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ANALYSIS

Consideration Of Value-Based Pricing For Treatments And Vaccines Is Important, Even In The COVID-19 Pandemic

ABSTRACT Prices send signals about consumer preferences and thus stimulate producers to make more of what people want. Pricing in a pandemic is complicated and fraught. The policy puzzle involves balancing lower prices to ensure access to essential medications, vaccines, and tests, and adequate revenue streams to provide manufacturers incentives to make the substantial, risky investments needed to develop products in the first place. We review alternative pricing strategies (cost-recovery models, monetary prizes, advanced market commitments) for coronavirus disease 2019 (COVID-19) drugs, vaccines, and diagnostics. Hybrid pricing strategies are undoubtedly needed in a pandemic, but even in a public health crisis, value-based pricing is important. Cost-effectiveness analyses can inform pricing. Ideally, analyses would be conducted from both a health system and societal perspective. Incorporating the added value of social benefits into cost effectiveness analyses doesn't mean manufacturers should capture the entire societal benefit of a diagnostic, vaccine, or therapy. Such analyses can provide important information and help policy makers consider the full costs and benefits of products and the wide-ranging ramifications of their actions. [*Editor's Note: This Fast Track Ahead Of Print article is the accepted version of the peer-reviewed manuscript. The final edited version will appear in an upcoming issue of* Health Affairs.]

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Pharmaceutical companies developing therapies and vaccines for coronavirus disease 2019 (COVID-19) face a unique challenge—not only creating and testing products amidst a public health crisis, but balancing shareholder expectations with public distaste for reaping large profits in the middle of a pandemic.[1] "There is no playbook for pricing drugs in a pandemic," observed Daniel O'Day, the CEO of Gilead, maker of the antiviral drug Remdesivir.[2] Anticipating potential public blowback, several vaccine manufacturers have pledged they would make no profits from their products during the pandemic, or "very, very marginal profits."[3]

What this means in practice is unclear. Prices send signals about consumer preferences and thus stimulate producers to make more of what people want. But health markets are notoriously distorted—the presence of insurance and patents, layers of regulation, insufficient information among consumers, and above all, the need to ensure access to effective products, regardless

of people's ability to pay, mean that prices in a traditional sense do not serve their usual function in reflecting consumers' willingness to pay. At no time is that more true than in the midst of a pandemic.

Still, prices must be set and they must be based on something. In this paper, we review alternative pricing strategies for COVID-19 drugs, vaccines, and diagnostics and argue that, even in a public health crisis, value-based pricing warrants consideration. The key question is how to measure value. Health technology assessment organizations, such as the Institute for Clinical and Economic Review (ICER), have expressed concern about value-based prices that incorporate societal impacts because the data to support such estimates are lacking and, presumably, because the exercise may suggest eye-popping high prices.[4] But prices need not reflect the entire societal value created by a drug or vaccine to provide sufficient incentives for product manufacturers to produce the needed quantities. Still, a pricing exercise that accounts for the full value of a drug to society can help policy makers consider the full costs and benefits associated with their pricing policies and investment decisions as they seek to improve current and future population health given resource constraints.

Alternative Pricing Models

The drug industry enjoys considerable freedom to set prices in the US, though it is limited by various rules that differ across government agencies and types of products and by the degree of competition in a particular therapeutic class. Vaccine pricing in particular, in the US perhaps more than elsewhere, is influenced by a complex and often opaque interplay of private and public considerations.[5]

Various pricing models are possible. We highlight three popular models—cost-recovery models, monetary prizes, and advanced market commitments—that often receive attention.[6]

PRICING TO MAXIMIZE ACCESS A *cost-recovery* approach reimburses product manufacturers for their production and distribution costs, and possibly, the added costs of research and development.[6] In some cases reimbursement includes a mutually-agreed upon "fair profit" mark-up. This idea has obvious appeal: in times of national crisis, governments might take extraordinary actions, such as commandeering industries or paying essential producers with "cost-plus" pricing to ensure access to treatments, tests, and vaccines at low costs for millions of Americans who need them.[7]

The concept is not new. Federal contracts from the Department of Defense, Centers for Disease Control and Prevention and other agencies often follow a "cost-reimbursable" arrangement.[8] The War Powers Act and its successor, the Defense Production Act, allows the President broad authority to redirect domestic production during times of crisis.[9] Moreover, governments of low- and middle-income countries have deployed such models for decades,[10] enabling cash-strapped health systems to provide access to treatments and manufacturers to receive predictable revenues without risking operating losses. But experience with cost-recovery models for drugs is limited in the US. One example is an FDA regulation allowing manufacturers to recover the costs of investigational drugs with no alternatives when the drugs are made available to seriously ill patients.[11]

Cost recovery models have limitations. They require an estimation of costs, which can be difficult to calculate. For example, a company's research investment on an early compound may generate knowledge that leads to a follow-on compound, making cost apportionment difficult. Moreover, the cost recovery approach may not account for the low probability of success or the cost of capital. Importantly, paying manufacturers for costs incurred, instead of benefits conferred, rewards higher costs and inefficient processes and thus sends perverse signals to innovators.[7] Cost-plus pricing does little to incentivize future innovation.

DRIVING INNOVATION WITH PRIZES Rather than funneling payment to drug firms for each patient treated, companies could be rewarded with *monetary prizes*. Under a prize model, a company would receive a one-time large reward for developing a drug or vaccine meeting pre-specified criteria. The drug could straightaway go generic and therefore become immediately affordable.[12] The attraction is that it could target needed innovations in areas for which there are weak incentives for companies to invest. In theory, the monetary prizes model may be used to encourage new antibiotics; treatments for diseases affecting small populations; medicines needed in low-income countries; and critical therapies, vaccines, and diagnostics needed during a possible pandemic.[13] In the current pandemic, the XPRIZE Foundation, which aims to spur technological innovation, has offered a $5 million prize for development of a new COVID-19 rapid test.[14]

The priority review voucher program, created by Congress in 2007, is yet another kind of award-based approach. Under the program, companies that develop drugs for neglected or rare pediatric diseases receive a bonus voucher that grants priority review for a future drug.[15] A bill in Congress would extend the voucher program to COVID-19.[16] An advantage of the priority

review voucher program is that the government does not need to provide new funding through taxes or deficit spending.

Monetary prizes have drawbacks. They require large one-time payments that may be hard to generate and which are subject to the whims of government appropriations.[12] While the priority review voucher program avoids this requirement, the value of the voucher declines with the number of diseases for which it is offered.[17] Monetary prizes also involve logistical complications, such as coordination of prizes and intellectual property rights in different countries. For example, if the United States awards a prize for a new COVID-19 drug, can generic manufacturers produce copies of the drug for sale in other countries that do not participate in the prize system?[12] Prize models also reduce incentives for companies to invest in ongoing, incremental product improvements, or in product marketing and educational campaigns.[18] Importantly, prizes do not sidestep the need to measure value because the size of the prize must correspond to the benefits at stake.

DRIVING PRODUCTION WITH ADVANCED PURCHASE COMMITMENT Yet another option is for governments or purchasing consortia to commit to buying a certain amount of drug or vaccine at a mutually agreed-upon price, before the product is available. In such *advanced market commitments* (AMCs), pricing is typically tied to research and development costs with an assumed profit margin. A recent example is the US government's arrangement to purchase an initial 100 million doses of the Pfizer/BioNTech vaccine (which had just completed Phase I trials) for $1.95 billion contingent on FDA approval or emergency use authorization.[19] Under the agreement, the government can acquire up to 500 million additional doses. The European Union has announced similar agreements with other manufacturers.[20]

AMCs are often subject to a multiple-bid process, allowing the government to select the companies willing to produce sufficient volume at the most favorable prices. Winning contracts usually include all phases of production, distribution, outreach, and delivery.[21] The appeal of AMCs is that they mitigate risks for manufacturers while ensuring widespread availability of products once approved.[22]

A downside of advanced market commitments is that a large financial obligation for a "first mover" vaccine or treatment might limit the availability of funding for later, more effective interventions. Another drawback is that the government may only purchase doses of treatment or vaccine, not the intellectual property or patent associated with it, so future pricing remains at the whim of manufacturers. Furthermore, there is the question of how to set terms in the first place. Indeed, the Pfizer/BioNTech advanced market agreement has already received criticism for including a profit margin that may exceed 60%.[23] Like prizes, AMCs do not build in incentives for ongoing, incremental product improvement. Finally, they do not eliminate the need to measure value. At a first approximation, they amount to an advanced-payment volume purchase, and the per-treatment price should, as with conventional pricing, correspond to the value of the benefit.

The Value Of Value-Based Prices

However companies are paid, aligning prices with the value conferred by drugs, vaccines or diagnostics can encourage firms to produce what people want—products that improve health and well-being—and thereby further stimulate appropriate innovation.

But how to measure value? Because market distortions prevent any alignment between consumers' willingness to pay and price, value must therefore be measured by external parties (e.g., a government agency or independent nonprofit organization). A favored approach is to describe value as the ratio of each intervention's incremental costs to its incremental benefits (e.g., in terms of quality-adjusted life years or QALYs) in a *cost-effectiveness analysis*.[24] The cost-effectiveness ratio can be thought of as a proxy for "price." Smaller ratios, like lower prices, are more favorable because they indicate that an intervention produces health gains at a lower cost.

The use of cost-per-QALY ratios for resource allocation decisions has well known limitations.[25] Prioritizing the most efficient strategies can omit interventions for people with conditions that are expensive and difficult to treat, which seems unjust. The use of QALYs as a measure of health benefit may omit important elements of value related to uncertainty, such as the value of insuring against uncertain events, and the fear of contagion).[26] Cost-per-QALY ratios also do not reflect how a product may affect distributional or equity concerns (e.g., a disproportionate impact of an investment on lower-income populations).[24] Still, the cost-per-QALY ratio has endured as the "gold standard" for value-based price calculations, though as one of many considerations for ultimate valuation and pricing decisions. As philosopher and ethicist Peter Singer has observed (with apologies to Winston Churchill), cost-per-QALY ratios may be the worst way to measure value except for all of the others.[27]

The Importance Of A Societal Perspective

Even if we agree on the cost-effectiveness ratio as a useful value metric, which costs and benefits should we measure? The analytic perspective or viewpoint determines which elements are included. A study can take the perspective of a patient, payer, the healthcare sector, or the entire society. This choice can influence the estimated cost-effectiveness ratio and subsequent reimbursement and coverage decisions.

Most published cost-effectiveness analyses have assumed a narrower health care sector or payer perspective and therefore limit consideration to the patient's health and to costs incurred by the health care system.[28] Notably, in its recent evaluations of remdesivir for COVID-19, ICER excluded consideration of broader societal benefits.[6]

As depicted in supplemental exhibit 1,[29] our search of the literature, conducted in early September, 2020, identified 23 economic evaluations of COVID-19-related interventions, including 14 cost-effectiveness analyses, 5 cost analyses, and 4 benefit-cost analyses. These analyses evaluated a range of interventions, including policy measures (social distancing or lockdown orders), treatments (dexamethasone, remdesivir), screening strategies, and hypothetical vaccines. Fourteen of these analyses (60%) have focused narrowly on the expected health benefits and/or costs of the intervention itself. Only 9 analyses explicitly considered non-health consequences, such as income loss due to sick days or being furloughed and none of these examined the consequences comprehensively.

The narrower health care perspective may align better with the interests of payers, whose budgets do not generally consider non-health consequences. It can also avoid placing less value on people without paid employment, or introducing uncertain assumptions when relevant data are lacking, as it often is for non-health consequences.

But a restricted study perspective omits potentially important elements, a matter critical for COVID-19 treatments, vaccines, and diagnostics, whose value lies not simply in mortality and morbidity benefits, but also in their potential to prevent health systems from being overwhelmed and to help restore daily routines, such as returning workers to their jobs and students back to school.[30] Limiting value assessment to the health care sector perspective means potentially undervaluing interventions. Consensus groups have recognized the importance of a societal perspective because counting all benefits and costs provides the basis for comprehensive and consistent analyses "in the broad public interest."[31,32] Crucially, failing to recognize value outside the health care sector sends the wrong signals to product manufacturers about the value society places on the benefits conferred by their products. Ultimately, it can lead to underinvestment in the innovation that undergirds future therapies and their potentially substantial societal benefits.

ICER's analysis of remdesivir underscored the hazard of ignoring a societal perspective in cost-effectiveness analyses. ICER stated puzzlingly that "policymakers would view it inappropriate to set a price for a treatment for COVID-19 to capture the potential broader societal benefits associated with future economic recovery."[4] It is unclear which policy makers and what time horizon ICER had in mind. To paraphrase Northwestern economist Craig Garthwaite, when it comes to pricing, the key question is "in which way would you rather be wrong?"[33] In other words, the risk of overpaying for products today may be far outweighed by the risk of underpricing and having few effective products for the next pandemic.

Discussion

When it comes to product pricing in a pandemic, the terrain is tricky. The policy puzzle involves striking an appropriate balance between lower prices today (to ensure access to essential tests, vaccines, and medications) and adequate revenue streams that incentivize manufacturers to make the substantial, risky investments needed to develop those drugs in the first place.[34] Even in a pandemic, value matters. The government's leverage to force lower prices may save the system money in the short run but with consequences for developing new products to address future pandemics. The lack of investment over the years in measures to address other risks with catastrophic potential, such as antibiotic-resistant microbes, offers cautionary tales.[35,36]

Hybrid approaches to product pricing will almost certainly be needed. For example, advanced market commitments will be important and may be best suited for COVID-19 vaccines and diagnostic tests, given the need for population-wide access. Still, it will be useful for government negotiators to have a cost-effectiveness analysis in hand to help set the terms of the arrangement. A value-based price as part of the commitment would send appropriate signals to future innovators. Importantly, the US and European Union will still need to subsidize vaccine purchase and distribution in lower-income countries to ensure global access. Lower-resourced countries will require significant manufacturer concessions. Nonetheless, as noted, even with these arrange-

ments, there will be a need to set a price, and to consider value, as a starting point, when doing so.

There is also the important question of whether drug prices should reflect contributions the government makes to their development. For example, the National Institutes of Health supports broadly applicable basic research.[37] However, virtually all industries benefit from basic government-funded research and infrastructure investments; for example, Google benefits from the government's development of the early Internet.[38,39] Government invests in basic research because it is a public good, and the private sector left to its own devices would underinvest from a society's perspective because a private company cannot easily capture the full benefit of its investment if other companies can hitch a free ride off a company's basic research.[40] Businesses "pay" for government investment in basic research through taxes rather than by lowering prices. It would be difficult in any case to trace the link between the government's basic research investment and marketed products to adjust prices.

The matter is different when the government invests in later stage clinical research. In this case, value-based pricing—with an adjustment—makes sense. Allowing a company to recoup all of its revenue from a compound that benefited from government research will lead to inappropriately high returns and overinvestment in future similar products. That is, the pricing signal would be too strong. Moderna's COVID-19 vaccine provides an example. The US government contributed $483 million to the development of Moderna's vaccine.[41] It would be reasonable to subtract from Moderna's payment the portion of the vaccine's value that derives from government-funded development costs.

As a general example, if a successful vaccine is valued at $10 billion, the development costs total $1 billion, and the government paid half the development costs, the vaccine company should not get to keep the full return of $9.5 billion ($10 billion – $500 million). Just as if they had taken a 50% share in the development of a vaccine with an industry partner, they should be entitled to half the revenues, (half the value)—$5 billion.

All of these pricing strategies should be informed by formal health technology assessment and cost-effectiveness analysis. ICER has performed a constructive role in reviewing the clinical and economic evidence of new therapies. While manufacturers and payers may conduct their own economic evaluations, ICER serves as a trusted, independent external source of information. Its evaluation has helped place the value of remdesivir into perspective, suggesting that, even under conservative assumptions (e.g., valuing a quality adjusted life year at $50,000, substantially less than its typical benchmark range of $100,000 to $150,000, and excluding potential societal benefits),[7] a price of $3,000 to $5,000 per dose likely reflects a reasonable value.

Assessments are also needed for other products and across countries and settings. Economic evaluations should be extended to vaccines in coordination with the Advisory Committee on Immunization Practices (ACIP), the federal advisory committee which provides guidance on the optimal use of vaccines. ACIP established a COVID-19 Vaccine Workgroup earlier this year,[42] and economic evaluations are already part of ACIP's evidence review framework.[43] Value-based prices for vaccines, to be given to hundreds of millions of healthy people who would not have contracted the infection even without these vaccines, will likely be orders of magnitude lower than for therapies, such as remdesivir, that are reserved for only the sickest of the infected. Pricing and payment considerations for diagnostics will require their own judgments, given uncertainties about the changing prevalence of COVID-19 in different regions and populations, questions about whom to test and how often, and vagaries in the accuracy of testing results.[44] The value of a diagnostic is generally thought of in terms of its clinical utility for an individual tested (i.e., how a test will influence subsequent treatment). However, value assessments for COVID-19 tests should also consider the broader benefits, such as reducing community spread of the coronavirus.

Ideally, value assessments of diagnostics, therapies, and vaccines will be based on analyses from both a health system and a societal perspective, the latter reflecting *all* costs and benefits. Such benefits include the impact on untreated patients from reducing fear and uncertainty, thus helping workers return to jobs and students to school.[45,46] Analyses should include an impact inventory, a standardized list of health and nonhealth consequences. An impact inventory can help track and convey which consequences have been included or excluded in cost-effectiveness estimates and whether analyses are likely to under- or overestimate value.[30,32]

Although estimating the full value of a drug for COVID-19 is difficult, the pandemic's economic impact leaves little doubt that it would be substantial. Goldman Sachs estimated that compared to a "no vaccine" scenario, a vaccine that is "widely available" by mid-2021 would increase the GDP growth rate in the U.S. by 4 percent, a difference of nearly a trillion dollars in cumulative output over a single year.[47] Economists sur-

veyed by the University of Chicago believe that even immunizing half the population would substantially speed the economic recovery.[48] Notably, some international health technology assessment organizations seem to have shied away from conducting evaluations. A representative of England's National Institute for Health and Care Excellence stated in May that it was too early to consider cost-effectiveness and value propositions for new COVID-19 interventions and that pricing would work itself out if "all parties are reasonable."[49]

Only by putting all of the information in the open, and updating analyses as more data become available, is it possible for stakeholders to identify prices for innovations that optimize feasibility and incentives.[7] Critically, including societal benefits in value determinations does not mean that the manufacturer should capture the entire societal benefit of a diagnostic, vaccine, or therapy. Paying a price reflecting the entire societal value for many innovations will almost certainly be infeasible; nor will it be necessary to ensure an adequate signal for future innovations. Still, an analysis incorporating societal benefits will serve as an important input into pricing discussions, helping policy makers consider the full costs and benefits of products and the wide-ranging ramifications of their actions.

There are no easy answers to pricing in a pandemic. However, had earlier and more extensive investments been made in effective therapies and vaccine platforms against novel coronaviruses, the pandemic might have ended considerably sooner, saving the world trillions of dollars and avoiding substantial suffering. People may understandably recoil from the idea that drug companies will pocket billions, but pricing to value will help achieve the ultimate goal of ensuring more innovations are available for the next pandemic.

In July of this year, Clifford Lane and Anthony Fauci of the National Institute of Allergy and Infectious Diseases wrote, "It was once widely held that the setting of an outbreak is not an appropriate venue for conducting rigorous clinical research because when people are dying, any and all possible therapies should be "given a chance," rather than studied in rigorous ways." However, Lane and Fauci concluded: "Scientifically robust and ethically sound clinical research remains the quickest and most efficient pathway to effective treatment and prevention strategies for patients with COVID-19."[50] In a similar vein, people may believe that the setting of a pandemic is not the appropriate venue for value-based pricing. However, robust and sound value assessments to inform product prices can help ensure that tests, treatments, and vaccines are available for this crisis and for crises yet to come. ■

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NOTES

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