

# Alternative Policies for Pricing Novel Vaccines and Drug Therapies for COVID-19

Sarah K. Emond, MPP  
Steven D. Pearson, MD, MSc



INSTITUTE FOR CLINICAL  
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# Introduction

The COVID-19 global pandemic has changed the way we live and work, while putting the conversation about the limits of our existing health care resources at the top of policymakers' agenda. Leaders in government, business, and society all seek to adopt policies that will spur the development of treatments and preventive therapies such as vaccines that can be delivered as rapidly as possible in an affordable and equitable manner. The choices among policy options to achieve these goals present profound scientific, ethical, and political questions. Is the power of government best exercised by funding research with private partners and then stepping back to let the free market determine pricing and distribution? Should the government instead take control of the development and distribution process in its entirety? Or is it best to adopt a hybrid approach in which government takes some role in regulating intellectual property, pricing, and distribution? Ultimately, policymakers must determine who will own the treatments that society needs, and how much they will cost. These questions are not new, but in the exceptional circumstances of the coronavirus pandemic their answers will guide decisions in the coming months that will have enormous short and long-term consequences for the United States and the rest of the world.

This report provides a brief overview of approaches to manage the pricing of preventive therapies such as novel vaccines, and treatments in times of public health emergencies. Starting with a summary of experience and lessons learned from previous epidemics and the annual flu vaccine, we will then analyze the potential advantages and disadvantages of alternative policy options. Each option takes a different approach toward the role of government and the private market, with pricing being one element in a broader policy platform. This report is intended as a short introductory overview to inform public and policymaker discussion regarding the best way to harness public and private efforts to achieve rapid, equitable, and affordable treatment for COVID-19 in the US.

## Historical context

A look back at how vaccines and treatments were first developed and priced during three relevant previous public health emergencies, along with an overview of how the annual flu vaccine is developed, can offer context for policymakers today.

- **Spanish Flu Pandemic of 1918:** While no effective vaccines or treatments were developed during the 1918 flu pandemic, there were numerous accounts of price gouging and promotion of unproven therapies. [In one example](#) a “druggist” in Tampa was excoriated in the press for increasing the price of a purported flu treatment from \$6 to \$55. Whiskey was thought by some to be an effective treatment, and the [price for a bottle of whiskey](#) subsequently increased rapidly. Within the medical community itself,

an unproven theory was widely accepted that a bacterium dubbed “Bacillus influenzae” was causing the disease and that vaccines against it could prevent influenza, leading to [hundreds of thousands of people being inoculated](#) with an ineffective vaccine.

- **Polio Vaccine:** The inventor of the first polio vaccine, Jonas Salk, received the majority of the funding for the vaccine’s development from charitable sources that would eventually become the modern day [March of Dimes](#). In order to conduct the large clinical trials needed to test its effectiveness, the Salk vaccine needed to be produced on a massive scale, and well-known companies like Eli Lilly and Company, Wyeth Laboratories, and Parke, Davis and Company [agreed to produce it](#). When the vaccine was determined to be safe and effective, Salk’s public statements around the achievement were noteworthy for their emphasis on broad access. When asked who owned the patent, [Salk replied](#), “Well, the people, I would say. There is no patent. Could you patent the sun?” After its effectiveness had been confirmed, the U.S. government licensed the manufacture of the vaccine to a private company, ensuring mass production and wide access.
- **HIV Treatments:** The first approved therapy for HIV, azidothymidine (AZT), [was originally developed by scientists with NIH funding](#) in the 1960s as a potential cancer treatment. AZT was identified as a [possible treatment option for HIV](#) by researchers at the National Institutes of Health’s National Cancer Institute, and Burroughs Wellcome Co. (now GlaxoSmithKline) [conducted the necessary clinical trials](#) to prove AZT’s effectiveness.

Following FDA approval in 1987, the launch price for AZT was set at \$10,000 per year, and [protests over that price level](#) began immediately. Not long afterward, under pressure from the HIV community, the company lowered the price by 20 percent to \$8,000, and the price remained at that level until 1989, when continued criticism from HIV patient and allied community groups, coupled with a threat from the U.S. government to allow a different firm to manufacture the drug, led the company [to reduce the price by another 20%](#).

- **Annual Flu Vaccine:** Most vaccines that come to market today are patented, but for the past 50 years the annual flu vaccine has been developed through a mechanism without intellectual property being assigned to corporations. Through the World Health Organization’s Global Influenza Surveillance and Response System (GISRS), a network of laboratories spanning 110 countries and funded by governments and foundations, experts from around the world convene twice a year to analyze and discuss the latest data on emerging flu strains. These experts then decide which strains should be included in each year’s vaccine. No intellectual property rights are involved in this effort, [allowing GISRS to operate on an “open science” basis](#) and make its information available to companies and countries around the world.

# Approaches to Pricing Novel COVID-19 Vaccines and Treatments

Below we describe six different approaches to pricing preventive therapies such as novel vaccines, and treatments for COVID-19. The focus on novel interventions is intentional. Drugs already in clinical practice may be found to be effective for COVID-19 but the considerations around appropriate pricing for these drugs, particularly generic drugs, are different. Some of the following approaches would still be relevant, but here we focus on various alternatives for establishing the initial price of a new vaccine or treatment. The six approaches examined are:

- 1 Status quo: Unrestricted pricing.** Private companies develop vaccines and treatments, are rewarded with patent rights, and are allowed to decide how much to charge for the resulting products within a monopoly pricing paradigm.
- 2 Cost-recovery pricing.** Private companies develop vaccines and treatments, are rewarded with patent rights, but government and/or private insurers use an analysis of the cost of development and production to set a ceiling price.
- 3 Value-based pricing.** Private companies develop vaccines and treatments and are rewarded with patent rights, but government and/or private insurers use some form of cost-benefit analysis to set a ceiling price based on the degree of added benefit for patients and society.
- 4 Monetary prizes.** Government establishes a specific prize amount to incentivize discovery, with the first private company to discover a successful vaccine being awarded the prize. The government keeps the intellectual property and contracts separately with entities to manufacture and distribute the vaccine at cost.
- 5 Compulsory licensing.** In exchange for royalties paid to the innovator, government permits others to make, use, sell, or import patented pharmaceuticals without the patent-holder's permission. This approach includes the possibility of exercising "march-in" rights to mandate licensing of the product directly to the federal government.
- 6 Advanced market commitments and subscription models.** Advanced market commitments (AMCs) are designed to incentivize the development of novel treatments and vaccines by subsidizing the research and development costs through a commitment by the funder or a pool of funders to a future purchase price, if the development is successful. Subscription models can work somewhat similarly, with

funders and innovators agreeing on a price for a treatment in a way to provide a guaranteed minimum return on investment and a cap on total costs no matter how many patients need treatment.

## Status Quo: Unrestricted Pricing

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The prevailing US paradigm for drug development and pricing involves a combination of substantial federal support for basic research, private investment for both basic and clinical development, and a regulatory structure that provides patent and exclusivity protection for new drugs while prohibiting federal negotiation on prices. This approach features substantial federal tax incentives for private research and development and laws requiring broad coverage among both public and private insurers.

Continuing with this approach during the current pandemic has potential advantages and disadvantages. Patent protection and unrestricted pricing yields high pricing leverage for innovators, which can be viewed as providing incentives strong enough to trigger wide private mobilization of existing and future resources to develop effective vaccines and treatments for COVID-19. Relatively high prices in the US market, moreover, may allow a private manufacturer to discount their treatment, even to a point below cost of production, for less developed nations around the world. However, it is possible that even with unrestricted pricing, public scrutiny and pressure during the exceptional period of a pandemic would lead private companies to judge that the price they would be able to charge without damaging their long-term reputation would be too low to make investment in this area a wise use of capital, especially for riskier investments in new agents. This risk of inadequate incentives even with unrestricted pricing has been viewed as [a problem in vaccine development](#) for many years.

In contrast, if a private company has monopoly pricing power over a distinctly effective treatment or vaccine, and public pressure can be overcome, the largest concern is that the price might be set at a level too high to make rapid and broad access achievable without serious adverse consequences for federal, state, and private health system budgets. Even if the immediate costs of a novel treatment can be covered, pricing at too high a level could threaten a short-term escalation in private insurance premiums the following year that would threaten the affordability of the employer-based insurance system. This problem in [pricing “too high”](#) for a public health emergency [was viewed by many](#) as tarnishing the history of the deployment of the first wave of highly-effective new treatments for chronic hepatitis C starting in 2013-2014. Leaving the current status quo on pricing intact for COVID-19 would seem to run a relatively high risk that the costs of single new vaccines, other preventive therapies, and treatments, or especially the cumulative cost for multiple new treatments, would create a similar or worse crisis of affordability and might result in government and private payers restricting access.

## Cost-Recovery Pricing

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Cost-recovery pricing would set the price for an individual vaccination/preventive therapy or course of therapy at the level necessary to return to the innovator/manufacturer an amount that would cover the full costs accrued for the development and production of the treatment. Two paths can be considered in this approach: 1) “cost of production,” in which the price is set to compensate the innovator just for the costs of manufacture and distribution, with no attempt to factor in the costs of earlier development efforts; and 2) “cost of development and production,” in which the price provides full cost recovery to the innovator for the entire research and development effort that ultimately produced the new treatments, as well as the necessary costs for manufacture and distribution.

To provide some context on potential cost-recovery pricing levels for treatments of COVID-19, researchers have calculated the cost to produce several of the existing therapies currently being tested for efficacy against the coronavirus. [For remdesivir](#), they estimate a course of treatment would cost \$9.00; for hydroxychloroquine, \$1.00 for a course of treatment; and \$0.30 for a course of treatment with chloroquine. No efforts to date have tried to estimate the cost-recovery pricing levels on potential treatments for COVID-19 that would cover the costs of earlier development efforts.

There is a [long lineage to the arguments](#) about whether the costs of the research and development that precede the launch of a new drug factor into the price set by the innovator, and if so, how those costs should be measured. Those [who argue for its inclusion](#) as a factor in pricing emphasize the riskiness of drug development, the long timeline often necessary for bringing a drug through development to market, and the impact on incentives for future innovation should adequate return on earlier investments not be assured. In contrast, [those who argue that earlier development costs are irrelevant](#) to considerations around the price of a new drug [point to how little those earlier costs matter](#) to innovators, highlighting that the current market realities at the time of drug launch play the largest role in price considerations. [Some analysts even turn the equation on its head](#) and argue that it is the price that innovators believe can be charged that determines the amount they will spend on research and development, and not the other way around.

Whether the price is set to recover short-term costs of production or the broader costs of development plus production, the most obvious potential advantage of a cost-recovery approach is that it would produce a relatively low cost, maximizing affordability for governments and private payers. A cost-recovery approach would also, if self-adopted by the innovator, maximize its reputational gain. Any company that develops a new, effective vaccine or treatment for COVID-19 and announces its intention to price it at a cost-recovery level, would instantly be viewed as a national hero, with potential long-term strategic benefits not only for the individual company but for the pharmaceutical industry as a whole.

The potential disadvantages of cost-recovery pricing are few in the short term, but more relevant for considerations of the incentives for innovation over the intermediate or long-term time frames. In the short term, there would likely be little dispute over methods to capture the costs of production and distribution, but if a company tried to present an account of development costs stretching back over many years, conflict would be likely over many of the details. Would the costs accrued for other drugs in that development group that did not make it to market be included? How would the cost of capital over many years be measured and factored in? If the drug arose from research performed by another company that was subsequently purchased by the final innovator, should the purchase price of the originator company be included in full? And, perhaps, most contentious of all, how should any contribution of research support from the federal government be factored into the calculation? All these questions would complicate the process of agreeing to a price based on full accounting for the costs of production plus earlier development.

The most important potential disadvantage of this approach is that it might dampen incentives for research into preventive therapies and treatments that would come after the very first wave of effective treatments is introduced. Cost-recovery pricing might provide incentives that are too weak to convince innovators to invest in research that would take several years and then, even if successful, would not produce the same return on investment as other current research options. Therefore, if the first wave of vaccines and treatments are not entirely sufficient to control COVID-19, a cost-recovery pricing approach to early treatments might undermine private research into subsequent treatments.

## Value-Based Pricing

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Value-based pricing builds upon the general process for research, development, and patent protection and leaves that all intact while adding on at the end a method for regulating the ceiling price that an innovator would be allowed to charge for a new vaccine or treatment for COVID-19. This approach is [used directly or indirectly in many European countries](#) in determinations of coverage within public insurance systems, and is the technique [that we use at ICER](#) to frame suggested price benchmarks for new drugs and other treatments in the US health care system under normal circumstances.

The method used to determine a ceiling price is grounded in cost-effectiveness analysis, and provides a [recommended price ceiling](#) scaled in proportion to the added health and economic benefits of a new treatment. Policymakers are provided with information on broader health and societal effects and other contextual considerations for integration with cost-effectiveness results. The scaling of the price to the intervention's benefits is set to provide the highest price at which those benefits could be rewarded without causing more harm than good due to estimated increases in downstream insurance premiums and the resultant health losses from individuals no longer being able to afford insurance.

There are three main potential advantages of value-based pricing. First, incentives for private companies are set above the minimal cost-recovery level, likely drawing in far more private investment of time and resources in efforts to discover effective vaccines and treatments. This may counteract natural public sentiment pushing for rock bottom prices, giving innovators a transparent, objective standard by which they could claim prices high enough to justify their earlier investments. Second, value-based pricing rewards innovators in proportion to how much better their vaccine or treatment is compared to other options, thus incentivizing even costly investments for interventions that have a chance of being a cure or a more effective vaccine. And third, although more generous than cost-recovery pricing, value-based pricing does create a price ceiling to prevent the most egregious excesses of unrestricted pricing.

There are two significant potential disadvantages to a value-based pricing approach. First, cost-effectiveness analysis can be very uncertain when the data on the overall clinical effectiveness of a treatment are early and evolving. During this pandemic it is likely that treatments will be approved and need to be priced at a time when the evidence is rapidly evolving, making any pricing recommendation unstable and likely to evolve as the data evolve. It is possible that the price that the government or private payers would pay could be allowed to evolve over time in conjunction with updated cost-effectiveness results, but this adds a layer of complexity.

The second potential disadvantage to value-based pricing is that cost-effectiveness does not factor in the number of patients to be treated. It can generate a ceiling price per patient, but this price does not change whether there is one patient to be treated or 100 million. This feature means that the standard pricing thresholds linking patient benefits to ceiling price can be unaffordable in the short-term when the patient population to be treated is vast, and when treatment is needed immediately for many or most patients. All European and other health systems that use value-based pricing include a separate consideration for short-term affordability. This suggests that value-based pricing applications to vaccines and treatments for COVID-19 would need to address affordability, either by adopting some complementary maximum budget impact ceiling, and/or by using a lower cost-effectiveness threshold for determining a value-based price. As an example, under normal circumstances ICER uses a threshold range for value-based pricing between \$100,000 to \$150,000 for an additional quality-adjusted life year, but we have selected [a lower threshold of \\$50,000 per quality-adjusted life year](#) as the basis for our value-based price ceiling for remdesivir.

## Monetary Prizes

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One approach to incentivize private companies to develop vaccines and treatments with the option to control affordability is [to award a cash prize](#) to the individuals or companies that ultimately develop effective products in exchange for the intellectual property. The total award does not need to be a fixed amount; it could be scaled accordingly to the total number of people treated. Bonus payments could be offered for improved vaccines with greater efficacy or treatments with more efficacy or less frequent or severe side-effects. Whatever the design, once



government has paid the prize, its ownership of the intellectual property would allow it to contract separately for the production and distribution of the vaccine or treatment without the need to distribute future revenue from the sale of the product to the innovator.

Using prizes, instead of patented intellectual property, is not a new idea. The British government used the approach to spur [the invention of a chronometer](#) in the early 18<sup>th</sup> century. In 2010, an act of Congress established a framework for federal agencies to run prize competitions, and more than 100 federal agencies [have administered nearly 1,000 prize competitions](#) amounting to \$300 million dollars. The Bill & Melinda Gates Foundation, in partnership with several national governments are using prizes to spur the development and dissemination of a vaccine against pneumococcal disease, so far resulting in the immunization of [more than 183 million children across 59 countries](#).

A prize would allow the government to forecast the amount that would be spent and set that amount at whatever level is judged affordable. However, this approach also offers a unique opportunity to pool money from many governments, allowing for a larger prize to incentive vigorous private company efforts while sharing the economic burden in a way that could be worked out to address equity concerns up front. A global prize approach would also help ensure global access, as each government that contributed would have the right to license the vaccine's manufacturing and distribution in their own countries.

The most important potential disadvantage of a prize approach is that it is impossible to know what prize amount is sufficient to generate the level of private effort and investment that will lead to successful products. Set the prize amount too high and affordability might be undermined. Set it too low and too few companies might put too little into the effort, leading to a dead end. Based on several factors, legal scholars Daniel Hemel and Lisa Larrimore Ouellette have addressed the options for the size of a prize for a vaccine, suggesting that it be scaled to \$500 per vaccinated person, which would be [more than double the price](#) of any other major vaccine on the market today. At this price, if everyone in the US took the vaccine, the total cost to the federal government would be about \$165 billion, far more than any individual company has made from a previous vaccine, yet less than 3.5% of the federal budget, and a figure dwarfed by the economic disruption from COVID-19. Other standards by which to set a prize amount would have their advocates, and other design questions, such as how effective the vaccine or treatment must be, would also require somewhat arbitrary answers. Difficulty sorting out these design features without the guide of a clear precedent during a public health emergency would present the greatest risk to adopting a prize approach for COVID-19.

## Compulsory Licensing

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The prize approach described above involves the award-giver (the government) obtaining the license to the product after it is developed. This decoupling of ownership (and thus pricing) from development of the product is also a main component of the compulsory licensing approach.

According to the [World Trade Organization](#), “compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.” In this model, the patent holder is compensated for the use of their patent. Typically, this approach is reserved for circumstances where voluntary licensing has failed. However, the WTO does identify “national emergencies, other circumstances of extreme urgency” as acceptable circumstances to bypass the voluntary phase. While this approach has most often been discussed for developing nations, the circumstances of this pandemic offer a unique opportunity for the government to consider identifying and licensing existing IP that could be used to ease the public health burden.

In the U.S., compulsory licensing could come through two mechanisms. First, as Amy Kapczynski and Aaron Kesselheim [explain](#), under 28 U.S.C. §1498, the government could start manufacturing (or threaten to start manufacturing) generic versions of a patented vaccine or treatment that is priced too aggressively. The government would have to pay “reasonable and entire compensation” to the patent holder. But that compensation could be set at a level well below what the manufacturer would charge otherwise. Section 1498 is no panacea—it leaves [private insurers paying the full cost](#) unless the government resells generic versions. But even if the federal government were to wield this law as a potential alternative to a successful negotiation, it could give the government real leverage with innovators to keep the price within affordable bounds.

The second mechanism for a version of compulsory licensing would be federal exercising of “[march-in rights](#)” under the 1980 Bayh-Dole Act. Before Bayh-Dole, the [government retained the intellectual property rights](#) if the inventions were supported by government investment, but after Bayh-Dole, researchers own those inventions. While the federal government can assert march-in rights to license the invention so that it is “[available to the public on reasonable terms](#),” it can also do so when “[action is necessary to alleviate health or safety needs](#).” [Some health policy experts](#) have argued that if the price of drug is unreasonable or harms public health because of reduced access, then the federal government can [ensure the availability](#) of cheaper generic versions by the authority granted in Bayh-Dole.

Although not a form of compulsory licensing, a related option of pooled intellectual property also deserves consideration. Several [existing frameworks](#), most notably a product of the global activism of the HIV/AIDS community, are structured to allow the pooling of intellectual property with royalties being paid back to the inventors by the entities that will produce and distribute the medicines in more of a voluntary model. The [Medicines Patent Pool](#), a United Nations-backed effort “to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries,” has recently expanded its focus to include [treatments and vaccines for COVID-19](#). These patent pools allow the owners of certain IP rights to “donate” the patent for a product to a collective pool. The owner of the IP will receive royalties on the product if that product is selected for manufacture and distribution, and the patent pool organizer selects generic drug makers to then manufacture and distribute the product at a low cost.

In the current COVID-19 pandemic, the U.S. has not taken the approach of other countries such as, Germany, the U.K., and Canada, [which have signaled](#) that they may limit patent rights to ensure broad access to treatments or vaccines. Costa Rica is signaling support for a pool of IP rights for technologies to fight COVID-19 organized by the WHO, and Israel recently [invoked an emergency patent suspension clause](#) clearing the way for importation of a generic version of an AbbVie Inc. drug because it may be able to treat the virus.

Compulsory licensing has several potential advantages. First, using existing legal pathways, it would be the quickest way for the government to get what it would need to begin producing massive amounts of a vaccine or treatment at the lowest possible cost. If the IP were pooled with that from companies in other countries, all nations would benefit from the ability to draw upon the IP to create redundant and diverse supply chains aimed at producing and distributing effective products in large amounts.

Legal challenges to compulsory licensing would almost certainly complicate this process, perhaps undermining the benefits of rapid action. And the most obvious potential disadvantage to this approach would be the chilling effect it might have on future investments for vaccines or treatments for COVID-19. Critics of compulsory licensing suggest that even the threat of its use would severely undermine the incentives for private industry to take the risks and to make the efforts needed not just for the first set of effective vaccines and treatments, but for those that may be needed in the future.

## Advanced Market Commitments and Subscription Models

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Advanced Market Commitments (AMCs) are designed [to incentivize the development of novel treatments and vaccines](#), often for underserved populations, by subsidizing the research and development costs through a commitment by the funder to a future purchase price, if the development is successful. The funder, a government or a group of donors, can guarantee payment for a successful product, thus eliminating the uncertainty a developer faces for investing in an expensive development program without a guarantee of return.

[Rena Conti and Joshua Sharfstein](#) have suggested that an approach based on advanced market commitments would be the best way to incentivize development of both vaccines and treatments for COVID-19. They argue that, similar to prize mechanisms, advanced market commitments can [set safety and quality standards for a product to meet](#), and if no suitable product is developed, no payments would be made. The government would be able to determine, in advance, the total price it would pay for as many doses as are needed to control COVID-19. This approach also gives the innovator a degree of certainty since if a company that is successful in making an effective product sees the immediate need for the product subsidy, the company would still be rewarded. After the first financial commitment is fulfilled, the innovator is expected [to offer the treatment at or near cost](#), or allow for the intellectual property to be licensed to another manufacturer.

While advanced market commitments address both the development and pricing of a new therapy or vaccine for COVID-19, a subscription model, sometimes called a “Netflix” model, offers an approach for pricing of an already developed intervention. To create a subscription agreement, [a payer guarantees a pricing arrangement](#) that protects the innovator by guaranteeing a minimum price to be paid per person up to a certain number of individuals immunized or treated. This minimum price could be set to cover all costs of manufacturing and distribution, along with some negotiated profit margin. A subscription agreement also protects the payer by setting a fixed upper cost to be paid for the vaccine or treatment no matter how many individuals receive the product. This approach is best known through its use by the [Louisiana](#) state Medicaid program in an agreement with Gilead that capped costs for medication to treat however many patients with chronic hepatitis C were referred for treatment.

There are two major potential disadvantages to subscription model arrangements and advanced market commitments. First, there is the problem, as with prizes, of knowing ahead of time how to set the levels of payment when there will be so much uncertainty about the future need for any particular vaccine or treatment as others are continuing to emerge. Second, in contrast with prizes, the intellectual property is retained by the innovator, which may create a more complicated path toward assuring that pricing represents an affordable level for the government or ultimate payer. The innovator will have some leverage over pricing that it does not have in a prize approach, but it could be argued that the power of a government purchaser (if government takes this role from private insurers) would outweigh any advantage the innovator has through retained intellectual property.

## Conclusion

The COVID-19 pandemic presents challenges for the U.S. unlike any that the nation has faced in generations. Among the many challenges will be how to adapt the policy structure surrounding the development, pricing, and payment for new vaccines and treatments. The status quo may suffice, but many policymakers will feel they should explore options that may be better able to achieve the overall goal of fostering rapid development and equitable distribution of effective vaccines and treatments. This brief report offers historical context to inform the thinking of policymakers today, while outlining the potential advantages and disadvantages of several alternative approaches. No single policy option will gain consensus as the best approach. But now is the time when the public and policymakers should be actively debating how pricing will be managed within an overall platform to develop treatments for COVID-19 while achieving affordable access. The consequential discussion about the trade-offs and priorities involved with different pricing approaches cannot wait.

## Alternative Approaches to Pricing Novel Vaccines and Treatments for COVID-19

Pricing Approach	Advantages	Disadvantages
<b>Status quo: Unrestricted pricing</b>	<ul style="list-style-type: none"> <li>• Tried and true approach that has produced truly innovative products with significant clinical benefits for patients</li> <li>• Existing biopharmaceutical infrastructure positioned to respond to crisis with unrestricted pricing as the incentive</li> <li>• High prices in U.S. gives companies the opportunity to offer lower prices in developing nations</li> </ul>	<ul style="list-style-type: none"> <li>• Prices could be set so high as to create significant affordability problems, leading to access issues and increasing health insurance premiums</li> </ul>
<b>Cost-recovery pricing</b>	<ul style="list-style-type: none"> <li>• Would ensure the products are priced relatively low, maximizing affordability for governments and other payers</li> <li>• If self-adopted by the innovator, would maximize reputational gain</li> </ul>	<ul style="list-style-type: none"> <li>• Potential conflict on how to include “cost of development” in cost-recovery calculation, especially if federal investment was used</li> <li>• Prices in a cost-recovery model may be too weak to incentivize innovation of new effective treatments and vaccines</li> </ul>
<b>Value-based pricing</b>	<ul style="list-style-type: none"> <li>• Sets a ceiling price for new treatments based on clinical benefit patients receive, a price well-above a cost-recovery price for truly innovative products</li> <li>• Gives needed incentive to companies to invest in development</li> <li>• Creates a price ceiling to protect against most egregious excesses of unrestricted pricing</li> </ul>	<ul style="list-style-type: none"> <li>• Uncertainty of clinical benefit when a new treatment is first available can make calculations of value-based prices difficult</li> <li>• Value-based price calculations do not account for size of potential patient population, thus short-term affordability concerns not addressed</li> </ul>
<b>Monetary prizes</b>	<ul style="list-style-type: none"> <li>• Gives government certainty about costs, as the prize amount is set ahead of time</li> <li>• Using a pooled approach with funds from multiple governments allows for multiple production streams of the successful product(s) and broad international access</li> </ul>	<ul style="list-style-type: none"> <li>• Difficult to know how big to make the prize to incentivize companies to invest in developing an effective treatment</li> </ul>
<b>Compulsory licensing</b>	<ul style="list-style-type: none"> <li>• Ensures the government has a pathway to respond to a public health crisis by creating affordable access to treatments</li> </ul>	<ul style="list-style-type: none"> <li>• Legal challenges from patent holders are almost certain, making the viability of this approach questionable</li> <li>• May also provide inadequate incentives for discovery and development</li> </ul>
<b>Advanced market commitments and subscription models</b>	<ul style="list-style-type: none"> <li>• Gives government and other payers budget certainty when a new treatment or vaccine is available</li> <li>• Can set quality and efficacy standards ahead of time to incentivize development and ensure government does not pay for ineffective treatments</li> <li>• Company is assured revenue even if the immediate need for the product subsides</li> </ul>	<ul style="list-style-type: none"> <li>• Uncertainty about how to set the payment level ahead of time, and how to predict the patient population needing treatment, could lead to overpaying for the invention</li> <li>• Companies retain the IP and can exercise pricing power outside an advanced market commitment, or when one ends, that could lead to affordability issues</li> </ul>