

# Reference Pricing For Drugs: Is It Compatible With U.S. Health Care?

Reference pricing in the United States would be consistent with current efforts to change private coverage, and possibly Medicare, from a defined-benefit approach to a defined-contribution approach.

by **Panos Kanavos and Uwe Reinhardt**

**ABSTRACT:** To control spending on prescription drugs, health insurance systems abroad have experimented in recent years with a novel form of patient cost sharing called “reference pricing.” Under this approach, the insurer covers only the prices of low-cost, benchmark drugs in therapeutic clusters that are deemed to be close substitutes for one another in treating specific illnesses. Patients who desire a higher-price substitute in a cluster must then pay the full difference between the retail price of that drug and the reference price covered by the insurer. This paper explores the difficult trade-offs that policymakers must make in designing such a system, drawing where relevant from experience abroad.

INSURERS HAVE THREE METHODS for requiring patients to share the cost of covered prescription drugs. First, they can require patients to make a fixed copayment per prescription that is independent of the price the insurer pays the dispensing pharmacy. Second, they can require patients to pay a fixed coinsurance percentage of that price. (Both methods may be “tiered” by requiring lower copayments or coinsurance rates for drugs that are “preferred” by the insurer.) Third, insurers can require patients to pay the full difference between the retail price charged at the pharmacy and a so-called reference price reimbursed by the insurer, the latter being the price of a low-cost drug in a therapeutic cluster of drugs thought to be clinically equivalent—or at least similar—in the treatment of the illness in question.<sup>1</sup> In principle, to help control the volume of drugs used, the insurer could reimburse only a fraction (say, 80 percent) of the reference price of the low-cost drug, thereby grafting coinsurance onto reference pricing.

The first method, fixed copayments, insulates patients completely from the full retail prices insurers pay for prescription drugs. Advocates of “consumer-driven”

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health insurance may view this as a major shortcoming. Other policy analysts, however, score it as an advantage. In her critique of reference pricing, for example, Patricia Danzon argues that with the copay method, “patients face only a limited surcharge for nonpreferred drugs, hence have better insurance. This should lower the administrative cost of appeals and preserve incentives for manufacturers to develop improved drugs in established classes.”<sup>2</sup>

Although reference pricing (RP) has long been used by insurers for durable items such as eyeglasses or wheelchairs, its application to prescription drugs is more novel. Germany’s Statutory Health Insurance System, generally viewed as the pioneer in this regard, introduced RP for prescription drugs in 1989, which was followed in Europe by the Netherlands in 1991, Denmark and Sweden in 1993, Spain in 2000, and Belgium and Italy in 2001. Norway adopted RP in 1993 but abandoned it in 2001 because the expected cost savings did not materialize.<sup>3</sup> Outside of Europe, RP has been adopted by Australia, the Canadian province of British Columbia, and New Zealand.<sup>4</sup> In a recent edition of this journal, Haiden Huskamp and colleagues proposed that RP be adopted by U.S. Medicare as well, should Congress add a drug benefit to that program.<sup>5</sup>

With appeal to the standard economic theory of consumer choice, the proponents of RP for prescription drugs see it as a form of fair and efficient market competition that can avoid altogether price regulation by government and make “consumers and physicians (as agents of consumers) sensitive to the relative prices of drugs used to treat a particular illness.”<sup>6</sup> Opponents argue that patients may not have the information required for an efficient RP system and may opt for less-than-optimal drug therapy. That response, argue the critics, would be not only inefficient but also inequitable, as low-income families are more likely to respond that way than high-income families are. These opponents also warn that RP could effectively vitiate the intent of patent laws and, in any event, reduce the drug industry’s incentives to invest in research and development (R&D).<sup>7</sup>

In this paper we explore the analytically complex and politically sensitive decisions that would have to be made by U.S. policymakers should they embrace the idea of RP. We draw on the experience of RP systems abroad (especially Germany), although we cannot offer detailed and comprehensive descriptions of these systems within the limits of this paper.<sup>8</sup> Thereafter we comment on what research would be required to evaluate properly the operation of RP systems from the viewpoint of health policy, on the obstacles faced by that research, and on what is known about the effect of RP on the cost and quality of health care.

## **Basic Design Parameters Of An RP System**

In designing an RP system for prescription drugs, policymakers must make a number of difficult trade-offs on several crucial facets of the structure: (1) its scope and administrative structure; (2) the principles on which the breadth of the therapeutic clusters are set (including whether on-patent drugs are to be in-

cluded); and (3) the rules for setting the reference price for each group.

■ **Scope and administrative structure.** An RP system may be national in scope, as it is in most other nations, or it could be more decentralized, as it would be if U.S. private insurers each constructed their own RP system and, as Danzon proposes, if government insurance programs relied on competing private pharmacy benefit managers (PBMs) to administer these programs' drug benefits.<sup>9</sup>

As shown in Exhibit 1, most RP systems abroad are highly centralized. In Germany, until mid-2001, the grouping of drugs into therapeutic clusters was performed by a national committee, for the entire Statutory Health Insurance System, with equal representation of physicians and the nongovernmental, nonprofit sickness funds (Bundesausschuss Ärzte und Krankenkassen). The reference price for each group was then set for all sickness funds in the entire country by the federal associations of the several major types of sickness funds in the system. Australia, too, operates its RP system as part of its national, government-subsidized Pharmaceutical Benefits Scheme (PBS) under which patients have access to a list of government-subsidized drugs deemed necessary and cost-effective, albeit subject to copayments.<sup>10</sup> Formally, the Australian minister of health and ageing operates the RP system for the entire national health system, albeit on the advice of nongovernmental advisory committees that include medical practitioners, pharmacists, consumer representatives, and health economists. The RP system (Pharmicare) of British Columbia is administered by that province's government.

*Pros and cons of centralization.* A highly centralized RP system is likely to reduce the system's administrative costs and to be less confusing to patients and physicians than a more decentralized system would be. It would shift relatively more market power from the supply side of the market for prescription drugs to the demand side, thereby increasing the downward pressure that the demand side can exert on drug prices.

Such a system, however, would diffuse errors in composing the therapeutic clusters or the setting of reference prices throughout the entire health system. A more decentralized system would limit the impact of such errors on individual manufacturers. From the perspective of a manufacturer's capital budgeting for investments in R&D, a highly centralized RP system therefore would likely add to the uncertainty surrounding the future cash flow expected from new drug launches, which in turn would make investments in R&D less financially attractive, other things being equal.

*Opposition to centralization.* Because of the market clout it allocates to the demand side, and the greater uncertainty it visits on the cash flow of individual drug manufacturers, a highly centralized RP system would be likely to maximize opposition to the method by the pharmaceutical industry, which would also be likely to seek relief in the political arena and before the courts. The German pharmaceutical industry, for example, has fought that nation's centralized RP system in the courts on the ground that it violates German antitrust laws, the Maastricht Treaty

## EXHIBIT 1 Features Of Reference Pricing Models In Selected Countries, 2002

Country	Administration	Scientific principle for setting the reference price	Reference price <sup>a</sup>	Includes patented products <sup>b</sup>
Germany	Central (initially Association of Sickness Funds; subsequently Ministry of Health) <sup>c</sup>	Chemical and pharmacological equivalence	Not higher than the lower third of prices in the cluster group	No <sup>d</sup>
Australia	Central (Ministry of Health and Ageing) <sup>e</sup>	Chemical, pharmacological, and therapeutic equivalence	Lowest of each defined cluster	1st phase: No 2nd phase: Yes
British Columbia	Provincial (administered by province's drug benefit program, Pharmacare)	Chemical, pharmacological, and therapeutic equivalence	Lowest of each defined cluster	Yes
Italy	Central (Ministry of Health, on advice by its Pharmaceutical Committee, CUF)	Chemical and pharmacological equivalence	Lowest available generic	No
Spain	Central and regional <sup>f</sup>	Chemical and pharmacological equivalence	Weighted average of cheapest alternatives accounting for 20% of retail market by volume	No
The Netherlands	Central (Ministry of Welfare, Health, and Culture) <sup>g</sup>	Chemical, pharmacological, and therapeutic equivalence	Multitier averaging of cluster products	Yes

**SOURCE:** Authors' analysis.

<sup>a</sup> The criteria on which the reference price is calculated also may vary by country and may include one or more of the following: active ingredient, identified standard pack and units per standard pack, cost per Defined Daily Dosage (DDD), daily or monthly maintenance cost (weighted or unweighted), formulation/strength, and mode of administration.

<sup>b</sup> At the time of its introduction.

<sup>c</sup> Until mid-2001 the grouping of drugs into "equivalent" clusters was performed by a national committee with equal representation of physicians and sickness funds. Reference prices were set for all sickness funds in the entire country, by the federal associations of sickness funds in the Statutory Health Insurance System. See text for details.

<sup>d</sup> The German reference price system also envisaged its introduction in three steps; whereas step one did not include on-patent products, steps two and three envisaged their inclusion. German courts ruled against including on-patent products in reference clusters in January 1996. Germany's government now proposes to remove this protection of on-patent drugs from reference pricing once again. A bill to that effect has already passed the Bundestag (roughly analogous to the U.S. House of Representatives) and awaits consideration by the Bundesrat (roughly analogous to the U.S. Senate).

<sup>e</sup> The minister's decision is based on the recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC), a twelve-member advisory committee that includes physicians, pharmacists, consumer representatives, and health economists, on which medical products qualify for the government's Pharmaceutical Benefits Scheme (PBS) list of subsidized drugs.

<sup>f</sup> In Spain the Ministry of Health and Consumption sets national reference prices. Given the decentralized nature of the Spanish health care system, Andalusia, one of its autonomous regions, has announced the implementation of its own version of reference pricing, which sets prices 17 percent on average lower than the national version.

<sup>g</sup> The secretary of state for welfare, health, and cultural affairs is responsible for classifying products into lists, based on the advice of the Medicines Reimbursement Limits Commission of the Sickfund Council.

of the European Union, and the German constitution. After an initial ruling against Germany's RP system by the Federal German Social Court (Bundessozialgericht) in 2001, both the clustering of drugs into groups and the setting of reference prices have been transferred to the federal government, effective July 2001, and at least until the end of 2003, to sidestep the antitrust issue.<sup>11</sup> More recently,

the Federal Constitutional Court (Bundesverfassungsgericht) ruled on 17 December 2002 that the original administration of the RP system was constitutional after all, which means that the system may revert to its original administrative structure after 2003.<sup>12</sup>

*Implications for the U.S.* The lesson for U.S. policymakers is that a highly centralized RP system carries with it major hurdles to implementation. In opposing such a scheme, the pharmaceutical industry would be able to marshal an array of economists who would present standard capital-budgeting models demonstrating RP's deleterious effects on investments in R&D.<sup>13</sup> Finally, if a centralized RP system nevertheless were chosen for a public insurance program in the United States, allied science policies should be pursued to encourage innovation in drug therapy, for example, by keeping truly innovative products outside of the RP system and rewarding them with commensurately higher prices.

■ **Breadth of therapeutic clusters.** The construction of therapeutic clusters for RP is by far the most controversial task in the development of such systems. These clusters may be narrowly or broadly defined: (1) products with the same active chemical ingredients, (2) products with chemically related active ingredients that are pharmacologically equivalent, and (3) products that may be neither chemically identical nor pharmacologically equivalent but have comparable therapeutic effects.

By its nature, the first type of cluster includes only off-patent brand-name drugs and their generic substitutes. The second and third may include on-patent drugs, especially the so-called me-too drugs with only slightly altered molecules, although they may have somewhat superior attributes to the drugs they replace. Policymakers may theorize that by subjecting "me-too" drugs to pricing pressure from RP, they can induce drug manufacturers to shift their R&D investments more to truly innovative products that would not come under RP, which might serve to increase the social rate of return to such investments.

*Impact on innovation.* The inclusion of on-patent drugs in RP probably is the main source of controversy over the RP method. Commenting critically on Huskamp and colleagues' proposal to use RP for the U.S. Medicare program, for example, Danzon argues that the consumer-driven price competition unleashed by RP would be fair and efficient only if all drugs in a therapeutic class were, in fact, perfect substitutes for one another (the first type of cluster), rather than products with different compounds that may have different attributes (the second and third type of clusters). "In theory," she continues, "patients could pay a surcharge for a superior product, but physicians may be reluctant to spend the time (unreimbursed) to explain the differences. Evidence from other countries indicates that brand prices typically drop to the reference price, which under [Huskamp and colleagues'] proposal would typically be a generic. Thus, reference pricing effectively eliminates patent protection for new drugs as soon as a generic becomes available for any drug in the same product class, because the generic price becomes the reference price, which in turn becomes a price ceiling on other drugs

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in the class.”<sup>14</sup> That dire conclusion seems widely shared among critics of RP. In their “Review of the Literature on Reference Pricing,” Guillem Lopez-Casasnovas and Jaume Puig-Junoy flatly state that “the literature unanimously agrees on the potential negative incentives for pharmaceutical innovation when patented products are covered by RP.”<sup>15</sup> Elsewhere Danzon notes: “Whether [the collapse of prices toward the relevant reference price] reflects physicians’ unwillingness to pay a time price [for instructing patients], rather than patients’ unwillingness to pay an excess charge, unfortunately cannot be determined from the available data.”<sup>16</sup>

The argument that RP per se “effectively eliminates patent protection” and will stifle innovation in drug therapy is not immediately obvious and requires further exploration. Patent laws are meant to help research-based manufacturers recover their R&D investments, but only to the extent that they yield to society commensurate value. If patented drugs in a therapeutic cluster really have better attributes than their generic substitutes, then patients ought to be willing to pay an out-of-pocket premium for the added value.

*Patients’ willingness to pay for added value.* To be explained, then, is why patients do not see the added value that manufacturers claim for patented drugs in therapeutic clusters, or why they are unwilling to pay for that value if they do see it. Is this behavior triggered strictly by RP, or would it be manifest also in a market without insurance coverage—because information about product quality is imperfect in most markets for pharmaceuticals, perhaps because physicians themselves lack reliable information on the attributes of rival prescription drugs or fulfill their role as the patients’ agents imperfectly?<sup>17</sup> If so, one can ask whether the market for prescription drugs—or for many other forms of health care—can ever work efficiently, unless some third party steps in to undertake the proper benefit-cost calculus on behalf of patients and operates a payment system that reflects it—in plain English—or unless health care is “managed” by experts from outside the doctor-patient relationship. The implication of either scenario is that the idea of “consumer-driven” health care, increasingly popular among U.S. policymakers, is doomed to fail.

*Physicians’ role.* Critics of RP believe that the crux of the problem lies in an imperfect agency role on the part of physicians. Danzon, for example, points out that in some countries (such as Germany) physicians are required by law to justify to patients the prescription of drugs priced above the reference price for “referenced” drugs, which is not required for “nonreferenced” drugs.<sup>18</sup> Perhaps to save time, physicians therefore will either gravitate to the generic that requires no copayment or to nonreferenced drugs that may require copayments but not an explicit

justification to patients. Can that hypothesis alone explain why drug prices within therapeutic clusters under RP tend to collapse toward the reference price?

Further insight on this question might be had in the future from the newly emerging behavioralist school of economists who are more comfortable than are mainstream economists in thinking outside the confines of neoclassical economic theory.<sup>19</sup> Conceivably, the very existence of a reference price system may alter the perceptions and behavior of either patient or physician in predictable ways that might not be predicted by standard consumer-choice theory. For example, the availability of a drug at zero cost to the patient may act as so powerful a signal that it draws attention away from the attributes of other drugs in the therapeutic cluster. Alternatively, the grouping of prescription drugs into therapeutic clusters by panels of clinical experts may alter the physician's previous evaluation of these drugs, which may have been highly subjective and have rested on sketchy information or casual empiricism. Indeed, future studies of RP should explore also exactly how, and on what information base, physicians have traditionally formed their opinions of various drugs, in the absence of reference pricing, and which perception is more accurate, the physician's or that incorporated in the therapeutic clusters used in reference pricing.

*Equity concerns.* Finally, critics of broad therapeutic clusters under RP fault them not only for their deleterious impact on innovation, but also on grounds of equity. Martin Egler and Robert Geursen, for example, argue that low-income patients may not be able to afford a higher-price drug that, for genetic or other reasons, may be more effective for them than lower-cost generic substitutes in the same cluster.<sup>20</sup> Danzon makes the same point, as do Lopez-Casasnovas and Puig-Junoy.<sup>21</sup>

The proponents of RP must forthrightly acknowledge the possibility that RP may visit inequities on patients. Such inequities are more likely to occur, the broader the therapeutic clusters for which reference prices are set. Inequities among patients, however, are not unique to RP for prescription drugs. They are inherent in all of the "defined-contribution" models for health insurance (also called "consumer-driven") that are now being developed by U.S. private health insurers. By design, these models seek to put the patient's "skin in the game," as the saying goes, a strategy that may induce especially lower-income households to settle for less than the most effective medical treatments, not only in drug therapy, but many in other forms of therapy as well. To be logically and ethically consistent, then, critics who fault the application of RP to prescription drugs over the issue of equity presumably would also decry the entire idea of consumer-driven health care.

*Implications for U.S. policymakers.* The bottom line of this lengthy discussion for U.S. policymakers is that the optimal breadth of therapeutic clusters for RP is an issue far from settled among policy analysts, who, so far, have debated it mainly at the level of conflicting theories. Whether patients, especially low-income patients, actually would fare worse under an RP system with even fairly wide clusters depends crucially on their insurance coverage prior to the introduction of RP,

on the quality of the information about prescription drugs available to them prior to the introduction of RP, and on the diligence of physicians as their patients' agents under the status quo.<sup>22</sup> As Mark Roberts has observed on this point, "The mere fact that RP alters patients' incentives does not automatically mean it will produce worse outcomes than whatever system it replaces."<sup>23</sup> This point is all too frequently overlooked in the debate on RP.

From a practical perspective, however, it is safe to conclude that the wider the therapeutic clusters in an RP system, the more likely will they evoke stiff opposition from the pharmaceutical industry, on the grounds that RP is inequitable among patients and will stifle innovation in drug therapy, especially if the clusters include on-patent drugs.<sup>24</sup>

■ **Setting the reference price.** Upon completion of the negotiations that lead to the establishment of the relevant therapeutic clusters for RP, a reference price must be set for each such cluster. This task turns out to be technically complex, and strategic facets of it are politically controversial.

The more technical aspect of this task involves setting reference prices for different package sizes and dosages of the benchmark drug. In Germany, for example, reference prices for different combinations of package size and dosage are statistically derived from regressions whose dependent variable is the manufacturers' price for a given dosage and package size, and the explanatory variables are dosage strength (mg per tablet) and package size (tablets per package).<sup>25</sup> In the Netherlands, the reference price is normalized on a modified version of the World Health Organization's "standard daily dose," an approach, however, that has been criticized because it can lead to economically perverse outcomes.<sup>26</sup>

*Which set of prices to use.* The strategic part of setting the reference price involves two separate facets. First, in the United States, a decision would have to be made whether the prices to be used for that purpose should be the market prices of drugs generated in the private sector of the economy, or prices negotiated with suppliers, or prices determined through competitive bids solicited by government. If market prices from the private sector were to be used, the question is which of the plethora of such prices for each drug (of a given package size and dosage) ought to be used to set the reference price—the lowest price achieved by some buyer in the private economy, or some weighted average of private-sector prices. There is the added problem of collecting actual transaction prices, rather than the often fictitious average wholesale price (AWP) and average selling price (ASP) reported to the government for payment purposes.

*Where to set prices.* Whatever set of prices ultimately would be used for this purpose, there next comes the question of where in the resulting distribution of product prices for a given therapeutic cluster should its reference price be set: at the minimum price in the distribution, or somewhere higher up in the distribution (for example, at the median, or at the weighted or unweighted average).

If the chosen reference price is the lowest price in the distribution (as it is in

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Australia, New Zealand, and British Columbia), then patients may have to pay out of pocket for most other drugs in the group, unless the prices of all drugs in the cluster have, indeed, collapsed to the reference price.<sup>27</sup> The financial inducement for patients to forgo higher-price drugs in the cluster would be the higher, the more successful the administrators of the RP system were in achieving a low reference price (for example, through competitive bidding). That circumstance, in turn, would be likely to trigger opposition from the pharmaceutical industry. It would also make RP unpopular among patients and their physicians.

On the other hand, if the reference price were located higher up in the distribution, then the power of the RP system to yield cost savings would be blunted, because the retail prices below that reference price could be expected to drift up quickly toward the reference price. Pharmacists might be able to take advantage of this solution, if through a competitive process they could procure drugs sold at the reference price from wholesalers at prices much below the reference price.

Because the setting of prices under RP is of such strategic importance to both insurers and manufacturers, it inevitably tends to be the product of negotiations with the drug industry. German drug manufacturers, for example, appear to have lobbied successfully to move the reference price up in the distribution of prices within therapeutic clusters. An interim reform bill on reference pricing passed by the German parliament in July 2001 stipulates that the reference price within a therapeutic cluster must be set so that “at least one third of all scripts and at least one fourth of all packages are available [to the patient without out-of-pocket payments]; at the same time the sum of the respective percentages of the scripts and packages that are not available at the reference price must not exceed a value of 100.”<sup>28</sup> Evidently, the setting of reference prices can be circumscribed through the political process in highly complex ways, to the point of requiring administrators to be schooled in understanding the art of numerical iteration.

*Implications for U.S. policymakers.* The lesson for U.S. policymakers is that whatever administrative scope an RP system may have, and however wide its therapeutic clusters may be, selecting the reference price for each cluster itself is not only technically daunting but also highly politically sensitive. If RP were applied to Medicare, for example, that task would be no less complex and politically charged than operating the current Medicare payment systems for hospitals and physicians.

## **Evaluating RP Systems**

Ideally, research on the merits of RP systems for prescription drugs would give policymakers conclusive, empirical evidence on the impact of RP jointly on (1) the quality of medical treatments; (2) their overall cost (as distinct from merely the

cost of drug therapy); and (3) the probable long-run progress of innovation in drug therapy. Here we observe that the most efficient cost containment approach for prescription drugs involves a trade-off by policymakers among these three impacts in ways that may appear politically incorrect.

■ **Effectiveness versus efficiency.** Critics of RP for prescription drugs may believe that their case is made if they have shown that RP reduces the clinical effectiveness of drug therapy, relative to some hypothetical ideal or to the status quo. To medical practitioners, and even to politicians, that proposition may seem self-evident. Among noneconomists, policy proposals that explicitly countenance reductions in the quality of health care tend to be dead on arrival.

Economists searching for efficient allocations of resources, on the other hand, judge alternative cost containment policies not merely by their impact on clinical effectiveness, but by their cost-effectiveness. Thus, a policy that raises the quality of care, but also its cost, may be rejected if the added quality cannot justify the associated added cost. Conversely, a policy that reduces both cost and quality may be acceptable on economic grounds if the cost savings achieved thereby can be judged to warrant the sacrifice in quality. On these principles, merely demonstrating empirically or conjecturing theoretically that RP systems might impair the effectiveness of drug therapy is not sufficient by itself to reject that approach.

■ **Empirical evidence on RP.** Unfortunately, empirical research on RP is more challenging than may be supposed by impatient policymakers, for several reasons. First, the impact of an RP system on the three metrics mentioned above (quality, cost of treatments, and innovation) is largely driven by the particular design parameters of the RP system. As noted earlier, these can vary enormously among systems. Second, as noted earlier as well, the impact of any operating RP system on the three metrics depends crucially on the particulars of the prior system it has replaced, which may have been characterized by imperfect agency on the part of physicians and imperfect information all around. Third, the imposition of RP for prescription drugs on a health system typically is accompanied or followed by many other economic or policy changes, which makes it difficult to isolate statistically the impact of the RP system, assuming that all other things had remained constant. Fourth, most RP systems abroad are of relatively recent vintage, so that their long-run impact on innovation in the drug industry cannot be discerned from the short-lived empirical record. Finally, the market for pharmaceutical products is global. The adoption of RP by smaller countries (such as New Zealand or Denmark) is unlikely to have a major impact on the R&D programs of the foreign drug manufacturers that meet these countries' demand for drugs. At the same time, the imposition of RP in larger countries with sizable drug industries (such as Germany) will not affect the large fraction of the industry's revenue that is earned from exports to other countries.

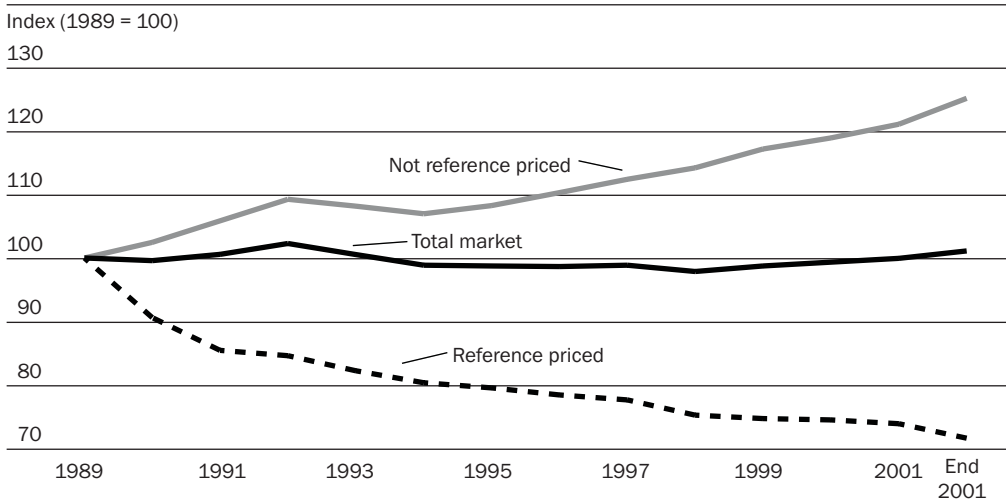
In sum, as one researcher on RP (Eva Pichler) put it, in the jargon of economics: "The appropriate analytical approach [to evaluate RP] would be a full-fledged model of the health sector," which means a complete, econometrically estimated,

mathematical description of a nation's entire health sector, replete with its global linkages.<sup>29</sup> Because that approach will remain infeasible, in practical terms, in the foreseeable future, researchers can at best offer policymakers partial empirical glimpses of the problem. No pretense can be made, however, that a comprehensive summary of that research can be offered within the space of this paper.

*Evidence from Germany.* As noted earlier, Germany's RP system is the oldest such system in operation. In their most recent report on prescription drugs, researchers of the Wissenschaftliches Institut der AOK, the federal research arm of the largest association of sickness funds in Germany, report that since the inception of RP in Germany in 1989, the price index for products under RP, which in 2001 represented 61.4 percent of all prescriptions and 36.8 percent of total spending on drugs, has fallen by about 30 percent over the period 1989–2001. During the same period the price index for products not under RP has increased by 25 percent.<sup>30</sup> Overall, the price index for prescription drugs has remained stable throughout the decade, fluctuating narrowly around its index value of 100 in 1989 (Exhibit 2). That index had risen by 14 percent during 1983–1991.<sup>31</sup> Here it must be added, however, that between 1993 and 1997 Germany's Statutory Health Insurance System was subject to global budget caps for outpatient prescription drugs, a mechanism that was replaced in 2001 by physician-specific guidelines and budgets.<sup>32</sup> In addition, there was a 5 percent price cut and a three-year freeze on the prices of drugs not under RP.<sup>33</sup> These other cost-control measures make it difficult to isolate the impact on spending of the RP system by itself.

*Evidence from British Columbia.* Sebastian Schneeweiss and colleagues conclude

**EXHIBIT 2  
Pharmaceutical Prices In Germany, Indexed To 1989, 1989–2001**



**SOURCE:** K. Nink and H. Schröder, "Der Arzneimittelmarkt in Deutschland," in *Arzneiverordnungs-Report 2002*, ed. U. Schwabe and D. Paffrath (Bonn: Springer, 2002), Figure 52.3.

from their study of British Columbia that RP “achieved a sustained reduction in drug expenditures.”<sup>34</sup> The researchers did not find any changes in the overall use of antihypertensive therapy or in health care use and costs. British Columbia’s Pharmacare itself has estimated that since its implementation in 1995, the Reference Drug Program (RDP) has saved the province approximately CAN\$161 million.<sup>35</sup> British Columbia’s Ministry of Health documents indicate that the policy likely saved the province approximately CAN\$44 million in 1999 alone.<sup>36</sup>

*Evidence from New Zealand.* Evidence from New Zealand’s Pharmaceutical Management Agency (PHARMAC), the agency that negotiates prices with pharmaceutical manufacturers and manages the country’s formulary, suggests that without the agency’s interventions—including, among other things, a restrictive RP system—the drug subsidy bill for 2002 would have been NZ\$473 million higher (or 95 percent of the total actual pharmaceutical expenditure for 2002).<sup>37</sup>

*Other evidence.* Other researchers, however, contend that there is little evidence that RP constrains the growth of prescription drug spending, let alone overall health spending.<sup>38</sup> That conclusion, of course, cannot be inferred simply from increased spending after the imposition of RP, because in its absence spending might have risen even faster. Even so, RP targets only the price component of spending and not volume, which may conceivably increase once prices are reduced.<sup>39</sup> There is also the possibility that physicians who do not wish to deal with the RP system avoid it by shifting their prescriptions into nonreferenced drugs. In any event, Norway, which had implemented an RP system in 1993, discontinued it in 2001, in response to an evaluation commissioned by the Ministry of Health and Social Affairs from a Norwegian consulting firm.<sup>40</sup> The study concluded that Norway’s RP system imposed a net cost on society and recommended that the system be scrapped.

We are not aware of any conclusive empirical studies documenting the impact of RP on clinical outcomes, health status of patients, total system costs (as distinct from spending on prescription drugs), or the pace of innovation in the drug industry.

## Concluding Observations

Critics of RP complain that “to an uniformed public, [RP] seems to be a *simple* and *fair* approach to containing costs in the health sector [which] may explain why the RP system has become popular in many countries.”<sup>41</sup> On its face, this is a fair comment. Unfortunately, these critics typically hold up RP to ideal, theoretical standards of both efficiency and (egalitarian) equity that are not attained by any of the existing arrangements to be replaced by RP. Only rarely does this literature offer more efficient, equitable, and workable alternatives to RP or to existing systems other than tacitly accepting the status quo.<sup>42</sup>

In a thoughtful but hard-hitting essay on “the [economic] theories commonly used to analyze the implication of pharmaceutical cost containment policies, including reference pricing,” economist Mark Roberts argues persuasively that in

this context, these theories “often are applied incorrectly or inappropriately, leading to questionable policy options and preferences.”<sup>43</sup> Roberts, however, also writes off RP as “an imperfect half measure that is inferior to alternative approaches.” Alas, the superior alternative he has in mind turns out to be nothing less than fully capitated, integrated health systems that would give physicians incentives and information to balance against one another the costs of all inputs going into medical treatments, in the form of full-fledged, evidence-based disease management. As the experience of the 1990s showed, Americans do not seem comfortable with this approach, either.

RP for prescription drugs in the United States would be ethically and logically consistent with current efforts to change both private health insurance coverage and, possibly, Medicare from their traditional defined-benefit approach to one based on defined contributions, because reference prices are nothing other than defined contributions toward the purchase of prescription drugs.

**T**HE MAIN LESSON TO BE LEARNED from this paper, however, is that putting in place the basic building blocks of an RP system for prescription drugs is more complicated than may appear at first blush. The task involves a number of politically sensitive trade-offs and a number of technical problems of implementation. Given the importance of the U.S. pharmaceutical industry to the nation’s and, indeed, the world’s health care systems, the uncertainty still surrounding the impact of RP on health care, and the political capital that must be spent to implement such a system, U.S. public policymakers probably will want to venture cautiously into this terrain. It would mean, at the least, shying away from highly centralized RP systems, at least initially, and also from broad therapeutic clusters, until further empirical research on this still rather novel cost containment approach (ideally funded by independent foundations) can better inform public policy on its long-run effect on quality, cost, and innovation in health care.

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*The authors are grateful to four anonymous referees and to Don Metz of Health Affairs. Panos Kanavos gratefully acknowledges the support of the Commonwealth Fund. The views presented here are those of the authors and not necessarily those of the Commonwealth Fund, its directors, officers, or staff.*

## NOTES

1. In most nations the insurer pays its share directly to the pharmacy or other retailer. In principle, the insurer could make patients pay the full price at the pharmacy or other retail outlet and then claim reimbursement from the insurer. The incentives facing the insured patient would be the same, although under the reimbursement mode the patient would at least know the full retail price.
2. P.M. Danzon, "Pharmaceutical Benefit Management: An Alternative Approach," *Health Affairs* (Mar/Apr 2000): 24–25, quote at 25.
3. B. Jönsson, "Reference Pricing: Central Economic and Policy Issues," in *Reference Pricing and Pharmaceutical Policy*, ed. G. Lopez-Casasnovas and B. Jönsson (Barcelona: Springer Verlag Ibérica, 2001), 82–83.
4. D.J. Birkett, A.S. Mitchell, and P. McManus, "A Cost-Effectiveness Approach to Drug Subsidy and Pricing in Australia," *Health Affairs* (May/June 2001): 104–114; Government of British Columbia, "Pharmacare Low Cost Alternative Reference Drug Program Booklet," 15 January 2003, [www.healthservices.gov.bc.ca/pharme/outgoing/booklet.pdf](http://www.healthservices.gov.bc.ca/pharme/outgoing/booklet.pdf) (March 2003); and R. Braae, W. McNee, and D. Moore, "Managing Pharmaceutical Expenditure while Increasing Access: The Pharmaceutical Management Agency (PHARMAC) Experience," *Pharmacoeconomics* (December 1999): 649–660.
5. H.A. Huskamp et al., "The Medicare Prescription Drug Benefit: How Will the Game Be Played?" *Health Affairs* (Mar/Apr 2000): 8–23.
6. *Ibid.*, 13.
7. See Lopez-Casasnovas and Jönsson, eds., *Reference Pricing and Pharmaceutical Policy*.
8. A more detailed survey of these systems can be found in G. Lopez-Casasnovas and J. Puig-Junoy, "Review of the Literature on Reference Pricing," in *Reference Pricing*, ed. Lopez-Casasnovas and Jönsson, 1–41.
9. Danzon, "Pharmaceutical Benefit Management," 25.
10. L.N. Sansom, "Reconciling Rising Health Care Costs and Getting Value for Money" (Paper presented at the Commonwealth Fund 2002 International Symposium on Health Policy, Washington, D.C., 23–25 October 2002).
11. The law mandating this change is effective only until the end of 2003, at which point new arrangements are to be legislated if RP is to continue beyond that point. In the meantime, the Ministry of Health has been asked by Parliament to make recommendations for a new, constitutionally acceptable arrangement.
12. "Verfassungsrichter bestätigen Festbetragsverfahren," *G+G Blickpunkt* (December 2002): 1.
13. See, for example, E. Pichler, "Is Reference Pricing Based on Economic Criteria?" in *Reference Pricing*, ed. Lopez-Casasnovas and Jönsson, 50–54, and other essays in that volume.
14. Danzon, "Pharmaceutical Benefit Management," 25.
15. Casasnovas and Puig-Junoy, "Review of the Literature," 13.
16. P.M. Danzon, "Reference Pricing: Theory and Evidence," in *Reference Pricing*, ed. Lopez-Casasnovas and Jönsson, 86–126.
17. See, for example, A. Maynard and K. Bloor, "Dilemmas in Regulation of the Market for Pharmaceuticals," *Health Affairs* (May/June 2003): 31–41.
18. Danzon, "Reference Pricing," 100–101.
19. For example, Princeton psychologist Daniel Kahneman received the Nobel Prize in economics in 2002 for his work in behavioral economics.
20. M. Egler and R. Geursen, "Festbetragsysteme: Triumph der Hoffnung ueber die Wirklichkeit," *Die Pharmazeutische Industrie* 64, no. 4 (2002): 316–323.
21. Danzon, "Reference Pricing," 92–93; and Lopez-Casasnovas and Puig-Junoy, "Review of the Literature," 11–12, 29.
22. Medicaid patients might, in fact, be worse off under RP than they are now under the current program with comprehensive, first-dollar coverage for prescription drugs.
23. M.J. Roberts, "Would We Be Able to Recognize a Socially Desirable Pricing System If It Bit Us in the Ankle?" in *Reference Pricing*, ed. Lopez-Casasnovas and Jönsson, 174.
24. Some critics of RP argue that it stifles innovation even if on-patent drugs are excluded from it. The argument is that brand-name products can typically maintain a premium over generics even after they go off patent, a premium that would be forcefully whittled away under RP. The result is that RP lowers the expected future cash flow from R&D investments whether or not it includes on-patent drugs. See Pichler, "Is Reference Pricing Based on Economic Criteria?"

25. The markup for wholesalers and retailers is regulated in Germany.
26. Danzon, "Reference Pricing," 95. For further detail, see also Lopez-Casasnovas and Puig-Junoy, "Review of the Literature," Tables 2–8.
27. *Ibid.*
28. *Gesetz zur Anpassung der Regelungen ueber die Festsetzung von Festbeträgen für Arzneimittel in der gesetzlichen Krankenversicherung (Festbetrags-Anpassungsgesetz-FABG)* (27 July 2001), sec. 35a (2).
29. Pichler, "Is Reference Pricing Based on Economic Criteria?" 58.
30. K. Nink and H. Schröder, "Der Arzneimittelmarkt in Deutschland," in *Arzneiverordnungs-Report 2002*, ed. U. Schwabe and D. Paffrath (Bonn: Springer, 2002), 859, Figure 52.3.
31. Helmut Schröder, head, German Pharmaceutical Price Index, Wissenschaftliches Institut der AOK (Scientific Research Institute of the Federal Association of the General Local Sickness Funds), personal communication, 13 January 2003.
32. Nink and Schröder, "Der Arzneimittelmarkt," 853–854.
33. Danzon, "Reference Pricing," 99.
34. S. Schneeweiss et al., "Outcomes of Reference Pricing for Angiotensin-Converting-Enzyme Inhibitors," *New England Journal of Medicine* (14 March 2002): 822–829.
35. A. Cassels, "Paying for What Works: BC's Experience with the Reference Drug Program as a Model for Rational Policy Making" (Vancouver: Canadian Centre for Policy Alternatives, March 2002).
36. British Columbia Ministry of Health and Ministry Responsible for Seniors, "Strategic Planning/Pharmacare Briefing Note" (Vancouver: BC Ministry of Health, April 2000).
37. PHARMAC (Pharmaceutical Management Agency), "Annual Review 2002," 2003, [www.pharmac.govt.nz/pdf/AR02.pdf](http://www.pharmac.govt.nz/pdf/AR02.pdf) (20 March 2003).
38. See, for example, J.R. Graham, "Reference-Based Pricing in British Columbia's Pharmacare: A Fiscal Failure," *Fraser Forum* (May 2001): 19; and B. Jönsson, "Reference Pricing: Central Economic and Policy Issues," in *Reference Pricing*, ed. Lopez-Casasnovas and Jönsson, 80–85 (emphasis in original).
39. Maynard, "Reconciling Rising Health Care Costs," 11.
40. ECON Center for Economic Analysis, *Evaluation of the Reference Pricing System for Medicines*, Report no. 44 (Oslo: LMI, 2000).
41. Pichler, "Is Reference Pricing Based on Economic Criteria?" 44–45.
42. A welcome exception is Danzon, "Pharmaceutical Benefit Management."
43. Roberts, "Would We Be Able to Recognize a Socially Desirable Pricing System?" 161.