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TECHNICAL REPORT

Negotiation Strategies for Antiretroviral Drug Purchasers in the United States

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HEALTH

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Summary

Antiretroviral (ARV) treatment has transformed HIV from a death sentence to a chronic condition, allowing people living with HIV (PLHIV) to live longer and healthier lives. However, PLHIV face significant barriers to accessing and affording life-saving—but expensive—ARV medications. These barriers are particularly severe for low-income PLHIV and disproportionately affect racial and ethnic minorities. High ARV prices create pressure for government payers to contain costs either by rationing care or by restricting eligibility for public programs. Limited funding, coupled with a growing demand for HIV care and treatment, is likely to make these hard programmatic decisions about who is covered more difficult over time. Therefore, it is important to identify options for reducing the cost of providing ARVs to allow more people to receive treatment.

This study focuses on options for negotiating lower procurement costs of ARVs. A case-study approach is used to assess the array of options that different stakeholders could deploy in negotiating ARV price discounts with drug manufacturers, given the regulatory and market constraints that exist in the United States.

The Economics of ARV Drug Pricing

Two characteristics of the market for ARVs are especially salient for understanding the alternatives for reducing costs. First, the prices for most ARVs are not determined in a free market but are typically negotiated between buyers and a single seller, the drug manufacturer, who enjoys considerable market power. Patent protection, which is intended to encourage drug manufacturers to invest in the development of new drugs, enables a single manufacturer to maintain a monopoly on selling a new ARV drug for 20 years. Thus, a key challenge for government payers is to balance the need to incentivize ARV drug manufacturers to undertake research and development (R&D) with the need to keep present drugs affordable.

Second, although drug manufacturers argue that high prices are needed to sustain the development of new drugs, the development costs appear to be overstated, for a number of reasons. In particular, there is a lack of credible data on manufacturers' costs, and without such data, it is impossible to determine the "fair" or "right" price for ARVs. Moreover, it is clear that development of ARVs has benefited from substantial federal and university contributions and that the fast-tracking Food and Drug Administration (FDA) process for many ARVs has substantially reduced their costs. However, it appears that drug companies may not be passing on these cost savings to consumers.

The Characteristics of the U.S. ARV Market

It is important to understand the mechanisms through which the three largest public ARV payers—the AIDS Drug Assistance Program (ADAP), Medicaid, and Medicare—currently attempt to lower ARV prices. The market power specific to drug sellers and purchasers (including available information about the market) determines the extent to which deviations from a competitive market price can be reduced through price negotiations. Government restrictions are also highly relevant for delineating payers' scope of action.

For payers in the U.S. ARV market, government regulation sets a ceiling price and mandatory rebate levels for each drug to ensure lower prices to Medicaid and public health payers, including ADAP. State Medicaid and ADAP agencies may choose to capitalize on these price controls and mandatory rebates, with greater participation potentially leading to greater negotiation leverage with manufacturers. Meanwhile, the federal government also requires minimum formularies, which further constrains the ability of public payers to customize their formularies for greater discounts.

Information about the ARV market is limited. Manufacturers have complete information about their costs of production (R&D, marketing, etc.) and the different prices they offer to different payers, but such data are not publicly available, and purchasers of drugs often do not know the prices other buyers have negotiated. Further, many payers, such as state Medicaid agencies, do not negotiate directly with manufacturers. Pooling demand is one of the few tools wholesalers and retail pharmacies can use to negotiate for lower prices, and private buyers have minimal options within the market for ARV drugs other than attempting to put "moral pressure" on drug manufacturers.

Cross-National Comparisons of HIV Drug Financing

Case studies of three comparable developed countries with sizable drug markets—the United Kingdom, Canada, and Switzerland—indicated that although government drug-price regulations in these countries appear to result in lower prices for patented drugs, including ARVs, the impact of drug prices on health payers and patients is highly moderated by the health insurance systems. For example, PLHIV have nearly complete ARV coverage in the United Kingdom and Switzerland, but in the United States and Canada, many find themselves piecing together coverage from different programs to offset large out-of-pocket burdens. Some drug-price negotiation options used in other countries, including greater transparency in development costs and greater coordination among drug purchases, point to options that might be appropriate for use in the United States.

Policy Options for Reducing ARV Prices in the United States and the Implications of Health Reform

Systemic-Level Options

Systemic-level options for changing the way prices are set can be realized only by entities that have the power to use them—typically, the government. Five such options are

- **Reference pricing,** under which prices are tied to those paid in other markets (e.g., in other countries or for drugs with identical or similar therapeutic benefits).
- **Switching of dually eligible beneficiaries from Medicare Part D to Medicaid,** which pays lower prices, especially for drugs on the "protected list" maintained by the Centers for Medicare and Medicaid Services (CMS), including AIDS drugs.
- **National procurement of prescription drugs,** in which the government would be the single payer for AIDS drugs.
- **Increasing price transparency,** so that all players have a better understanding of drug manufacturer pricing information.
- **Easing minimum formularies (i.e., baseline levels of essential drug benefits),** which restrict the negotiating power of payers by limiting the ability to exclude more-expensive drugs if an affordable price cannot be negotiated.

Such systemic changes are likely to affect ARV prices by bringing the market closer to a free-market situation in which the prices are equal to manufacturing and development costs. However, some options (such as easing minimum formularies) may not be viable strategies in the United States.

Changes to the Patent System

Changes to the patent system could address some of the shortcomings of the system as currently implemented in the United States. One alternative would be to pay rewards or subsidies for investors, such as prizes or commitments to pay a certain amount of money for delivering a drug that fulfills some technical specifications that were laid out in advance. Another option would be subsidies to support innovation. Such policies would de-couple prices charged for drugs from their development costs and would provide a one-time, lump-sum reward to drug innovators. These policies would affect the bargaining position of drug manufacturers and would decrease the need for regulations, since the drugs would be made by generic producers.

Two essential parameters of a patent also might be adjusted: patent length, or the duration during which a drug company benefits from exclusivity in the market, and patent breadth, which determines the reach of the market exclusivity granted. Such options might be worth considering, particularly for ARV developers that have received substantial federal funding for basic R&D and other cost-reducing factors such as fast-tracked FDA approval.

Negotiation Strategies

Negotiation strategies that could be pursued within the currently existing system in the United States include demand pooling (i.e., increasing negotiating power through combined purchasing power), formulary restrictions (i.e., easing baseline drug benefits provided by insurers), preferential contracts (contracts with fewer pharmacies or pharmacy networks in exchange for lower prices), and moral pressure/public relations.

The most promising of these mechanisms are demand pooling, particularly among Medicare Part D drug plans, and moral pressure (given the pharmaceutical industry's concern with public relations, particularly for ADAP). While formulary restriction could theoretically be a powerful mechanism for all players, it has serious ethical and clinical drawbacks when applied to ARVs specifically.

The limited range of negotiation mechanisms available within the current ARV payer system means that health reform is unlikely to open new options for lowering ARV prices to

most payers. Only Medicaid is likely to see lower prices. Further, the ability to use moral pressure on the pharmaceutical industry will most likely be diminished under the Affordable Care Act (ACA) as the role of ADAP, which is HIV-specific and has traditionally had strong advocacy efforts attached to it, diminishes.

Winners and Losers from Policy Change

Decisionmakers who wish to change policy to lower ARV prices must consider who is likely to win and who is likely to lose from the changes. Such issues would be particularly important if U.S. policymakers decided to apply lessons from other countries, since the financial impact of regulating drug prices on both publicly funded programs and private out-of-pocket expenditures is highly dependent on features of the health insurance system. The benefits of regulation need to be evaluated in light of the equitable distribution of benefits and the prevailing health insurance system.

With the introduction of laws in the United States that mandate health insurance coverage, equity considerations may result in increasing the cost burden on public insurance programs. At the same time, with greater consolidation of public programs and increased demand for drugs through universal coverage, public programs might be in a better position to negotiate drug prices.