

# CRS Report for Congress

## Pharmaceutical Costs: An International Comparison of Government Policies

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## Summary

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173) addressed the rising costs of prescription drugs for the elderly by providing a mechanism for beneficiaries to obtain affordable prescription drug insurance coverage. The Medicare prescription drug benefit, otherwise known as Part D, was designed to take advantage of market competition. In accordance with market competition principles, the drug plans that administer the drug benefit are private and public corporations (i.e., non-government) that may rely on price negotiating, rebate negotiation, and price-volume discounts as a way to affect prices.

A provision in the MMA, termed the “noninterference” provision, prevents the federal government from stepping in to try to further lower drug prices. Both the incoming Speaker of the House and incoming Senate Majority Leader have reportedly expressed their support for repealing the “noninterference” provision, and regard it as a priority for consideration in the 110<sup>th</sup> Congress. Should the provision be repealed, Congress may wish to provide guidance on how prices would be negotiated.

Examining the policies of Canada, Australia, and European nations could help to inform the discussion of drug pricing policies for the Medicare drug plan. Like Medicare, these governments’ policies affect the prices paid for pharmaceuticals. All of these nations rely on policies to mitigate increases in pharmaceutical spending. These policies include reference pricing, price ceilings, reimportation, profit sharing, and value-based pricing.

In systems that use reference pricing, prices are often determined by clustering drugs by class and setting a uniform rate for all drugs in the cluster. Drug clusters tend to be controversial because they may ignore differences in safety profiles, efficacy, and application forms. Price ceilings set the maximum price that manufacturers may charge certain customers. Customers (e.g., Part D drug plans) may then negotiate prices below the ceiling.

Reimportation, similar to “parallel trade” in Europe, implies importing pharmaceutical prices, as well as the products, and would allow the U.S. to tacitly use other countries’ drug pricing systems. FDA laws prohibit reimportation, but the MMA includes a provision allowing the Secretary of Health and Human Services to circumvent these laws. The present Secretary has chosen not to exercise this option. In addition to these legal barriers, pharmaceutical manufacturers have indicated that they may restrict the supply of drugs if the U.S. legalizes reimportation from Canada.

Profit-sharing mechanisms require manufacturers to share all or part of the profits that are predetermined to be in “excess.” Value-based pricing sets drug prices using a relative value metric. The hurdle for the former pricing mechanism requires determination of the “appropriate” profit limit. The latter requires determination of an acceptable value-added as well as an “appropriate” comparison drug. This report will be updated as legislative activity warrants.

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## Background

One of the motivating factors for Congress to create Medicare Part D in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173) was seniors' rising out-of-pocket drug costs. Prior to MMA, 38% of Medicare beneficiaries did not have drug insurance coverage.<sup>1</sup> People without sufficient drug insurance were paying drug prices that were 15% higher on average than the prices paid by insurance companies.<sup>2</sup> Some Medicare beneficiaries who did not have drug insurance coverage coped with these higher prices by filling fewer of their prescriptions and taking medications less frequently than their doctors recommended.<sup>3</sup>

Medicare Part D provides voluntary insurance coverage of drugs for beneficiaries, albeit at a high price to the federal government.<sup>4</sup> The federal cost of Part D benefits is estimated to be \$44.7 billion in 2007.<sup>5</sup> Medicare Part D was designed to take advantage of market competition. In accordance with market competition principles, the drug plans that administer the drug benefit are private and public (i.e., non-government) corporations who may rely on price negotiating, rebate negotiation, and price-volume discounts as a way to affect prices.

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<sup>1</sup> For more statistics on drug coverage in the Medicare population from 1996-1999, see Mary A. Laschober, Michelle Kitchman, et al., "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999," *Health Affairs*, February 2002, W127-138.

<sup>2</sup> From the *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices* (Washington: DHHS, April 2000).

<sup>3</sup> One study found that Medicare beneficiaries with drug coverage were 6%-17% more likely to fill their prescriptions and medicate than beneficiaries without drug coverage. For more information on this statistic and others, see Bruce Stuart and James Grana, "Ability to Pay and the Decision to Medicate," *Medical Care*, vol. 36, no. 2 (February 1998), pp. 202-211.

<sup>4</sup> For more information about MMA, see CRS Report RL31966, *Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by Jennifer O'Sullivan, Hinda Chaikind, Sibyl Tilson, Jennifer L. Boulanger, and Paulette C. Morgan.

<sup>5</sup> For more details, see the March 2006 Baseline Budget Projections from the U.S. Congressional Budget Office, available at [<http://www.cbo.gov/budget/factsheets/2006b/medicare.pdf>]. Last accessed December 19, 2006. Although more recent CBO budget projections are available for aggregate Medicare spending, the March 2006 baseline contains the most recent detailed projections for Medicare Part D.

A provision in the MMA, termed the “noninterference” provision, prevents the federal government from being a third party in drug price negotiations between the Part D drug plans and pharmaceutical manufacturers. Both the incoming Speaker of the House and incoming Senate Majority Leader have reportedly expressed their support for repealing this “noninterference” provision, and regard it as a priority for consideration in the 110<sup>th</sup> Congress.<sup>6</sup> According to one poll, the overwhelming majority (85%) of Americans also seem to support repealing the provision and allowing the government to negotiate prices.<sup>7</sup>

Should the “noninterference” provision be repealed, Congress may wish to provide guidance on how the Secretary of Health and Human Services (HHS) would negotiate prices. A debate could occur about the options and mechanisms of a new drug pricing policy for the Medicare drug plan. In order to clarify and inform the debate, this report provides an overview of the policies used in other nations. This report first provides a brief background of the way pharmaceutical prices are currently determined for Medicare. The report then discusses the types of policies used by the Canadian, Australian, and European governments to determine the price of drugs: reference pricing, price ceilings, parallel trade, profit sharing, and value-based pricing. It should be noted that this paper focuses on policies used for brand-name (non-generic) pharmaceuticals, as these policies are more pertinent to the current debate than those used for generic pharmaceuticals. Generics are less expensive and have more price competition than brand-name pharmaceuticals, and thus have not been the focus of debates in the U.S.

## Medicare Pharmaceutical Pricing

Under current law, prescription drugs for Medicare beneficiaries are provided through prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans. Unlike MA-PDs, which cover the costs of the entire set of Medicare benefits (Parts A, B, and D), the PDPs only cover the costs of prescription drugs (Part D). The Part D plans have contracts with the Centers for Medicare and Medicaid Services (CMS) to provide prescription drug coverage to Medicare beneficiaries. Individually and with a great deal of flexibility, the plans construct benefit packages (including the formulary, deductible, co-payments, and utilization management

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<sup>6</sup> For more details, see press release from the Senate Democratic Communications Center, “Reid: Congress Must Improve Medicare Part D,” December 8, 2006; see also Drew Armstrong, “Democrats’ First 100 Hours: Big Pharma Braces for Heavier Federal Hand in Drug Pricing Policy,” *CQ Weekly*, November 20, 2006; see also Rebecca Adams, “Pharma Braces for Battle,” *CQ Weekly*, November 27, 2006.

<sup>7</sup> A poll by the Harvard School of Public Health and Kaiser Family Foundation indicates that 85% of adults (92% of Democrats, 85% of Independents, and 74% of Republicans) support allowing the federal government to negotiate drug prices for the Medicare program. For more information, see The Henry J. Kaiser Family Foundation, “Public Sees Health Care Prices as Unreasonable and Wants Government to Take Steps to Lower Them,” December 8, 2006. Available at [<http://www.kff.org/kaiserpolls/pomr120806nr.cfm>]. Accessed December 15, 2006.

tools), arrange a network of pharmacies to dispense the drugs, and negotiate rebates and drug prices with the pharmaceutical manufacturers.<sup>8</sup>

The success of each individual plan's ability to negotiate lower prices has a direct impact on the amount enrollees pay. Enrollees are required to make copayments (which is the *entire* price if the drug is not covered<sup>9</sup>) and pay premiums that are directly affected by the negotiated drug prices (i.e., the lower the prices paid by the plan, the lower the amounts the plan must charge). Much of beneficiaries' satisfaction with their drug plan may be tied to the amount they pay for drugs.

## Negotiation

As stated before, the greatest legal impediment to changing the way Medicare drugs are priced is the "noninterference" provision in MMA. Specifically, this provision forbids the Secretary of Health and Human Services (HHS) from negotiating the price of prescription drugs on behalf of Medicare beneficiaries. Section 1860D (i) of the MMA states, "in order to promote competition under this part and in carrying out this part, the Secretary - (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary to institute a price structure for the reimbursement of covered Part D drugs." The conference report adds that, "conferees expect PDPs to negotiate price concessions directly with manufacturers."<sup>10</sup> Most of the policies used by other nations, as discussed later in this report, could not be implemented in the U.S. without repealing this provision.

Repealing the "noninterference" clause may lead to changing the drug pricing policy for Medicare. Although not strictly necessary, if Congress repeals the provision and allows the Secretary of HHS to negotiate drug prices, it may also wish to provide some guidance as to what type of drug pricing policy it wants the Secretary of HHS to negotiate. Since the number of different policies is innumerate, examining policies that have been applied in other settings may help in exploring the options.

In theory, the federal government may be able to leverage its market share to negotiate lower prices. The extent to which the federal government could negotiate lower prices than the Part D drug plans is unknown. Without this knowledge, it is impossible to predict whether a new pricing policy would lead to lower costs for Medicare beneficiaries, the federal government, or other U.S. consumers. Importantly, any new drug pricing policy for Medicare may have ripple effects on manufacturers' research and development of new pharmaceuticals, Part D drug plans'

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<sup>8</sup> For more information on PDPs, see "The Nuts and Bolts of PDPs," by Mary Ellen Stahlman, George Washington University, *National Health Policy Forum*, Issue Brief no. 817, November 8, 2006.

<sup>9</sup> One example of when a drug may not be covered for Part D beneficiaries is in the "doughnut hole" — the common term for beneficiary's drug expenditures between \$2,251 and \$5,100.

<sup>10</sup> For more information, see H.Rept. 108-391, p. 461.

role and ability to compete, pharmacies' profits, as well as other U.S. consumers. The size of these ripples will depend upon the type of pricing policy selected, and the extent to which the federal government negotiates lower prices.

## Other Policies

Examining and understanding the policies of Canada, Australia, and European nations could help to inform the discussion of drug pricing policies for the Medicare drug benefit. These policies are used in other nations not just to price drugs, but also to determine reimbursement rates and manage utilization. Like Medicare, these governments' policies affect the prices paid for pharmaceuticals. Consequently, the pharmaceutical pricing policies in these countries have a noticeable impact upon the pharmaceutical sales revenues. Similarly, any change in drug pricing policies for Medicare could have a noticeable impact upon total pharmaceutical sales in the U.S.

Canada, Australia, and European nations use reference pricing, price ceilings, parallel trade, profit sharing, or value-based pricing policies to mitigate increases in pharmaceutical expenditures due to price increases. Nations may rely on more than one of these methods, and other methods are typically used to control pharmaceutical utilization. Moreover, these countries also use policies currently used by Part D drug plans, Medicaid, and other U.S. health payers, such as price negotiating, rebate negotiation, and price-volume discounts.

## Reference Pricing

Germany and the Netherlands<sup>11</sup> are examples of countries in which reference pricing is used for pharmaceuticals.<sup>12</sup> Prices are often determined by clustering drugs by class and setting a uniform rate for all drugs in the cluster. The reimbursement rates are determined through cross-country (or jurisdiction) comparisons or within country comparisons of similar therapies. The cross-country comparisons result in regulation prices in one country directly affecting prices in another country.

The drug clusters are controversial because they may ignore differences in safety profiles, efficacy, and application forms across drugs.<sup>13</sup> For example, a manufacturer may argue that its drug is an improvement over others in the same cluster because it causes fewer side effects and can be administered as a pill rather than an injection; however, the value of these improvements may not be fully captured by pricing drugs in clusters. To deal with such nuances, new or innovative products may be excluded from clusters.

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<sup>11</sup> Note that these countries use a mixture of pricing mechanisms and reference pricing is only one of the mechanisms used by these countries. For more information, see Christine Huttin, "Drug Price Divergence in Europe: Regulatory Aspects," *Health Affairs*, vol. 18, no. 3 (May/June 1999), p. 245-249.

<sup>12</sup> France, Italy, Portugal and Spain are also among the many European countries that use reference pricing, especially in patent-expired products.

<sup>13</sup> For more information, see Christine Huttin, *op. cit.*

## Price Ceilings

In Canada, the Patented Medicines Prices Review Board (PMPRB) sets the maximum price manufacturers may charge distributors, hospitals, retail pharmacy chains, and others who purchase drugs in Canada directly from the manufacturer (the price ceiling).<sup>14</sup> Pharmaceutical manufacturers may be fined by the PMPRB if they attempt to charge prices higher than the price ceiling. Canadian purchasers can negotiate prices lower than the price ceiling with manufacturers. In the U.S. Medicare system, the equivalent arrangement would be for the Secretary of HHS to ban manufacturers from setting prices higher than the price ceiling, and allow the Part D drug plans to negotiate prices lower than the price ceiling.

## Reimportation (Parallel Trade)

Reselling pharmaceuticals to people in other nations commonly occurs in Europe and is termed parallel trade. Manufacturers can not prevent the movement of pharmaceuticals from one European country to another due to the absence of trade barriers among the countries of the European Union. U.S. legislation on the issue has used the term reimportation in recognition of the fact that the U.S. is the largest exporter of pharmaceuticals; importing pharmaceuticals into the U.S. would be, for the most part, tantamount to re-importing them.

Reimportation implies importing foreign pharmaceutical prices, as well as the products, and would allow the U.S. to tacitly use other countries' pricing systems. It is one of the few pricing policies that would not require repealing the "noninterference" provision in the MMA. Reimportation of prescription drugs is currently illegal in the United States.

The Federal Food, Drug, and Cosmetic Act (FFDCA)<sup>15</sup> prohibits anyone from importing prescription drugs into the United States, unless they are the original manufacturer of the drugs. Consequently, it is illegal for someone to import a drug from a pharmacy in another country, even if the drug was originally manufactured in the United States. All drugs sold in the U.S. must be manufactured and packaged for U.S. sale. The rationale for prohibiting reimportation is that the Food and Drug Administration (FDA) can not guarantee the safety of the drug once it has left the agency's regulatory control. Moreover, the version produced by U.S. drug manufacturers for foreign markets may not meet all of the requirements for U.S. sales and marketing approval.

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<sup>14</sup> Canada uses prices in France, Germany, Italy, Sweden, Switzerland, the U.K., and the United States to establish Canadian benchmark prices for drug sales. For more details on the PMPRB regulations and policies, see The Patented Medicines Prices Review Board, *Compendium of Guidelines, Policies, and Procedures*, October 2003. Available at [<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=654>]. Accessed December 18, 2006. Also see Valérie Paris and Elizabeth Docteur, "Pharmaceutical Pricing and Reimbursement Policies in Canada," *OECD Health Working Papers*.

<sup>15</sup> The FFDCA is the legislation authorizing the Food and Drug Administration (FDA) to regulate food, drugs, and cosmetics in the United States. U.S.C. Title 21, Chap. IX.



The MMA includes a provision that circumvents the FFDCA. It authorizes the FDA to allow drug reimportation from Canada, if the Secretary of HHS certifies that importation of prescription drugs is both safe and cost-saving<sup>16</sup> — the present Secretary has chosen not to exercise this option. The provision does not permit drug reimportation from any countries other than Canada.

Even if a Secretary of HHS deems importation to be safe and cost-saving, and allows reimportation from Canada, Medicare beneficiaries may encounter drug supply limits. While the MMA provision was being discussed in 2003, pharmaceutical manufacturers announced that they would respond to any law permitting reimportation by limiting the supply of drugs available to Canadian distributors and pharmacies.<sup>17</sup>

## Profit Sharing

Another drug pricing method that may be used by payers is profit sharing, whereby manufacturers share all or part of the profits that are predetermined to be in “excess.” This type of pricing method operates well in systems where pharmaceutical manufacturers can accurately ascertain what portion of the profits are derived from the payer in question. The largest challenge in profit-sharing schemes is defining the “appropriate” profit limit. One example of profit sharing is the Pharmaceutical Price Regulation Scheme (PPRS)<sup>18</sup> in the United Kingdom (U.K.).<sup>19</sup>

The PPRS regulates the pharmaceutical prices and profits of branded (non-generic) drugs in the U.K. for the National Health Service (NHS).<sup>20</sup> Price and profit

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<sup>16</sup> For more details on the legality of prescription drug importation, see CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Jody Feder. For more details on the safety and policy issues regarding prescription drug importation, see CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by Susan Thaul and Donna U. Vogt.

<sup>17</sup> For more information, see Ceci Connolly, *Pfizer Cuts Supplies to Canadian Drugstores*, Washington Post, February 19, 2004, A10. Also see Theresa Agovino, *GlaxoSmithKline Threatens to Cut Off Drug Sales to Canada*, The Associated Press, January 10, 2003.

<sup>18</sup> For additional details on the PPRS, see from the U.K. Department of Health, *The Pharmaceutical Price Regulation Scheme*, November 2004. Available at [<http://www.dh.gov.uk/assetRoot/04/09/32/32/04093232.pdf>]. Accessed December 18, 2006.

<sup>19</sup> The “risk corridors” designed for the Medicare Part D plans are an example of profit sharing used in the U.S. health care system, and limit both the profits and losses of the Medicare Part D drug plans. The plans receive what is essentially an actuarially based premium for each Medicare enrollee that is based on expected cost. At the end of the calendar year, the CMS compares the expected and actual costs of drug plans. If the actual costs exceed the expected costs by the pre-determined percentage, then the plans are partially compensated with additional federal payments. On the other hand, if the expected costs exceed the actual costs by the pre-determined percentage, then the plans share these “excess” profits with the federal government.

<sup>20</sup> Note that the U.K. uses the term “profit controls” rather than “profit sharing.”

schemes are arrived at through negotiations every five years<sup>21</sup> between the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry, and the U.K. Department of Health.<sup>22</sup> The profit-sharing scheme specifies that any profits in excess of the agreed upon return-on-capital threshold<sup>23</sup> must either be repaid to NHS, or the company must lower existing and future prices. This type of profit sharing provides a strong incentive for manufacturers to set their prices so that profits do not exceed the return-on-capital threshold. To help enforce the return-on-capital limits, the current scheme creates a tiered system of profit reporting and financial transparency requirements.<sup>24</sup>

## Value-Based Pricing

Value-based pricing sets drug prices using a relative value metric, where each drug is compared to other drugs to assess whether the improved safety profile or efficacy is worth the additional cost. Cost-effectiveness<sup>25</sup> and cost-benefit<sup>26</sup> analysis are both examples of relative value metrics. While value-based pricing is not traditionally used in other countries as a method of pricing drugs, and instead has a greater role in formulary development, the term “value-based pricing” is nonetheless used in this report so as to be consistent with other papers and reports on the topic. Other reports, and academics in particular, have suggested “value-based pricing” as a way for manufacturers, specifically biotechnology companies, to price their products.<sup>27</sup> Countries have primarily used value-based pricing in conjunction with other pricing methods, yet in theory this method could also operate singly and be used by governments to establish drug prices.

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<sup>21</sup> The latest scheme of prices came into effect in January 2005.

<sup>22</sup> Individual manufacturers can choose whether or not to participate in the negotiated scheme, but non-participants do not have their drugs covered by NHS. The U.K. system does not dictate the manufacturers’ drug prices. Rather, pharmaceutical manufacturers can set any price for their product at the beginning of a scheme term but the U.K. Department of Health must agree to any price increases during the term.

<sup>23</sup> For the current scheme, the allowable return-on-capital is 21% a year.

<sup>24</sup> The current scheme specifies that any manufacturer with total NHS sales less than £5 million per year is not required to provide financial information. Any manufacturer with total NHS sales between £5 and £25 million per year is required to provide a copy of its audited accounts, which provides the breakdown of NHS and non-NHS sales. Manufacturers with sales for the NHS in excess of £25 million are required to submit to the Department of Health all data on sales, costs, assets, and profitability.

<sup>25</sup> Cost-effectiveness is typically assessed by dividing the additional dollars a drug costs by the additional quality adjusted life years (QALYs) a drug provides, to arrive at a \$/QALY ratio.

<sup>26</sup> Cost-benefit is assessed by first determining the monetary value of the “benefits” gained from the drug and then subtracting the costs of the drug from the “benefits.”

<sup>27</sup> For more information, see James C. Robinson, “Biotech: Value-Based Pricing in Biotechnology,” *Health Affairs Blog*, October 23, 2006. Available at [<http://healthaffairs.org/blog/2006/10/23/biotech-value-based-pricing-in-biotechnology>]. Accessed December 18, 2006.

In practice, value-based pricing has primarily been used as a way to determine the status of a drug (i.e., preferred, restricted use, excluded) in the country's health coverage and reimbursement scheme. Drug prices are typically set prior to evaluating a drug's status on a formulary, but, in theory, prices also could be set using value-based pricing. Discussions of value-based pricing have been raised in the U.S. with particular regard to pricing of biotechnology products, such as the \$50,000+ costs per patient per year for new cancer products.

The crux of the problem with this method is that the definition of "value" can be subjective. It requires establishing how much the payer will pay for improvements in health and drug safety profiles. Value-based pricing also requires defining an "appropriate" comparison drug. A cancer drug that costs \$35,000 per patient per year would appear to be a bargain if compared to the drugs costing \$50,000+ per patient per year. Would this be an "appropriate" comparison? How many additional years of life would the \$50,000 drug need to provide in order to justify its cost?

The U.S. Public Health Service convened a panel of experts in 1993 to provide recommendations for conducting cost-effectiveness analyses and assessing the "value" of new medical technologies, including drugs.<sup>28</sup> The panel of experts included physicians, economists, philosophers, as well as other prominent researchers. The panel provided good guidance on what should and should not be included in cost-effectiveness analyses, but only *suggested* an appropriate amount to pay for improvements in health and drug safety profiles. They also left the door open for researchers to use *any* drug (or other medical technology) as the comparison drug.

The recommendations from the panel set the standard for high-quality academic research in the cost-effectiveness of medical technologies and, with only minor revisions, the same standards are used today — 14 years later. Despite its prolific use in the academic literature, cost-effectiveness analysis and other value-based decision tools have struggled to gain a strong foothold as a tool for drug coverage and reimbursement decision making in U.S. government programs.<sup>29</sup> Part of the struggle to use value-based decision tools in this manner stems from the difficulties in defining value and appropriate comparison groups.

Australia addressed this challenge of defining the "appropriate" comparison drug by allowing pharmaceutical manufacturers to select the comparison drug. Specifically, a manufacturer that wishes to list its drug on the Australia

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<sup>28</sup> The recommendations can be found in Marthe R. Gold, et al., "Cost-Effectiveness in Health and Medicine," Oxford University Press, 1996.

<sup>29</sup> For more information on the historical use of value-based decision making in the Agency for Healthcare Research and Quality (AHRQ) and the Medicare Coverage Advisory Committee, see Wilhelmine Miller, "Value-Base Coverage Policy in the United States and the United Kingdom: Different Paths to a Common Goal," *National Health Policy Forum*, November 29, 2006. For more information on the historical use of value-based decision making in the Oregon Health Plan, see T. Bodenheimer, "The Oregon Health Plan — Lessons for the Nation — First of Two Parts," *New England Journal of Medicine*, August 28, 1997; 337 (9) 651-656, and T. Bodenheimer, "The Oregon Health Plan — Lessons for the Nation — Second of Two Parts," *New England Journal of Medicine*, September 4, 1997; 337(10) 720-723.

Pharmaceutical Benefits Scheme (PBS),<sup>30</sup> the formulary for the Australia national health system, first selects the comparison drug. Then, the Pharmaceutical Benefits Advisory Committee (PBAC) weighs the relative cost and effectiveness of the drugs and decides whether to recommend including the manufacturer's drug in the PBS.

The U.K.'s National Institute for Clinical Excellence (NICE) takes a different approach, allowing committees, which are comprised of academic and NHS experts, to determine the "appropriate" comparison drugs.<sup>31</sup> NICE is a quasi-independent organization that assesses the cost-effectiveness of treatments in the U.K, and provides guidance on treatments for patients using the NHS. Drugs receiving positive recommendations tend to have cost-effectiveness ratios below \$46,000 per quality adjusted life year (QALY), but NICE has not defined a strict cut-off ratio for distinguishing drugs that add "value" from those that do not. Instead, NICE recommendations use cost-effectiveness as *one* factor in their recommendations. Even though NICE recommendations weigh the drug costs compared to the benefits, the recommendations do not explicitly factor in affordability and NHS budget constraints. Thus, a drug costing \$50,000 may receive a positive NICE recommendation if it provides enough benefit to produce a favorable ratio.

The explicit separation, between NHS budget constraints and NICE recommendations, may partially explain the less authoritative role NICE has in the U.K. compared to the role PBS has in Australia. In contrast to the PBS, NICE only recommends, and does not determine, whether the treatments should be included in the NHS formulary. Regardless of the NICE recommendation, treatments can not be denied to U.K. patients who are shown to need them. One of the goals noted by the U.K. PPRS is to promote the uptake of effective new medicines that have received a positive recommendation from NICE; however, non-positive appraisals for a drug do not explicitly result in punitive actions, such as exclusion from the NHS formulary.

## Conclusions

Understanding the drug pricing policies of other countries helps to inform drug pricing discussions in the U.S. The pricing policies used by other developed countries, specifically Canada, Australia, and European nations, are challenging to implement. The "noninterference" provision in the MMA and Food and Drug Administration laws prevent these policies from being implemented by the federal government for Medicare at the present time. Legal constraints and market share are

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<sup>30</sup> For more details on PBS, see Australian Government Department of Health and Ageing, *PBS - How do drugs get on the scheme?* Available at [<http://www.health.gov.au/internet/wcms/publishing.nsf/content/health-pbs-general-pbs-phbenbir.htm>]. See also Amanda Biggs, *Pharmaceutical Benefits Scheme - An Overview*, Department of Parliamentary Library: Canberra (January 2003). Available at [<http://www.aph.gov.au/library/INTGUIDE/SP/pbs.htm>]. Last accessed December 18, 2006.

<sup>31</sup> For a thorough description of NICE and its responsibilities, see Wilhelmine Miller, "Value-Based Coverage Policy in the United States and the United Kingdom: Different Paths to a Common Goal," *National Health Policy Forum*, November 29, 2006.

the two primary determinants to which payers can effectively implement the policies. With the 110<sup>th</sup> Congress facing the issue of Medicare drug pricing, clarifying the characteristics of each policy may help to elucidate possible pricing options.