs.¹⁶⁰

Medicare Advantage (Part C)¹⁶¹ and the Medicare Prescription Drug Program (Part D)¹⁶² offer beneficiaries a managed care benefit and an outpatient prescription drug plan, respectively. Medicare Advantage plans can include prescription drug coverage.¹⁶³ Both programs utilize private insurance plans that submit benefit proposals for approval by CMS. CMS does not negotiate prescription drug prices with the plans and therefore does not directly influence pricing levels offered to beneficiaries. Instead, CMS attempts to foster competition among plans by providing beneficiaries with

154. MEDICARE BENEFIT POLICY MANUAL, Chap. 15 Sec. 50 (Rev. 109 2009).

155. *Hearing on Medicare Reimbursement of Physician-Administered Drugs Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 109th Cong. 1 (2006) (statement of Robert A. Vito, Regional Inspector General for Evaluation and Inspections, Office of Inspector General., U.S. Department of Health and Human Services), available at <http://oig.hhs.gov/testimony/docs/2006/60713fin.pdf> [hereinafter *Hearing on Medicare Reimbursement*].

156. *Id.*

157. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2006.

158. *Hearing on Medicare Reimbursement*, *supra* note 155.

159. *Id.* at 1-2.

160. *Id.* at 2.

161. Balanced Budget Act of 1997, Pub. L. 105-33, § 4001, 111 Stat. 251, 275, amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 101, 117 Stat. at 2071.

162. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 201, 117 Stat. at 2176.

163. U.S. Dep't of Health & Human Servs., Medicare Advantage Plans, <http://www.medicare.gov/choices/advantage.asp> (last visited Oct 18, 2009).

comparison information and the opportunity to choose.¹⁶⁴

b. Medicaid

The Medicaid program helps 59 million low-income individuals access health care services through state-administered programs with joint Federal and State funding.¹⁶⁵ All state Medicaid programs cover prescription drugs,¹⁶⁶ but they vary widely in their prescription drug coverage.¹⁶⁷ States can place caps on prescription drug reimbursement,¹⁶⁸ impose cost containment measures such as co-pays,¹⁶⁹ designate categories of preferred drugs,¹⁷⁰ limit the number of prescriptions that can be filled,¹⁷¹ and form multi-state purchasing coalitions to negotiate with pharmaceutical manufacturers.¹⁷² In 2006, Medicaid funded nine percent of the \$217 billion of the total national spending on prescription drugs, over \$19 billion.¹⁷³ The Medicaid program does not purchase drugs directly. State Medicaid agencies reimburse retail pharmacies that dispense prescription drugs to Medicaid beneficiaries.¹⁷⁴ The pharmaceutical manufacturer then pays the state agency a rebate calculated according to a formula defined by statute.¹⁷⁵

In 1990, Congress established the Medicaid rebate system to lower net drug costs for states.¹⁷⁶ Manufacturers were allowed to enter into rebate

164. Tricia Newman et al., Kaiser Fam. Found., Prescription Drug Benefit Under Medicare: Background Brief, http://www.kaiseredu.org/topics_im.asp?id=131&imID=1&parentID=66 (last visited Oct. 18, 2009).

165. KAISER FAM. FOUND., MEDICAID: A PRIMER 1-3 (2009), <http://www.kff.org/medicaid/upload/7334-03.pdf>.

166. *Id.* at 10.

167. *Id.* at 12.

168. *Id.*

169. *Id.*

170. Steven Soumerai, *Benefits and Risks of Increasing Restrictions On Access to Costly Drugs in Medicaid*, 23 HEALTH AFF. 135, 135 (2004).

171. *Id.* at 135-36.

172. See BRENDAN KRAUSE, NGA CTR. FOR BEST PRACTICES, STATE PURCHASING POOLS FOR PRESCRIPTION DRUGS: WHAT'S HAPPENING AND HOW DO THEY WORK? (2004), <http://www.nga.org/cda/files/0408PRESCRIPTION.pdf>.

173. KAISER COMM'N ON MEDICAID AND THE UNINSURED, KAISER FAM. FOUND., THE MEDICAID PROGRAM AT A GLANCE 1 (2008), http://www.kff.org/medicaid/upload/7235_03-2.pdf.

174. Letter from John E. Dicken, Director, Health Care, Gov. Accountability Office, to Joe Barton, Chairman, Comm. on Energy & Commerce, H. of Rep. (Dec. 22, 2006), <http://www.gao.gov/new.items/d07239r.pdf>.

175. Center for Medicare and Medicaid Services, U.S. Dep't of Health & Human Servs., Overview Medicaid Drug Rebate Program, <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/> (last visited Oct 18, 2009).

176. U.S. GOV. ACCOUNTABILITY OFFICE, GAO-05-102, MEDICAID DRUG REBATE PROGRAM (2005), <http://www.gao.gov/new.items/d05102.pdf>.

agreements with the Department of Health and Human Services.¹⁷⁷ States could receive federal matching payments for prescription drugs only from manufacturers that entered into such agreements.¹⁷⁸

Most states calculate rebates based on the AWP.¹⁷⁹ Ceilings are established for certain multiple-source Medicaid drugs by the Federal Upper Limit (FUL) or State Maximum Allowable Cost programs.¹⁸⁰ The Deficit Reduction Act of 2005 attempted to change the basis for calculating the FUL to Average Manufacturer Price (AMP)¹⁸¹ and to require CMS to share AMP data with states, but an injunction and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) delayed implementation.¹⁸² Thus, FUL is still calculated based on the lowest published prices (AWP or wholesale acquisition cost (WAC)¹⁸³), which the Office of the Inspector General believes may result in inflated payments for Medicaid prescription drugs.¹⁸⁴

177. DANIEL R. LEVINSON, U.S. DEP'T OF HEALTH & HUMAN SERVS., OEI-03-07-00350, *COMPARING PHARMACY REIMBURSEMENT: MEDICARE PART D TO MEDICAID 5* (2009), <http://oig.hhs.gov/oei/reports/oei-03-07-00350.pdf>.

178. KAISER COMM'N ON MEDICAID AND THE UNINSURED, KAISER FAM. FOUND., *MEDICAID AND PRESCRIPTION DRUGS 2* (2000), <http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13591>.

179. LEVINSON, *supra* note 177, at i.

180. *Id.*

181. The Average Manufacturer Price (AMP) is a benchmark that Congress created in 1990 for calculating Medicaid rebates. It is not publicly available. The AMP represents the average price wholesalers pay manufacturers for drugs distributed to retail pharmacies. According to the Congressional Budget, AMP is an estimated 20 percent lower than AWP for approximately 200 pharmaceuticals frequently purchased by Medicaid beneficiaries. Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., Pharmacy Affairs & 340B Drug Pricing Program, <http://www.hrsa.gov/opa/glossary.htm> (last visited Oct. 18, 2009) [hereinafter Pharmacy Affairs & 340B Drug Pricing Program].

182. Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008) (prohibits CMS from imposing FULs for multiple source drugs prior to October 1, 2009); *see also* Ctr. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Federal Upper Limits, http://www.cms.hhs.gov/Reimbursement/05_FederalUpperLimits.asp (last visited Oct. 18, 2009).

183. The WAC is "... the manufacturer's list price for the drug to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available." ROBERT A. VITO ET AL., DEPT. OF HEALTH & HUMAN SERVS., OEI-03-05-00200, *MEDICAID DRUG PRICE COMPARISON: AVERAGE SALES PRICE TO AVERAGE WHOLESALE PRICE 2* (2005), <http://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf>; *see* Pharmacy Affairs & 340B Drug Pricing Program, *supra* note 181.

184. VITO ET AL., *supra* note 183, at ii; *see also* Alex Sugarman-Brozan & James Woolman, *Drug Spending and the Average Wholesale Price: Removing the AWP Albatross from Medicaid's Neck*, 13 HEALTH CARE POL'Y REP. 1177 (2005), available at <http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-6G8NPZ>.

c. 340B Programs

Established in 1992 by the Veterans Health Care Act of 1992,¹⁸⁵ the 340B program allows certain federally-funded grantees and other safety net providers to purchase prescription drugs at reduced prices.¹⁸⁶ In 2005, 340B entities spent \$4 billion on outpatient prescription drugs.¹⁸⁷

Drug companies entitled to sell their products under Medicaid must agree to sell their products to 340B covered entities at a reduced price.¹⁸⁸ The program results in significant savings on prescription drugs for entities including Federally Qualified Health Centers, Disproportionate Share Hospitals, the Indian Health Service, and Centers for Disease Control entities treating sexually-transmitted diseases and tuberculosis.¹⁸⁹

The “340B Ceiling Price” requires discounts of at least fifteen percent of the AMP for brand-name drugs and eleven percent of the AMP for generics.¹⁹⁰ Covered entities can negotiate sub-ceiling prices. A “prime vendor” is selected to negotiate favorable prices for 340B entities.¹⁹¹

d. FSS

The Federal Supply Schedule (FSS) is a group of multiple award contracts with various vendors.¹⁹² These contracts are used by federal agencies and other government entities to purchase goods and services, including prescription drugs.¹⁹³ The Veterans Administration (VA) negotiates the FSS pharmaceutical schedule based on prices drug manufacturers charge their “most-favored” non-federal purchasers.¹⁹⁴ Manufacturers cannot charge the VA, Department of Defense (DOD), Public Health Service (PHS), and Coast Guard more than the Federal Ceiling Price (FCP) for brand-name drugs.¹⁹⁵ The FCP must be twenty-four percent or more below the non-Federal AMP.¹⁹⁶

185. Veterans Health Care Act of 1992, 42 U.S.C § 256b (2006).

186. *Hearing on the 340B Drug Pricing Program Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 109th Cong. (2005) (statement of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services, available at <http://oig.hhs.gov/testimony/docs/2005/340bHouseE&C12-05.pdf>).

187. *Id.*

188. KAISER FAM. FOUND., *PRESCRIPTION DRUG TRENDS* (2008), http://www.kff.org/rxdrugs/upload/3057_07.pdf.

189. Pharmacy Affairs & 340B Drug Pricing Program, *supra* note 181.

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

e. Veterans Administration

The Veterans Administration (VA) offers veterans medical benefits that include an outpatient drug benefit with lower out-of-pocket costs than is available to Medicare beneficiaries under Part D. VA pharmacies fill prescriptions for an \$8 (in 2007) co-payment with no deductible, no cap, and no doughnut hole,¹⁹⁷ and the prices the VA obtains for their formulary are frequently the lowest available in the nation.¹⁹⁸ Additionally, the VA imposes price ceilings on certain drugs.¹⁹⁹ The drugs must be prescribed by a VA provider and filled at a VA pharmacy or through the VA's mail order pharmacy.²⁰⁰ In 2005, the VA spent \$4.2 billion on pharmaceuticals.²⁰¹ The VA negotiates with manufacturers for discounts and uses blanket purchase agreements to negotiate prices below those available under FSS. It further reduces prices by using preferred drug distributors known as prime vendors to purchase drugs and deliver them to VA facilities; the VA receives further discounts through prime vendors.²⁰²

3. Pharmaceutical Assistance Programs

A number of programs supported by states, nonprofit organizations, and pharmaceutical manufacturers offer help in accessing and affording prescription drugs for individuals who lack insurance coverage.²⁰³ Some of these organizations have recently increased the assistance that they offer.²⁰⁴ Information about pharmaceutical assistance programs is available by telephone or online.²⁰⁵

E. Pharmaceutical Pricing Dynamics

The health care industry is comprised of a variety of business entities.

197. Austin B. Frakt et al., *Controlling Prescription Drug Costs: Regulation and the Role of Interest Groups in Medicare and the Veterans Health Administration*, 33 J. HEALTH POL. POL'Y & L. 1079, 1081 (2008).

198. Pharmacy Affairs & 340B Drug Pricing Program, *supra* note 181.

199. John E. Dicken, *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payors and Federal Programs*, Testimony before the Committee on Finance, U.S. Senate, General Accounting Office GAO-07-358Tat 2 and 8 (Jan. 11, 2007).

200. *Id.* at 8.

201. *Id.* at 6.

202. *Id.* at 12-13.

203. Kevin Sack, *Slump Pushing Cost of Drugs Out of Reach*, N.Y. TIMES, June 4, 2009, at A1.

204. Francesca Lunzer Kritz, *Get Help Paying for Drugs*, L.A. TIMES, Mar. 30, 2009, at E3.

205. See Partnership for Prescription Assistance, www.pparx.org (last visited Nov. 10, 2009); RxAssist, www.rxassist.org (last visited Nov. 10, 2009); NeedyMeds, <http://www.needymeds.org> (last visited Nov. 10, 2009).

Most hospitals are not-for-profit corporations, and physicians' offices and group practices tend to be member-owned small business entities.²⁰⁶ Disease-specific nonprofit organizations raise money to fund research, raise awareness, disseminate information about diagnosis and symptoms, and subsidize the cost of treatment. Manufacturers of devices and pharmaceuticals, their wholesalers, pharmacy chains, health insurance companies, and employers that sponsor health plans tend to be large, for-profit entities with an obligation to their shareholders to maximize profits and secure a return on investment. Drug companies develop pricing policies to increase revenue and market share, utilizing various pricing strategies over time to influence prescriber and consumer behavior.

1. First Entry, Patented, and Single Source Drugs

Patent protection is important to the pharmaceutical industry because of the enormous cost of R&D and the ease with which a new drug, once developed, can be manufactured by generics manufacturers; the innovator's profit depends on its right to patent protection.²⁰⁷ The pharmaceutical industry's economic structure and ability to obtain financing depend on its ability to secure patents for new products.²⁰⁸

A pharmaceutical manufacturer that holds a monopoly position with respect to a drug, whether due to patent protection or because there is no other drug in its class, can charge what the market will bear. The prices of specialty drugs, prescription medications used to treat rare disorders, tend to be high even if their patents have expired because there are frequently no competing drugs. Some specialty drugs are granted exclusive marketing rights for a longer period under federal "orphan drug" laws.²⁰⁹

Examples of highly priced specialty drugs include the products of the biotechnology corporation Genzyme, which markets drugs for very small groups of patients with rare disorders. Genzyme charges patients with Gaucher disease as much as \$200,000 a year for Cerezyme.²¹⁰ Only 5,000 patients in the world use the drug, which had \$1.1 billion in sales in 2007.²¹¹ Ovation Pharmaceuticals Inc. also specializes in pharmaceuticals for rare medical conditions. In 2005, it purchased the U.S. rights to Indocin, a drug for babies born with the heart defect patent ductus arteriosus (PDA) and

206. Field, *supra* note 3.

207. *Id.*

208. *Id.*

209. See 21 U.S.C. § 360cc (2006).

210. Larkin, *supra* note 129.

211. Editorial, *When a Drug Costs \$300,000*, N.Y. TIMES, Mar. 23, 2008, Editorial Desk, at 8.

raised its price from \$26 to \$36 per vial.²¹² The following year Ovation purchased NeoProfen, the only drug that competed with Indocin, and priced NeoProfen at \$483 a vial.²¹³ Questcor Pharmaceuticals recently raised the price of H.P. Acthar Gel, used to treat children with a severe form of epilepsy, from \$1,600 a vial to \$23,000.²¹⁴ Solaris, a specialty drug for a rare blood disorder, can cost \$389,000 a year.²¹⁵

2. Subsequent Entry or “Me-Too” Drugs

The first pharmaceutical product in its classification commands a high price due to market exclusivity. If the product is patented, the second entry into the market must either challenge the patent or utilize a formulation that does not infringe on the patent. To compete, second and subsequent non-infringing entries, or “me-too” drugs, must either provide a lower price or a better outcome.²¹⁶ While the introduction of me-too drugs can thus provide lower-cost options, they do not always lead to a reduction in the price of the first entry, even though the appearance of me-too drugs can lead payors to place first entry drugs whose prices remain high into higher formulary tiers. The manufacturer of a first entry drug may elect to retain its high price point with the expectation that physicians and patients will be reluctant to discontinue a medication that has worked, preferring to sell the product at a high price to a smaller number of patients rather than selling it to more patients at a lower price.²¹⁷

3. First Generic Entry

The first generic to enter the market of a brand-name drug generally enters at a seventy to eighty percent of the price of its brand-name counterpart, and in a short time it can acquire a substantial market share.²¹⁸ Due to the Hatch-Waxman Act, the first generic entry may be entitled to a 180-day period of market exclusivity, sharing the market with the brand-

212. Jonathan D. Rockoff, *FTC Sues Ovation in Dispute on Drug Prices*, WALL ST. J., Dec. 17, 2008, at B3.

213. *Id.* (The Federal Trade Commission has filed suit to prevent Ovation from owning both NeoProfen and Indocin, and to disgorge profits, alleging unfair competition).

214. Milt Freudenheim, *The Middleman's Markup*, N.Y. TIMES, Apr. 19, 2008, at C1.

215. *Id.*

216. Thomas H. Lee, “*Me-Too*” Products – Friend or Foe?, 350 NEW ENG. J. MED. 211, 211 (2004).

217. *Id.* at 212.

218. *Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 110th Cong. 7 (2007) (statement of the Federal Trade Commission), available at http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf [hereinafter *FTC Prepared Statement*].

name drug to which it is equivalent and gaining substantial profits.²¹⁹

4. Subsequent Generic Entries

Generics that enter the market second or subsequent to the first entrant must compete on price and often discount eighty percent or more off the price of the brand-name drug, prompting generics that entered earlier to lower their prices.²²⁰

IV. TRENDS IN THE PHARMACEUTICAL INDUSTRY THAT AFFECT ACCESS

A. The Patent Cliff and the Shrinking Pipeline

According to IMS Health, prescription drugs with sales approximating \$120 billion will lose patent protection by 2013, including ten of the top 20 brand-name drugs.²²¹ By 2016, pharmaceutical companies are expected to lose \$140 billion in annual sales due to patent expiration and the entry of generics.²²²

The impact of this “patent cliff” is heightened by the relatively few potential blockbuster drugs currently in the developmental pipeline of innovator pharmaceutical companies. The FDA approved more drugs in 2008 than in each of the prior three years, but few of the new drugs appear likely to be blockbusters.²²³

Although innovator manufacturers more than doubled spending on R&D, they brought to market 43 percent fewer new pharmaceuticals between 2002 and 2006 than they did between 1995 and 2000, and drugs currently under development lack the commercial potential of earlier drug pipelines.²²⁴

As a result, the pharmaceutical industry is employing strategies to expand revenue from existing product lines, such as raising prices (the average price per pill has increased 63 percent since 2002)²²⁵ and increasing marketing. Advertising spending increased from \$2.5 billion in 2001 to \$5.3 billion in 2006, and the number of industry sales reps has nearly tripled since 1995.²²⁶ Pharmaceutical innovators are also more likely to own

219. Avery, *supra* note 12.

220. *FTC Prepared Statement*, *supra* note 218.

221. Pettypiece, *supra* note 102.

222. Reuters UK, *Drugmakers warned of \$140 billion patent “cliff.”* Mar. 5, 2009, <http://uk.reuters.com/articlePrint?articleId=UKGRI22300720070502>.

223. Jared A. Favole & Jennifer Corbett Dooren, *FDA Approved More Drugs in 2008*, WALL ST. J., Jan. 2, 2009, at A9.

224. Martinez & Goldstein, *supra* note 93.

225. *Id.*

226. *Id.*

generic subsidiaries or contract with generics manufacturers for the production of “authorized generics.”²²⁷

B. Slowing Growth in Demand for Prescription Drugs

The patent cliff is one factor mitigating drug spending growth: the availability of generic versions of blockbuster name-brand drugs is expected to lead to more moderate spending growth in 2012 and 2013.²²⁸ The growth of demand for pharmaceuticals is already experiencing a slowdown due to the availability of generics, safety concerns arising out of recent FDA warnings,²²⁹ a leveling-off in the pace of Medicare drug spending following the Part D launch in 2006,²³⁰ fewer new drugs being approved by the FDA, and fewer new blockbuster drugs in development by pharmaceutical innovators.²³¹ The slowdown is expected to continue as consumers cut back on medicines due to lack of insurance coverage or increased co-pays and deductibles.²³²

By 2007, pharmaceutical spending growth had slowed to the lowest rate in forty-five years.²³³ In 2009, IMS Health expects the drug industry to grow less than two percent.²³⁴ Layoffs in the pharmaceutical industry appear to confirm these projections: Pfizer, AstraZeneca, Johnson & Johnson, and Glaxo have recently announced layoffs, and the wealth management company RegentAtlantic Capital expects that perhaps 50,000 pharmaceutical industry jobs will be lost in the next ten years.²³⁵

The current recession has impacted growth in demand for pharmaceuticals as consumers switch to generics or fill fewer prescriptions. However, a recession can also lead to increased enrollment in government

227. Stephanie Saul, *More Generics Slow the Surge in Drug Prices*, N.Y. TIMES, Aug. 8, 2007, at A1.

228. Andrea Sisko et al., *Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook*, 28 HEALTH AFFAIRS w346, w350 (2009).

229. Bruce Japsen, *Safety Fears Help Put Brakes On Prescription Drug Growth*, CHI. TRIB., Jan. 8, 2009, at C25.

230. Vanessa Fuhrmans & Jane Zhang, *U.S. News: Health-Care Outlays Climb at Slowest Rate in Years*, WALL ST. J. Jan. 6, 2009, at A4.

231. IMS Health *New Report Highlights Dramatic Change in U.S. Drug Spending Trends, Policy Implications*, Dec. 23, 2008 <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=841365272046e110VgnVCM100000ed152ca2RCRD&vgnnextchannel=41a67900b55a5110VgnVCM10000071812ca2RCRD&vgnnextfmt=default>.

232. Fuhrmans & Zhang, *supra* note 230.

233. *Id.*

234. Ceci Connolly, *With More Oversight on the Horizon, Drugmakers Work to Polish Image*, WASH. POST, Jan. 8, 2009, at A01.

235. See Martinez & Goldstein, *supra* note 93; see also Scott Hensley, *Reports: Glaxo Prepares to Ax 6,000 More Jobs*, WALL ST. J. HEALTH BLOG, Feb. 2, 2009, <http://blogs.wsj.com/health/2009/02/02/reports-glaxo-prepares-to-ax-6000-more-jobs/>.

health programs, which can offset a decrease in private spending.²³⁶ The generics dispensing rate is expected to level off between 2014 and 2018, and new drug approvals are expected to drive the growth of drug spending, particularly in the market for specialty drugs,²³⁷ whose prices are increasing much faster than prices of pharmaceuticals.²³⁸

Comparative effectiveness analysis, a process by which researchers compare various medical treatments for the same illness, may further decrease the demand for prescription drugs that prove ineffective relative to other treatments. The recently passed \$787 billion economic stimulus bill allocates \$1.1 billion for comparative effectiveness analysis in an effort to save health care costs by discouraging the use of ineffective treatments.²³⁹

“Personalized medicine,” another development that promises to decrease demand for pharmaceuticals, involves genetic screening and other tests that could enable doctors to design treatment regimens for individual patients.²⁴⁰ Such treatments could improve care and decrease costs. It is estimated that prescription drugs work for only about half the people for whom they are prescribed, wasting much of America’s approximately \$300 billion annual spending on pharmaceuticals and exposing many patients to the side effects of drugs that do not improve their conditions.²⁴¹

Although there is currently no system in place to approve genetic tests for drug effectiveness or to evaluate their accuracy, when such testing becomes available pharmaceutical manufacturers could lose market share for each product that becomes the subject of a genetic test with the capacity to determine that a drug is inappropriate for a portion of a population of patients with a given condition.²⁴² The blockbuster model, which has led pharmaceutical manufacturers to focus on new drugs that promise to command high prices in large markets, is vulnerable to advances in genomics, which could lead to increasingly personalized medicine and smaller markets for individual drugs.²⁴³

236. CTRS. FOR MEDICARE AND MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES PROJECTIONS 2008-2018 2 (2008), <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf>.

237. Sisko et al., *supra* note 228, at w354-55.

238. Freudenheim, *supra* note 214.

239. Robert Pear, *U.S. to Study Effectiveness of Treatments*, N.Y. TIMES, Feb. 16, 2009, at A1 [hereinafter Pear, *U.S. to Study Effectiveness*].

240. Andrew Pollack, *Patient’s DNA May be Signal to Tailor Drugs*, N.Y. TIMES, Dec. 30, 2008, at A1.

241. *Id.*

242. *Id.*

243. Field, *supra* note 3, at 258.

C. The Financial Outlook for Pharmaceutical Companies

Pharmaceutical industry revenue is expected to decline between 2011 and 2012 for the first time in forty years.²⁴⁴ Growth in demand for pharmaceuticals is slowing.²⁴⁵ The pharmaceutical industry is likely to face increased costs due to liability exposure as a result of the U.S. Supreme Court's ruling in *Wyeth v. Levine*²⁴⁶ that state liability for failure to warn of a product's dangers is not preempted by federal law regarding FDA approval of a product's warning label. Specialty drug prices are increasing faster than those of pharmaceuticals²⁴⁷ and the potential of biotechnology is affecting the financial outlook for the pharmaceutical industry. In spite of the financial risks associated with the development of biotech drugs, the outlook for the biotechnology industry may be more promising than for pharmaceuticals, as evidenced by the increase in value of the shares of a number of large biotech corporations in 2008.²⁴⁸ For example, Wyeth reported in January 2009 that its revenue from products such as vaccines and biotech drugs is outpacing revenue growth from traditional pharmaceuticals.²⁴⁹ Pfizer, Inc. Chairman and Chief Executive Jeffrey Kindler said Pfizer's \$68 million acquisition of Wyeth in January 2009 was part of its new focus: transitioning from developing blockbuster drugs to biotechnology.²⁵⁰

Consequently, the pharmaceutical industry appears to be shifting its emphasis from pharmaceuticals to biotechnology products: since 2005, large drug companies have spent almost \$76 billion to buy biotechnology companies.²⁵¹ Drug company interest in biotechnology may be due in part to the lack of generic competition in the biotech market. Biotechnology products are difficult for generics manufacturers to reproduce because they are made from living tissue. Moreover, the United States currently has no approval process for generic biotechnology drugs.²⁵²

244. Martinez & Goldstein, *supra* note 93.

245. See Japsen, *supra* note 229.

246. *Wyeth v. Levine*, 129 S. Ct. 1187, 1204 (2009).

247. Freudenheim, *supra* note 214, at C1.

248. See Damian Troise, *Biotech Proves Defensive Against Tough 2008 Market*, S.F. CHRONICLE, Dec. 31, 2008, <http://www.sfgate.com/cgi-bin/article.cgi?f=/n/a/2008/12/31/financial/f062301S40.DTL>.

249. Linda A. Johnson, *Wyeth Exec: Nontraditional Products Fueling Growth*, NETSCAPE MONEY & BUS., Jan. 14, 2009, <http://webcenters.netscape.com/serve.com/pf/story.jsp?floc=FF-APO-1333&idq=ff/story/0001%2F20090114%2F1534270437.htm&sc=1333>.

250. Bruce Japsen, *Pfizer's Future Tied to Biotechnology*, CHI. TRIB. Feb. 12, 2009, at C27.

251. Martinez & Goldstein, *supra* note 93.

252. Troise, *supra* note 248.

V. INDUSTRY STRATEGIES THAT AFFECT PRICE AND ACCESS

A. Product Migration Pricing Strategy

Pharmaceutical manufacturers may price drugs strategically to “migrate” demand from one product to another.²⁵³ “Product migration strategy” involves using price to incent consumers to choose one product over another, thus causing demand to “migrate.”²⁵⁴

For example, Cephalon, Inc. raised the price of Provigil, a drug for narcolepsy, twice in 2008, and by November 2008, the drug cost seventy-four percent more than it did in 2004.²⁵⁵ This price increase impacts not only the uninsured, but also insured patients who use Provigil for a disorder other than narcolepsy (such as for Parkinson’s disease) who may be required to pay the increased price out-of-pocket if his or her insurer refuses to pay for off-label drug use.²⁵⁶

The tactic appears to be intended to steer patients from the generic competition that will enter the market in 2012. Cephalon plans to launch Nuvigil, a longer-acting version of Provigil, in 2009.²⁵⁷ By raising the price of Provigil and launching Nuvigil at a lower price point than Provigil, Cephalon may hope to migrate demand to the new, patent-protected drug, for which there will be no generic equivalent.²⁵⁸ The strategy could undermine the market for the generic by thwarting state laws and health plan policies mandating generic substitution: a pharmacy cannot automatically substitute the generic form of Provigil when a patient presents a prescription for Nuvigil. To compete with Nuvigil, the manufacturer of the generic for Provigil may have to consider undertaking its own marketing campaign because it may not be able to rely on Cephalon’s promotional activities and automatic substitution to lead to sales of the generic. However, budgeting for promotional expenditures would likely increase the cost of the generic.

B. Switching Prescription Drugs to Over-the-Counter Status

A pharmaceutical innovator may attempt to switch a brand-name product to over-the-counter (OTC) status to compete against a new generic and to expand its market by linking the OTC switch to a direct-to-consumer

253. Jonathan D. Rockoff, *How a Drug Maker Tries to Outwit Generics*, WALL ST. J., Nov. 18, 2008, at B1.

254. Reed Holden, *Giving Generics a Headache With Pharma Pricing*, (Nov. 18, 2008), <http://reedholden.wordpress.com/2008/11/18/giving-generics-a-headache-with-pharma-pricing/>.

255. Rockoff, *supra* note 253.

256. *Id.*

257. *Id.*

258. *Id.*

advertising campaign alerting consumers to the product's availability without a prescription. The information provided in the advertising, packaging, and labeling must enable individuals to make informed decision about product use and their possible need for medical oversight, particularly for long-term treatment of chronic conditions.²⁵⁹ While such a move might increase the market for the drug, it could raise costs for patients with insurance whose prescription drug coverage does not cover OTC products.

The Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act provides that the FDA can approve a drug's exemption from prescription dispensing requirements if the requirements are not necessary to protect the public from the drug's toxicity, harmful potential, or its method of use, and the drug is safe and effective to be used as directed for self-medication.²⁶⁰ A drug company is required to perform studies of label comprehension and actual use before the FDA will approve a drug's switch from prescription to OTC status, but the studies are short and relatively small.²⁶¹

C. Promotional Activities

Pharmaceutical companies promote their products through communications and marketing campaigns that include advertising to physicians, pharmacists, and consumers in order to attempt to increase the size of the market for the drug or the drug's market share in the case of multi-source products. Fewer promotional and advertising activities are undertaken with respect to specialty drugs because they are used by a smaller population.²⁶²

Pharmaceutical promotional activities include sales representative visits and gifts to physicians, conferences, speeches, educational programs and events, and televised or print direct-to-consumer (DTC) advertising.²⁶³ Merck's extensive efforts to promote Gardasil, a vaccine against several types of human papillomavirus (HPV) that can cause cervical cancer,²⁶⁴ illustrate the variety of marketing activities available to drug manufacturers: Merck financed activities for women's groups, issued grants to train speakers on college campuses, and provided kits to promote the vaccine at

259. See Tinetti, *supra* note 31, at 2730.

260. Durham-Humphrey Amendment, ch. 578, § 503(b)(1), 65 Stat. 648, 648 (1951) (current version at 21 U.S.C. §§ 353-355 (2000)).

261. Tinetti, *supra* note 31, at 2729.

262. Martinez & Goldstein, *supra* note 93.

263. See JEROME P. KASSIRER, ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH (2005).

264. See Merck, Learn About Gardasil, <http://www.gardasil.com/what-is-gardasil/index.html> (last visited Nov. 15, 2009).

college health services.²⁶⁵

VI. PROPOSALS FOR REFORM

The reform proposals discussed below have been advanced with the goal of improving the access and affordability of prescription drugs. Current trends in the pharmaceutical industry and strategies employed by drug companies to enhance the success and competitiveness of their products will influence whether a reform proposal will be effective or whether it will be easily circumvented by the industry's strategic reaction to its implementation.

A. Proposals to Promote Generics

Generic drugs tend to be priced thirty to eighty percent less than equivalent brand-name pharmaceuticals. As more generic substitutes for brand-name drugs become available, consumers have the option of choosing a lower-priced alternative for medications prescribed by their treatment providers. The following reform proposals thus attempt to increase drug affordability by facilitating generic development, promotion, and market entry.

1. Prohibiting Reverse Payment Patent Litigation Settlements

Prior to generic entry, brand-name pharmaceutical companies and generics manufacturers sometimes litigate the validity of a patent, or whether it would be infringed upon by a proposed generic equivalent, pursuant to the scheme developed under the Hatch-Waxman Act. The litigants may settle such patent litigation by agreeing upon a market entry date for the generic product, settlement payments from the innovator to the generics manufacturer, or other settlement provisions such as licensing agreements. Such agreements currently protect ten brand-name drugs with U.S. sales totaling approximately \$17 billion.²⁶⁶ The Federal Trade Commission, has argued that such settlements amount to "pay for delay" and hurt consumers by obstructing generic market entry while permitting brand-name drugs to continue to charge monopoly prices.²⁶⁷ Because the Hatch-Waxman Act allows the first generics challenger a 180-day period of exclusivity, delaying the first challenger's market entry creates a "bottleneck" that impedes the market entry of additional generics until 180

265. Elisabeth Rosenthal, *Drug Makers' Push Leads to Vaccine's Fast Rise*, N.Y. TIMES, Aug. 20, 2008, at A1.

266. Jonathan D. Rockoff, *U.S. News: Democrats Target Deals to Delay Generics*, WALL ST. J., Mar. 31, 2009, at A3 [Hereinafter *Democrats Target*].

267. *FTC Prepared Statement*, *supra* note 218.

days beyond the market entry date agreed upon in the settlement.²⁶⁸

Outside of the pharmaceutical industry, patent litigation is frequently settled by agreements whereby the challenger pays the patent holder for a license which can be limited in time or area. Settlements of patent litigation filed pursuant to Hatch-Waxman, however, are sometimes referred to as “reverse payment” settlements because the patent holder pays the challenger.²⁶⁹

The FTC maintains that these settlements are highly profitable to brand-name firms because they enable the continuation of monopoly profits until the agreed-upon generic market entry date, as well as to generics firms which can receive more in settlement payments than the anticipated profits from the generic drug. However, reverse payment settlement can harm consumers by delaying generic entry.²⁷⁰ The FTC has challenged such settlements, arguing that they allow drug patent holders “to buy more protection from competition than congressionally-granted patent rights afford. . . [and] disrupt the careful balance between patent protections and encouraging generics entry that Congress sought to achieve in the Hatch-Waxman Act.”²⁷¹ Access to Affordable Pharmaceuticals, Title XI of the Medicare Reform Act of 2003,²⁷² allows FTC review of settlements.

Critics of such settlements point out that the interests of the litigants are aligned when settling patent infringement or invalidating litigation pursuant to Hatch-Waxman,²⁷³ which could lead to settlements that benefit the litigants at the expense of consumers. In support of the settlements, commentators have pointed out that the law generally favors settlement of litigation and that forcing companies to conclude litigation could stifle innovation.²⁷⁴ Moreover, reverse payment settlements have allowed generics market entry prior to the expiration date of the litigated patent.

Proposed legislation to prohibit patent holders in the pharmaceutical industry from compensating a generics manufacturer to delay market entry of a generic drug characterizes such settlements as collusion contrary to free competition.²⁷⁵ The proposal would amend the Clayton Act²⁷⁶ to make

268. Avery, *supra* note 12, at 175-76.

269. *Id.* at 181.

270. See *FTC Prepared Statement*, *supra* note 218, at 11.

271. *Id.*

272. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355 (2006).

273. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1593-94 (2006).

274. Sheila Kadura, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded-and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647, 664 (2008).

275. S. 316, 110th Cong. (2007).

276. 15 U.S.C. §§ 12-27 (2006).

settlements of pharmaceutical patent infringement litigation unlawful if a generics manufacturer that files an abbreviated new drug application (ANDA)²⁷⁷ under the Hatch-Waxman Act receives anything of value and agrees not to market the product for a period of time.

A blanket prohibition could have the unintended effect of discouraging generics manufacturers from challenging patents under the Hatch-Waxman Act because the ensuing litigation may need to proceed to a final court decision and exhaust any possible appeals, thus increasing the time and expense of such a challenge. Because the proposal refers to “the sale of a drug product” with reference to definitions under FDA regulations,²⁷⁸ it is unclear whether it would apply to both pharmaceutical and biotechnology products.

Pharmaceutical and generics manufacturers may be able to circumvent prohibitions on reverse payment settlements by structuring the deals so that no money changes hands between the parties. Medicis Pharmaceutical Corp. recently settled litigation over the patent for its acne drug challenged by generics manufacturer Teva Pharmaceutical Industries Ltd. with an agreement that required Teva to delay selling its product until 2011.²⁷⁹ However, Teva had already earned \$25 million for sales of the generic prior to settlement, and the agreement allowed it to keep this revenue.²⁸⁰ Similar strategies could enable settlements that do not violate proposed prohibitions but still benefit innovators and generics manufacturers at the expense of consumers.

2. Generic Biotechnology Drugs

The Hatch-Waxman Act provides a regulatory scheme for approving generic equivalents of brand-name pharmaceutical drugs, but the U.S. has no comparable means for generics manufacturers to obtain approval to copy a biotechnology drug.²⁸¹ Generic biotech drugs could cost an estimated one-

277. The Hatch-Waxman Act (*see* Eureka, *supra* note 7) provides for the approval of generic drugs by allowing a generics manufacturer to file an abbreviated new drug application (ANDA). Whereas an innovator pharmaceutical company seeking approval of a new drug must file a new drug application (NDA) proving the drug is safe and effective, the ANDA can rely on the innovator’s clinical trials, thereby saving research costs and decreasing the cost of generics. Avery, *supra* note 12, at 175-76.

278. 21 C.F.R. § 314.3(b) (2008) (“*Drug substance* means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use in the synthesis of such ingredient.”).

279. *Democrats Target*, *supra* note 266.

280. *Id.*

281. A. Taylor Corbitt, *The Pharmaceutical Frontier: Extending Generic Possibilities to Biologic Therapies in the Biologics Price Competition and Innovation of Act of 2007*, 18 DEPAUL J. ART, TECH. & INTELL. PROP. L. 365, 375-76 (2008).

third less than their brand-name counterparts.²⁸² High development costs and tougher regulatory scrutiny for generic biologics are likely to increase their prices relative to generic pharmaceuticals.²⁸³ Duke University health economist Prof. Henry G. Grabowski predicts that prices for generic biologics may decline less than for generic pharmaceuticals.²⁸⁴

The Biotechnology Industry Organization (BIO), a trade association for the biotech industry, argues that generic biologics would decrease incentives for R&D.²⁸⁵ However, the introduction of generic pharmaceuticals after passage of the Hatch-Waxman Act in 1984 does not appear to have stifled R&D. The Congressional Budget Office stated:

Between 1983 and 1995, investment in [R&D] as a percentage of pharmaceutical sales by brand-name drug companies increased by 14.7 percent to 19.4 percent. Over the same period, U.S. pharmaceutical sales by those companies rose from \$17 billion to \$57 billion (in current dollars). Overall, then, the changes that have occurred since 1984 appear to be favoring investment in drug development.²⁸⁶

The biotechnology industry warns that biotech drugs are so complex that an exact duplication is impossible to achieve; an attempted copy must be tested in humans before it is approved as safe and effective.²⁸⁷ Critics claim that a difference in how a generic biologic is made in comparison with the brand-name original could change its effect on the human body, possibly decreasing its effectiveness or causing an allergic reaction.²⁸⁸

Due to the nature and complexity of biologic synthesis, minor changes in biotech compounds could have serious consequences in humans.²⁸⁹ Since perfect duplication is impossible, generic biologicals are referred to as “biosimilars” rather than “bioequivalents.”²⁹⁰ A biosimilar may not be an automatic substitute for the brand-name biologic.²⁹¹ State laws mandating

282. *Bill Would Allow Copying of Biotech Drugs*, N.Y. TIMES, Feb. 15, 2007, at C12.

283. Thomas Gryta, *Tough Road for Biologics - Generic Makers Could Face High Development, Marketing Costs*, WALL ST. J., Mar. 4, 2009, at B4.

284. Pear, *Congress Seeks Compromise*, *supra* note 14.

285. Press Release, Biotechnology Industry Org., *New Senate Bill Takes Shortcuts on Path to Biosimilars* (Mar. 26, 2009), http://www.bio.org/news/pressreleases/newsitem.asp?id=2009_0326_01.

286. CONGRESSIONAL BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY* ix, xv (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

287. Pear, *Congress Seeks Compromise*, *supra* note 14.

288. Catherine Larkin, *Obama Plan to Copy Biotech Drugs May Get Early Push (Update2)*, BLOOMBERG, Mar. 10, 2009, <http://www.bloomberg.com/apps/news?pid=20601110&sid=a4qYpDq065g0>.

289. Corbitt, *supra* note 281, at 366-67.

290. Gryta, *supra* note 283.

291. *Id.*

generic substitution may not apply to biosimilars.²⁹² Dr. Janet Woodcock, chief medical officer of the Food and Drug Administration, told Congress that the FDA is capable of determining the human and laboratory tests needed to approve generic biotech drugs.²⁹³

In the U.S., biologics are approved by the Public Health Service (PHS) rather than the FDA.²⁹⁴ Proposed legislation to provide a regulatory structure for the approval of biosimilars²⁹⁵ would amend the Public Health Service Act to allow for the filing of an Abbreviated Biological Product Application proving a product “comparable or interchangeable with the reference product”²⁹⁶ which would be reviewed by the FDA. The proposal provides for a 180-day period of market exclusivity.²⁹⁷

Legislation to regulate generic biologics was reintroduced by Representative Henry Waxman, who chairs the House Energy and Commerce Committee, on March 11, 2009.²⁹⁸ A similar bill was introduced in the Senate on March 24, 2009.²⁹⁹ The bill gives brand-name biologics the right to five years of guaranteed market exclusivity, in addition to patent protection, and the biotech industry has argued for a fourteen-year exclusivity period of data exclusivity to run concurrently with the patent term.³⁰⁰ The combination of the 180-day biosimilar exclusivity, patent protection and innovator market exclusivity would render the regulatory scheme vulnerable to reverse payment settlements.

3. Proposal to Ban Authorized Generics

Proposed legislation³⁰¹ would prohibit brand-name pharmaceutical companies from marketing authorized generic versions of their products on the grounds that authorized generics harm consumers by decreasing the incentives for generics manufacturers to enter the market.³⁰²

292. *Id.*

293. Pear, *Congress Seeks Compromise*, *supra* note 14.

294. 42 U.S.C. § 262 (2007).

295. H.R. 1038, 110th Cong. (2007).

296. *Id.* § 3.

297. *Id.*

298. Alicia Mundy, *Corporate News: Firms Prepare for a Fight Over Generic Drugs*, WALL ST. J., Mar. 12, 2009, at B4.

299. Gardiner Harris, *Bill Would Let Copycats Compete With Biotech Drugs*, N.Y. TIMES, Mar. 27, 2009, at A17.

300. Press Release, Biotechnology Industry Org., Setting the Record Straight: Generic Drug Industry Lobby ‘Flat Out Wrong’ About BIO Position on Follow-On Biologics (Apr. 1, 2008), http://www.bio.org/news/pressreleases/newsitem.asp?id=2008_0401_02.

301. H.R. 806, 110th Cong. (2007); S. 438, 110th Cong. (2007).

302. Deborah Platt Majoras, *Maintaining our Focus at the FTC: Recent Developments and Future Challenges*, in *Protecting Consumers and Competition*, Keynote Address Before the ABA Section of Antitrust Law 7th Annual Forum, (Nov. 15, 2007) (transcript available

4. Follow-on Drugs

When faced with an expiring patent or a patent challenge from a generics manufacturer, brand-name pharmaceutical manufacturers can develop a new formulation for the product (for example, an extended release version or a formulation that does not need to be taken with food), obtain a patent, and migrate demand through pricing to the new formulation. Such a product is sometimes called a “follow-on” drug, and the technique is referred to as “product hopping.”³⁰³ If the brand-name manufacturer proceeds to discontinue the original version of the drug, it can thwart generic competition that relies on state laws or insurance company policies requiring automatic substitution, because physicians will no longer be able to prescribe the formulation for which there is a generic. The generics manufacturer would be required to brand and promote its product to prescribers, adding substantially to its costs. The FTC is investigating follow-on drugs to determine whether improvements they offer consumers are offset by their anticompetitive potential.³⁰⁴

5. Public Education Campaigns to Encourage Use of Generics

Lower generics prices can benefit consumers, but barriers to information about generic pharmaceuticals may prevent consumers from accessing these medications.³⁰⁵ According to one study, “. . . one-third of the most expensive medications used by Medicare beneficiaries who exceeded their pharmacy benefits in managed care plans had generic equivalents or a lower cost therapeutic alternative. . . .”³⁰⁶ Prescribers, consumers, and physicians frequently lack accurate information about prescription drug prices and quality that would enable them to make cost-effective choices.³⁰⁷

An estimated \$2.76 billion could be saved through an education program such as the “Consumer Reports Best Buy Drugs Program” if “Best Buy” drug selections were fully substituted in the four classes of cardiovascular medications studied.³⁰⁸ The Consumer Reports program is “a national educational program that provides consumers with price and effectiveness information on prescription drugs.”³⁰⁹

at <http://www.ftc.gov/speeches/majoras/071115fall.pdf>).

303. Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1471 (2008).

304. Majoras, *supra* note 302.

305. Donohue et al., *supra* note 64, at 1557.

306. *Id.* at 1558.

307. *Id.*

308. *Id.* at 1565.

309. *Id.* at 1557.

The FDA Amendment Act of 2007³¹⁰ may improve consumer access to information about drug safety and effectiveness through a data bank of clinical trials that will be accessible to consumers. The Amendments are “intended to provide a mechanism for the public to learn about clinical trials that are being conducted, as well as the results of those trials”³¹¹ and enable the FDA to require post-approval surveillance of pharmaceuticals. It is uncertain whether the data bank will ultimately help consumers afford prescription drugs by enabling them to make choices regarding the cost effectiveness of treatment. Cost effectiveness research, discussed in Section VI.E. below, may also yield information that would enable consumers and their physicians to choose pharmaceutical treatment options that decrease costs and improve outcomes.

Communicating information to physicians, other providers, and prescribers about generics availability and other cost-effective drug treatment strategies could also promote consumer access and pharmaceutical affordability. Physicians currently receive information about drugs from pharmaceutical companies through print media, conferences and events, and visits from sales representatives or “detailers.” Pennsylvania has implemented a “counter-detailing program” that employs “academic detailers” to visit physicians and promote evidence-based medicine by providing research from Harvard University about drug cost and effectiveness.³¹² Similar programs are underway in Vermont and Mississippi. Vermont will also participate in a multi-state effort with Maine and New Hampshire.³¹³

B. Importation and re-importation of pharmaceuticals

The Obama-Biden health plan proposed lowering costs by increasing competition in the drug and insurance industries; one element in the plan would allow consumers to “import safe drugs from other countries.”³¹⁴ Almost eighty percent of American adults, who pay higher out-of-pocket

310. Food and Drug Amendment Act of 2007, Pub. L. 110-85, 121 Stat. 823.

311. Mary Ann Liebert, *Draft Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff: Certifications to Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(J) of the Public Health Service Act, Added by Title VIII of the Food and Drug Administration Amendments Act of 2007*, 27 BIOTECHNOLOGY L. REP. 336, 336 (2008).

312. Rachel Brand, *Marketing Drugs: Debating the Real Cost*, STATE LEGISLATORS, Sept. 2008, at 26, 26, available at http://www.ncsl.org/Portals/1/documents/magazine/articles/2008/08SLsep08_drugs.pdf.

313. *Id.* at 29.

314. Press Release, Barack Obama and Joe Biden’s Plan to Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage for All, <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf>.

medical expenses than consumers in many industrialized countries,³¹⁵ support the idea of purchasing drugs from Canada.³¹⁶ If Americans were to pay drug prices comparable to other industrialized nations, the savings would be sufficient to close the Medicare Part D doughnut hole.³¹⁷

Under the Food Drug and Cosmetic Act (FDCA), interstate shipment of drugs lacking required FDA approval is illegal, with limited exceptions for personal use.³¹⁸ However, importation occurs through state programs that facilitate such purchases through Web links to foreign pharmacies³¹⁹ and bus tours to Canada for the purpose of purchasing medication.³²⁰

The Pharmaceutical Market Access Act of 2009³²¹ would amend the FDCA to require the Secretary of the United States Department of Health and Human Services (HHS) to promulgate regulations that would permit pharmacies and wholesalers to import qualifying pharmaceuticals from certain countries.³²² The proposal would require that HHS inspect importers' and exporters' facilities and records and educate consumers about drug importation.³²³ The proposal would also implement anti-counterfeiting packaging requirements.³²⁴ Pharmaceutical companies would be unable to allege patent infringement against importers of licensed patented drugs first sold abroad. The act would prohibit drug manufacturers from discriminating against importers by denying them supplies of drugs or charging them higher prices.³²⁵

Critics of drug importation argue that safety is compromised by the introduction of counterfeit drugs into the marketplace.³²⁶ Counterfeits can endanger patients because they are ineffective or because they are made from dangerous or even toxic ingredients.³²⁷ It is also difficult to monitor imported drugs for modified expiration dates and to ensure that drugs with

315. Schoen et al., *supra* note 44, at 289.

316. KAISER SPOTLIGHT, *supra* note 29, at 18.

317. Karen Davis & Sara R. Collins, *Medicare at Forty*, 27 HEALTH CARE FINANCING REV. 53, 57 (2005-2006), available at <http://www.cms.hhs.gov/HealthCareFinancingReview/downloads/05-06Winpg53.pdf>.

318. FDA, Travelers Alert, <http://www.fda.gov/ForIndustry/ImportProgram/ucm173743.htm> (last visited Nov. 10, 2009).

319. See, e.g., State of Wisconsin, Prescription Drug Resource Center, <http://www.drugsavings.wi.gov/> (last visited Nov. 10, 2009).

320. See *Drug Bus – Canada Bound* (NH Pub. Radio broadcast June 11, 2002), available at <http://www.nhpr.org/node/3249>.

321. S. 80, 111th Cong. § 1 (2009).

322. *Id.* § 3.

323. *Id.* § 4.

324. *Id.* § 505E.

325. *Id.* § 8.

326. See Brian A. Liang, *A Dose of Reality: Promoting Access to Pharmaceuticals*, 8 WAKE FOREST INTELL. PROP. L.J. 301, 303-04 (2007-2008).

327. *Id.* at 305-06.

specific storage requirements have been properly handled during transportation. Importation entrusts inspection responsibilities to the governments of exporter nations, which may not undertake to ensure the safety of drugs not intended for dispensation to their citizens.

Governmental policies of nations where prescription drugs are priced lower than in the U.S. often involve the imposition of direct and indirect price controls. Among the major industrialized countries, the U.S. is alone in not regulating pharmaceutical prices.³²⁸

France and Italy regulate pharmaceutical prices directly through price controls, Germany and Japan regulate drug prices indirectly, through limits on reimbursement under various social insurance schemes, and the United Kingdom employs profit controls to indirectly regulate prices.³²⁹

According to the U.S. Department of Commerce, “[t]he principal methods these governments employ are reference pricing,³³⁰ approval delays and procedural barriers, restrictions on dispensing and prescribing, and reimbursement.”³³¹ Certain governments that are members of the Organisation for Economic Co-Operation and Development (OECD)³³² establish sales prices and make it illegal to sell pharmaceuticals at any other price, leverage their bargaining power as dominant market participant to negotiate below-market prices, and establish reimbursement rates for new drugs at levels far below market price in order to force consumers to bear the difference between the market price and reimbursement level (potentially shrinking the market for new drugs).³³³

Pricing policies that affect the market’s supply side (manufacturers and distributors) include: controlling the prices of individual products, reference pricing, average pricing, imposing pricing constraints on sellers, and formularies.³³⁴ Countries that regulate pricing on the demand side use “. . . government regulated patient co-payments, advice, guidelines, and/or budgets for physicians, parallel imports, and even the transfer of products

328. John A. Vernon et al., *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 AM. J.L. & MED. 175, 176 (2006).

329. *Id.* at 176-77.

330. *Id.* at 177 (“reference pricing . . . establishes a price based upon the price of the same or similar drugs in other countries”).

331. INT’L TRADE ADMIN., U.S. DEP’T OF COMMERCE, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION viii (2004), available at <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>.

332. See Org. for Econ. Co-Operation & Dev., Member Countries, http://www.oecd.org/countrieslist/0,3351,en_33873108_33844430_1_1_1_1_1,00.html (last visited Nov. 10 2009).

333. See INT’L TRADE ADMIN., *supra* note 331 at ix.

334. Vernon et al., *supra* note 328, at 177.

from prescription-only to over-the-counter (OTC) status.³³⁵

As an alternative to importation, the U.S. could analyze the practices of other industrialized countries and adopt those policies that appear most suitable to the American economy and health care system. The Department of Commerce argues that Americans would benefit if OECD nations eliminated their pharmaceutical price controls: the savings could amount to an estimated \$5 to \$7 billion per year.³³⁶ Some analysts believe price controls also decrease R&D spending and result in fewer new drugs, particularly the most innovative drugs that have the greatest potential benefit but may be costliest to produce.³³⁷

C. Government Price Negotiation under Medicare Part D

Federal price negotiation for prescription drugs is already taking place in connection with FSS, VA, and 340B drug purchases. Medicare Part D is currently barred by law from setting or negotiating drug prices, interfering with negotiations between Part D plan sponsors and pharmaceutical manufacturers, or establishing a formulary.³³⁸ Reforming Medicare Part D to allow for government price negotiation or formulary restrictions may lead to lower reimbursement rates for prescription drugs. However, the government may retain the resulting decrease rather than passing it on to Medicare beneficiaries in the form of lower premiums, deductibles, or cost sharing or by shrinking the doughnut hole. The decrease could therefore result in tax savings, but may not improve Medicare beneficiaries' access to drugs.

A number of legislative proposals have been introduced to allow Medicare Part D to negotiate drug prices and eliminate the doughnut

335. *Id.* In the U.S., some argue that changing a prescription drug to OTC status would harm insured consumers by requiring them to pay the entire price out-of-pocket; such a move is sometimes seen as an attempt by a pharmaceutical company to increase its market by advertising the OTC status to consumers and thus avoiding the role of the prescriber and the threat of State-mandated automatic generic substitution. The proposed Non-Prescription Drug Modernization Act of 2007, H.R. 4038, 110th Cong. (1st Sess. 2007) and S. 2311, 110th Cong. (1st Sess. 2007) would (1) enhance the FDA's power to revoke authorization to market a drug over-the-counter if it determines that doing so poses a risk to consumers, and (2) expand the FDA's authority to regulate advertising of nonprescription drugs.

336. INT'L TRADE ADMIN., *supra* note 331, at xi.

337. Carmelo Giacotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 211 (2005).

338. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, § 1860D-11(h)(i)(1)-(2), 117 Stat. 2098 (2003) (“(i) NONINTERFERENCE. —In order to promote competition under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”).

hole.³³⁹ The Medicare Prescription Drug Savings and Choice Act of 2009 would allow the government to negotiate Part D drug prices and create a plan to compete with private plans under Part D.³⁴⁰

The government's reluctance to harness its regulatory tools and bargaining power may have resulted in a considerable cost burden to beneficiaries.³⁴¹ According to a Kaiser Family Foundation study, eighty-five percent of adults would support the federal government's negotiating with pharmaceutical companies for lower drug prices for Medicare beneficiaries.³⁴² A Congressional Research Service Report states that harnessing the bargaining power of 43.7 million Medicare beneficiaries might result in decreased pharmaceutical pricing,³⁴³ but CMS may lack the track record and the bargaining strength of large PBMs, which cover even larger populations.³⁴⁴ The Congressional Budget Office and the Chief Actuary at CMS have determined that negotiations on behalf of Part D beneficiaries might not exceed the price concessions achievable by private plans.³⁴⁵ Moreover, such involvement on behalf of CMS may lead to a restricted formulary that would decrease choice and drug availability for Part D beneficiaries.³⁴⁶ The government's development of a Medicare Part D formulary could lead to cost savings by directing prescribers and patients toward lower-cost drug choices, by creating competition among drug companies, and by intensifying the government's bargaining power.³⁴⁷ However, a restricted formulary can decrease quality of care³⁴⁸ since determining the formulary structure requires trade-offs involving cost savings, patient preferences, and the properties of various drugs.³⁴⁹

The Office of the Attorney General has alleged that Part D plan sponsors overcharge beneficiaries and that the Centers for Medicare & Medicaid Service (CMS) has failed to identify incidences of overpayments through audits, resulting in an estimated \$4.4 billion in overpayments in 2006

339. See S. 18, 109th Cong. (2005); S. 2240, 109th Cong. (2006); S. 2340, 109th Cong. (2006); S. 2342, 109th Cong. (2006); H.R. 4, 109th Cong. (2006).

340. H.R. 684, 111th Cong. (2009) (enacted).

341. Davis & Collins, *supra* note 317, at 57.

342. KAISER SPOTLIGHT, *supra* note 29, at 19.

343. Jim Hahn, Cong. Research Serv., *Federal Drug Price Negotiations: Implications for Medicare Part D* 10 (2007), <http://lieberman.senate.gov/documents/crs/drugneg.pdf>.

344. *Id.* at 11. Advance PCS, a large PBM, covers 75 million individuals; Medco Health Solutions covers 65 million; Express Scripts covers 57 million.

345. *Id.* at 12.

346. *Id.*

347. Haiden A. Huskamp et al., *The Impact of a National Prescription Drug Formulary on Prices, Market Share, and Spending: Lessons for Medicare?*, 22 HEALTH AFF. 149, 150 (2003).

348. *Id.* at 156.

349. *Id.* at 157.

alone.³⁵⁰ Increased audits of Part D plan sponsors could produce cost savings for plan participants without requiring the passage of additional legislation.

Prescription drug costs for Part D beneficiaries could also be lowered with the elimination of “reference-based pricing,” a practice employed by approximately ten percent of Part D plans.³⁵¹ Reference-based pricing is intended to encourage consumers to choose generic drugs: patients who select a brand-name drug when a generic is available are typically charged a price representing a co-pay plus the difference between the cost of the brand-name drug and the generic.³⁵² Although CMS now requires plan sponsors to inform beneficiaries about the practice, the Plan Finder tool that beneficiaries use to select a Part D plan does not always clearly identify plans that use reference-based pricing.³⁵³ Reference-based pricing adds complexity and potentially increases beneficiaries’ drug costs in an attempt to lower them. Eliminating the practice in favor of less punitive means of encouraging generics could simplify Part D and lower the cost of prescription drugs for beneficiaries of a Medicare prescription drug plan.

Similar to proposals for Medicare Part D negotiations, the proposed United States National Health Care Act or the Expanded and Improved Medicare for All Act would establish the United States National Health Care (USNHC) Program, which would establish a formulary, negotiate prices, and promote the use of generics as part of a scheme to provide medically necessary health care to all residents of the United States.³⁵⁴

D. Reforming Reimbursement Calculations for Part B Drugs

Medicare spending on Part B drugs increased from \$3 billion in 1997 to \$11 billion in 2004, a 267 percent increase.³⁵⁵ During that same period, overall Medicare spending rose 47 percent.³⁵⁶ Medicare Part B reimburses a limited number of pharmaceutical products that are generally administered in a physician’s office; many of these drugs are treatments for cancer.³⁵⁷

350. David Goldstein, *Insurers Overcharged Medicare for Prescriptions, Report Finds*, MCLATCHY NEWSPAPERS, Feb. 2, 2009, <http://www.mcclatchydc.com/washington/story/61200.html>.

351. Jane Zhang & Vanessa Fuhrmans, *Medicare Plans Draw Criticism on Drug Pricing*, WALL ST. J., Dec. 16, 2008, at D1.

352. *Id.*

353. *Id.*

354. United States National Health Care Act, H.R. 676, 111th Cong. § 205 (2009).

355. Catherine Arnst, *Soaring Cancer Drug Costs May Cripple Medicare*, BUS. WK., Jan. 27, 2009, available at http://www.businessweek.com/technology/content/jan2009/tc20090127_588803.htm?chan=top+news_top+news+index++temp_technology.

356. *Id.*

357. See CTRS. FOR MEDICARE & MEDICAID SERVS., DEP’T OF HEALTH & HUMAN SERVS., *Covered Medical and Other Health Services*, in MEDICARE BENEFIT POLICY MANUAL § 50

Newer cancer drugs are often priced at levels far in excess of the prices of older drugs:

Most of the newest treatments are taken along with older chemotherapies, and some are even taken in combination with one another, adding pricey drug on top of pricey drug. Dr. Leonard Saltz of Memorial Sloan-Kettering Cancer Center in New York says that 10 years ago the drugs used to treat colon cancer cost about \$500. Today, the tab is \$250,000. Over the same 10-year period, the average life expectancy for colon cancer patients increased from 11 months to a little more than two years. “We’re excited about these drugs,” he says, “but not everyone can get them. Something has to give.”³⁵⁸

The newer drugs are patented and tend to have little competition from “me-too” drugs, so manufacturers have no incentive to lower prices. Some patients are willing to mortgage their homes to obtain the drugs, while others refuse treatment because they are unable to afford them.³⁵⁹

Reimbursement under Medicare Part B was reformed to use the ASP benchmark rather than AWP.³⁶⁰ Current reimbursement levels are pegged at 106 percent of ASP for most Part D drugs.³⁶¹ The Secretary of Health and Human Services conducted a study on sales of Part D drugs and biologicals to determine whether prices paid by large volume purchasers (such as PBMs and Health Maintenance Organizations (HMOs)) are representative of the prices a prudent physician pays for the drugs.³⁶² The purpose of the study was to determine whether sales to such purchasers should be excluded from ASP calculation.³⁶³ The Secretary was unable to complete the analysis because manufacturers refused to provide ASP data by type of purchaser due to the proprietary nature of this data.³⁶⁴ The Secretary concluded that physicians are generally able to obtain the drugs at prices below the reimbursement rate.³⁶⁵ The study did not determine whether Medicare and beneficiaries were overcharged for the drugs.

Reforming the cost of Part B drugs could involve the imposition of revised pricing benchmarks. Legislation introduced in the U.S. Senate in

(2009), <http://www.cms.hhs.gov/Manuals/downloads/bp102c15.pdf>.

358. Catherine Arnst, *Going Broke to Stay Alive*, BUS. WK., Jan. 30 2006, available at http://www.businessweek.com/magazine/content/06_05/b3969051.htm.

359. *Id.*

360. MICHAEL O. LEAVITT, DEP’T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS—REPORT ON SALES OF DRUGS AND BIOLOGICALS TO LARGE VOLUME PURCHASERS 2 (2006), http://www.cms.hhs.gov/reports/downloads/LVP_RTC_2_09_06.pdf.

361. *Id.*

362. *Id.*

363. *Id.*

364. *Id.*

365. *Id.* at 5.

2006 proposed assuring that Medicare reimbursement for outpatient cancer drugs does not exceed or fall short of actual ASP for such drugs.³⁶⁶ The legislation further proposed continuing demonstration projects to assess oncology services and the development of quality indicators to evaluate oncology care.³⁶⁷

To determine which cancer treatments may be reimbursed under Part B, CMS relies on compendia.³⁶⁸ Critics argue some compendia have financial ties to the pharmaceutical industry and that a compendium's inclusion of a drug for a specific application may not be supported by substantial clinical evidence.³⁶⁹

Peter B. Bach, M.D., M.A.P.P., has proposed establishing a Center for Comparative Effectiveness that would evaluate clinical research to determine which cancer drugs are superior and which are interchangeable.³⁷⁰ Based on these results, some cancer drugs may qualify as multi-source drugs which would enable Medicare to lower reimbursement by calculating payment under rules for blended reimbursement.³⁷¹

The findings of a Center for Comparative Effectiveness could also provide the basis for payment using a "least costly alternative" calculation, which would enable Medicare to reimburse a drug at the price of the least expensive interchangeable drug.³⁷² However, implementing a least costly alternative calculation would require legislation, as the U.S. District Court for the District of Columbia has held that the Secretary of Health and Human Services lacks the authority to implement these reimbursement rates.³⁷³

A first step toward decreasing the cost of cancer drugs through

366. S. 2340, 109th Cong. § 2 (2006).

367. S. 2340, §§ 3-4.

368. See Katherine Tillman et al., *Compendia and Anticancer Therapy Under Medicare*, 150 ANNALS INTERNAL MED. 348, 348 (2009), available at <http://www.annals.org/cgi/reprint/150/5/348.pdf>. "In the pharmaceutical industry, a compendium is a comprehensive listing of drugs and biologicals. It typically includes a summary of the pharmacologic characteristics of each listed drug or biological; information on dosage; and, often, recommended uses for specific diseases. Some insurers refer to compendia when making policy decisions, thus creating a strong financial incentive for manufacturers to obtain a favorable compendium recommendation. The Fee-for-Service Medicare program recognizes certain published compendia as authoritative references to identify medically accepted, unlabeled uses of drugs and biologicals in anticancer treatment regimens."

369. Reed Abelson & Andrew Pollack, *Medicare Widens Drugs It Accepts for Cancer Care*, N.Y. TIMES, Jan. 27, 2009, at A1.

370. Peter B. Bach, *Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs*, 360 NEW ENG. J. MED. 626, 632 (2009).

371. *Id.*

372. *Id.* at 627.

373. *Hays v. Leavitt*, 583 F. Supp. 2d 62, 68 (D.D.C. 2008).

comparative effective analysis may be the result of the \$1.1 billion allocated for researchers to compare various medical treatments for the same illness under the recent economic stimulus bill.³⁷⁴ Other nations, including France and the U.K., attempt to decrease health care costs by discouraging the use of ineffective treatments; both nations have bodies that assess various medical treatments to compare their effectiveness and sometimes their costs.³⁷⁵

Critics, including lobbyists for the pharmaceutical industry, are concerned that research findings will be used to deny coverage or ration care and that it could allow government to intrude on the physician-patient relationship.³⁷⁶ Some women and minority groups have expressed concerns that the research may not identify differences in the response to treatment options that are specific to gender or ethnicity.³⁷⁷

Supporters of the initiative include consumer groups, unions, large employers, and pharmacy benefit managers who anticipate the program will provide needed information to physicians and patients.³⁷⁸ Cost effectiveness analysis may give drug companies an incentive to compile effectiveness data of their own, potentially increasing research, development, and testing costs which would in turn increase the price of their products.³⁷⁹

E. Regulating Pharmaceutical Companies' Promotional Activities

Efforts to reform drug company marketing practices are based in part on the notion that industry-wide restrictions will enable companies to realize savings in the form of decreased marketing budgets, and that such savings will be passed along to consumers in the form of lower price reductions. Individual drug companies may be reluctant to risk the competitive disadvantage of decreasing marketing activities without such uniform regulation. In addition, reform efforts designed to curb certain practices, such as direct-to-consumer advertising and the gifts and payments drug companies offer prescribing physicians, aim to suppress the impact of these practices on physician and patient behavior.

374. Pear, *U.S. to Study Effectiveness*, *supra* note 239, at A1.

375. *Id.*

376. *Id.* See also Emily Waltz, *Comparative Effectiveness Casts First Shadows Across U.S. Industry*, 27 NATURE BIOTECHNOLOGY 211, 211 (2009).

377. Pear, *U.S. to Study Effectiveness*, *supra* note 239, at A1.

378. *Id.*

379. For an analysis of the pharmaceutical industry's possible response to pharmacoeconomic analysis, see generally STEVEN SEGET, BUS. INSIGHTS, PHARMACEUTICAL PRICING STRATEGY: OPTIMIZING RETURNS THROUGHOUT R&D AND MARKETING (2003).

1. Direct-to-Consumer Advertising

Direct-to-consumer (DTC) pharmaceutical advertising, which is prohibited in many European countries,³⁸⁰ is used in the U.S. to increase awareness of, and the size of the market for, prescription drugs.

Representative Henry A. Waxman supports legislation that would enable the FDA to ban selected DTC advertising during a drug's initial years on the market, which tend to be the period of most aggressive marketing for a prescription drug.³⁸¹ Waxman points to the risk that advertising may expose more consumers to side effects that do not become apparent until a drug has been on the market for a period of time.³⁸² Promotional expenses, which may exceed the cost of R&D for pharmaceutical manufacturers,³⁸³ increase pharmaceutical manufacturers' costs.

2. Marketing Disclosure Legislation

Critics of the pharmaceutical industry have argued that gifts, payments to physicians, and fees to physicians who consult or speak on behalf of drug companies' products influence prescribing behavior, which could induce physicians to prescribe a drug that is not the most cost-effective for a patient.³⁸⁴ The drug industry spent over \$6.8 billion on logo items, meals,

380. Rosenthal, *supra* note 265.

381. Connolly, *supra* note 234.

382. *Id.*

383. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLoS MED. 0029, 0032 (2008), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2174966/pdf/pmed.0050001.pdf>.

384. See Eric G. Campbell, *Doctors and Drug Companies—Scrutinizing Influential Relationships*, 358 NEW ENG. J. MED. 1796, 1796 (2007). "From a policy perspective, the debate centers on the overall effect of these relationships [physician relationships with the pharmaceutical industry] on patient care. Although most physicians deny that receiving free lunches, subsidized trips, or other gifts from pharmaceutical companies has any effect on their practices, research has shown that physician-industry relationships do influence prescribing behavior. After all, if these relationships didn't affect physician behavior in such a way as to increase sales, companies wouldn't spend \$19 billion each year establishing and maintaining them." See also *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the S. Comm. on Aging*, 110th Cong. 23-24 (2007) (prepared statement of Peter Lurie, Deputy Director, Public Citizen's Health Research Group). "Pharmaceutical marketing to physicians includes free samples, promotional detailing, and continuing medical education activities, and has been shown to alter physician behavior. . . . [C]ontact with pharmaceutical company representatives is associated with changes in the prescribing practices of residents and physicians and more rapid adoption of new drugs by prescribers. Sponsorship of continuing medical education programs by a pharmaceutical company and all-expenses-paid travel to conferences are associated with increases in the prescribing rate of the sponsor's drugs. Finally, interactions with a pharmaceutical company representative are associated with an increased likelihood of requesting that the representative's company's drugs be added to the hospital formulary." See also Kirby Lee, *Has the Hunt For Conflicts of Interest Gone Too Far?*, 366 BRIT. MED. J. 477, 477 (2008). "[R]esearch in social science shows that gifts of any size from drug

and office visits, according to a 2005 report in the *New England Journal of Medicine*.³⁸⁵

Several states have enacted legislation mandating pharmaceutical company disclosure of gifts and payments to physicians and other providers, and proposed federal legislation would require such disclosure as well.³⁸⁶ Critics argue that existing state legislation has been ineffective either because: (1) it may lack enforcement mechanisms; (2) the information gathered is not available in a form that is conveniently accessible to the public; and (3) pharmaceutical company information submitted as “trade secrets” are withheld from public scrutiny.³⁸⁷

Members of the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association for the prescription drug industry, announced the voluntary adoption of a marketing code³⁸⁸ under which about forty companies agree to no longer distribute free products with product logos to doctors and nurses. The code also restricts the meals pharmaceutical companies may purchase for physicians.³⁸⁹ BIO (the Biotechnology Industry Organization), a trade group for biotechnology, has not adopted the advertising code.³⁹⁰

The American Medical Association (AMA),³⁹¹ the American College of Physicians, and the American Society of Internal Medicine have all adopted additional voluntary codes to serve as guidelines.³⁹² The HHS Office of Inspector General issued a Compliance Program Guidance for Pharmaceutical Manufacturers.³⁹³ In spite of the existence of these codes and guidelines, promotional practices of pharmaceutical companies continue to receive harsh criticism and scrutiny.³⁹⁴

companies create feelings of obligation and reciprocity.”

385. Connolly, *supra* note 234.

386. Robert Steinbrook, *Disclosure of Industry Payments to Physicians*, 359 *NEW ENG. J. MED.* 559, 559-60 (2008).

387. Joseph S. Ross et al., *Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota*, 297 *J. AM. MED. ASS'N* 1216, 1221 (2007).

388. PHARM. RES. & MFRS. OF AM., *CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS* 3 (2009), <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

389. Connolly, *supra* note 234.

390. *Id.*

391. AM. MED. ASS'N, *Opinion 8.061—Gifts to Physicians from Industry*, in *CODE OF MEDICAL ETHICS* (2009), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>.

392. Ross et al., *supra* note 387, at 1217.

393. *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 *Fed. Reg.* 23731 (May 5, 2003).

394. See Barry Meier & Benedict Carey, *Drug Maker is Accused of Fraud*, *N.Y. TIMES*, Feb. 26, 2009, at B1. See also Duff Wilson, *Patching a Wound*, *N.Y. TIMES*, Mar. 3, 2009, at B1.

A further method to influence drug prices by controlling pharmaceutical promotional activities involves restricting pharmaceutical company access to doctor-prescription drug data. Drug company representatives may use such information to target doctors for pharmaceutical industry perks or to direct promotional efforts to encourage certain doctors to prescribe more expensive drugs.³⁹⁵ A federal appeals court in Boston recently held that states have the right to prohibit the sale of such data in order to control state health care costs.³⁹⁶ The lead sponsor of New Hampshire legislation prohibiting the sale of prescriber data was motivated in part by concern that state Medicaid costs were inflated due to the pharmaceutical industry's coaxing doctors to prescribe brand-name drugs.³⁹⁷

F. Compulsory Licensing or Auctioning of Patents

In their 2008 book, *Reasonable Rx: Solving the Drug Price Crisis*, Stan Finkelstein and Peter Temin propose a scheme to overhaul the pharmaceutical industry on a scale comparable to that implemented in the telecommunications industry with the break-up of AT&T.³⁹⁸ The authors propose de-integrating the pharmaceutical industry, splitting each corporation into an R&D firm and a manufacturer/marketing (M&M) firm.³⁹⁹ A new federal agency, the Drug Development Corporation (DDC) would broker drug patents by auctioning exclusive rights to the M&M firms on behalf of the R&D owner.⁴⁰⁰ Critics argue that the plan would preclude competition and would dismantle a major American industry that "has no peer in the world for bringing new drugs into the market."⁴⁰¹ An additional concern is the challenge of conducting an informed auction for a newly patented drug for which there is no market experience.⁴⁰² The Finkelstein proposal is similar to a plan proposed by economist Michael Kremer which would allow the government to purchase pharmaceutical patents for a sum sufficient to reimburse R&D investment and sell the patents in competitive markets in order to increase the availability of new pharmaceuticals while

395. Stephanie Saul, *Doctors Object to Gathering of Drug Data*, N.Y. TIMES, May 4, 2006, at A1.

396. Associated Press, *New Hampshire: Ruling on Prescriptions*, N.Y. TIMES, Nov. 19, 2008, at A23.

397. Warren Ross, *The Battle of New Hampshire*, MED. MARKETING & MEDIA, Nov. 2006, at 60, 61 (2006), http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/New_Hampshire/heBattleofNewHampshire.pdf.

398. Peter Stein, *First, Do No Harm*, 27 HEALTH AFF. 1736, 1736 (2008) (reviewing STAN FINKELSTEIN & PETER TEMIN, *REASONABLE RX: SOLVING THE DRUG PRICE CRISIS* (2008)).

399. *Id.*

400. *Id.*

401. *Id.*

402. *Id.* at 1737.

supporting and compensating R&D efforts.⁴⁰³

An alternative proposal would permit the U.S. government to issue requests for grant proposals from public and private institutions to research pharmaceutical drugs and to retain any patents generated.⁴⁰⁴ The government would then license the patents free of charge to any competent producer.⁴⁰⁵ The goal of the proposal is to lower drug prices and redirect R&D to achieve greater public welfare.⁴⁰⁶

A bill to overhaul patent litigation was recently introduced in the U.S. Senate that would award damages for patent infringement by imposing a reasonable royalty or requiring the infringer to reimburse the patent holder for profits lost.⁴⁰⁷ The Coalition for 21st Century Patent Reform has criticized the proposal, stating that it would permit patented technology to be copied without consequence.⁴⁰⁸

CONCLUSION

The pharmaceutical industry, particularly when analyzed on a global scale, is a complex web of competing interests that interact to research, develop, regulate, promote, market, prescribe, and utilize prescription drugs for the treatment of human disease. Individuals who are unable to access or afford needed medications may face preventable pain, disability, unemployment and other economic losses, and even death.

The complexity of the American health care market makes it difficult to improve accessibility across the board because various consumers are affected by different programs, plans, and policies. Some receive their prescription medications under various federal programs such as Medicare, Medicaid, 340B, FSS, or the VA. Others have private insurance through an employer that may or may not cover prescription drugs, and those that do often impose cost sharing measures that require consumers to spend out-of-pocket for their medications. The uninsured, who have no program or plan to negotiate drug prices on their behalf, often pay the highest prices of all, and are the most likely to go without needed medication, a situation with a disproportionate impact on the poor, elderly, and chronically ill.

A wide variety of reform proposals are currently being debated to

403. Douglas Gary Lichtman, *Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals*, 11 HARV. J.L. & TECH. 123, 123-24 (1997).

404. Peter Stein & Ernst Valery, *Competition: An Antidote to the High Price of Prescription Drugs*, 23 HEALTH AFF. 151, 154, 158 (2004).

405. *Id.* at 154.

406. Stein, *supra* note 398, at 1737.

407. William McQuillen, *Patent Bill Pushed to Boost Economy, Lawmakers Say*, BLOOMBERG, Mar. 3, 2009, <http://www.bloomberg.com/apps/news?pid=20670001&refer=&sid=arhhfAyJxN4w>.

408. *Id.*

remedy the problem of drug access in America. Some advocate reforming patent laws to make patented pharmaceutical innovations more widely accessible to manufacturers, to facilitate the development and marketing of generic biotechnology drugs, or to restrict pharmaceutical companies' ability to employ follow-on drugs and product-hopping. Other proposals would promote the use of generics by restricting "authorized generics" or educating consumers or providers as to the availability and advantages of generic drugs. Others aim to encourage competition by preventing brand-name companies from settling infringement litigation with generics manufacturers that would delay generics market entry and perpetuate brand-name monopoly profits.

Proposals to import pharmaceuticals from abroad indirectly benefit from the pharmaceutical pricing regulations of other industrialized governments. Importation proposals risk the introduction of counterfeit drugs into the American health care system, as well as drugs whose safety is compromised due to improper storage or expiration. As an alternative to importation, the U.S. could adopt selected price regulation strategies that have been tested in other developed nations. For example, price negotiations for prescription drug plans under Medicare Part D could result in savings for elderly and disabled Americans. Reforming reimbursement calculations for Medicare Part B drugs, which include many expensive cancer treatments, could lead to important price reductions.

Reform proposals that attempt to restrict or direct the behavior of pharmaceutical manufacturers (for example, by restricting settlement negotiations or prohibiting certain promotional activities or mandating their disclosure), risk being thwarted by the industry's ability to respond strategically to challenges that arise in the market, economic, technical, and regulatory environments.

Americans who need but cannot afford prescription drugs would benefit most, and in the least amount of time, from proposals to educate consumers about the generics choices that are already available but underutilized and a program to inform physicians about cost effectiveness for prescription pharmaceuticals. A public relations campaign for consumers and academic detailers to provide physicians information on the cost effectiveness of competing treatment options and the availability of generic or other lower cost drug choices would decrease prescription drug costs and promote generics acceptance and use.

Promoting chain pharmacy generics discount programs could also help consumers access affordable drugs. Helpful reforms could include exempting such discount programs from predatory pricing or unfair competition laws and mandating that they not discriminate against Medicare Part D beneficiaries. Informing consumers about prescription assistance programs that are already in place could lead to the programs'

increased utilization, thereby enhancing access and affordability. Improving the Medicare Part D Plan Finder tool to facilitate beneficiary understanding of plan options, such as tiers and reference-based pricing, could help Medicare beneficiaries better afford their prescriptions.

The patent cliff will soon enable generics manufacturers to produce versions of name-brand drugs without the burden of Hatch-Waxman patent litigation and the potential for an FTC challenge of any resulting settlement. The greatest threat to the availability of generics that will result from the patent cliff is the potential for innovators to develop follow-on drugs, engage in product-hopping (particularly if the original brand-name version will be discontinued to thwart state mandatory substitution laws), and market authorized generics, which can discourage generics entry by making any “unauthorized” generic a second or subsequent market entry. A reform proposal to prevent innovators from discontinuing original formulations and from marketing authorized generics could lead to improvements in pharmaceutical access and affordability through the availability of generic versions of brand-name drugs that lose patent protection during the next seven years. As an alternative or complement to such an initiative, generics manufacturers who must undertake promotional campaigns due to discontinuation of the brand-name equivalent could be permitted to utilize academic detailers to deliver information about their product’s availability. Direct-to-consumer innovator advertising could be regulated to prevent its impairing the effectiveness of a consumer-oriented education campaign.

Biotech generics have the potential to benefit consumers through lower prices (although savings are unlikely to be as great as those provided by generic pharmaceuticals). However, legislative, regulatory, and technical hurdles and the absence of a patent cliff for biotech drugs will delay the benefits of the proposed legislation.

Attempting more broad-based patent law reform to lower drug prices would involve a massive undertaking with myriad consequences that will affect not only the pharmaceutical industry but related industries throughout the supply chain, as well as unrelated industries that rely heavily on patent protection, such as electronics technology. The complexity and delay inherent in crafting and implementing broad patent law reforms render such reforms unlikely to help a significant number of consumers better afford their prescription drugs in the near future.

Reform proposals to allow Medicare Part D price negotiations, formulary development, and to reform reimbursement calculations for Part B drugs could save taxpayer dollars, but these savings may not benefit consumers in the form of substantially lower drug prices. Inter-agency cooperation would maximize bargaining power and provide negotiation expertise: such a scheme would draw on the experience of agencies that administer the VA, FSS, and 340B programs and would concentrate the massive purchasing

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power of the federal government through the combination of the currently fragmented federal drug-purchasing programs.