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### MEDICINE AND SOCIETY 2: PEER-REVIEWED ARTICLE

#### What Should US Policymakers Learn From International Drug Pricing Transparency Strategies?

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##### Abstract

This article analyzes differences in prescription drug pricing transparency practices among 3 Organisation for Economic Co-operation and Development member nations: the United Kingdom, Germany, and Canada. Specifically, this article compares these countries' policies on list and net price disclosures and on how international reference pricing is used to evaluate merits and drawbacks of different pricing transparency approaches. Finally, the article summarizes what policymakers in the United States should learn from these comparisons.

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##### Transparency Cuts Both Ways

High prescription drug prices in the United States (US) are driven by the fact that brand-name drug manufacturers are freely able to **set prices** at the time of launch, whereas in other industrialized countries around the world, prices are more systematically negotiated on the basis of the benefits that the drugs provide. The distinct approach to drug pricing in the US has spurred debate over reforms to bring US drug prices more in line with those in other industrialized countries, since the US spends far more per capita on pharmaceuticals than all other members of the Organisation for Economic Co-operation and Development (OECD).<sup>1</sup>

One area of substantial debate is prescription drug pricing transparency reforms, or efforts to improve the disclosure of drug prices and price-establishment mechanisms.<sup>2</sup> Prescription drug price transparency can be a powerful tool for competition, negotiation by insurers, and patient information and drug selection. However, such measures can also weaken the negotiation positions of certain payers by preventing manufacturers from granting additional, confidential rebates or discounts to certain insurers and not others, as is currently done.

Here, we discuss issues in drug pricing transparency, analyze differences in prescription drug pricing transparency practices among 3 OECD member nations—the United

Kingdom, Germany, and Canada—and summarize what US policymakers should learn from these comparisons.

### Information and Its Uses

Debates over drug pricing transparency tend to focus on 2 key issues: (1) disclosure of *list vs net* prices and (2) how publicly available prices should be or are used. A drug's list price is set by a drug's manufacturer but can be decreased through rebates and discounts to payers to a so-called net price. Rebating or discounting processes might be required by law (eg, as they are for Medicaid, the US state-based health insurer for poor patients) or be implemented by a private insurer or its pharmacy benefit manager.<sup>3</sup> Although net prices are closer to actual prices to payers for drugs, only list prices are disclosed in the US.<sup>2</sup> Broader **drug price transparency** might come in the future, given the issuance of the Transparency in Coverage final rule, which mandates disclosure of historical net and current list prices for prescription drugs (which became effective on January 1, 2022<sup>4</sup>) and a later executive order granting the US Department of Health and Human Services (HSS) authority to enforce price transparency rules in health care organizations.<sup>5</sup>

How price transparency is implemented could affect both US drug prices and drug prices in other countries if the US were to adopt international reference pricing. International reference pricing is the practice of citing a “basket” (eg, a collection of prices) from other countries, usually with comparable economies, to regulate domestic drug prices. The practice gained notoriety in the US when a federal judge blocked an HSS rule that would have used international reference pricing to control spending on prescription drugs paid through Medicare Part B, the US federal government's insurance programs for hospital- or physician-administered drugs to patients over age 65.<sup>6</sup> Congress later focused on a legislative approach to negotiating drug prices.<sup>7</sup> International reference pricing could decrease drug spending by tying US drug prices to lower prices in other countries where they are negotiated based on the clinical benefits those drugs provide. Importantly, the use of international reference pricing could also lead to unintended complications, such as delaying drug entry in other nations and raising list, or even net, prices abroad.

When designing pricing transparency reforms, US policymakers should consider lessons learned from systems in the United Kingdom (UK), Germany, and Canada.<sup>8</sup> These countries are particularly apt comparators due to the distinctive approaches taken in each setting and their similar levels of economic development to the US. Germany and Canada spend the third- and fourth-highest amount per capita, respectively, on pharmaceuticals in the OECD, while the UK spends roughly the OECD median.<sup>1</sup> We sought to evaluate how pricing transparency factors into these countries' price regulation systems and what lessons these cases have for the impact of pricing transparency reforms in the US.

### United Kingdom

In the UK, drug prices are regulated by the Voluntary Scheme for Branded Medicines Pricing and Access.<sup>9</sup> Under the Voluntary Scheme, drug prices are controlled through the UK's National Institute for Health and Care Excellence (NICE).<sup>9</sup> For each product with a new active ingredient, NICE conducts a health technology assessment comparing the cost-effectiveness of the product to existing alternatives to determine whether the National Health Service (NHS) should cover the drug.<sup>9,10</sup> NICE recommendations are binding on the NHS and constrain drug prices by forcing manufacturers to either avoid

selling the drug in the UK or to lower list prices and offer discounts until NICE deems the drug cost-effective.<sup>10,11</sup>

Alternatively, a minority of manufacturers of branded drugs choose to participate in the Statutory Scheme instead of the Voluntary Scheme.<sup>12</sup> Under this scheme, NICE does not evaluate a new drug; the government instead determines a maximum price for the drug, taking into account factors like the drug's development cost, the manufacturer's profit margin, and more.<sup>12</sup>

For generic medications, the UK relies solely on market competition to lower prices, resulting in slightly higher generic prices than in the US.<sup>12,13,14</sup> However, for all drugs, if spending on certain medications causes major budgetary strain for the NHS, prices may further be negotiated down or subjected to competitive bidding.<sup>12</sup>

The UK's pricing mechanisms result in certain price disclosure practices. List prices paid to NHS pharmacy contractors are disclosed in the monthly Drug Tariff released by the government.<sup>15</sup> List prices for NICE-reviewed drugs are also disclosed, and if the drug is deemed cost-effective, the list price becomes the net price.<sup>10,16</sup> However, for pharmaceuticals with non-cost-effective list prices or with prices negotiated by the government or priced through bidding or special discounts, net prices are not disclosed due to the confidentiality of these processes.<sup>17,18</sup> Additionally, the UK does not use international reference pricing but instead relies solely on NICE's framework of tying a product's price to its assessed clinical value—an arrangement known as value-based pricing.<sup>19</sup> Many high-income countries that use international reference pricing reference UK prices, so UK list prices (or disclosed net prices) affect prices beyond its borders.<sup>20</sup>

### **Canada**

In Canada, drug prices undergo government review through a variety of different mechanisms. Patented brand-name medications are regulated at the federal level by the Patented Medicine Prices Review Board (PMPRB), an agency that sets ceilings for drug prices.<sup>17</sup> Net prices are set at the provincial level through negotiations between drug companies and the provinces.<sup>21,22</sup> The Canadian Agency for Drugs and Technologies in Health (CADTH) may make recommendations to payers about the cost-effectiveness of certain medications—an approach similar to NICE in the UK, although, unlike NICE, CADTH's decisions are nonbinding and do not reflect actual net prices.<sup>23,24</sup>

In terms of transparency, in Canada, as in the UK, list prices for drugs are available, while net prices are not because of confidential discounting and negotiations.<sup>18</sup> Canadian list prices for medications can be found in online formularies released by each province.<sup>25</sup> Canada does rely on international reference pricing through the PMPRB, which uses a basket of 11 peer industrialized countries to establish price ceilings for patented medicines.<sup>26</sup> Often, only list prices are available to inform the PMPRB price. The final price ceilings from the PMPRB are also confidential.<sup>26</sup>

### **Germany**

In Germany, manufacturers independently set a new brand-name product's price for the first year of market availability.<sup>9</sup> In subsequent years, prices are negotiated between drug manufacturers and the National Association of Statutory Health Insurance Funds ("Sickness Funds"), an association representing German insurers.<sup>27</sup> For a new product, the Gemeinsame Bundesausschuss (G-BA)—an independent body governing German physicians, hospitals, and health insurers—commissions a government health

technology assessment agency to issue a nonbinding, advisory opinion on whether a new drug is innovative or offers a therapeutic benefit over current products.<sup>27,28</sup> This process of evaluation is similar to the health technology assessment and value-based pricing standards used by CADTH and NICE. If the drug is deemed innovative and has comparators, the Sickness Funds and the drug manufacturer will directly negotiate the maximum reimbursement that insurers will pay for the product, creating a maximum price for the product.<sup>10,27,29</sup> If the product is not deemed innovative, however, the G-BA classifies the drug in an existing therapeutic class and then references the German prices of other current drugs in that class to set the maximum reimbursement for the product—a process of domestic therapeutic reference pricing.<sup>10,27,29</sup>

The nature of the German drug pricing system results in several distinct pricing transparency practices. Unlike in the UK and Canada, in Germany, both list and net prices are publicly available in the Rote Liste, a comprehensive database of drug prices.<sup>29,30</sup> This transparency leads other countries to reference some, but not all, German net prices when negotiating their drug prices,<sup>19</sup> since Germany also selectively uses international reference pricing, like Canada.<sup>27</sup> For example, Germany uses international reference pricing to set ceilings or maximum reimbursements—as proposed in the US and done in Canada—and, in negotiations over the prices of innovative products that lack therapeutic competitors, German negotiators reference a basket of prices from 15 European countries as one factor in negotiations.<sup>14,31</sup>

In sum, different price transparency practices exist across the UK, Canada, and Germany. While these countries release list prices, 2 key differences relate to net price disclosure and reliance on disclosure of prices in other countries.

### **Lessons for US Policymakers**

These examples of pricing transparency regulations abroad contain important lessons for US policymakers. In recent years, political actors have claimed that reforms to price transparency disclosure could help lower US drug prices.<sup>2</sup> For example, efforts to disclose domestic list and net prices in the US could provide information to strengthen insurer negotiating positions and allow cost-exposed US patients to make more **cost-effective decisions**, resulting in lower drug spending.<sup>2</sup> Disclosure could also put public pressure on policymakers to take evidence-based steps to contain prices.<sup>32</sup> Furthermore, as Germany's example shows, net price disclosure can have positive collateral effects, as other countries can reference net prices negotiated on the basis of drugs' clinical value, which are more realistic than list prices.<sup>33</sup> It is estimated that US use of international reference pricing could save the federal government billions of dollars each year.<sup>34</sup> Lastly, although confidentiality can enable manufacturers to maintain higher net prices, some manufacturers argue that confidential negotiations allow them to give larger discounts to certain insurers and improve payers' ability to negotiate lower prices.<sup>2</sup>

However, important practical complications limit the potential of these pricing transparency reforms. First, insurers might misrepresent rebates to prevent disclosure of true net prices.<sup>2,35</sup> Second, despite the fact that many US patients bear direct costs for high-priced drugs, they are often unfamiliar with the nuances of drug pricing and insurance, which hampers their ability to choose cheaper drugs or insurance plans regardless of price transparency.<sup>36</sup> Third, the evidence is inconclusive as to whether drug pricing transparency results in lower drug spending due to several factors, including confidential agreements between various insurers and manufacturers,

nondisclosure of select rebates and discounts, and improper reporting of prices.<sup>2,37</sup> As a result, nations with more reasonable drug pricing systems, such as the UK, Germany, and Canada, do not rely on price transparency alone to limit drug prices. Rather, these states supplement transparency with other approaches, such as negotiations like those led by the German Sickness Funds or health technology assessments like those done by NICE or CADTH. In all 3 cases, price transparency is used as part of a centralized, multimodal approach to tie prices to a drug's clinical value.

Similar implementation challenges would emerge with US efforts to use international reference pricing to cap prices directly. Although US international reference pricing could lower drug spending by using foreign prices to set price ceilings or inform price negotiations,<sup>38</sup> the lack of international net price disclosure in most foreign countries would force US policymakers to reference high foreign list prices, hindering potential benefits from international reference pricing and underscoring the importance of accounting for various price transparency regulations in other nations.<sup>39,40</sup> Moreover, international reference pricing can create delays in market entry abroad, as pharmaceutical manufacturers try to ensure that higher prices are referenced first.<sup>39</sup> One study found that, in the European Union, drugs usually first appear in Germany, followed by either the UK, Austria, or Denmark (not necessarily in that order), and then other countries because this arrangement ensures that other European states reference the high German prices.<sup>39</sup> International reference pricing use in certain countries has also been linked to collateral price increases.<sup>38</sup> US use of international reference pricing could similarly cause delays or collateral drug price increases in foreign drug markets, as the size of the US market could lead drug manufacturers to either delay market entry or to try to hike prices for medications in countries referenced by the US.<sup>39</sup>

Thus, international reference pricing and net price disclosure reforms alone will be insufficient to meaningfully address excessive drug prices in the US. The US should pair these efforts with other reforms to lower net prices more directly. For example, the US could permit national payers like Medicare to negotiate lower drug prices or, ideally, employ value-based pricing frameworks to decrease net prices by tying them to drugs' clinical value. These efforts should supplement pricing transparency reforms to address unnecessary spending on brand-name drugs more effectively.

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