

FROM THE FIELD

Closing The Doughnut Hole: No Easy Answers

Using cost-effectiveness analysis would be a better strategy than opening up drug importation into the United States.

by **Patricia M. Danzon**

ABSTRACT: The price differentials reported by Gerard Anderson and colleagues are not fully representative and are probably biased upward. If Congress does seek to reduce drug prices, there are no simple, effective, and efficient strategies. The most likely is drug importation, which would be ineffective at lowering U.S. drug costs and would pose sizable safety risks, yet it would reduce research and development (R&D) costs and access for foreign consumers. Careful cost-effectiveness analysis would be more appropriate than trying to import other countries' price controls. Income-related subsidies are a better strategy for dealing with excessive cost sharing for low-income seniors.

THE PAPER BY Gerard Anderson and colleagues argues that if U.S. drug prices were reduced by 45 percent, comparable to prices in Canada, the United Kingdom, and France, Congress could close Medicare's "doughnut hole" while remaining within spending targets.¹ However, the price differentials they report are not fully representative, and adopting foreign prices may be both problematic and inappropriate. Thus, the choices before Congress are not as simple as these authors suggest.

How Large Are Price Differences?

Anderson and colleagues report that drug prices are 52 percent (40 percent) lower in Canada than in the United States, 59 percent (48 percent) lower in France, and 47 percent (34 percent) lower than in the United Kingdom (the numbers in parentheses assume a 20 percent discount in the United States). By contrast, using a larger and more representative sample with 1999 prices, we found average price difference of 33 percent for Canada, 30

percent for France, and 6 percent for the United Kingdom, net of an average discount of 8 percent.²

Anderson and colleagues' considerably larger differentials may reflect several factors. First, we selected the leading 249 compounds by unit volume, to reflect frequency of use, whereas they selected the leading thirty compounds by value of sales, which biases the sample toward high-price drugs. Second, generics are almost certainly underrepresented in their sample, because of sampling based on value and eliminating products sold by different manufacturers in different countries, which is common for generics. Since generics account for almost half of U.S. volume and are typically cheaper in the United States, underrepresentation of generics biases upward the estimates of U.S.-foreign price differences. Third, the authors include only those products with identical presentations. In our analysis, restricting comparison to products that matched on form and strength (not manufacturer) reduced the sample by roughly half and biased upward the

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estimate of U.S.–foreign price differentials. Thus, it is impossible to say whether these authors' finding of larger price differences in 2003 than we found in 1999 simply reflects these biases in sample and methods or whether prices have indeed diverged since 1999. What is clear is that their sample is unlikely to provide a representative measure of current price differences.

Should The United States Pay The Same Prices?

Regardless of exact differences, it is surely true that drug prices are lower in Canada, France, and the United Kingdom than in the United States. Anderson and colleagues reflect conventional wisdom in assuming that these comparator countries “are similar in terms of economic development but differ in their approaches to regulating drug prices.” In fact, in 2003, gross domestic product (GDP) per capita was 20 percent lower in the United Kingdom than in the United States, 24.4 percent lower in Canada, and 27.4 percent lower in France.³ There is a growing consensus that drug prices should differ based on income differentials, as an appropriate way to share the joint costs of R&D cross-nationally. Thus, given these countries' lower per capita incomes, it would be inappropriate for the United States to adopt their price levels. In fact, our 1999 indexes found that drug price differentials roughly reflected income differences across industrialized countries; whether this is still true requires more representative indexes than reported by Anderson and colleagues. Differential pricing is an essential step toward making drugs affordable for less developed countries. This includes accepting reasonable price differences between industrialized countries as well as between industrialized and less developed countries.

How Might Drug Prices Be Lowered?

If Congress does seek to reduce U.S. prices,

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none of the available regulatory strategies offers practical and economically appropriate options, as Joseph Newhouse has discussed.⁴ One strategy suggested by Anderson and colleagues is that Medicare would set an aggregate price for pharmacy benefit managers (PBMs), just as it sets an all-inclusive price for health plans. However, placing PBMs at full risk without any tools to control volume would likely lead to widespread withdrawal from the market. They also list demand-side controls, such as three-tier copayments. There is no question that granting PBMs flexibility to design formularies with tiered copayments is essential if they are to achieve meaningful control over prices. However, it seems unlikely that these tools could achieve an additional 45 percent savings, beyond the 20 percent discount already assumed by the authors, without exposing consumers to sizable cost sharing that would simply substitute for the cost sharing in the doughnut hole.

If Medicare does achieve lower drug prices, other large payers—including private drug plans and Medicaid—would surely refuse to pay more. If so, the total loss in pharmaceutical revenues would be more than twice the savings to Medicare, assuming that Medicare accounts for 40 percent of drug spending. Thus, using economywide price controls to increase access for the subset of beneficiaries who may face excessive cost sharing resembles using a sledgehammer to kill a fly. The likely size and nature of reduction in research and development (R&D) would depend on the details of the controls. What is clear is that since R&D is a global public good, this would affect consumers' access to new drugs worldwide, not just in the United States.

Importation

If Congress seeks to reduce drug prices in the United States, then the most likely approach, given the current political climate and regulatory options, is to legalize drug importa-

tion. Importation appears to offer an easy approach to reducing U.S. prices to foreign levels without the ideological and bureaucratic complexities of regulating prices in the United States. In reality, though, legalizing drug importation would probably have a minimal effect on average drug costs for U.S. consumers and yet could greatly reduce drug companies' revenues and incentives for R&D and also reduce access for foreign consumers.

There are several reasons why legalizing importation would not simply reduce U.S. prices to foreign levels. First, mismatch of presentations marketed in different countries limits the opportunities for import substitution. Second, even if identical products were marketed abroad, the supply available for export from approved countries would likely be insufficient to meet U.S. demand. Let us assume that importation from Canada and the fifteen traditional European Union (EU) countries were legalized. Pharmaceutical sales in the United States are almost twice the aggregate sales in these countries combined. Assuming that unit volume is similar between the United States and these potential export countries, on-patent volume that matches on manufacturer and presentation is a small share of this.⁵ Even if wholesalers and pharmacies in these countries diverted some of their supply to the United States, in pursuit of higher profits, the total supply available would likely be insufficient to bring down U.S. prices to foreign levels.

In competitive markets, the market price is determined by the cost of the marginal supply, which in this case would be products purchased in the United States; inframarginal suppliers (those who obtain products abroad at lower prices) profit from the margin between the market price and their (lower) acquisition cost. Consistent with this, the experience of parallel trade in Europe indicates that savings are captured largely by the parallel traders and pharmacies, except to the extent that payers such as the U.K. National Health Service reduce their payments to pharmacies to reflect the pharmacies' average savings from purchasing parallel imports. Similarly, if im-

portation were legalized in the United States, some wholesalers and pharmacies would profit from importing some products at prices below U.S. prices. Large PBMs and health maintenance organizations (HMOs) may "claw back" some savings by cutting reimbursement to pharmacies. Thus, if they anticipate that pharmacies obtain 10 percent of their products at a 30 percent savings, they might reduce total reimbursement by 3 percent to reflect this reduction in pharmacy acquisition cost. Inevitably, these average payment cuts leave some pharmacies overpaid and others underpaid, depending on their ability to obtain cheap imports. Payers—Medicare, employers, and employees—may recoup some savings from the PBMs and HMOs, depending on competition and bargaining power. But under reasonable assumptions—that importation will be irrelevant for generics and that it will be limited for on-patent drugs, due to mismatching, limited supply, and possibly diminished price differentials over time—the savings to U.S. payers and consumers would be under 3 percent of total drug spending, even before subtracting costs of trying to police safety.

Of course, supply and savings might be greater if importation occurs—legal or not—from other countries, as the approved export countries become conduits for products from countries with less reliable quality controls. However, it seems highly unlikely that any savings to U.S. payers would be worth the serious safety risks, plus the loss in R&D, since revenue loss to manufacturers could far exceed savings to U.S. consumers.

Effects Of Closing The Doughnut Hole

Anderson and colleagues' rationale for closing the doughnut hole is to increase access for Medicare beneficiaries. But their empirical analysis assumes an elasticity of -0.3 , similar to most previous studies. This implies that, say, a 60 percent reduction in beneficiaries' cost sharing would lead to a 20 percent increase in drug use, some of which would probably be "appropriate" and some would not. Predicting

effects is fraught with uncertainty, since we have no comparable experiments. Extrapolating from increases in Medicaid copayments is inappropriate, because the current plan already covers cost sharing for low-income beneficiaries, who are most likely to forgo use if cost sharing is too high. However, if elasticities are indeed as low as most analysis suggests and as Anderson and colleagues assume, then the main effect of closing the doughnut hole will be to transfer resources from taxpayers to beneficiaries.⁶ If access barriers persist for low-income seniors, increasing the income-related subsidies would be a more target-efficient and economically efficient solution than increasing subsidies for everyone.

IF CONGRESS DOES SEEK to reduce drug prices—whether to close the doughnut hole or for other reasons—then there is a real risk that legalizing importation will appear to be the easiest, least regulatory “fix” with constituencies far beyond the Medicare population. Importation at best would be ineffective; at worst it could lead to serious health risks to U.S. consumers, reduction in R&D, and reduction in access for foreign consumers. If Medicare wants to reduce drug prices and spending, then careful use of cost-effectiveness analysis would be the least damaging approach. Simply adopting—or importing—other countries’ regulatory strategies would not assure their price levels; even if it did, that would be inappropriate.

NOTES

1. G.F. Anderson et al., “Doughnut Holes and Price Controls,” *Health Affairs*, 21 July 2004, content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.396.
2. P.M. Danzon and M. Furukawa, “Prices and Availability of Pharmaceuticals: Evidence from Nine Countries,” *Health Affairs*, 29 October 2003, content.healthaffairs.org/cgi/content/abstract/hlthaff.w3.521 (12 July 2004).
3. Data from the International Monetary Fund (IMF), 2003. The differentials using purchasing power parities (PPPs) are 18 percent for Canada, 24 percent for France, and 25 percent for the United Kingdom (2001 data). PPP-based comparisons may provide a better measure of relative purchasing power, but since exchange rates are used for comparing drug prices, they should also be used for comparing incomes.
4. J.P. Newhouse, “How Much Should Medicare Pay for Drugs?” *Health Affairs* 23, no. 1 (2004): 89.
5. Danzon and Furukawa, “Prices and Availability.”
6. See M.V. Pauly, “Medicare Drug Coverage and Moral Hazard,” *Health Affairs* 23, no. 1 (2004): 113.