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Using International Reference Pricing for US Government Drug Purchases

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Abstract— *International Reference Pricing is a mechanism used by many nations to set purchase prices from drug manufacturers by comparing purchase prices in other nations. The US has avoided using International Reference Pricing because of manufacturers' opposition. A recently issued Presidential Executive Order may signal a serious consideration of the practice*.

Keywords— *Drug Pricing, Executive Order, International Reference Pricing*.

I. INTRODUCTION

The growth of healthcare spending has become a major concern for individuals and governments in many nations. While advances in pharmaceutical science have lead to tremendous improvements in medical care, rapidly increasing drug prices and a sometimes lack of governmental willingness to control prices are causing consternation.

In the United States, after a more rapid period of pharmaceutical spending growth in the 1990s through 2016, the rate of spending growth began to moderate to a level more commensurate with hospital and physician expenditures (Feldstein, p. 401).

The late Princeton health economist Uwe Reinhardt writes that US citizens "pay much higher prices for a given drug than do citizens of other developed countries" (Reinhardt, 2019, p 32). Reinhardt continues by stating "drug manufacturers explain that the high cost of pharmaceuticals is partly the result of an elaborate and expensive drug distribution system (ibid p. 33). In return for allowing "the market" to set pharmaceutical prices, US healthcare has developed a complex of Pharmacy Benefit Managers, private insurance companies, drug wholesalers, and manufacturers rebates which work together to keep pharmaceutical prices higher than those found in other nations. Reinhardt states: "Total profits booked by all of the agents in the value chain collectively amount to $23 of the $100 paid for drugs by consumers (ibid, p. 36).

II. INTERNATIONAL REFERENCE PRICING

A glaring example of US reluctance to interfere with pharmaceutical pricing is the enactment of the Medicare Modernization Act of 2006 which established the Medicare Part D drug benefit to assist older patients with purchases of pharmaceuticals. Despite the fact that the law enabled the use of federal funds to subsidize Medicare beneficiaries purchase of drugs up to a certain level, the US Congress prohibited the Medicare program from negotiating drug prices with pharmaceutical companies. As a result, manufacturers were free to set their own prices, even though the federal government was using public funds to pay a part of the purchase price.

One pricing modification mechanism remaining to be tried in the US is international reference pricing, a methodology that "sets the price for prescription drug using the amounts paid for those drugs by entities in other countries" (LaPointe, 2020, p. 2). A survey of European nations by the World Health Organization found that 36 of 41 countries analyzed used the methodology for pricing some drugs and that 26 used it "as the sole mechanism for pricing policy (ibid)." Critics of the proposal, including the pharmaceutical industry, argue that restraints on drug pricing limit funding for new product research and development. Even so, the US remains a non-participant in the international reference pricing movement.

However, a recently promulgated Executive Order from US President Donald Trump might be an indication that the US is wiling to entertain the concept of international reference pricing. Supposedly concerned that the US Medicare program was paying consistently high prices for Part B and Part D drugs, the September 13, 2020 Executive Order specified, in part, as follows:

> Sec 2 Policy (a) It is the policy of the United States that the Medicare Program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price.
>
> (b) The "most-favored-nation price" shall mean the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization For Economics Co-Operation and Development (OECD) that has a comparable per-capita gross domestic product.

While the Executive Order is very basic, much policy making detail remains to be developed to make the order operational, and critics have threatened to go to Federal court to have the order rescinded.

III. CONCLUSION

The September 13, 2020 Executive Order is noteworthy because it raised the issue of international reference pricing in

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the Medicare program. But effective implementation of international reference pricing in the US will require significantly greater policy development efforts. The Commonwealth Fund identified five areas to be addressed "to increase access and affordability of medications for Americans" (Waxman, Carr, Sharp et al, 2020).

Two of the five areas have important implications for the development of an international reference pricing policy in the US:

1) allow the federal government to become a more responsible purchaser
2) fix incentives in the drug supply chain and make the supply chain more transparent (ibid)

In addition to establishing the price determining mechanism, such a system must have a quality determining mechanism to insure overall appropriateness of the drug in question. For example, cost effectiveness analysis might be employed as part of the effort to insure that the preferred US drug compares favorably in terms of efficacy.

The drug supply chain in the US must be simplified in the effort to make it more transparent. A complicated nexus of Pharmacy Benefit managers (PBM), fees generated from the supply chain, rebates from drug manufacturers and the "spreads" between PBM payments from health insurers and PBM payments to dispensing pharmacies adds costs to pharmaceutical distribution (Costello, 2020). Simplifying the flow of funds should lead to lower costs when linked to appropriate international reference pricing.

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