

# INTERNATIONAL PRESCRIPTION DRUG COST CONTAINMENT STRATEGIES AND SUGGESTIONS FOR REFORM IN THE UNITED STATES

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**Abstract:** Rising prescription drug prices have been a point of contention in the United States for decades. Questions such as who should shoulder the cost and what role the government should play in setting drug prices are central to the debate. Other nations face similar concerns and have developed prescription drug plans that incorporate various cost containment strategies. An analysis of prescription drug coverage in other nations may help educate domestic lawmakers on the complexities of these cost containment strategies. The United States could benefit from the lessons learned abroad.

## INTRODUCTION

The pharmaceutical trade is a profitable industry.<sup>1</sup> Over the last three decades, pharmaceutical companies in the United States experienced a return on equity more than 7% higher than that of all other industries.<sup>2</sup> With the United States experiencing a 16–20% increase in drug spending per year, the success of pharmaceutical companies may be expected to continue.<sup>3</sup> Many Americans, however, turn a critical eye to pharmaceutical companies, perceiving that pharmaceutical companies have been “price-gouging and profiteering from the American public for years.”<sup>4</sup> It is not uncommon for Americans to pay over twice as much as their European counterparts for the same drug

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<sup>1</sup> See Robert H. Ballance, *Market and Industrial Structure*, in *CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS* 95, 103–04 (Peter Davis ed., 1996).

<sup>2</sup> *Id.*

<sup>3</sup> See Scott Hensley & Joni James, *How Pfizer Gained an Edge in Battle over Drug Prices*, WALL ST. J. EUR, July 9, 2001, at A1, available at 2001 WL-WSJE 21832589.

<sup>4</sup> Christiane Sauter, *Drug Companies Out for Themselves*, THE POST-STANDARD (London), Jan. 18, 2002, at A11, available at 2002 WL 5979242 (letter to the editor).

and dosage.<sup>5</sup> This fact has led many to complain that the United States is in fact subsidizing European health care.<sup>6</sup>

One proposed solution to the apparent unfair allocation of drug development costs is for the United States to impose its own drug cost regulations.<sup>7</sup> Pharmaceutical companies and other skeptics, however, argue that increased price controls and other governmental regulations affecting the sale of prescription drugs will lead to decreased innovation with regard to new prescription drugs.<sup>8</sup> Congress finds itself in the middle of the debate. It must balance the demands of a public that expects constant advances in medical technology against the financial needs of the pharmaceutical companies that conduct the research and produce the life-saving drugs.<sup>9</sup>

Part I of this note exposes the dilemma of price controls, as well as the economics of research and development (R&D) and cost recouping by pharmaceutical companies. Part II reviews the different options available to Congress for a U.S. prescription drug plan by surveying the different types of regulations employed by other governments. Part III explores some of the alternative solutions to government price controls, including the programs several U.S. states are in the process of implementing. Part IV discusses the strengths and weaknesses of the various prescription drug plans discussed in Parts I through III. Finally, Part V of this note argues for Congressional adoption of a Medicare prescription drug coverage plan and describes the characteristics of such a plan.

## I. BACKGROUND: THE ECONOMICS OF PRESCRIPTION DRUG PRICING

### A. *Overview of the Principles Behind Prescription Drug Differentials and Governmental Regulations*

Government regulation of prescription drugs entails, among other things, price regulations and patent protection.<sup>10</sup> Government

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<sup>5</sup> See David J. Gross, et al., *Prices for Prescription Drugs: The Roles of Market Forces and Government Regulation*, in *CONTESTED GROUND*, *supra* note 1, at 124, 134.

<sup>6</sup> Tom Buerkle, *EU Weighs Lifting of Price Controls—Bid to End Market Distortions*, INT'L HERALD TRIB., Nov. 18, 1998, at A20, available at 1998 WL 4795412.

<sup>7</sup> See *Review & Outlook: Europe's Addiction*, WALL ST. J., Jan. 2, 2002, at A18, available at 2002 WL-WSJ 3381809 [hereinafter *Europe's Addiction*].

<sup>8</sup> See PATRICIA M. DANZON, *PHARMACEUTICAL PRICE REGULATION: NATIONAL POLICIES VERSUS GLOBAL INTERESTS* 3-4 (1997).

<sup>9</sup> See Ballance, *supra* note 1, at 95.

<sup>10</sup> Gross, *supra* note 5, at 124.

regulation is one of the two most influential factors affecting prescription drug price differentials between countries.<sup>11</sup> The second determinant is market forces.<sup>12</sup> The primary market force behind the recouping of R&D of prescription drugs is the elasticity of the consumer demand for the drugs.<sup>13</sup>

Elasticity of demand reflects the consumer price responsiveness.<sup>14</sup> Economist Frank Ramsey argues that the most efficient way for a company to recoup costs does not entail charging all consumers the same price.<sup>15</sup> Instead, the company should charge those consumers whose valuation of the product is high a larger fee than those consumers whose valuation is low.<sup>16</sup> The logic behind this pricing scheme is that a consumer who values a product highly will pay more for that product than the consumer who remains indifferent to the product.<sup>17</sup> By charging the high-valuing consumer more for the service, the company can then charge the low valuing consumer less, thereby retaining the patronage of the latter.<sup>18</sup> The high-valuation consumer's demand is inelastic in relation to the price of the product.<sup>19</sup> Where consumer demand is relatively inelastic to price, pharmaceutical companies can charge more for a product than they could in a market where consumer demand is elastic, or fluctuating in response to drug price.<sup>20</sup>

An example of the impact of elastic consumer demand on the price of prescription drugs is the practice of pharmaceutical company discounts offered to hospitals.<sup>21</sup> Most hospitals operate their own in-house pharmacies.<sup>22</sup> As a result, a hospital can decide which drugs its physicians prescribe—limiting prescriptions to those drugs that the hospital pharmacy chooses to stock.<sup>23</sup> Hospitals thus have significant bargaining power in transactions with pharmaceutical companies.<sup>24</sup> In order to assure that the hospital will buy and use its drug, a pharma-

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 124–25.

<sup>13</sup> *Id.*; DANZON, *supra* note 8, at 11.

<sup>14</sup> *See* Gross, *supra* note 5, at 126.

<sup>15</sup> DANZON, *supra* note 8, at 11–12.

<sup>16</sup> *Id.* at 12.

<sup>17</sup> *See id.*

<sup>18</sup> *Id.*

<sup>19</sup> *See id.* at 11.

<sup>20</sup> *See* DANZON, *supra* note 8, at 11.

<sup>21</sup> STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 104 (1997).

<sup>22</sup> *See id.*

<sup>23</sup> *See id.*

<sup>24</sup> *See id.*

ceutical company will regularly offer a substantial discount on bulk purchases of its product.<sup>25</sup>

Individual commercial pharmacies service a broad range of private customer needs.<sup>26</sup> As a result, such pharmacies must stock a diverse and large quantity of pharmaceutical drugs.<sup>27</sup> A private pharmacy's selection of drugs is more passive than that of a hospital pharmacy.<sup>28</sup> A private pharmacy's demands for drugs are thus relatively price inelastic, since its goal is to maintain a stock of all major drugs on the market in order to meet the demands of its customers.<sup>29</sup>

Drug prices also reflect various government regulations of prescription drugs, some of which are discussed *infra*.<sup>30</sup> Governments primarily implement drug price regulations to help control, and reduce, public spending on prescription drugs.<sup>31</sup> While government regulation certainly can be an effective means to reduce the individual cost of drug therapy, it may not be the most efficient.<sup>32</sup> No existing governmental regulation has succeeded in curbing the steady increase in overall drug spending.<sup>33</sup> For example, in France, price control regulation allows for some of the lowest prescription drug prices in Europe.<sup>34</sup> Overall, drug spending in France is still 16% of total health care costs—about double its counterpart proportion in the United States.<sup>35</sup>

At the core of the drug price controversy remains the fact that pharmaceutical companies ultimately set the price of prescription drugs in the United States.<sup>36</sup> Pharmaceutical companies fix drug prices based almost exclusively on their R&D costs and profit goals.<sup>37</sup>

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<sup>25</sup> *See id.*

<sup>26</sup> *See* SCHWEITZER, *supra* note 21, at 104.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *See id.*

<sup>30</sup> Gross, *supra* note 5, at 124.

<sup>31</sup> DANZON, *supra* note 8, at 15–16. A secondary goal of price regulation is to promote the domestic development and production of drugs. *Id.*

<sup>32</sup> *See id.* at 30.

<sup>33</sup> *See id.* at 15, 30.

<sup>34</sup> SCHWEITZER, *supra* note 21, at 149.

<sup>35</sup> *Id.*

<sup>36</sup> *See* Trudy Lieberman, *Health Matters: Why Health Costs Sting Again*, L.A. TIMES, Jan. 21, 2002, at S1, available at 2002 WL 2447989. At least one state is pursuing criminal charges against major pharmaceutical companies, alleging that the companies used bogus pricing schemes to defraud both the state and consumers of tens of millions of dollars. Brendan Riley, *Nevada Sues Major Drug Firms*, AP ONLINE, Jan. 18, 2002, available at 2002 WL 10032815.

<sup>37</sup> Lieberman, *supra* note 36.

Compounding this element is the fact that some consumers regularly pay for prescription drugs out-of-pocket, as opposed to receiving third-party coverage.<sup>38</sup>

### B. *Impact of Price Regulations on the Innovation of Drugs*

Critics of government regulation of drug prices argue that government-regulated limitations on a pharmaceutical company's ability to turn a profit will remove the company's incentive to invest in R&D.<sup>39</sup> This concern is not unfounded.<sup>40</sup> Canada experienced a drop of more than 50% in domestic drug research after it implemented price controls in the 1960s.<sup>41</sup> A similar trend occurred in other countries following their introduction of price controls.<sup>42</sup> In fact, in recent years, many companies have moved their R&D dollars to the United States—a forum unbridled by price controls.<sup>43</sup>

## II. GOVERNMENTAL REGULATION SCHEMES AIMED AT REDUCING THE COST OF PRESCRIPTION DRUGS TO THE CONSUMER

Foreign price regulations have a “spill-over effect” on the American drug market.<sup>44</sup> Price regulations abroad have a vast impact on the way pharmaceutical companies operate in the United States.<sup>45</sup> Conversely, any attempts by the United States to regulate the pharmaceutical industry will impact the pharmaceutical market of other countries.<sup>46</sup> As such, politicians must evaluate all of the alternatives with an eye toward the long- and short-term benefits that such a regulatory scheme might have for consumers, against the long-term effect on society.<sup>47</sup>

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<sup>38</sup> SCHWEITZER, *supra* note 21, at 97.

<sup>39</sup> See generally DANZON, *supra* note 8.

<sup>40</sup> See John Stossel, *The Price of Medicine: Quit Blaming the Drug Companies*, ACNEWS.COM, Jan. 18, 2002, available at [http://abcnews.go.com/sections/2020/daily-news/gmab\\_drugco\\_020118.html](http://abcnews.go.com/sections/2020/daily-news/gmab_drugco_020118.html) [hereinafter *Price of Medicine*].

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> See *Europe's Addiction*, *supra* note 7.

<sup>44</sup> See DANZON, *supra* note 8, at 2.

<sup>45</sup> See *id.*

<sup>46</sup> See *id.*

<sup>47</sup> Ballance, *supra* note 1, at 95.

### A. United States' Health Care System

The United States is one of a few nations whose health care system does not fit one of the common national health care formats.<sup>48</sup> The United States has no cohesive health care system, but rather a mix of private and public health care plans.<sup>49</sup>

#### 1. Private Health Care Systems and Cost Containment Strategies for Prescription Drugs Currently Employed

The private health care industry is a conglomerate of indemnity programs, through which an insurance company reimburses the client for medical care rendered, and managed care programs, whereby the insurance company closely manages the administration by providers of medical care to patients.<sup>50</sup> Prescription drug coverage varies from program to program.<sup>51</sup> Recently, the United States has experienced a shift towards greater use of managed care.<sup>52</sup>

Almost every prescription coverage plan in the United States employs similar cost containment strategies.<sup>53</sup> The most significant of these include manufacturer discounts, drug formularies, and forced generic substitution.<sup>54</sup> As discussed *supra*, major purchasers, such as hospitals and health plans, can negotiate with pharmaceutical companies for lower drug prices.<sup>55</sup> Major purchasers may choose to purchase the lowest priced drug in a drug class.<sup>56</sup> This is particularly true where there is little difference between the different drugs in a specific drug class.<sup>57</sup> Where prescription drug comparisons are not available, major purchasing groups may utilize cost-effectiveness strategies, such as choosing to buy a more costly drug that tends to keep patients out of the hospital longer than do cheaper drugs.<sup>58</sup> Major purchasers may also receive cost savings by dealing with drug

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<sup>48</sup> Albert Wertheimer, et al., *Pharmacy in the Western World Health Care Systems*, in CONTESTED GROUND, *supra* note 1, at 159, 169.

<sup>49</sup> See *id.* at 169–70.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 170.

<sup>52</sup> SCHWEITZER, *supra* note 21, at 171.

<sup>53</sup> *Id.* at 174.

<sup>54</sup> *Id.* at 174–77.

<sup>55</sup> *Id.* at 175.

<sup>56</sup> *Id.*

<sup>57</sup> SCHWEITZER, *supra* note 21, at 175.

<sup>58</sup> *Id.*

wholesalers, who in turn negotiate drug discounts with drug manufacturers.<sup>59</sup>

Many health care plans attempt to reduce the cost of prescription drugs through the use of formularies.<sup>60</sup> A formulary is a means by which the plan lists drugs by their efficiency and cost.<sup>61</sup> Plans typically create a committee made up of physicians and pharmacists to evaluate the dose requirements, side effects, and efficiency of a drug, as well as its cost.<sup>62</sup> The committee then ranks the drugs accordingly.<sup>63</sup> Doctors are limited to prescribing only those drugs listed on the formulary.<sup>64</sup>

Health care plans face efficiency problems when implementing drug formularies.<sup>65</sup> Because drugs affect patients in different ways, formularies must include mechanisms to take special situations into account.<sup>66</sup> With too much flexibility, the formulary cannot effectively contain costs, since the point of a formulary is to restrict the type of drug a physician can prescribe.<sup>67</sup> However, if the formulary is too strict, the patient faces the possibility of taking a drug that is not well suited for her.<sup>68</sup> Health care plans must take both costs into consideration when creating their formularies.<sup>69</sup>

Many managed care systems require their patients to consume generic versions of drugs when available.<sup>70</sup> Generic drugs cost less than their brand-name counterparts, and are a useful substitute for therapeutically similar prescription drugs.<sup>71</sup> Likewise, such plans sometimes encourage the use of over-the-counter medicines that also tend to be less expensive and that do not need physician-directed prescription refills.<sup>72</sup>

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<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> SCHWEITZER, *supra* note 21, at 175.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 176.

<sup>66</sup> *Id.*

<sup>67</sup> SCHWEITZER, *supra* note 21, at 176.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 177.

<sup>71</sup> *See id.*

<sup>72</sup> SCHWEITZER, *supra* note 21, at 177.

## 2. Public Health Care Systems and Cost Containment Strategies for Prescription Drugs Currently Employed in the United States

The public health care system in the United States includes Medicare and Medicaid programs.<sup>73</sup> Medicare provides health care to elderly or disabled persons.<sup>74</sup> Employers and employees provide funding for Medicare via contributions made throughout the individual's career, augmented by small premiums during the period that the individual receives coverage.<sup>75</sup> Medicare does not yet provide coverage for outpatient prescription drug costs, although Congress is currently debating the possibility of introducing Medicare prescription drug coverage.<sup>76</sup> Medicaid is a state and federally funded program that covers the poor and unemployed.<sup>77</sup> Medicaid offers prescription drug coverage, which includes guidelines that set the amount of reimbursement to the pharmacies and manufacturers.<sup>78</sup>

Since Medicaid prescription drug coverage is state run, drug plans differ from state to state.<sup>79</sup> Patients covered by Medicaid generally receive their medications from private independent pharmacies.<sup>80</sup> Medicaid covered consumers may be required to make a nominal co-payment at the time of purchase.<sup>81</sup> The Medicaid program then reimburses the pharmacy a set amount for the prescription drug.<sup>82</sup> This amount is usually a fixed percentage less than the estimated acquisition cost.<sup>83</sup> In this manner, the state pays the actual acquisition cost, plus a slight retail mark-up.<sup>84</sup> Medicaid programs also employ formularies, restricting the drugs for which they will reimburse.<sup>85</sup>

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<sup>73</sup> Wertheimer, *supra* note 48, at 170.

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*; see generally *Laying the Groundwork for a Medicare Prescription Drug Benefit*, Before the House Comm. on Ways and Means, 107th Cong. (2001) (statement of Dan L. Crippen, Director, Cong. Budget Office), available at <http://www.cbo.gov/testimony.cfm> [hereinafter CBO Medicare Testimony].

<sup>77</sup> Wertheimer, *supra* note 48, at 170.

<sup>78</sup> *Id.* at 171.

<sup>79</sup> SCHWEITZER, *supra* note 21, at 183.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> SCHWEITZER, *supra* note 21, at 183–84.

<sup>85</sup> *Id.* at 184.



### B. National Health Insurance System

France and Germany both operate a form of a National Health Insurance (NHI) system.<sup>86</sup> The governments raise funds used to pay for health care provided by the private doctors, government-run clinics, community hospitals, and the like.<sup>87</sup> The governments thus become *monopsonists*—the opposite of monopolists—thereby becoming lone buyers instead of single suppliers.<sup>88</sup> The governments use the power afforded them as the single prescription drug buyers to implement their own agendas and policy initiatives, including the imposition of price controls for prescription drugs.<sup>89</sup> The French and German National Health Insurance Systems regulate drug prices in different ways.<sup>90</sup>

#### 1. Prescription Drug Coverage in France

France maintains a list of products approved for reimbursement.<sup>91</sup> Almost all prescription drugs make it to the reimbursement list; however, there are different lists for outpatient and hospital use.<sup>92</sup> France established a transparency commission to both regulate the price of prescription drugs and determine the amount the government shall reimburse patients.<sup>93</sup> Because of strict guidelines regarding the commission's pricing of prescription drugs, pharmaceutical prices in France are among the lowest in the world.<sup>94</sup> Consumers in France first pay for drugs themselves at the point of purchase, and then apply for a reimbursement from the social security agency.<sup>95</sup> After reimbursement, the patient generally pays very little out of pocket for the drug.<sup>96</sup>

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<sup>86</sup> Wertheimer, *supra* note 48, at 162.

<sup>87</sup> *Id.* at 161.

<sup>88</sup> *Id.*; *Europe's Addiction*, *supra* note 7, at A18.

<sup>89</sup> *See id.*

<sup>90</sup> *Id.* at 162.

<sup>91</sup> Wertheimer, *supra* note 48, at 162.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 162–63.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 163.

<sup>96</sup> Wertheimer, *supra* note 48, at 163.

## 2. Prescription Drug Coverage in Germany

Germany enjoys a health care system that covers 100% of its population.<sup>97</sup> This is achieved through a combination of regional health insurance agencies known as "sickness funds," government employee health care coverage, and private health care plans.<sup>98</sup> Ninety-two percent of Germans are covered under the sickness funds, which receive financing via public payroll taxation.<sup>99</sup> These sickness funds use a negative prescription drug list that lists drugs for which the government will not reimburse.<sup>100</sup> Most of the drugs listed on the negative drug registry treat minor ailments, such as colds, or life style drugs, including oral contraceptives.<sup>101</sup> A national association that represents doctors and the sickness funds determines the negative list.<sup>102</sup>

Germany does not set the price of prescription drugs.<sup>103</sup> However, it does establish a reference price for prescription drugs, thereby setting the maximum amount the sickness fund will pay for a selected group of drugs.<sup>104</sup> Reference prices are set for certain generic categories, products that are pharmacologically similar—but not generically equivalent—and products that have a similar therapeutic action.<sup>105</sup> The reference price is set slightly higher than the lowest priced drug in the group so as to insure innovation, to insure sufficient supply of drugs, and to induce effective price competition.<sup>106</sup>

The reference price for a product may be divided into subgroups to reflect different dosages of a product as well as a diverse means of delivering the product (e.g., by way of a topical patch as opposed to sublingual).<sup>107</sup> German patients are required to pay a certain amount for each subgroup, and must pay the difference if their prescribed drug is more expensive than the reference price.<sup>108</sup> The government regularly audits a prescriber's performance to evaluate his or her

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<sup>97</sup> *Id.* at 164–65.

<sup>98</sup> *Id.* at 164.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 165.

<sup>101</sup> Wertheimer, *supra* note 48, at 165.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> Wertheimer, *supra* note 48, at 165.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 166.

efficiency.<sup>109</sup> Also, if a doctor is found to have exceeded his or her fixed pharmaceutical budget by 15%, he or she must provide an explanation.<sup>110</sup> If the budget is 25% more than her fixed amount, the doctor may face repayment.<sup>111</sup>

### C. National Health Service System

In a National Health Service (NHS) system, the government owns the health care facilities and employs the health care workers.<sup>112</sup> Since the government administers the whole of the health care industry, it can directly regulate drug prices.<sup>113</sup> Britain operates a NHS that is funded largely by an income tax payable to a national insurance fund and augmented by a co-payment by the patient for some services.<sup>114</sup>

Britain influences prescription drug prices by implementing three policy tools: (a) the Prescription Price Regulation Scheme (PPRS), (b) the drug list, and (c) the drug tariff.<sup>115</sup> The PPRS is based on a voluntary collective agreement between the British government's Department of Health and Social Security (DHSS) and the Association of the British Pharmaceutical Industry (ABPI), which represents large pharmaceutical companies operating in Britain.<sup>116</sup> Under the PPRS, the DHSS negotiates with individual pharmaceutical corporations in order to set maximum profit margin percentages, advertising cost limitations, and R&D budgets.<sup>117</sup> Under the PPRS, pharmaceutical firms are free to set their own prices for the first five years a drug is on the market, subject only to the profit margin limitation.<sup>118</sup> After the five-year period, any price increases must be approved by the

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<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> Wertheimer, *supra* note 48, at 166.

<sup>112</sup> *Id.* at 166–67.

<sup>113</sup> *Id.* at 167.

<sup>114</sup> *Id.*

<sup>115</sup> See *id.*; Christine Huttin, *Price Control Policies in the Pharmaceutical Industry: A Selection of Case Studies*, in *STUDIES IN PHARMACEUTICAL ECONOMICS* 275, 276 (Mickey C. Smith, ed., 1996).

<sup>116</sup> Huttin, *supra* note 115, at 276. Britain's National Health Service only monitors pharmaceutical firms that have over \$500,000 in sales a year. Wertheimer, *supra* note 48, at 167.

<sup>117</sup> Huttin, *supra* note 115, at 276.

<sup>118</sup> Wertheimer, *supra* note 48, at 167–68.

DHSS.<sup>119</sup> Note that Britain does not directly regulate the prescription drug prices.<sup>120</sup>

In addition to the PPRS, Britain maintains a Selected List—a register of drugs for which the NHS will not reimburse.<sup>121</sup> The list contains 16 categories of drugs that include analgesics, cold medicines, and vitamins that are typically used to treat minor conditions, and most of which are available over-the-counter.<sup>122</sup>

Lastly, the NHS encourages the use of generic drugs by implementation of a drug tariff.<sup>123</sup> Drug tariff prices are determined by major generic drug manufacturers and published and distributed to physicians on a monthly basis.<sup>124</sup> Since most generic drug manufacturers are too small to be covered under the PPRS, the drug tariff establishes the reimbursement amount for generic drugs.<sup>125</sup> Britain also encourages the use of generic drugs via a budget mechanism.<sup>126</sup> The NHS proscribes a budget for services each group of physicians provides per capita—per patient enrolled with the physician's group.<sup>127</sup> The NHS also allows for reallocation of prescription funds when the physician saves money by prescribing generic drugs.<sup>128</sup> Because of the NHS treatment of generic drugs, 43% of all prescriptions filled in Britain are for generic drugs.<sup>129</sup>

### III. ALTERNATIVES TO GOVERNMENT REGULATION OF PRESCRIPTION DRUG COST

Currently, there are numerous prescription drug plans that are offered by entities other than the federal government.<sup>130</sup> Recognizing the increased attention being given to the rising costs of prescription drugs, several private industries have created industry-friendly pro-

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<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 167.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> Wertheimer, *supra* note 48, at 168; Huttin, *supra* note 115, at 277.

<sup>124</sup> Wertheimer, *supra* note 48, at 168; Huttin, *supra* note 115, at 277.

<sup>125</sup> See Wertheimer, *supra* note 48, at 168; Huttin, *supra* note 115, at 277.

<sup>126</sup> See Wertheimer, *supra* note 48, at 168.

<sup>127</sup> *Id.* at 168–69.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 168.

<sup>130</sup> See e.g., PhRMA, *Pharmaceutical Company Patient Assistance Programs*, at <http://www.phrma.org/pap/more.cfm> (last visited Jan. 1, 2003) [hereinafter *PhRMA Assistance Programs*]; RxHope.com, *About RxHope.com*, at <http://www.rxhope.com/about/main.asp> (last visited Jan. 1, 2003) [hereinafter *RxHope*]; RxAssist, *Accessing Pharmaceutical Patient Assistance Programs*, at <http://www.rxassist.org/default.cfm> (last visited Jan. 1, 2003).

grams that attempt to reduce the strain of prescription drug costs on certain classes of consumers.<sup>131</sup> In addition to private programs, a handful of states have recently enacted programs aimed at reducing state spending on prescription drugs covered under the state Medicaid plan.<sup>132</sup>

In fact, the federal government recently elicited cooperation from private discount card companies to create a Medicare-endorsed prescription drug discount card.<sup>133</sup> This card is meant to provide immediate, albeit limited, relief to Medicare recipients who do not have prescription drug coverage.<sup>134</sup> The federal government has also discussed adopting a Medicare prescription drug plan.<sup>135</sup>

### A. Pharmaceutical Industry Created Agreements

The Pharmaceutical Research and Manufacturers of America (PhRMA) is the lobbying front of drug manufacturers in the United States.<sup>136</sup> It stresses that drug manufacturers are committed to providing programs that enable receipt of prescription drugs by patients who might not otherwise be able to afford them.<sup>137</sup> Most manufacturers offer some sort of program that provides free medicine to the most needy patients.<sup>138</sup> Other manufacturers set a flat fee for their drugs when sold to eligible seniors.<sup>139</sup> Each program provides some

<sup>131</sup> See PhRMA Assistance Programs, *supra* note 130; RxHope, *supra* note 130.

<sup>132</sup> See, e.g., Act to Establish Fairer Pricing for Prescription Drugs, ME. REV. STAT. ANN. tit. 22, § 2681 (2002) [hereinafter Maine Bill]; Pharm. Researcher & Mfrs. of Am. v. Dep't of Cmty. Health, 2002 WL 31810210 (describing the Michigan supplemental and basic rebate programs for prescription drugs) [hereinafter Michigan Program]; S.R. 55 (Wis. 2001), H.R. 144 (Wis. 2001) [hereinafter Proposed Wisconsin Bill].

<sup>133</sup> See, e.g., Medicare Program: Medicare-Endorsed Prescription Drug Card Assistance Initiative, 42 C.F.R. § 403 (US Dep't of Health and Human Svcs., proposed Nov. 5, 2002), available at [http://www.nacds.org/user-assets/PDF\\_files/feb02\\_pdc\\_initiative.pdf](http://www.nacds.org/user-assets/PDF_files/feb02_pdc_initiative.pdf) [hereinafter *HHS Medicare Initiative*].

<sup>134</sup> *Id.*

<sup>135</sup> See generally, CBO Medicare Testimony, *supra* note 76; see also Medicare Reform: Providing Prescription Drug Coverage for Seniors, *Before the House Comm. on Energy and Commerce*, 107th Cong. (2001) (statement of Dan L. Crippen, Director, Cong. Budget Office), available at <http://www.cbo.gov/testimony.cfm>.

<sup>136</sup> See PhRMA Assistance Programs, *supra* note 130.

<sup>137</sup> *Id.*

<sup>138</sup> PhRMA, *Directory of Prescription Drug Patient Assistance Programs*, at <http://www.phrma.org> (last visited Jan. 1, 2003) [hereinafter *PhRMA Directory*].

<sup>139</sup> Press Release, Pfizer, Pfizer to Provide Health Benefits, Including \$15 Flat Fee for Pfizer Prescriptions, to Low-Income Seniors Across America (Jan. 15, 2002), at [http://www.pfizer.com/are/news\\_releases/mn\\_2002\\_0115.html](http://www.pfizer.com/are/news_releases/mn_2002_0115.html) [hereinafter *Pfizer Press Release*].

relief to low-income patients struggling to pay prescription drug bills.<sup>140</sup>

## 1. Prescription Drug Assistance Programs

PhRMA compiles a directory of company programs that supply drugs to doctors whose patients cannot afford them.<sup>141</sup> PhRMA describes the directory as a continuation of the pharmaceutical industry's tradition of providing prescription drugs to physicians at no cost so that their disadvantaged patients can obtain the drugs they need.<sup>142</sup> A physician must first look up the prescription drug that they wish to dispense to their needy patients, and then determine if the patient meets the requirements set forth by the manufacturer of the drug.<sup>143</sup> For example, a doctor seeking to obtain any Abbott Laboratories drug products free-of-charge must request an application on behalf of the patient, fill it out, and wait for a response from the drug manufacturer.<sup>144</sup> The physician becomes a go-between for the patient and pharmaceutical company since the manufacturer will only ship its drugs to the doctor's office.<sup>145</sup>

## 2. RxHope.com

RxHope.com is a privately held company that provides an internet-based patient assistance and sampling web portal in the pharmaceutical industry.<sup>146</sup> RxHope.com essentially provides doctors access to information regarding the drug assistance programs described above.<sup>147</sup> It offers an *Assistance Finder* that matches patient needs to available state, federal and private assistance programs.<sup>148</sup> The website also provides web-based requisition forms, which the doctor can access and complete on his or her private computer.<sup>149</sup> RxHope.com adds to the PhRMA directory service by including state and federal programs in its database of patient drug assistance programs, offering

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<sup>140</sup> See *id.*

<sup>141</sup> *PhRMA Directory*, *supra* note 138, at 1.

<sup>142</sup> *Id.*

<sup>143</sup> See *id.*

<sup>144</sup> See *id.*

<sup>145</sup> See *id.*

<sup>146</sup> RxHope, *supra* note 130.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

an *Assistance Finder* search application, and web-enabling the requisition process.<sup>150</sup>

### 3. Pfizer for Living

Pfizer is a leading American-based pharmaceutical company.<sup>151</sup> It began its assistance program for low-income Americans in 1982, but recently extended its services directed at Medicare-enrolled patients.<sup>152</sup> Pfizer created its *Share Card* that charges a flat \$15 fee for each thirty-day Pfizer prescription.<sup>153</sup> To be eligible to enroll in the card program, a patient must be sixty-five years of age or older, or otherwise a Medicare enrollee, receive an annual income of less than \$18,000 separate, or \$24,000 filed jointly, and have no other prescription drug coverage.<sup>154</sup> Pfizer anticipates that the card will be accepted by most pharmacies across the United States.<sup>155</sup> In addition, Pfizer plans to operate a help-line with live operators to provide information to seniors regarding the *Share Card* program as well as other programs, both state and federal, for which the patient may be eligible.<sup>156</sup>

### 4. PharmacyCareOneCard

The National Association of Chain Drug Stores (NACDS) is currently developing the PharmacyCareOneCard program.<sup>157</sup> The card will be made available to low-income seniors, who would then present it to participating community pharmacies to receive the multiple benefit programs offered by individual pharmaceutical companies.<sup>158</sup> The manufacturers are free to determine the extent of their participation in the discount card program.<sup>159</sup> NACDS anticipates that the pooling of low-income seniors in a single benefit card will result in

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<sup>150</sup> See *id.*

<sup>151</sup> See JAMES TAGGART, *THE WORLD PHARMACEUTICAL INDUSTRY* 35 (1993).

<sup>152</sup> *Pfizer Press Release*, *supra* note 139.

<sup>153</sup> *Id.*; Pfizer, *Share Card Questions and Answers*, at <http://www.pfizerforliving.com/sharecard/nucardqa.jhtml?cardImageOver=5> (last visited Jan. 1, 2003) [hereinafter *Share Card Fact Sheet*].

<sup>154</sup> *Share Card Fact Sheet*, *supra* note 153.

<sup>155</sup> *Id.*

<sup>156</sup> *Pfizer Press Release*, *supra* note 139.

<sup>157</sup> NACDS, *News Releases: Pharmacy Care Alliance Stacks Multiple Drug Savings Into One Senior Benefit* (Mar. 11, 2002), at <http://www.nacds.org/wmspage.cfm?parm1=1738> [hereinafter *NACDS News Release*].

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

significant benefits to enrollees.<sup>160</sup> The benefits appear to stem from the convenience of a card that contains all information pertinent to drug assistance programs eligibility, as well as direct-to-consumer sales of drugs under these programs.<sup>161</sup> This card program seems to be a pharmaceutical industry counteroffer to the Medicare-Endorsed Drug Card proposed by the U.S. Department of Health and Human Services, discussed *infra*.<sup>162</sup>

### B. State Government Prescription Drug Programs

Many states are taking steps beyond Medicaid coverage to provide relief to their uninsured citizens from soaring prescription drug costs.<sup>163</sup> Generally, the pharmaceutical industry fights such programs where they lack government funding and pressures manufacturers to reduce prescription drug prices.<sup>164</sup>

#### 1. Michigan's Rebate and Reference Pricing Scheme

In late 2001, the Michigan Department of Community Health (Department) adopted a policy of routinely refusing to pay for drugs in Medicaid or other state-funded plans unless the manufacturer agreed to pay a rebate to the state.<sup>165</sup> The rebate must be large enough to reduce the price of the manufacturer's drug to the amount of the lowest price in its therapeutic class.<sup>166</sup> The Department will require doctors to receive "prior authorization" to prescribe drugs made by pharmaceutical companies that refuse to pay the state the rebate.<sup>167</sup> The purpose of this requirement is to create a disincentive for doctors to prescribe drugs manufactured by companies that refuse to participate in the state rebate program.<sup>168</sup> The overall goal of the De-

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<sup>160</sup> *Id.*

<sup>161</sup> *See id.* As noted earlier, manufacturers that offer drug assistance programs currently send their products to doctors' offices, and not to the low-income patients. *PhRMA Directory*, *supra* note 138.

<sup>162</sup> *See NACDS News Release*, *supra* note 157; *see also HHS Medicare Initiative*, *supra* note 133.

<sup>163</sup> *See e.g.*, Michigan Program, *supra* note 132; Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132.

<sup>164</sup> *See* Michigan Program, *supra* note 132; Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132.

<sup>165</sup> Michigan Program, *supra* note 132.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*



partment's policy is to reduce the amount the Department must pay for drugs in its Medicaid and state-run health care plans.<sup>169</sup>

## 2. Wisconsin's T-Rx Program

Wisconsin recently introduced a bill that would harness market forces to reduce the cost of prescription drugs for its citizens.<sup>170</sup> The state would negotiate with manufacturers, much in the same way health insurance companies do, to garner reduced drug prices.<sup>171</sup> Companies that refuse to participate in the program could be placed on a list that would require pre-approval for their drugs as prescribed under Medicaid and other state-funded health plans.<sup>172</sup> Those opposed to the bill declare that the plan will result in limiting the access of some people to certain black-listed brand-name drugs.<sup>173</sup>

## 3. Maine Manufacturer Rebate Scheme

Maine introduced a mandatory drug-rebate program in 2001.<sup>174</sup> Under the plan, the state has the authority to negotiate manufacturer rebates, the proceeds of which shall be set aside in a special fund.<sup>175</sup> Maine will use the proceeds of the fund to reimburse pharmacies that offer discounts on prescription drugs.<sup>176</sup> Maine mandates the participation of all manufacturers that receive Medicaid funding.<sup>177</sup> Manufacturers subject to the requirement that refuse to agree to lower their prices will be placed on a list requiring pre-authorization for prescription of their drugs to Medicaid enrollees.<sup>178</sup> Manufacturers that continue to refuse to reduce prices by July 2003 will be subject to state price controls.<sup>179</sup> PhRMA objected to the legislation because it illegally limits Medicaid participants' access to certain brand-name drugs and violates the Commerce Clause in its attempts to regulate com-

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<sup>169</sup> *Id.*

<sup>170</sup> Proposed Wisconsin Bill, *supra* note 132.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> Maine Bill, *supra* note 132; *see also* Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 71 (1st Cir. 2001) (upholding Maine's Act to Establish Fairer Pricing for Prescription Drugs, ME. REV. STAT. ANN. tit. 22, § 2681 (2002)).

<sup>175</sup> Maine Bill, *supra* note 132.

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

merce outside Maine.<sup>180</sup> After an initial injunction granted to PhRMA, Maine was allowed to proceed with its plan, so long as it agreed to impose no restriction on single-source drugs, to allow for a 72-hour emergency supply of pre-authorization drugs, and to grant or deny pre-authorization requests within twenty-four hours.<sup>181</sup> It is the first program of its type that includes the possibility that the state will impose price controls.<sup>182</sup>

### C. Federal Government Prescription Drug Programs

The federal government is currently grappling with the way in which it will approach the prescription drug price crisis.<sup>183</sup> A current initiative proposes a short-term alleviation of rising prescription drug costs through prescription drug discount cards.<sup>184</sup> One federal office recently directed its focus toward ways in which to incorporate a prescription drug coverage service into the Medicare system.<sup>185</sup> On the whole, the pharmaceutical industry favors the latter as the most effective and comprehensive solution to providing prescription drugs to low-income and uninsured individuals.<sup>186</sup>

#### 1. Medicare-Endorsed Prescription Drug Card Assistance Initiative

The U.S. Department of Health and Human Services (HHS) has proposed an initiative whereby the federal government will sanction qualified private sector prescription drug discount card programs as "Medicare-endorsed."<sup>187</sup> These Medicare-endorsed card programs must have the ability to obtain substantial manufacturer rebates or discounts on brand-name drugs. They then must be willing and able to pass on a portion of these discounts to their enrollees in order to reduce the price of prescription drugs.<sup>188</sup> The card program is required to provide a discount on at least one drug in each therapeutic drug class, group and sub-group representing those drugs that Medi-

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<sup>180</sup> Maine Bill, *supra* note 132.

<sup>181</sup> Michigan Program, *supra* note 132.

<sup>182</sup> *Id.*

<sup>183</sup> See, e.g., CBO Medicare Testimony, *supra* note 76, at 1.

<sup>184</sup> HHS Medicare Initiative, *supra* note 133.

<sup>185</sup> CBO Medicare Testimony, *supra* note 76, at 1.

<sup>186</sup> PhRMA, *Congress Should Enact a Prescription Drug Benefit* (Sept. 5, 2001), at <http://www.phrma.org/mediaroom/press/releases/05.09.2001.288.cfm>.

<sup>187</sup> HHS Medicare Initiative, *supra* note 133, at 7.

<sup>188</sup> *Id.* at 7–8.

care patients commonly take.<sup>189</sup> The card program must enroll all Medicare beneficiaries who want to participate in its plan.<sup>190</sup>

The NACDS strongly opposed a prior version of this initiative as being too exclusive and damaging to small community drug stores.<sup>191</sup> Apparently in response to this criticism, the HHS amended their initial initiative to require the card programs to offer a broad national or regional contracted retail pharmacy network.<sup>192</sup> In addition, the amended initiative requires that each discount card program publish a list of the drug prices it offers, so that enrollees may make an informed decision as to which plan they join, as well ensuring that the discount card programs compete with each other in obtaining the lowest price for prescription drugs.<sup>193</sup>

In adopting this initiative, HHS seeks to harness market strategies that currently afford private insurance companies and bulk prescription drug purchasers lower prescription drug prices.<sup>194</sup> HHS's requirement that Medicare patients enroll in only one discount card program at a time attempts to create a pool of drug purchasers that would give drug manufacturers an incentive to negotiate lower prices with the discount card program administrators.<sup>195</sup> The initiative also allows the discount drug programs the opportunity to employ other market-based strategies to reduce the cost of prescription drugs, including the creation of drug formularies, patient education, pharmacy networks, and mail order.<sup>196</sup>

## 2. Medicare Prescription Drug Coverage Proposals

The Congressional Budget Office (CBO) presented a report to the U.S. House of Representatives Committee on Ways and Means Subcommittee on Health in March 2001.<sup>197</sup> It proposed several versions of prescription drug coverage benefits to Medicare enrollees.<sup>198</sup> In general, all plans entail low cost-sharing requirements and a stop-loss protection—a dollar limit above which the enrollee would not be

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<sup>189</sup> *Id.* at 8.

<sup>190</sup> *Id.*

<sup>191</sup> Nat'l Ass'n of Chain Drug Stores Complaint at 17, Nat'l Ass'n of Chain Drug Stores v. Thompson (No. 1:01CV01554).

<sup>192</sup> *HHS Medicare Initiative*, *supra* note 133, at 8.

<sup>193</sup> *Id.* at 20.

<sup>194</sup> *Id.* at 9.

<sup>195</sup> *See id.*

<sup>196</sup> *Id.* at 11.

<sup>197</sup> CBO Medicare Testimony, *supra* note 76, at 1.

<sup>198</sup> *Id.* at 10–14.

required to cost-share.<sup>199</sup> All plans require some form of a monthly premium designed to cover a certain percentage of total cost of prescription drugs.<sup>200</sup> The enrollee would be required to make a co-payment for each prescription filled, up to the stop-loss amount.<sup>201</sup> The government would provide a subsidy for low-income enrollees so that they may participate without the burden of the monthly premiums or cost-sharing co-payments.<sup>202</sup>

The CBO anticipates possible employment of pharmacy benefit managers (PBM) to administer the Medicare drug coverage.<sup>203</sup> PBM's are common in private health plans.<sup>204</sup> They process claims, negotiate drug discounts with manufacturers, and try to steer beneficiaries to cost-saving alternatives—such as formularies, mail orders, or generic drugs.<sup>205</sup>

#### IV. DISCUSSION: TAKE-HOME SUGGESTIONS

##### A. *Lessons Garnered from Overseas*

##### 1. The French Experience

It is true that patients in France tend not to have many out-of-pocket expenses for prescription drugs.<sup>206</sup> Realizing that their patients will not pay for drugs, doctors in France feel little or no pressure to reduce the number of drugs they prescribe or to seek less expensive alternatives to prescription drugs.<sup>207</sup> Another consequence of low prescription drug prices in France is that neither patient nor doctor has much motivation to switch to generic drugs.<sup>208</sup> This may be the primary reason why generic drug use in France is low.<sup>209</sup>

Critics argue that the French system is inefficient and repressive to drug innovation.<sup>210</sup> The inefficiency argument stems from the fact that while France enjoys some of the lowest drug prices in the world,

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<sup>199</sup> *Id.* at 7.

<sup>200</sup> *See id.* at 10–14.

<sup>201</sup> *See id.*

<sup>202</sup> *See* CBO Medicare Testimony, *supra* note 76, at 10–14.

<sup>203</sup> *Id.* at 8.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> Wertheimer, *supra* note 48, at 163.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.* at 164.

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

it fails to keep overall prescription drug spending down.<sup>211</sup> The French system does not hold either the doctor or the patient accountable for the prescription drug use.<sup>212</sup> France is a prime example of why price regulation alone is not an efficient way to solve the problem of rising prescription drug spending.<sup>213</sup> The French system is arguably repressive to drug innovation as its price regulation bears little relation to pharmaceutical R&D costs.<sup>214</sup>

## 2. A German Tutorial

The German health care system includes a sophisticated accountability mechanism.<sup>215</sup> As discussed *supra*, German patients are required to pay a certain amount for each subgroup, and must pay the difference if their prescribed drug is more expensive than the reference price.<sup>216</sup> Doctors, therefore, avoid prescribing drugs that cost more than the reference price.<sup>217</sup> This selection process is one means by which Germany can reduce overall expenditure for prescription drugs.<sup>218</sup> Also, since the government regularly audits prescriber performance to evaluate efficiency, doctors have an incentive to substitute generic drugs when possible.<sup>219</sup> This is another vehicle for containing prescription drug costs.<sup>220</sup>

The key element of the German prescription drug system is that it requires both doctors and patients to share in the cost of health care coverage.<sup>221</sup> This forced accountability appears to have slowed the rate of increase in drug spending, as well as lowered the overall number of prescriptions issued.<sup>222</sup> Also important, however, is the fact that Germany provides some flexibility in its doctor-accountability scheme by allowing for a grace amount of budget overflow.<sup>223</sup> In this way, Germany appears to have tied accountability to both the pre-

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<sup>211</sup> See Wertheimer, *supra* note 48, at 163–64.

<sup>212</sup> See *id.*

<sup>213</sup> See *id.*

<sup>214</sup> See *id.*

<sup>215</sup> See *id.* at 165–66.

<sup>216</sup> Wertheimer, *supra* note 48, at 166.

<sup>217</sup> *Id.*

<sup>218</sup> *Id.* at 165–66.

<sup>219</sup> *Id.*

<sup>220</sup> See *id.*; see also SCHWEITZER, *supra* note 21, at 177.

<sup>221</sup> See Wertheimer, *supra* note 48, at 165–66.

<sup>222</sup> *Id.*

<sup>223</sup> See *id.* at 166.

scriber and the end user of a drug, while at the same time it has allowed doctors to meet the specific demands of each patient.<sup>224</sup>

### 3. The British Example

One important aspect of Britain's coverage of prescription drug use is the way in which the government actively negotiates with the pharmaceutical industry.<sup>225</sup> Direct negotiation with the pharmaceutical industry by major purchasers, as discussed *supra*, evens the bargaining power between drug purchaser and manufacturer.<sup>226</sup> This ultimately leads to reduced prices when compared to the prices that the drug manufacturers otherwise offer to individual drug consumers.<sup>227</sup>

Another interesting element of the British drug plan is that the government consciously seeks to protect R&D by allowing the pharmaceutical companies to make a profit on their drug sales in the Britain.<sup>228</sup> This is in drastic contrast to the overly stifling price controls imposed by France.<sup>229</sup> Yet, the British government seeks to limit the amount of profit a drug manufacturer can make on its British consumers by capping the profit margin.<sup>230</sup> In this way, Britain seems to balance the need to fund innovation and a desire to protect British consumers from overzealous drug manufacturers.<sup>231</sup>

Some critics argue that even this more relaxed approach discourages pharmaceutical R&D in Britain.<sup>232</sup> Critics point to a recent trend of pharmaceutical companies shifting their research dollars to the United States.<sup>233</sup> This may be due to the fact that, up to this point, the United States has afforded pharmaceutical companies the most fertile ground for investment by refusing to impose prescription drug price policies.<sup>234</sup> It is also unclear that the sole reason for decreased R&D spending in Britain is directly related to drug price negotiations, since several other factors would have an impact on a manufacturer's deci-

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<sup>224</sup> See *id.*

<sup>225</sup> See Huttin, *supra* note 115, at 276.

<sup>226</sup> See *id.*; see also SCHWEITZER, *supra* note 21, at 104.

<sup>227</sup> See Huttin, *supra* note 115, at 276; see also SCHWEITZER, *supra* note 21, at 104.

<sup>228</sup> See Huttin, *supra* note 115, at 276.

<sup>229</sup> See Wertheimer, *supra* note 48, at 164.

<sup>230</sup> See Huttin, *supra* note 115, at 276.

<sup>231</sup> See *id.*

<sup>232</sup> See *Europe's Addiction*, *supra* note 7.

<sup>233</sup> *Id.*

<sup>234</sup> See *Price of Medicine*, *supra* note 41.

sion to spend research dollars in a country.<sup>235</sup> Such factors include the country's patent laws and marketing regulations.<sup>236</sup> Furthermore, at least one study ranked Britain third among nations preferred by pharmaceutical companies for future R&D facilities—with the United States and Germany taking first and second.<sup>237</sup>

Britain incorporates an accountability scheme much like the one in Germany.<sup>238</sup> Again, successful price containment strategies seem to entail both a bargained-for prescription drug price and some measure of forced accountability for consumers.<sup>239</sup> Note that government regulation aimed at imposing prescriber and user accountability attempts to resolve the unique problem in prescription drug consumption: the end user being divorced from the entity that pays for the drug.<sup>240</sup>

### B. *The Advantage of Private Industry-Driven Programs*

One important conclusion that may be drawn from the proliferation of industry-sponsored prescription drug programs is that both the pharmaceutical companies and the pharmacies recognize a need to help individuals who desperately require their drugs, but who cannot afford them.<sup>241</sup> It also seems apparent that pharmaceutical companies will be willing to go a long way in cooperating with government action, so long as the government avoids imposing strict drug price controls.<sup>242</sup> A government initiative might result in more successful negotiation given the current atmosphere and the industry's overall condemnation of price controls.<sup>243</sup>

In addition, a government prescription drug program must be able to utilize the benefits that the private industry currently offers to its underprivileged consumers.<sup>244</sup> Since several manufacturers offer

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<sup>235</sup> See H.Th. van Asselt, *Policies on Pharmaceutical Patents: The Impact of Patent Protection on R&D*, in *THE PRESCRIPTION DRUG MARKET* 263 (Christine Huttin & Nick Bosanquet, eds., 1992); SCHWEITZER, *supra* note 21, at 147.

<sup>236</sup> See van Asselt, *supra* note 235, at 263; SCHWEITZER, *supra* note 21, at 147.

<sup>237</sup> See TAGGART, *supra* note 151, at 437.

<sup>238</sup> See Wertheimer, *supra* note 48, at 165–66; Huttin, *supra* note 115, at 276.

<sup>239</sup> See Wertheimer, *supra* note 48, at 165–66; Huttin, *supra* note 115, at 276.

<sup>240</sup> See Balance, *supra* note 1, at 95–96.

<sup>241</sup> See, e.g., Michigan Program, *supra* note 132; Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132.

<sup>242</sup> See, e.g., Michigan Program, *supra* note 132; Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132.

<sup>243</sup> See, e.g., Michigan Program, *supra* note 132; Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132.

<sup>244</sup> See, e.g., PhRMA Assistance Programs, *supra* note 130; see also HHS Medicare Initiative, *supra* note 133, at 1.

drugs at no charge to consumers who meet their requirements, a government program should be able to identify eligible recipients and provide assistance in obtaining the benefits that the industry currently offers.<sup>245</sup> However, since the drug assistance programs exclude consumers who receive prescription drug coverage, adoption of Medicare prescription drug coverage might remove even the most needy patients from the benefit of free prescription drugs.<sup>246</sup> Perhaps the government could negotiate an exemption for Medicare recipients who otherwise meet the manufacturers' requirements, but this issue is outside the scope of this note.<sup>247</sup>

### C. Issues Regarding State-Sponsored Programs

The availability of state prescription drug price schemes and discount cards demonstrates the ability of the government to utilize its bargaining power to benefit its citizens.<sup>248</sup> Michigan, for example, elicits rebates from drug manufacturers much like major private purchasers, such as hospitals.<sup>249</sup> Wisconsin and Maine have similar plans.<sup>250</sup> The state plans also operate pre-authorization lists that resemble the negative list maintained by France.<sup>251</sup> Both the negotiated rebates and the quasi-formulary approaches currently used by several states mirror the same cost containment strategies adopted by both domestic private health organizations and foreign governments.<sup>252</sup>

The major problem with state-run prescription drug schemes is that they are ad-hoc.<sup>253</sup> While the citizens of Maine, Wisconsin and Michigan enjoy the fruits of their government's bargaining, citizens of

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<sup>245</sup> See, e.g., *PhRMA Assistance Programs*, *supra* note 130; see also *HHS Medicare Initiative*, *supra* note 133, at 1.

<sup>246</sup> See, e.g., *PhRMA Assistance Programs*, *supra* note 130; see also *HHS Medicare Initiative*, *supra* note 133, at 1.

<sup>247</sup> See, e.g., *PhRMA Assistance Programs*, *supra* note 130; see also *HHS Medicare Initiative*, *supra* note 133, at 1.

<sup>248</sup> See Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132; Michigan Program, *supra* note 132.

<sup>249</sup> See Michigan Program, *supra* note 132; SCHWEITZER, *supra* note 21, at 104.

<sup>250</sup> See Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132.

<sup>251</sup> See Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132; Michigan Program, *supra* note 132; Wertheimer, *supra* note 48, at 162.

<sup>252</sup> See, e.g., Proposed Wisconsin Bill, *supra* note 132; see also SCHWEITZER, *supra* note 21, at 175.

<sup>253</sup> See Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132; Michigan Program, *supra* note 132.



states that lack such programs go unprotected.<sup>254</sup> One concern that such disparity raises is the possibility that uninsured patients in the non-prescription plan states will suffer higher drug prices as the pharmacies shift their costs to the decreasing number of underrepresented Americans.<sup>255</sup> It seems logical that one way to avoid such hardship is for the United States to adopt a federal prescription drug plan.<sup>256</sup>

#### D. *The Potential for Federal Prescription Drug Programs*

While the Medicare-endorsed prescription drug discount card is a step in the right direction, it does not go nearly as far as needed to ensure that the federal government fully harnesses market forces to reduce the overall prescription drug expenditure in the United States.<sup>257</sup> The discount cards create another middleman who can put manufacturer rebates in his pocket.<sup>258</sup> The rebates should go directly to the end user to reduce the cost of prescription drugs.<sup>259</sup> In addition, the availability of several competing discount prescription drug cards reduces the bargaining power of the individual programs, since it reduces the number of members in each program.<sup>260</sup>

The CBO's proposal for Medicare prescription drug coverage is the most promising solution to rising drug costs for elderly and disabled Americans.<sup>261</sup> Yet, the current proposal should incorporate cost containment strategies that other countries currently employ.<sup>262</sup> For example, the CBO contemplates the use of PBMs.<sup>263</sup> The advantage of PBMs is that they have the potential to help artificially impose accountability on both the doctor and patient.<sup>264</sup> The PBMs steer patients to less costly, yet therapeutically similar, prescription drugs.<sup>265</sup> With the development of a formulary, the PBM could also discourage

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<sup>254</sup> See Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132; Michigan Program, *supra* note 132.

<sup>255</sup> See *id.*; see also United States Department of Health and Human Services, *Medicare-Endorsed Prescription Drug Discount Card* (Feb. 28, 2002), available at [http://www.nacds.org/user-assets/PDF\\_files/feb02\\_pdc\\_summary.pdf](http://www.nacds.org/user-assets/PDF_files/feb02_pdc_summary.pdf).

<sup>256</sup> See generally CBO Medicare Testimony, *supra* note 76.

<sup>257</sup> See generally HHS Medicare Initiative, *supra* note 133.

<sup>258</sup> See *id.* at 13.

<sup>259</sup> See *id.*

<sup>260</sup> See *id.* at 20.

<sup>261</sup> See generally CBO Medicare Testimony, *supra* note 76.

<sup>262</sup> See *id.*; see generally Wertheimer, *supra* note 48.

<sup>263</sup> CBO Medicare Testimony, *supra* note 76, at 8.

<sup>264</sup> See *id.*

<sup>265</sup> *Id.*

doctors from prescribing drugs the manufacturers of which fail to issue discounts to Medicare beneficiaries.<sup>266</sup> Germany has demonstrated the potential success resulting from government imposition of prescriber answerability.<sup>267</sup> While it is doubtful that a Medicare prescription drug coverage plan would include audits of physician prescribing practices, it should contain some version of this prescriber accountability.<sup>268</sup>

The CBO also envisions some form of cost-sharing.<sup>269</sup> France has shown the need for imposing some financial burden on prescription drug users.<sup>270</sup> As discussed *supra*, France spends more than 16% of its total health expenditures on prescription drugs.<sup>271</sup> This is almost twice the average percentage of spending of Britain and the United States independently.<sup>272</sup> Part of the reason for France's large overall spending on prescription drugs is that the end user, the patient, pays very little money out of pocket for the prescription drug.<sup>273</sup> A Medicare prescription plan must include co-payments paid by the patient, provided that consumers who cannot afford the co-payments due to financial hardship are eligible for government subsidies that cover the cost of the co-payments.<sup>274</sup>

While the CBO report contains estimates on the anticipated cost of a Medicare prescription drug plan, it fails to assess the overall impact of such coverage on total Medicare expenditure.<sup>275</sup> Critics of the current system complain that some patients must choose between filling prescriptions and putting food on the table due to exorbitant prices.<sup>276</sup> The pharmaceutical industry argues that proper use of its drugs shortens the total number of days individuals spend in the hospital and reduces overall health care costs for certain chronic diseases.<sup>277</sup> It appears that a prescription drug coverage plan would en-

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<sup>266</sup> *See id.*

<sup>267</sup> *See* Wertheimer, *supra* note 48, at 165.

<sup>268</sup> *See id.*

<sup>269</sup> CBO Medicare Testimony, *supra* note 76, at 10.

<sup>270</sup> *See* Wertheimer, *supra* note 48, at 160.

<sup>271</sup> *Id.*

<sup>272</sup> *See id.*

<sup>273</sup> *See id.* at 163.

<sup>274</sup> *See id.*; *see also* CBO Medicare Testimony, *supra* note 76, at 10.

<sup>275</sup> *See generally* CBO Medicare Testimony, *supra* note 76.

<sup>276</sup> *See* Sauter, *supra* note 4.

<sup>277</sup> PhRMA, *The Myth of "Rising Drug Prices" Exposed*, at <http://www.phrma.org/publications/quickfacts/03.04.2001.206.cfm> (last visited Jan. 1, 2003).

courage patients to take drug prescribed to them, thereby alleviating the burden of hospital costs on the Medicare budget.<sup>278</sup>

#### V. ANALYSIS: RECOMMENDATIONS FOR A FEDERAL MEDICARE PRESCRIPTION DRUG COVERAGE PLAN

Absent the formation of a cohesive national health plan, and the imposition of prescription drug regulation, no single federal program can fully alleviate the burden of prescription drug costs for all Americans.<sup>279</sup> As demonstrated by France's situation, even strict price regulation cannot solve the issue of rising drug expenditures.<sup>280</sup> Therefore, the best solution appears to be a federal Medicare prescription drug plan that provides drug coverage to the patients who need such coverage the most—elderly and disabled Americans.<sup>281</sup>

A U.S. prescription drug plan must balance the public's desire for innovative drugs and the need to keep drugs affordable.<sup>282</sup> To meet the affordability demands, the government should look to nations overseas for suggestions.<sup>283</sup> It appears that the best way to achieve reductions in prescription drug prices is for the government to harness market forces, as opposed to direct government price regulation. As shown by other countries, as well as by the private medical insurance industry, some of the ways to harness market forces to reduce the cost of prescription drugs include: pooling consumers to create bargaining power, instituting drug lists or formularies, and artificially imposing accountability on doctors and patients.<sup>284</sup>

One way for the federal government to pool prescription drug consumers is for it to enact a Medicare prescription drug coverage plan.<sup>285</sup> Several states have demonstrated that the government can effectively bargain for manufacturer rebates and reduce prescription drug prices when it negotiates on behalf of the consumers enrolled in state-operated Medicaid programs.<sup>286</sup> The United States might benefit from the adoption of a negotiation structure similar to the one em-

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<sup>278</sup> See *id.*

<sup>279</sup> See generally CBO Medicare Testimony, *supra* note 76; HHS Medicare Initiative, *supra* note 133.

<sup>280</sup> See Wertheimer, *supra* note 48, at 160.

<sup>281</sup> See generally CBO Medicare Testimony, *supra* note 76.

<sup>282</sup> See Ballance, *supra* note 1, at 95.

<sup>283</sup> See Wertheimer, *supra* note 48, at 175.

<sup>284</sup> SCHWEITZER, *supra* note 21, at 174–75.

<sup>285</sup> See *id.* See generally CBO Medicare Testimony, *supra* note 76.

<sup>286</sup> See Proposed Wisconsin Bill, *supra* note 132; Maine Bill, *supra* note 132; Michigan Program, *supra* note 132.

ployed by Britain.<sup>287</sup> The pharmaceutical industry in the United States could form a representative coalition that bargains on behalf of pharmaceutical manufacturers operating in the United States, much like the ABPI in Britain.<sup>288</sup> The federal government would then form a voluntary collective agreement with the pharmaceutical coalition to encourage manufacturer rebates, establish reference pricing, and possibly, set profit margins.<sup>289</sup>

This voluntary agreement helps to reduce the cost of prescription drugs used by Medicare recipients while it avoids direct government price regulation.<sup>290</sup> The mechanism of a bargained-for prescription drug price helps to ensure that the R&D needs of the pharmaceutical industry are met while it harnesses market forces to reduce prescription drug prices.<sup>291</sup> Establishing a reference price encourages competition between pharmaceutical companies to reduce their prescription drug prices.<sup>292</sup> Establishing profit margins is another means by which the government can encourage pharmaceutical companies to continue pursuing innovative drugs while it protects American citizens from price gouging.<sup>293</sup>

To ensure that Medicare prescription drug dollars are efficiently spent, the United States should incorporate cost containment strategies employed by the private health insurance industries and other countries.<sup>294</sup> It should utilize PBMs to create drug formularies, encourage the use of generic drugs, and provide education to doctors and patients on proper prescription drug use.<sup>295</sup> The formulary must be flexible enough to allow the prescribing doctor to meet the individualized needs of her patient.<sup>296</sup> Yet, the formulary cannot be so adaptable that it fails to influence prescribing behavior.<sup>297</sup> Also, the Medicare recipient should be encouraged, if not mandated, to use generic versions of therapeutically equivalent drugs when possible.<sup>298</sup>

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<sup>287</sup> See Wertheimer, *supra* note 48, at 167–68.

<sup>288</sup> See *id.* at 167.

<sup>289</sup> See *id.* at 167–68.

<sup>290</sup> See *id.*

<sup>291</sup> See *id.* at 168.

<sup>292</sup> See Wertheimer, *supra* note 48, at 168.

<sup>293</sup> See *id.* at 167–68.

<sup>294</sup> See *id.* at 166; SCHWEITZER, *supra* note 21, at 187.

<sup>295</sup> SCHWEITZER, *supra* note 21, at 181.

<sup>296</sup> See *id.* at 176.

<sup>297</sup> See *id.*

<sup>298</sup> See *id.* at 177.

A PBM should educate doctors on the Medicare formulary as well as on the availability of generic drugs.<sup>299</sup>

A Medicare prescription drug coverage plan must have some mechanism for making the drug prescriber and the user accountable.<sup>300</sup> The United States might benefit from a co-payment scheme similar to that which is used in Germany.<sup>301</sup> The United States could set a nominal co-payment fee that would decrease if the patient used a generic alternative.<sup>302</sup> The federal government could then set reference prices for drugs in the same therapeutic class.<sup>303</sup> The reference price could be set as part of the negotiations between the pharmaceutical coalition and the U.S. government as described *supra*.<sup>304</sup> Patients whose drug costs exceeds the reference price would then be responsible for the excess amount, in addition to the co-payment.<sup>305</sup> This cost-sharing system encourages patients and doctors to choose the least expensive drug available to the patient in a therapeutic class.<sup>306</sup>

### CONCLUSION

Americans are justified in their concerns that they subsidize prescription drug regulations abroad. And yet, calls for government price controls miss the issues at the heart of the debate. The fact that some patients pay more for a drug than do others should not be the major concern for Americans. Price differentials reflect several factors, most of which lie outside the ambit of the federal government. Instead, Americans should realize that the real threat is that patients who need life-saving drugs the most cannot afford them.

The United States already has a system in place to assist these patients in need of medical attention—the U.S. Medicare program. The easiest way to ensure that Medicare enrollees can afford the cost of their prescription drugs is by enacting a Medicare prescription drug benefit. The prescription drug plan can minimize its costs by employing the cost containment strategies used by nations abroad. The United States should also learn from the mistakes made by other nations. Through careful observation of the successes and failures of

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<sup>299</sup> See *id.* at 190.

<sup>300</sup> See Wertheimer, *supra* note 48, at 168.

<sup>301</sup> See *id.* at 166.

<sup>302</sup> See *id.*

<sup>303</sup> See *id.*

<sup>304</sup> See *id.* at 166–67.

<sup>305</sup> See Wertheimer, *supra* note 48, at 166.

<sup>306</sup> See *id.*

other countries, the United States can enact a prescription drug plan that effectively encourages drug innovation while protecting the financial needs of its citizens.