

Note

State Price Control Laws are the Wrong Prescription for the Problem of Unaffordable Drugs

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INTRODUCTION

Many Americans struggle to pay for their prescription drugs.¹ This problem increases daily with the ever-growing elderly population,² which requires a relatively large amount of prescription drugs.³ Both state and federal levels of government feel pressure to do something about this problem.⁴

One approach governments can take to help individuals obtain their needed prescription drugs is to pay for all or part of their prescription drug costs. For example, the federal government and state governments share the costs of the Medicaid program, which purchases prescription drugs for low-income individuals and families.⁵ Currently, the federal government is considering adding a

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¹ See MINORITY HOUSE STAFF OF HOUSE COMM. ON GOV'T REFORM AND OVERSIGHT, 106TH CONG., PRESCRIPTION DRUG PRICING IN THE UNITED STATES: DRUG COMPANIES PROFIT AT THE EXPENSE OF OLDER AMERICANS 1-2 (Comm. Print 1999).

² The elderly population is growing and will soon "swell with aging baby boomers." John Carey et al., *What's Fair?*, BUS. WEEK, Dec. 10, 2001, at 60.

³ Elderly people comprise just 12% of the U.S. population, yet they take one-third of all drugs prescribed in the U.S. MINORITY HOUSE STAFF OF HOUSE COMM. ON GOV'T REFORM AND OVERSIGHT, *supra* note 1, at 1.

⁴ See Robert Pear, *States Creating Plans to Reduce Costs for Drugs*, N.Y. TIMES, Apr. 23, 2001, at A1.

⁵ CONGRESSIONAL BUDGET OFFICE, HOW THE MEDICAID REBATE ON PRESCRIPTION DRUGS AFFECTS PRICING IN THE PHARMACEUTICAL INDUSTRY 5 (January 1996).

The Social Security Amendments of 1965 established the Medicaid program. Medicaid provides health care coverage primarily to low-income families with dependent children and to low-income aged or disabled individuals. The federal

prescription drug benefit to the Medicare program, which would benefit the elderly.⁶ And at the state level, many governments have already enacted programs that provide prescription drug benefits for their elderly residents.⁷

Unfortunately, just like many Americans, governments have a hard time affording prescription drugs.⁸ Thus, we are, in a sense, back to the original problem.

Taking another approach, a number of states are experimenting with prescription drug price controls.⁹ As of August 2000, seventeen states had proposed, filed, or enacted price control bills for prescription drugs.¹⁰ At least twenty-eight states considered price control legislation in 2000.¹¹ One commentator said that, while the federal government is doing little to solve the problem of unaffordable prescription drugs, "states are performing their traditional role as laboratories of social policy, just as they pioneered the regulation of workers' wages and hours in the early 20th century."¹²

However, controlling prices of prescription drugs is neither a new

government funds 50 percent to 83 percent of Medicaid payments to health care providers in each state (state governments pay the remainder). The federal share is inversely related to the state's per capita income and equals about 57 percent on average.

The states administer the Medicaid program under broad federal guidelines that allow each state to determine, within established limits, exactly who is covered, the extent of services offered, and the method for reimbursing health care providers. Although states are not required to cover outpatient prescription drugs for Medicaid beneficiaries, all states do offer such coverage to most of their beneficiaries.

Id. (citations omitted). See generally 42 U.S.C.A. §§ 1396-1396v (West 2002) (federal statutory provisions relevant to the Medicaid program).

⁶ See Pear, *supra* note 4.

⁷ *Id.*

⁸ See Lorraine Woellert, *The States Step into the Breach*, BUS. WEEK, Aug. 6, 2001, at 33.

⁹ See *Maine Enacts Drug Price Controls; 16 Other States Taking Similar Action*, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, IMPACT REPORT, July/Aug. 2000, at 1, 3.

¹⁰ *Id.*

¹¹ *Id.*

¹² Pear, *supra* note 4.

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nor a good idea. Canada, the United Kingdom, France, Japan, and other countries have implemented pharmaceutical price controls for many years.¹³ The forms of their price regulations vary, but they all stifle competition and discourage innovation in the pharmaceutical industry.¹⁴ As a result, consumers get less value for their money and fewer innovative drugs. Economists argue that any form of price regulation will harm consumers,¹⁵ and that especially damaging

¹³ Jerry Stanton, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 160-64 (2000); see also PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION 15-29 (Ann Petty ed., 1997).

¹⁴ See Stanton, *supra* note 13, at 165-71; see also DANZON, *supra* note 13, 58-64.

¹⁵ See Jeffrey H. Birnbaum, *Keep Prices Out of Control*, FORTUNE, June 25, 2001, at 36.

Two words rarely appear in the same sentence: economists and consensus. But on the issue of price controls, they belong together. The famously divided profession agrees that government-imposed price caps generally don't work and, in fact, only make matters worse. "Ninety-five percent of economists would say that price controls are always dumb or that there should be a very strong presumption against price controls," says Robert Litan of the liberal-leaning Brookings Institution.

Id. For example, economist Patricia M. Danzon objects to any form of pharmaceutical price controls. Patricia M. Danzon, *Making Sense of Drug Prices*, REGULATION, Spring 2000, at 56 ("Any form of price regulation, including the setting of uniform prices within the United States or cross-nationally, would discourage innovation and competition."). Economist Fiona M. Scott Morton also objects to price controls:

The imposition of price controls on a well-functioning, competitive market harms society by reducing the amount of trade in the economy and creating incentives to waste resources. . . . In the case of pharmaceuticals, the most damaging area is likely to be the reduction in innovation, which will harm all future generations of patients.

Fiona M. Scott Morton, *The Problems of Price Controls*, REGULATION, Spring 2001, at 54. In *The Problems of Price Controls*, Morton also provides a historical background of price controls, which helps explain their existence in western economies: "Government gains favor with voters and constituents when it lowers the price of popular goods." *Id.* at 51.

Economists objected to pharmaceutical price controls suggested during the Clinton presidency. See, e.g., Henry Grabowski, *The Impact of the Clinton Health Care Reform Plan: Health Reform and Pharmaceutical Innovation*, 24 SETON HALL L. REV. 1221, 1257-58 (concluding that the proposed price controls would harm consumers).

From a public policy perspective, little can be gained from the proposed cost controls over new drugs and a great deal lost. Even if the government were to eliminate all profits from new drugs coming into the market in the future, the prospective savings in terms of overall health care costs would be very small (less than one percent of health care costs). However, these actions would have precipitous effects on the incentives for research on innovative new medicines. Over the long term, patient welfare would be lower and total health care costs higher from such an unfortunate outcome.

Id. at 1259. In fact, 562 economists signed a letter objecting to the price controls proposed during the Clinton presidency:

consequences can result from price controls in the major pharmaceutical markets of the world, such as the U.S.¹⁶ Consequently, the sudden popularity of price controls in the U.S. should be of extreme concern for consumers of prescription drugs everywhere.

As an alternative to implementing price controls, lawmakers should make prescription drugs more affordable for Americans by encouraging enrollment in competing private health plans. Private health plans that purchase prescription drugs obtain significant discounts off of retail prices by hiring pharmacy benefit management companies (hereinafter "PBMs") that create formularies, or preferred lists of drugs, for their clients.¹⁷ Drug manufacturers compete for preferred status by offering discounts on their drugs.¹⁸ Thus, PBMs reduce prescription drug prices by encouraging drug manufacturers to practice price competition, which is consonant with a market economy.

Government programs that provide prescription drug benefits should allow beneficiaries to choose from a number of competing private health plans that use PBMs to control their drug spending. The Federal Employee Health Benefits Program has already adopted this approach,¹⁹ and the federal government is considering this

The Health Security Act of 1993 will result in price controls, according to a group of the nation's leading economists. A January 13 letter sent to President Clinton, signed by 562 economists, maintains that setting provider fees, capping annual spending limits, limiting insurance premiums, and imposing price limits on new and existing drugs are all examples of price controls. The economists warned that quality of health care will be significantly reduced if the President does not remove these mandates from his plan by citing examples of price controls that have failed in other industries.

Healthcare Financial Management Association, *Nation's Economists Caution Against Price Controls*, HEALTHCARE FIN. MGMT., Mar. 1994, at 7.

¹⁶ See DANZON, *supra* note 13, at 93.

¹⁷ See CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 6-8 (July 1998).

¹⁸ *Id.* at 23-24.

¹⁹ GENERAL ACCOUNTING OFFICE, REP. NO. HEHS-97-47, PHARMACY BENEFIT MANAGERS: FEHBP PLANS SATISFIED WITH SAVINGS AND SERVICES, BUT RETAIL PHARMACIES HAVE CONCERNS 1 (Feb. 1997).

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approach for a Medicare prescription drug benefit.²⁰ Likewise, governments should encourage the uninsured to enroll in private health plans that use PBMs.

Part II of this Note explains how state prescription drug price controls will harm consumers. This part begins by describing aspects of the pharmaceutical industry that give rise to pricing complaints, such as patents and differential pricing, and why these complaints are unwarranted. This part then discusses how price controls in other countries have had negative effects on competition and innovation in the pharmaceutical industry, how price controls under the Medicaid program have had similar effects, and finally how state price control laws will follow suit.

To illustrate the harmful effects of state price controls, Part III of this Note describes and analyzes the Maine Rx Program, a price control system established by Maine's Act to Establish Fairer Pricing for Prescription Drugs.²¹ This part begins by explaining why the Maine Rx Program is particularly attractive to examine. Then this part summarizes the legislation and discusses how it will harm consumers of prescription drugs.

Finally, Part IV of this Note suggests, as an alternative to price controls, that states make prescription drugs more affordable by encouraging their residents to take advantage of private health plans that use PBMs. This part also considers how prescription drug purchasers may fare if states do not seek this alternative solution.

II. HOW STATE PRESCRIPTION DRUG PRICE CONTROLS WILL HARM CONSUMERS

State prescription drug price controls will harm consumers by discouraging competition and innovation in the pharmaceutical industry. Some groups claim that prices in the U.S. are unfairly high, but these claims are unwarranted. Price controls in states will harm consumers just as price controls in other countries and price controls

²⁰ See Pear, *supra* note 4.

²¹ ME. REV. STAT. ANN. tit. 22 §§ 2681-2698 (West 2002).

under the Medicaid program have harmed consumers.

A. Complaints That Prices in the U.S. Are Unfairly High

Critics of the pharmaceutical industry have a number of different reasons for believing that drug manufacturers charge Americans unfairly high drug prices. Some argue that patents allow drug manufacturers to reap excessive profits from their innovations.²² Others believe, incorrectly, that drug companies increase retail prices to make up for price discounts given to private health plans.²³ Still others point to drug prices in other countries such as Canada and Mexico that are lower than prices charged in the U.S.²⁴

1. Do Patents Lead To Excessive Profits?

A patent is the “governmental grant of a right, privilege, or authority.”²⁵ Patent laws vary from country to country, but the 144 countries of the World Trade Organization (hereinafter “the WTO”), including the U.S., have agreed to the following minimum standards: Subject to restrictions generally irrelevant to drug patents, “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”²⁶ The WTO provides that patent owners may, inter alia, prevent third parties from

²² See, e.g., Dan Goldblatt, *Gore Plays the Pharma Card*, BUS. NEWS N.J., July 11, 2000, at 8 (reporting that then-Presidential candidate Al Gore accused the pharmaceutical industry of “price gouging”).

²³ See, e.g., Whitney Magee Phelps, *Maine’s Prescription Drug Plan: A Look into the Controversy*, 65 ALB. L. REV. 243, 246 (2001) (“[H]ealth maintenance organizations and large insurance companies are able to buy drugs at discounted prices, resulting in higher costs for the uninsured in order to compensate for the discounts afforded to the insured.”).

²⁴ See, e.g., MINORITY HOUSE OF STAFF COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT, 106TH CONGRESS, PRESCRIPTION DRUG PRICING IN THE 7TH CONGRESSIONAL DISTRICT OF MARYLAND: AN INTERNATIONAL PRICE COMPARISON i (Comm. Print 1999).

²⁵ BLACK’S LAW DICTIONARY 1147 (7th ed. 1999).

²⁶ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27, Marrakech Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

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making, using or selling a patented product, prevent third parties from using a patented process, and prevent third parties from using or selling the product directly obtained by a patented process.²⁷ The patent term must last at least twenty years from the date that the application for the patent was filed.²⁸

Patents affect drug prices. A drug manufacturer can obtain a patent on the chemical formulation or process of manufacture of an innovative drug.²⁹ Then, for the duration of the patent term, the patent owner can prevent others from selling the patented chemical formulation or from using the patented process of manufacture.³⁰ Consumers cannot shop around to find the lowest price for this patent-protected drug (known as an “on-patent” drug). If consumers want the on-patent drug, they have to pay the patent owner’s price or the price of someone authorized by the patent owner.³¹ This situation leads to a higher price for an on-patent drug than would occur if the drug were not patent-protected.³²

However, if it were not for the patent protection, the innovative drug might not exist at all. Pharmaceutical research and development (hereinafter “R&D”) is risky and expensive.³³ Drug developers invest heavily in R&D because they expect to profit from it.³⁴ Without patent protection, they could not profit from R&D because competing drug manufacturers would undersell the developers before the developers recouped their investment in R&D and made a profit from it.³⁵ With patent protection, a drug developer

²⁷ TRIPS Agreement, art. 28.

²⁸ TRIPS Agreement, art. 33.

²⁹ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 2.

³⁰ See TRIPS Agreement, art. 28.

³¹ See *id.*

³² See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 3.

³³ See Grabowski, *supra* note 15, at 1234-40; see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 2-3.

³⁴ CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 2 (“Producers of innovator drugs invest heavily in research and development (R&D), hoping to recoup that investment in profits from future sales while a drug is under patent and they have a monopoly on its manufacture”); see also Grabowski, *supra* note 15, at 1258 (“A firm undertaking long-term risky R&D programs on new drugs must make an investment decision on the bases of expectations”).

³⁵ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 2 (stating generic drug

can hopefully demand a price high enough to recoup the costs of R&D and make a profit.³⁶ Patents do not guarantee a profit for drug developers, but they make it a possibility by allowing drug developers to demand higher prices than they could without patent protection.

In theory, competition among drug developers should put their expected profits at competitive levels.³⁷ Anyone can invest in pharmaceutical R&D, as demonstrated by the large number of new startup R&D companies in the U.S.³⁸ If investors expect to profit from investing in pharmaceutical R&D, they will do so.³⁹ However, when investment in R&D increases, expected profits decrease because the increased R&D will cause more competing products to come to market.⁴⁰ Due to this competition, a balance should exist in which investment in pharmaceutical R&D occurs at the maximum level that is justifiable by the expected profits and, correspondingly, the expected profits are at the minimum level that justifies the investment in pharmaceutical R&D.⁴¹

Two separate studies indicate that this theory is fact: expected profits from pharmaceutical R&D are at competitive levels. A study by Henry Grabowski and John Vernon, economists at Duke University, examined the returns on R&D investment to all “new chemical entities” (hereinafter “NCEs”), which are chemically

manufacturers “do not need to duplicate the research effort of innovator firm[s] or invest nearly as much in getting approval” from the Food Drug Administration). “Without patents, many new drugs could be easily and quickly duplicated by other manufacturers, preventing the innovator firm from obtaining enough reward to justify its investment.” *Id.* at 3.

³⁶ *See id.*

³⁷ *See* Danzon, *supra* note 15, at 62. Danzon suggests that “[f]ree entry to pharmaceutical R&D—which is evidenced by the large number of startup companies—will reduce *expected* profits to competitive levels.” *Id.* (emphasis in original).

³⁸ *See* Danzon, *supra* note 15, at 62; *see also* Grabowski *supra* note 15, at 1244-45. R&D startup companies may have a difficult time taking their innovative drugs to market, due to the high costs of the testing required for approval from the Food and Drug Administration, and thus license their patents to one of the major drug firms. This does not change the fact that startup companies can invest in R&D and license their resulting innovations to one of a number of competing buyers.

³⁹ *See* OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS 104 (1993).

⁴⁰ *Id.*

⁴¹ *See id.*

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distinct new drugs approved for marketing, introduced to the U.S. from 1980-1984.⁴² The study found that the internal rate of return (hereinafter “IRR”)⁴³ for the mean NCE was 11.1%.⁴⁴ This was less than 1% more than the estimated 10.5% real cost of capital⁴⁵ for pharmaceutical firms over this period.⁴⁶

A similar study by the Office of Technology Assessment (hereinafter “the OTA”) examined the returns on R&D investment using a sample of NCEs introduced from 1981-1983.⁴⁷ The OTA study used some different assumptions than the Grabowski-Vernon study, such as a variable cost of capital rather than a fixed cost.⁴⁸ However, the study reached the same conclusion: the pharmaceutical industry’s returns for the average NCE were within 1% of the industry’s estimated cost of capital.⁴⁹

⁴² See Grabowski, *supra* note 15, at 1236-37.

⁴³ IRR is a way to compare profit levels among disparate industries. Stanton, *supra* note 13, at 156. Technically, the IRR is the discount rate that makes the net present value of a series of cash flows equal to zero. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 95.

⁴⁴ Grabowski, *supra* note 15, at 1237.

⁴⁵ Cost of capital is the expected return that is forgone by investing in pharmaceutical R&D instead of comparably risky investments. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 48. The minimum expected return required to justify an investment is the cost of capital. See *id.* at 104. Competition among investors should, in theory, make expected returns equal to the cost of capital. See *id.*

⁴⁶ Grabowski, *supra* note 15, at 1237. The cost of capital varies widely across research projects, with successive investments in a progressing project, and day to day as the risk-free interest rate changes. OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 66. “[T]he cost of capital that should be assigned is the cost the investors actually faced at the time they made their investments.” *Id.* However, such data is unavailable. *Id.* Both the Grabowski-Vernon study and the Office of Technology Assessment study discussed in this Note “assumed the cost of capital was constant across all projects and over the entire period during which the R&D spending on the sampled NCEs was taking place.” *Id.*; see also Grabowski, *supra* note 15, at 1237. Both studies also based their estimates on the cost of capital for the NCEs studied on estimates of the cost of capital for pharmaceutical investments made during the 1980s. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 93; Grabowski, *supra* note 15, at 1237.

⁴⁷ Grabowski, *supra* note 15, at 1239; see also OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 73-94.

⁴⁸ Stanton, *supra* note 13, at 156; see also OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 73-94.

⁴⁹ See Grabowski, *supra* note 15, at 1239; see also Stanton, *supra* note 13, at 156-57.

This finding is often surprising to policy-makers and other observers familiar with accounting measures of return, such as those published in the Fortune 500 analysis

These studies examined actual returns, not expected returns. The actual return on an investment may be higher or lower than the expected return.⁵⁰ However, the fact that the actual returns in these studies were within 1% of the cost of capital suggests that the investors expected returns roughly equal to the cost of capital. Furthermore, other evidence indicates that actual returns slightly greater than the cost of capital were unexpected. First, the revenues from the sampled drugs were much higher than revenues from new drugs introduced in previous years.⁵¹ Second, as a result of these high returns, pharmaceutical expenditures R&D rose “dramatically” throughout the 1980s.⁵² The OTA study concluded:

The dramatic increase in real revenues to new drugs throughout the 1980s has sent signals to the industry that more investment will be rewarded handsomely. The industry has responded as expected, by increasing its commitment to investment, including investment in R&D. The resulting rise in R&D investment may have dampened internal rates of return as more money is poured into projects that, if successful, must share revenues with other competing products on the market.⁵³

Patricia M. Danzon, an economist at the Wharton School of the University of Pennsylvania, believes that “the best measure of whether current profits are too high is whether current R&D is

or Business Week. Indeed, in recent debates, legislators critical of the industry have pointed to the high accounting returns for pharmaceutical R&D as an indicator of serious performance problems in this industry. However, several economic studies have demonstrated that accounting returns are not good measures of the underlying internal rate of return for a firm or industry. These measures are subject to particularly significant bias in industries such as pharmaceuticals with high rates of intangible capital investment. Various empirical studies have corrected for this bias by depreciating intangible investment flows like R&D and advertising, and have found that adjusted returns on the total investment of pharmaceutical firms converge toward in the industry’s cost of capital.

Grabowski, *supra* note 15, at 1239 (citations omitted).

⁵⁰ See Danzon, *supra* note 15, at 62.

⁵¹ OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 39, at 104.

⁵² *Id.*

⁵³ *Id.*

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considered excessive.”⁵⁴ This belief is correct in light of the Grabowski-Vernon study and the OTA study, which show how drug developers compete for profits by investing in pharmaceutical R&D. Although current profit levels are the result of R&D investment decisions made ten to twenty years ago based on uncertain predictions about science, markets, and politics,⁵⁵ any action affecting current profit levels will affect expected profit levels as well, and therefore will affect current levels of R&D.

Thus, if one is satisfied with current levels of R&D, then one must be satisfied with the opportunity for profit that patents provide to drug developers, unless one favors another way for drug developers to profit⁵⁶ or another way to fund pharmaceutical R&D.⁵⁷ More generally, any criticism of opportunities for drug developers to profit must consider current levels of R&D. A few “blockbuster” drugs, for example, have generated incredible profits for their patent owners.⁵⁸ Laws that would limit the amount that drug developers can make from future blockbuster drugs would drastically reduce the expected profits for drug developers, and therefore would drastically reduce investment in pharmaceutical R&D.⁵⁹ The Hatch-Waxman Act allows an owner of a drug patent to extend the duration of the patent if pre-market testing and approval required by the Food and Drug Administration consumed a significant amount of the original patent term.⁶⁰ This law increased expected profits for drug

⁵⁴ Danzon, *supra* note 15, at 62.

⁵⁵ *Id.*

⁵⁶ For example, one could favor lengthening patent terms, which would increase profits, and increasing taxes on drug companies, which would decrease profits, such that net profits remained the same.

⁵⁷ The government, for example, can take a more active role in funding pharmaceutical R&D. See generally ALAN S. GUTTERMAN, INNOVATION AND COMPETITION POLICY: A COMPARATIVE STUDY OF THE REGULATION OF PATENT LICENSING AND COLLABORATIVE RESEARCH & DEVELOPMENT IN THE UNITED STATES AND THE EUROPEAN COMMUNITY 423-37 (1997) (suggesting alternatives to the current patent system). Or, lawmakers can change the existing patent system. See generally *Patently Absurd?*, THE ECONOMIST TECH. Q., June 23, 2001, at 42 (“[T]he patenting authorities need to find a greater variety of tools for protecting intellectual property than they have at present.”).

⁵⁸ See Stanton, *supra* note 13, at 169 (citing HENRY GRABOWSKI, HEALTH REFORM AND PHARMACEUTICAL INNOVATION 13-25 (1994)).

⁵⁹ *Id.*

⁶⁰ The Drug Price Competition and Patent Term Restoration Act of 1994 (Hatch-

developers, and therefore increased pharmaceutical R&D. Trademark protection, tax benefits, and television advertisements have also increased opportunities for drug developers to profit, and criticism of them should consider pharmaceutical R&D.⁶¹ Any claim that drug developers make excessive profits that does consider current levels of pharmaceutical R&D is unwarranted.

2. Do Retail Prices Compensate for Discounts Given to Private Health Plans?

Another complaint against the pharmaceutical industry is that drug manufacturers raise retail prices to make up for price discounts given to private health plans.⁶² Private health plans hire PBMs that negotiate discounts from drug manufacturers by moving market share towards certain drugs.⁶³ PBMs move market share by 1) negotiating large-volume purchases of prescription drugs for their clients, and 2) by creating formularies, or preferred lists of drugs that they encourage the patients of their clients to use.⁶⁴

Waxman Act) § 201, 35 U.S.C.A. § 156 (West 2002). The Hatch-Waxman Act has also had the unintended consequences of allowing anticompetitive agreements between brand name drug manufacturers and generic drug manufacturers. See David A. Balto, *Pharmaceutical Patent Settlements The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 330-31 (2000). Lawmakers are working on closing these "loopholes" in the act. See Denise Gellene, *Drug Makers' Healthy Profits Stir Consumer Indignation*. L.A. TIMES, Apr. 27, 2001, at C1.

⁶¹ Trademark protection increases profits of drug developers because drug developers generally sell their innovative drugs under brand names that acquire goodwill and allow the manufacturers to demand higher prices. See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 2. Generic drug manufacturers, companies that sell exact copies of off-patent brand name drugs, generally sell their products under the chemical names rather than giving them brand names. *Id.* at 2 n.1. The tax code increases profits of drug developers by allowing them to claim tax credits for certain R&D expenses and to deduct certain R&D expenditures from their taxable income. See, e.g., 26 U.S.C.A. §§ 41, 174 (West 2002). Television commercials allow drug developers to increase profits by increasing demand. See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 19-20.

⁶² See, e.g., Phelps, *supra* note 23, at 246.

⁶³ GENERAL ACCOUNTING OFFICE, REP. NO. HEHS-97-60, DRUG PRICES: EFFECTS OF OPENING FEDERAL SUPPLY SCHEDULE FOR PHARMACEUTICALS ARE UNCERTAIN 7-8 (1997); see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 6-7.

⁶⁴ See GENERAL ACCOUNTING OFFICE, *supra* note 63, at 7-8; see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 6-7. PBMs also negotiate substantial discounts from pharmacies. *Id.* Select pharmacies agree to give health plans discounts because their

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Formularies are powerful tools for moving market share.⁶⁵ PBMs may provide incentives to physicians to prescribe preferred drugs.⁶⁶ PBMs may require lower co-payments from patients for preferred drugs and may even refuse to provide patients with drugs that are not on the preferred list.⁶⁷ PBMs may also encourage pharmacists to substitute a preferred drug for a drug that has been prescribed.⁶⁸

Moreover, formularies are especially powerful tools for negotiating discounts from drug manufacturers, because PBMs consider price when creating formularies, and PBMs are extremely well informed about which drugs offer the most therapeutic value for the money. Generally, for any particular disease, more than one drug manufacturer sells a drug treatment.⁶⁹ Either generic equivalents exist, which are exact chemical copies of off-patent drugs, or therapeutic equivalents exist, which are drugs that use the same therapeutic mechanism as another, possibly on-patent, drug.⁷⁰ One

patients increase business for those pharmacies. *Id.* The system works as follows: The patient gets an enrollment card from the PBM. Then, the patient goes to a pharmacy that participates in the program and presents the enrollment card. The pharmacist uses a computer network to check the PBM's formulary as a guide in filling the prescription. The computer network allows the PBM to track all prescription drug purchasers by its members. This allows PBMs to arrange discounts between drug manufacturers, pharmacies, and private health plans, without ever physically handling prescription drugs. PBMs act as middlemen in these transactions and thus insert themselves into the payment system. Private health plans can also negotiate discounts for themselves, without using a PBM. Private health plans negotiating on their own use the same techniques as PBMs. *Id.*

⁶⁵ See GENERAL ACCOUNTING OFFICE, *supra* note 63, at 7-8; see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 6-7.

⁶⁶ See Danzon, *supra* note 15, at 60; see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 6.

⁶⁷ See Danzon, *supra* note 15, at 60, 61.

⁶⁸ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 6. For brand name drug substitution, the pharmacist must obtain the doctor's permission. *Id.*

⁶⁹ See *id.* at 18-19.

⁷⁰ *Id.* When generic equivalents do not exist, drug manufacturers still compete with each other by selling different patent-protected drugs that use the same therapeutic mechanism, or the same method of treating a particular disease. Patents usually do not prevent other companies from introducing similar but slightly differentiated drugs, and frequently they protect only a specific chemical formulation rather than a therapeutic mechanism. Often several different companies each find different chemical entities, or "me-too" drugs, that use the same basic mechanism to treat an illness. Thus, a "breakthrough drug," or the first brand name drug to use a therapeutic mechanism, usually has only one to six years, at most, of pure market exclusivity before a similar patented brand name drug enters the market and competes with it directly. *Id.*

of these drugs may offer more therapeutic value, in terms of efficacy and safety, for the money than another one of these drugs. However, doctors often write prescriptions with little knowledge of or concern for price.⁷¹ Thus, retail drug prices are rather uncompetitive.⁷² PBMs, on the other hand, which compete for the business of health plans, which in turn compete for the business of individual patients, must be extremely knowledgeable and concerned about drug prices if they want to stay in business.⁷³ PBMs create their formularies based on their knowledge of therapeutic value and price, and as a result they obtain competitive discounts from drug manufacturers seeking market share.⁷⁴

Discounts to private health plans do not create higher drug prices for retail purchasers.⁷⁵ Drug manufacturers charge retail purchasers prices that maximize profits.⁷⁶ Profits depend on the number of units sold and the price at which they are sold.⁷⁷ As the price goes up, consumer demand for the product goes down.⁷⁸ As the price goes down, consumer demand for the product goes up.⁷⁹ One price, known as the “equilibrium” price or profit-maximizing price, results in a price and demand combination that maximizes profits.⁸⁰ Any price higher or lower than the equilibrium price reduces profits from

⁷¹ See Danzon, *supra* note 15, at 58. A study by researchers at the Mount Sinai School of Medicine found that out of 134 physicians surveyed, 88% believed that the cost of medications was an important consideration in the prescribing decision, but 80% felt unaware of the actual costs and only 33% had easy access to drug cost information. See Steven Reichert et al., *Physicians' Attitudes About Prescribing and Knowledge of the Costs of Common Medications*, 160 THE ARCHIVES OF INTERNAL MED. 2799, at 2800-01 (2000). In addition, only 13% reported ever having any formal training about medication costs, and only 16% reported asking their patients about the costs of their medications. *Id.* at 2800.

⁷² See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 23-24.

⁷³ See Patricia M. Danzon, *Pharmaceutical Benefit Management: An Alternative Approach*, HEALTH AFF., Mar./Apr. 2000, at 24 (stating competing PBMs have to deliver value for money to keep customers).

⁷⁴ See *id.*

⁷⁵ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 24; see also Danzon, *supra* note 15, at 1.

⁷⁶ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 19-20; see also Danzon, *supra* note 15, at 62.

⁷⁷ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 19.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

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the maximum.⁸¹ If drug manufacturers were to increase retail equilibrium prices to make up for discounts, they would only reduce their profits.⁸² Thus, in a free market, drug prices depend only on consumer demand and the sensitivity of that demand to price.⁸³ Drug prices do not depend on prices charged to other groups.⁸⁴

In fact, the practice of drug manufacturers of charging different purchasers different prices, known as differential pricing, discriminatory pricing, or Ramsey pricing, actually maximizes the welfare of all prescription drug purchasers.⁸⁵ Differential pricing offers price-sensitive consumers, who would not participate in the market under a system of uniform pricing, low enough prices so that they are willing to participate in the market and contribute something to the shared costs of pharmaceutical R&D.⁸⁶ Although the purchasers paying the highest prices may complain, they are actually paying *less* than they would for the same level of R&D under a system of uniform pricing.⁸⁷ Differential pricing allows drug manufacturers to maximize profits, and therefore maximizes R&D for new medicines.⁸⁸ In economic terms, differential pricing is optimal when applied to industries with large joint costs, such as pharmaceutical R&D, relative to user-specific marginal costs, such as the cost of manufacturing a drug.⁸⁹ Differential pricing is practiced in many such industries including the airline, film, restaurant, and utility industries.⁹⁰

PBMs using formularies help all prescription drug purchasers by segmenting the market according to price-sensitivity such that

⁸¹ *See id.*

⁸² *See* Danzon, *supra* note 15, at 62; *see also* CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 19.

⁸³ *See* CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 19.

⁸⁴ *See id.*

⁸⁵ *See* DANZON, *supra* note 13, at 11-13. *See generally* KENNETH E. TRAIN, OPTIMAL REGULATION: THE ECONOMIC THEORY OF NATURAL MONOPOLY, Ch. 4 (1991) (explaining underlying theory of Ramsey pricing). Ramsey pricing is named after economist Frank Ramsey. DANZON, *supra* note 13, at 11.

⁸⁶ *See* DANZON, *supra* note 13, at 11-13.

⁸⁷ *See id.*

⁸⁸ *See id.*

⁸⁹ *See id.*

⁹⁰ *Id.*; Danzon, *supra* note 15, at 60.

differential pricing can occur. As discussed earlier, drug manufacturers base their prices on the price-sensitivity of purchasers.⁹¹ Uninsured retail purchasers appear price-insensitive because their demand is channeled through a doctor who may be uninformed or unconcerned about price.⁹² PBMs, on the other hand, may be extremely price-sensitive because they are informed and concerned about price when creating their formularies.⁹³ PBMs reflect the price-sensitivity of the health plans that employ them, which in turn reflect the price-sensitivity of their patient base.⁹⁴ A variety of competing PBMs and formularies exist to suit the price-sensitivity of different patient groups.⁹⁵ The result is that consumers can express their willingness to pay for innovative drugs, and drug manufacturers can charge them accordingly.⁹⁶

3. Do Lower Prices in Other Countries Call for Lower U.S. Prices?

Critics of U.S. prescription drug prices also point to lower prices in other countries, such as Canada and Mexico.⁹⁷ Lower prescription drug prices may exist in other countries because of a number of factors.⁹⁸ Two major factors are: 1) purchasers in other countries may be more price-sensitive than U.S. purchasers, and 2) regulations in other countries may control drug prices.⁹⁹ The first factor was addressed earlier: drug manufacturers that practice differential pricing maximize the welfare of all consumers of prescription

⁹¹ See *supra* text accompanying notes 75-84.

⁹² Danzon, *supra* note 15, at 60; see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 23-24; Richard, *supra* note 71, at 2800-01.

⁹³ Danzon, *supra* note 15, at 60; see also CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 23-24.

⁹⁴ See Danzon, *supra* note 15, at 61.

⁹⁵ See *id.* Some formularies, for example, are less restrictive than others. *Id.*

⁹⁶ See DANZON, *supra* note 13, at 14.

⁹⁷ See, e.g., MINORITY HOUSE OF STAFF COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT, *supra* note 24, at i.

⁹⁸ See Danzon *supra* note 15, at 58. These include different product liability laws, lack of patent laws, and an ability to obtain prescription medicines without a prescription. *Id.*

⁹⁹ See *id.*

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drugs.¹⁰⁰ Thus, the first factor does not justify lower prices in the U.S.

Price controls in other countries do not justify lower prices in U.S., either. Any prices less than what purchasers are willing to pay in a free market for innovative new drugs will hurt U.S. prescription drug purchasers by discouraging pharmaceutical R&D.¹⁰¹ Price controls may allow other countries to “free-ride” on those who fund innovation, because price controls may demand prices that cover only slightly more than the marginal cost of manufacturing a drug rather than contributing significantly to the costs of R&D.¹⁰² This practice discourages pharmaceutical innovation by making pharmaceutical R&D a less profitable investment. However, the U.S. would contribute to the problem if it were to pay the lower prices of other countries, hurting American consumers in the process. In addition, the U.S. has pressured other countries to relax their regulations on drug prices, and any price regulations by the U.S. could give these countries cause to tighten their price regulations.¹⁰³

B. The Effects of Prescription Drug Price Controls

Prescription drug price controls discourage competition and innovation in the pharmaceutical industry, and therefore harm consumers of prescription drugs. Price controls in other countries have had these negative effects,¹⁰⁴ as have price controls created by the U.S. federal Medicaid program.¹⁰⁵ State prescription drug price control laws will fare no differently.

¹⁰⁰ See *supra* text accompanying notes 85-90.

¹⁰¹ See sources cited *supra* note 15; see also Stanton, *supra* note 13, at 171.

¹⁰² See DANZON, *supra* note 13, at 93.

¹⁰³ See Christopher Scott Harrison, Comment, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT'L L. & COM. REG. 457, 457-62 (2001) (discussing how the U.S. pressured Canada to abandon its compulsory licensing law for patented pharmaceuticals).

¹⁰⁴ See Stanton, *supra* note 13, at 160-64; see also DANZON, *supra* note 13, at 15-29.

¹⁰⁵ See CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 25-44.

I. Price Controls in Other Countries

Many countries use pharmaceutical price controls to control drug spending. Some countries, such as France, Italy, and Canada regulate drug prices directly through controls on prices.¹⁰⁶ Germany and Japan regulate prices indirectly through limits on reimbursement under social insurance schemes.¹⁰⁷ The United Kingdom regulates drug price indirectly through profit controls.¹⁰⁸

A study by Patricia Danzon used empirical evidence to thoroughly examine the effects of each of these countries' price regulations on, *inter alia*, incentives for pharmaceutical innovation, production efficiency, goals of controlling total drug expenditures, and quality of patient care.¹⁰⁹ The evidence showed that no country with price controls has had innovative success in the pharmaceutical industry that matches that of the U.S.¹¹⁰ Danzon found "a rough negative correlation between the stringency of a country's price controls and the innovative success of its domestic pharmaceutical industry."¹¹¹ She also found that regulation in France has led to excessive use of capital and labor, reducing productivity.¹¹² Moreover, some price controls tend to undermine competition from manufacturers of generic and over-the-counter drugs, and can sustain domestically produced compounds that lack therapeutic merit but nevertheless comprise more than one-third of total drug spending in some countries.¹¹³ Danzon concluded that the pharmaceutical price regulations of these countries do not "balance the desire to control costs with the health concerns of individual patients today and the

¹⁰⁶ Danzon, *supra* note 15, at 56, 58.

¹⁰⁷ Danzon, *supra* note 15, at 56.

¹⁰⁸ *Id.*

¹⁰⁹ DANZON, *supra* note 13, at 3-4.

¹¹⁰ See DANZON, *supra* note 13, at 58-63. For example, U.S. researchers discovered 45% of the global drug products (defined as marketed in seven major markets) developed from 1975-1994. *Id.* at 60-62.

¹¹¹ *Id.* at 63.

¹¹² *Id.* at 80.

¹¹³ *Id.* at 45.

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need to preserve incentives for innovation to develop the drugs for tomorrow.”¹¹⁴

Danzon’s study is powerful evidence that pharmaceutical price controls harm consumers by discouraging innovation. Although factors other than price regulation can affect pharmaceutical innovation, her study used data from many different countries over many years to demonstrate that price regulations have a negative affect on innovation.¹¹⁵ This finding is consistent with economic theory.¹¹⁶ The negative impact of price controls on the domestic pharmaceutical industries may be surprising, since the pharmaceutical market is global and price controls in one market should affect both foreign and domestic industry equally. However, price controls have the greatest impact on domestic firms because domestic firms tend to have a disproportionate share of their home market, and domestic firms have cost and information disadvantages in entering foreign markets.¹¹⁷

2. Price Controls under the U.S. Medicaid Program

In the U.S., the Medicaid program obtains manufacturer’s discounts through indirect price controls.¹¹⁸ The Omnibus Budget Reconciliation Act of 1990 (hereinafter “the OBRA”) established the Federal Medicaid Rebate Program.¹¹⁹ The OBRA requires that manufacturers of brand-name drugs give Medicaid rebates equal to the greater of the best-price discount offered to any private purchaser or 15.1% off the average manufacturer price.¹²⁰ The OBRA requires that manufacturers of generic and over-the-counter drugs give Medicaid rebates equal to 11% off the average manufacturer price. The federal government will not pay for a drug unless the

¹¹⁴ *Id.* at 92.

¹¹⁵ *See id.* at 58-63.

¹¹⁶ *See sources cited supra* note 15.

¹¹⁷ DANZON, *supra* note 13, at 56-57.

¹¹⁸ *See Morton, supra* note 15, at 53; *see also* DANZON, *supra* note 13, at 17-18.

¹¹⁹ CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 5; *see also* 42 U.S.C.A. § 1396r-8 (West 2002).

¹²⁰ *See* CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 11-12.

manufacturer gives Medicaid the required rebate.¹²¹ The Medicaid rebate program seeks not to establish appropriate prices for prescription drugs, but to reduce government spending on prescription drugs.¹²²

Medicaid can set its own prices because it has monopsony power, functioning as the sole purchaser of medical goods and services.¹²³ Drug manufacturers that do not comply with the Medicaid price requirements will not sell any drugs to Medicaid recipients because only Medicaid purchases drugs for them. Thus, drug manufacturers cannot negotiate; they must accept Medicaid prices.

Like other forms of price control, the OBRA discourages competition and innovation in the pharmaceutical industry. Drug manufacturers do not use price to compete for the Medicaid market. To reach the Medicaid market, drug manufacturers just comply with the price requirements of the OBRA.¹²⁴ Medicaid sales represent 10 to 15% of the prescription drug market in the U.S., so drug manufacturers have a large incentive to push the OBRA prices as high as possible.¹²⁵ Because the OBRA price requirements depend on either the best-price discount or the average manufacturers price, the OBRA affects the prices paid by private health plans and retail purchasers.¹²⁶

The OBRA affects the prices paid by private health plans because it discourages discounting by drug manufacturers.¹²⁷ A study by the Congressional Budget Office (hereinafter “the CBO”) found that, following the enactment of the OBRA, from 1991 to 1993, the average best-price discount declined from 36% to 20%.¹²⁸ For 24%

¹²¹ *Id.*

¹²² *See id.* at 5

¹²³ *See* Danzon, *supra* note 73, at 24.

¹²⁴ Some states may further restrict Medicaid drug purchases by using formularies. *See* CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 9. However, drug companies do not use price to compete for preferred status on these formularies, because states can use Medicaid’s monopsony power to demand any price they want. *See infra* notes 167-70 and accompanying text.

¹²⁵ *See* CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 2.

¹²⁶ *Id.* at 25-48.

¹²⁷ *Id.* at 27.

¹²⁸ *Id.* at 28.

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of the drugs studied, the best-price discount fell by 30% or more.¹²⁹ Brand-name drug manufacturers resist giving private purchasers discounts larger than 15.1% because if they do, the OBRA requires them to give the same discount to Medicaid.¹³⁰ This decrease in best-price discounts is especially troubling because it has occurred even though the price-sensitivity of the market has increased through formularies:

The Medicaid rebate discourages discounting in the pharmaceutical industry. Ironically, the size of best-price discounts has fallen in a market in which the price sensitivity of buyers may be increasing. Enrollment in health maintenance organizations and other managed care organizations is on the rise, and formularies are increasingly used to link price with prescription choice. Yet counter to this trend, manufacturers have reduced the size of their best-price discounts.¹³¹

Thus, the OBRA prevents optimal differential pricing according to price-sensitivity. This makes drugs unaffordable for some purchasers and reduces returns on investments in pharmaceutical R&D, discouraging innovation.

The OBRA also increases prices paid by uninsured purchasers in the retail sector.¹³² When brand-name drug manufacturers do not offer private purchasers discounts greater than 15.1% off the average manufacturer's price, the OBRA still requires a minimum rebate of 15.1% off the average manufacturer's price.¹³³ Manufacturers of generic and over-the-counter drugs must give a rebate of 11% off the average manufacturer's price.¹³⁴ Drug manufacturers increase launch prices to lessen the effect of these rebates.¹³⁵ The CBO study concluded "[h]ow great the effect of the Medicaid rebate on the

¹²⁹ *Id.* at 27.

¹³⁰ *See id.* at 27-44.

¹³¹ CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 27.

¹³² *Id.* at 26.

¹³³ *Id.* at 11-12.

¹³⁴ *Id.*

¹³⁵ *See id.* at 25-26.

pricing of new drugs will be depends on how large the expected Medicaid market share of the new drug is.”¹³⁶ These price increases harm consumers by making drugs less affordable for many, thus reducing access to medicine and contributions to the shared costs of pharmaceutical R&D.

3. State Prescription Drug Price Controls

State prescription drug price controls will harm consumers just as price controls in other countries and price controls under the Medicaid program have harmed consumers. According to economic theory, any form of price control will harm consumers in one way or another.¹³⁷ Thus, even if each state adopts a different system of price regulation, they will, in theory, all harm consumers. However, many of the new state regulations are similar and will harm consumers in a similar way. Most of them regulate drug prices to levels equal either to Medicaid prices, Federal Supply Schedule (hereinafter “FSS”) prices, or the best prices offered to private purchasers.¹³⁸

The Federal Government pays prices listed on the FSS.¹³⁹ The Department of Veterans Affairs (hereinafter “the VA”) administers the pharmaceutical FSS, seeking from drug manufacturers prices comparable to the best prices offered to private purchasers.¹⁴⁰ Under the Veterans Health Care Act (hereinafter “the VHCA”), drug manufacturers must make their drugs available through the FSS in order for Medicaid to offer reimbursements for their drugs.¹⁴¹ Thus, the VHCA uses the monopsony power of Medicaid to control drug prices and exacerbates the harm caused by the OBRA.

Whether states regulate prices to Medicaid prices, FSS prices, or the best prices offered to private purchasers, the result will be similar

¹³⁶ *Id.* at 26.

¹³⁷ See sources cited *supra* note 15.

¹³⁸ See *Maine Enacts Drug Price Controls; 16 Other States Taking Similar Action*, *supra* note 9, at 3.

¹³⁹ See GENERAL ACCOUNTING OFFICE, *supra* note 63, at 4-9.

¹⁴⁰ *Id.* at 6; see also 48 C.F.R. § 538.270 (2000).

¹⁴¹ GENERAL ACCOUNTING OFFICE, *supra* note 63, at 5; see also 38 U.S.C.A. § 8126 (West 2002).

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to that brought on by the OBRA and the VHCA: discouraging differential pricing. By increasing the size of the market locked into the Medicaid prices, states will amplify the negative affects of Medicaid discussed earlier.¹⁴² Drug manufacturers will be less inclined to offer competitive discounts to private purchasers, because they will have to give those discounts to Medicaid and the market affected by the state price regulations. Likewise, states that regulate prices to the best prices offered to private purchasers or FSS prices (which are based on the best prices offered to private purchasers) will also reduce the amount of competitive discounts offered to private purchasers.

States that regulate one group's prices to that of another group will harm consumers by discouraging differential pricing in favor of uniform pricing.¹⁴³ Under this form of regulation, drug companies will no longer base prices on the price-sensitivity of smaller groups. Rather, they will base their prices on the price-sensitivity of the larger group that is locked into the same price. As a result, prescription drugs will become *less* affordable for many price-sensitive purchasers, while price-insensitive purchasers who are willing to pay more for innovative new medicines will not be able to do so. Access to medicine and investment in pharmaceutical R&D will be reduced, thus harming consumers.

III. AN ANALYSIS OF THE MAINE RX PROGRAM

On May 11, 2000, Maine's governor signed into law An Act to Establish Fairer Drug Pricing (hereinafter "the Act"), which established the Maine Rx Program (hereinafter "the Rx Program").¹⁴⁴ The Rx Program is an interesting example of a state prescription

¹⁴² See *supra* text accompanying notes 124-36.

¹⁴³ Imagine, for example, if airlines had to charge the same price for every seat on an airplane. Price-sensitive purchasers would not be able to get cheap coach seats, and price-insensitive purchasers would not be able to pay more for first class. In addition, the airline industry's profits would decrease, which, given the competitiveness of the industry, would harm consumers.

¹⁴⁴ ME. REV. STAT. ANN. tit. 22 §2681 (West 2002).

drug price control system that will harm consumers by discouraging differential pricing.

A. What Is Interesting About the Maine Rx Program?

The Rx Program is particularly interesting for a number of reasons. First, the Rx Program does not look like a price control system. Rather, the Rx Program legislation ostensibly requires Maine to act as a PBM for its residents and negotiate discounts from drug manufacturers for them.¹⁴⁵ Another interesting aspect of the Rx Program is that it has become very popular: twenty-three states are considering enacting “clones” of the Rx Program legislation.¹⁴⁶ Finally, the Rx Program is well known because the Pharmaceutical Research and Manufacturers of America (hereinafter “PhRMA”), a trade group representing numerous drug manufacturers, has challenged the constitutionality of the Rx Program.¹⁴⁷ The U.S. Court of Appeals for the First Circuit has held the Rx Program legislation constitutional, but PhRMA has sought certiorari from the U.S. Supreme Court and currently awaits its decision.¹⁴⁸ Perhaps some states are waiting for the outcome before enacting their Rx Program clones.

B. The Maine Rx Program Legislation

The first subchapter of the Act established the Rx Program “to reduce prescription drug prices for residents of the State.”¹⁴⁹ The statute states that “[i]n implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and

¹⁴⁵ See *id.*

¹⁴⁶ See Woellert, *supra* note 8, at 33.

¹⁴⁷ See *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, at 72 (1st Cir. 2001), *petition for cert. filed*, 70 U.S.L.W. 3092 (U.S. July 31, 2001) (No. 01-188). PhRMA claimed that the Rx Program violated the dormant Commerce Clause and was preempted by the federal Medicaid statute under the Supremacy Clause. *Id.* The district court agreed and granted PhRMA a preliminary injunction to prevent implementation of the legislation. *Id.* The appellate court reversed in what it called “a close case.” *Id.* at 85.

¹⁴⁸ *Id.* at 85; *Concannon*, 70 U.S.L.W. at 3092.

¹⁴⁹ ME. REV. STAT. ANN. tit. 22 § 2681 (West 2002).

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pharmacy discounts on behalf of qualified residents.”¹⁵⁰ Further on, the statute states “[t]his subchapter is enacted by the Legislature to enable the State to act as pharmacy benefit manager in order to make prescription drugs more affordable for qualified residents.”¹⁵¹

A “qualified resident” is a resident with a Maine Rx enrollment card.¹⁵² The Maine Department of Human Services (hereinafter “the department”) decides which residents are eligible for enrollment, and must undertake outreach efforts to maximize enrollment of qualified residents.¹⁵³ The department has decided that any Maine resident is eligible for a Maine Rx enrollment card.¹⁵⁴

The Act requires the Commissioner of Human Services (hereinafter “the commissioner”) to “negotiate” rebates from prescription drug manufacturers.¹⁵⁵ The commissioner must “use the commissioner’s best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.”¹⁵⁶

The law punishes drug manufacturers that do not enter into rebate agreements with the commissioner.¹⁵⁷ The department “shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers. . . .”¹⁵⁸ This means Medicaid beneficiaries cannot receive drugs sold by nonparticipating manufacturers without the prior approval of the State Medicaid

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ See *Concannon*, 249 F.3d at 71 (stating the Rx Program is open to all residents of Maine).

¹⁵⁵ ME. REV. STAT. ANN. tit. 22 § 2681 (West 2002).

¹⁵⁶ *Id.* Pharmacies that participate in the program must charge Rx Program enrollees statutorily defined prices that reflect the rebates. Participating pharmacies may also charge a statutorily defined dispensing fee. The drug manufacturers pay the rebates directly to the State, and the State reimburses the participating pharmacies for selling discounted drugs to program enrollees. *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* The department also releases information on the participants and non-participants to health providers and the public on a regular basis. *Id.*

administrator.¹⁵⁹ This slows down the dispensing procedure so much that instead of waiting for approval, doctors and patients seek alternative therapies.¹⁶⁰ Thus, the Rx Program effectively prevents Maine's Medicaid program from purchasing drugs sold by manufacturers that do not enter into rebate agreements with the commissioner.¹⁶¹

C. Analysis

Under the Rx Program, Maine does not negotiate discounts from drug manufacturers by acting as a PBM for its residents. PBMs negotiate manufacturer discounts for their clients by moving market share through large-volume purchases and formularies.¹⁶² Rx Program enrollees do not make large-volume purchases or use formularies. Rx Program enrollees purchase prescription drugs for themselves from pharmacies just like every other individual purchasing prescription drugs.

Nothing can enable Maine to act as a proper PBM for its residents. Individuals cannot make large-volume purchases like private health plans. Formularies reflect the price-sensitivity of drug purchasers, so, to implement formularies, Maine would have to create a formulary for each individual purchaser participating in the program.¹⁶³ This would be a daunting task, if not an impossible one. Even if Maine created a formulary for each individual purchaser, an individual purchaser using a formulary cannot move enough market share to negotiate discounts from drug manufacturers.¹⁶⁴

Maine cannot solve the problem by purchasing prescription drugs for its residents, either. Although this would enable Maine to act as a PBM for itself, because it could make large-volume purchases and it

¹⁵⁹ *Id.*

¹⁶⁰ See Jesse C. Vivian, *State Prescription Benefit Programs*, available at http://www.uspharmacist.com/NewLook/DisplayArticle.cfm?item_num=745 (last visited Apr. 10, 2002).

¹⁶¹ *Id.*

¹⁶² See *supra* notes 63-74 and accompanying text.

¹⁶³ See *supra* notes 91-96 and accompanying text.

¹⁶⁴ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 24.

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could even use a formulary, this would make Maine a *monopoly* PBM. A monopoly PBM has little incentive to deliver value for money because its customers cannot take their business to a competitor.¹⁶⁵ In addition, a monopoly PBM prevents the market from segmenting according to price-sensitivity, because consumers cannot select from a number of PBMs and formularies that vary in price-sensitivity.¹⁶⁶ More problematic, a monopoly PBM using a formulary has monopsony power.¹⁶⁷ A monopsonist PBM controls prices because drug manufacturers have no negotiating power.¹⁶⁸

Because Maine cannot negotiate discounts by acting as a PBM for its residents, the Rx Program forces prices down by using the monopsony power of the Medicaid program. The commissioner seeks prices from drug manufacturers equal to or lower than the prices obtained by the Federal Government, which are the FSS prices.¹⁶⁹ Drug manufacturers that do not enter into rebate agreements with the commissioner may have their drugs effectively removed from the list of drugs provided by the Medicaid program to Maine residents.¹⁷⁰ Thus, the Rx Program uses Maine's Medicaid market power to control drug prices for Rx Program enrollees. In fact, the VHCA controls drug prices for the federal government in a similar way.¹⁷¹ The Rx Program will exacerbate the harmful effects of the OBRA and VHCA discussed earlier: namely, discouraging drug manufacturers from offering competitive discounts to private purchasers.¹⁷²

The Rx Program has also created a new concern, different from those created by the OBRA and the VHCA, because the Rx Program controls drug prices for all Maine residents. The OBRA and the VHCA only regulate prices for Medicaid and the federal government; these laws do not regulate prices paid by individuals and health plans in the private sector. Unless the department changes

¹⁶⁵ See Danzon, *supra* note 73, at 24.

¹⁶⁶ *See id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ See ME. REV. STAT. ANN. tit. 22 § 2681 (West 2002).

¹⁷⁰ *Id.*; see also Vivian, *supra* note 160.

¹⁷¹ See *supra* text accompanying notes 139-41.

¹⁷² See *supra* text accompanying notes 124-36, 139-41.

the eligibility requirements of the Rx Program, at least one of three unfortunate scenarios will likely arise.

First, private health plans may find it more economical to reimburse drug purchases made by Rx Program enrollees than to negotiate bulk purchases from drug manufacturers. The Rx Program demands FSS prices, which are the best prices obtained by any private purchaser, so a private health plan cannot possibly negotiate a better price from a drug manufacturer. In addition, Rx Program enrollees are not subject to formularies, unlike the beneficiaries of many health plans that use formularies to negotiate discounts from drug manufacturers. Uninsured and insured residents alike may all enroll in the Rx Program and rely on private purchasers in other states to negotiate best-price discounts. If this occurs, purchasers in other states will have to pay more because drug manufacturers will be less inclined to give competitive discounts when they have to give the same discounts to the entire state of Maine.

Alternatively, private health plans may continue to purchase drugs for their Maine resident beneficiaries, using the Rx Program as a tool to control the prices that they pay to drug manufacturers. Private health plans may wish to continue purchasing drugs for their Maine resident beneficiaries because they may be able to negotiate smaller markups from wholesalers and pharmacies than those obtained by the Rx Program.¹⁷³ However, health plans will not pursue this course unless they obtain discounts from drug manufacturers which, when combined with the discounts from pharmacies and wholesalers, offer a better deal than the Rx Program drug prices. Thus, health plans may use the Rx Program prices as a tool to demand prices from drug manufacturers that are only slightly more than the Rx Program prices. The difference in price would depend on how much of a discount the health plans can get from pharmacies and wholesalers. The practical effect of this scenario would be the same as the first scenario described, though to a slightly lesser extent.

¹⁷³ See CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 12 (discussing how some institutional purchasers still obtain lower prices than Medicaid, because Medicaid allows for a markup by both the wholesaler and pharmacy).

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Finally, drug manufacturers may refuse to give the Rx Program the prices it demands. A drug manufacturer may find it more profitable to forego much of Maine's Medicaid market and charge Maine's residents a price based on free market principles than to comply with the requirements of the Rx Program. This might not completely prevent the manufacturer's drugs from entering Maine's Medicaid market. The State Medicaid administrator may give prior-authorization for a drug produced by a nonparticipating drug manufacturer. However, this would make some drugs more difficult for Maine's Medicaid recipients to obtain, which may harm their health and would have a negative impact on investment in pharmaceutical R&D by decreasing returns for drug developers.

This final scenario may occur even if the department reduces the number of Maine residents that are eligible for the Rx Program. But the likelihood of it occurring decreases as the size of the eligible market decreases, and, conversely, the likelihood of it occurring increases as the size of the eligible market increases. The General Accounting Office addressed this issue in a study of the possible effects of increasing the size of the market eligible for FSS drug prices:

The size of the market eligible to buy drugs at FSS prices if the schedule is opened to state and local governments would be a key factor in determining what would happen to drug prices. The size of the market involved would affect both VA's ability to negotiate and manufacturers' pricing strategies. The larger the market, the greater the incentive would be for manufacturers to raise FSS prices to limit the impact on their business of giving low prices to more purchasers.¹⁷⁴

The same is true for the size of the market eligible for the Rx Program, since the Rx Program essentially increases the size of the market eligible for FSS drug prices.

¹⁷⁴ GENERAL ACCOUNTING OFFICE, *supra* note 63, at 9.

IV. CONCLUSION: AN ALTERNATIVE WAY TO MAKE PRESCRIPTION DRUGS MORE AFFORDABLE

As an alternative to using price controls, states should make prescription drugs more affordable by encouraging the use private health plans that use PBMs. If states do not look to this alternative, prescription drug purchasers may suffer tremendously.

A. States Should Encourage the Use of Private Health Plans that Use PBMs

States that provide their residents with prescription drug benefits should require the beneficiaries to choose from competing private health plans. Government programs such as Medicaid, that pay for prescription drugs directly, have problems. On the one hand, government health providers, like all health providers, must use formularies to manage their spending on prescription drugs. On the other hand, government health providers that use formularies have monopsony power and control drug prices. The result is the OBRA, a price control that harms consumers of prescription drugs.

Instead, government programs that provide drug benefits should require the beneficiaries to choose from competing private-sector health providers. These health providers provide their patients with the best possible drug coverage for the money. They manage their drug spending by using PBMs that create formularies, and they do not have monopsony power to control prices like the OBRA. The Federal Employee Health Benefits Program has already adopted this approach, allowing its enrollees to choose among competing plans.¹⁷⁵ In addition, the federal government is considering this approach for a Medicare prescription drug benefit.¹⁷⁶ Fiona M. Scott Morton, an economist at Yale University, explains:

The overwhelming evidence against price controls naturally leads to consideration of other methods of

¹⁷⁵ See GENERAL ACCOUNTING OFFICE, *supra* note 19, at 1.

¹⁷⁶ See Pear, *supra* note 4.

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lowering purchasing costs. The private sector uses a number of methods that are both effective and consonant with a market economy. Such approaches, when used by the private market, are much less damaging to economic welfare than a government price control.¹⁷⁷

States should also encourage their uninsured residents to enroll in private health plans that provide prescription drug coverage. Uninsured purchasers in the U.S. pay higher prescription drug prices than any other purchasers in the U.S.¹⁷⁸ Uninsured purchasers appear most price-insensitive to drug manufacturers because their demand is not channeled through a price-sensitive PBM that created a formulary.¹⁷⁹ Rather, their demand is based solely on doctors who many be uninformed or unconcerned about price.¹⁸⁰ These purchasers cannot benefit from PBM formularies without enrolling in a health plan, because individual purchasers and even retail pharmacies cannot move enough market share to negotiate discounts from drug manufacturers.¹⁸¹ For this reason alone, no one should be without prescription drug coverage.¹⁸²

B. What If States Do Not Encourage the Use of Private Health Plans?

If states do not encourage the use of private health plans, prescription drug purchasers will suffer. Private health plans using PBMs make prescription drugs more affordable and promote differential pricing by drug manufacturers, which increases return

¹⁷⁷ See Morton, *supra* note 15, at 54.

¹⁷⁸ CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 24.

¹⁷⁹ *Id.*; see also Danzon, *supra* note 15, at 60.

¹⁸⁰ See Danzon, *supra* note 15, at 58; see also Richard, *supra* note 71, at 2800-01.

¹⁸¹ See CONGRESSIONAL BUDGET OFFICE, *supra* note 17, at 24.

¹⁸² Without enrolling in a health plan, these purchasers can still save significantly from pharmacy discounts by enrolling in a pharmacy discount program, which may be run by a PBM, or by purchasing drugs from a discount pharmacy. However, to obtain competitive discounts from drug manufacturers, uninsured patients must enroll in a health plan.

from and investment in pharmaceutical R&D. Prescription drug purchasers should have these benefits.

States that do not encourage private health plans will probably continue to implement price controls to make prescription drugs more affordable for their residents. If every state in the U.S. were to adopt prescription drug price controls, serious problems could arise. Nationwide price controls in the U.S. could greatly stifle pharmaceutical innovation, because the U.S. market is critical for funding pharmaceutical R&D.¹⁸³ In addition, the U.S. pressures other countries not to use pharmaceutical price controls, because price controls allow them to free-ride on the U.S.¹⁸⁴ Nationwide price controls in the U.S. could give cause to many of these countries to force their drug prices even lower.

Finally, if every state adopts legislation like the Rx Program and allows all their residents to participate, two problems may occur. First, drug manufacturers may stop giving competitive discounts and health providers may stop seeking them. This would cause every private purchaser in the U.S. to pay roughly the same prices. These prices would not reflect demand that is channeled through competing price-sensitive PBMs, because health providers would no longer rely on PBMs to reduce prices. Alternatively, Medicaid's monopsony power might not be strong enough to control prices for such a large market. Drug manufacturers could decide not to comply with the price controls, in which case their drugs would be subject to prior-authorization by state Medicaid administrators. Either scenario would harm purchasers of prescription drugs.

¹⁸³ The U.S. alone comprises one-third of the global pharmaceutical market. DANZON, *supra* note 13, at 57.

¹⁸⁴ *See, e.g.*, Harrison, *supra* note 103, at 457-62 (discussing how the U.S. pressured Canada to abandon its compulsory licensing law for patented pharmaceuticals).