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The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation

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Scientists are racing to develop vaccines against the novel coronavirus. While some vaccine candidates may enter the market in record time, the current vaccine innovation ecosystem exposes governance lacunas at both the international and domestic levels.

Scientists across the globe have been racing to develop vaccines against the novel coronavirus since its outbreak in early 2020. Following a period of [lukewarm interest](#) from the private sector, [dozens of companies and universities](#) quickly entered into vaccine development partnerships.

The most advanced vaccine candidates emerging from these partnerships started being [tested on human subjects](#) just a few weeks after initial research and development (R&D). This is a remarkably expedited timeline compared to the [multi-year timeline](#) usually needed to fully develop and produce a vaccine for testing.

In the United States, a vaccine developed by the National Institute of Allergy and Infectious Diseases in conjunction with an American biotech company, Moderna, began a six-week [clinical trial](#) in Seattle on March 16. Two days later, CanSino Biologics, a Chinese company, [announced](#) that its vaccine candidate, developed in partnership with the Chinese Academy of Military Medical Sciences, had also been cleared for human trials. That same week, a small German biotech company, CureVac, received [80 million euros](#) from the European Commission to bring a vaccine candidate into clinical trials by early summer. Another German company, BioNTech, [entered into a partnership](#) with

Pfizer to initiate clinical trials in April.

The quick-assembling mosaic of coronavirus vaccine development projects speaks to the propulsive effects of global health crises on vaccine R&D. At the same time, however, it sheds light on the systemic shortcomings affecting vaccine development targeting emerging pathogens.

First, investment in vaccine R&D remains unattractive to private-sector companies. Large pharmaceutical companies with the infrastructure necessary to produce massive amounts of vaccines tend to allocate resources elsewhere, as vaccine manufacturing is widely [deemed unprofitable](#). Second, outbreak-spiked funding for vaccine development is likely to decline precipitously as soon as the pandemic begins to wane, cutting short many of the development projects now underway, as was the case in the [recent outbreaks](#) of Ebola and Zika. And third, for the vaccines that are fully developed, there is [no guarantee](#) that they will be made available at affordable prices to all populations in need.

While some of these problems stem from the fact that the preventative nature of vaccines makes them less commercially appealing than drugs or treatments addressing mainstream diseases, others are the product of policy choices and legal infrastructure.

These problems relate partly to governance deficits in biopharmaceutical innovation systems. Even amidst public health crises, the process of developing cost-effective tools to prevent or curb outbreaks remains scattered among a multitude of players. While there are several transnational actors involved in global vaccine policy, there is no single institution or institutional network, focused primarily on the innovation dynamics surrounding vaccine development.

The World Health Organization (WHO), which oversees a large number of

vaccine-related areas, ranging from support and coordination of [clinical trials](#), to providing guidance on immunization [best practices](#) and on [vaccine policy](#), is not in a position to shift its attention and resources to address investment and market-related issues.

Over the past two decades, the primary mechanism to address problems surrounding the development and deployment of new vaccines has been through the formation of transnational public-private partnerships. Unlike the WHO and other global health actors, these partnerships operate exclusively in the area of vaccines. For instance, Gavi, a Geneva-based international organization, focuses on [expanding access](#) to vaccines in lower-income countries, thereby indirectly increasing demand for vaccine products. In the wake of the 2014 to 2016 Ebola outbreak, the Coalition for Epidemic Preparedness Innovations (CEPI) was created to [fund and coordinate](#) the development of vaccines targeting infectious diseases.

While the creation of CEPI constitutes a direct response to both shortcomings in the field of incentives to vaccine R&D and to coordination problems, it is unlikely to be enough. Although transnational public-private partnerships in the health space have been [proliferating](#) since the turn of the century, they face [several challenges](#). These include resource limitations, funding shortages, shifting transaction costs, and internal power asymmetries.

The problems created by resource scarcity at the beginning of the vaccine R&D pipeline are further compounded by problems arising at the end of the pipeline. Even in the case of vaccines that attract sufficient funding and are clinically successful, pricing and other intellectual property-related issues may arise during a vaccine's commercialization, rendering it unaffordable to large swaths of indicated populations.

Many components needed to develop new vaccines are [patented](#). Absent a

specific commitment to affordable pricing practices, the law gives companies holding rights over these vaccines the ability to prevent competitors from entering the market and thus charge supra-competitive prices. Even when legal frameworks require funders and patent holders to follow rules designed to increase competition and keep prices in check, these provisions often fail to be enforced. For instance, during the Zika outbreak, the U.S. Army [declined to negotiate](#) affordable pricing provisions with the manufacturer of the leading Zika vaccine candidate, citing, among other factors, its lack of expertise in this type of negotiation.

This problem stems from a [globalized](#) intellectual property framework, which has been implemented at the national level in ways that [increase](#) the rights of patent holders, but do not balance these rights with appropriate access and pricing provisions. International intellectual property treaties impose a [balance](#) between rights and obligations, particularly where [health](#) technologies are concerned. National applications of the international frameworks, however, routinely fall short of presenting a meaningful interpretation to balancing provisions, such as ensuring life-saving technologies like vaccines are not overpriced.

The case of the current coronavirus vaccines under development illustrates this point. On February 27, as the magnitude of the outbreak was becoming apparent, Secretary of U.S. Health and Human Services Alex Azar [stated](#) the government could not promise that the resulting vaccines would be sold at affordable prices.

Yet, nothing in international intellectual property frameworks prevents governments from taking such steps. In mid-March, Chile used an international law [mechanism](#) to pass a resolution allowing the government to [issue compulsory licenses](#) for any products needed to fight the coronavirus pandemic, including vaccines.

As outbreaks of infectious diseases are predicted to [occur more frequently](#) in our globalized world, this dissociation between the public health value of vaccines and the institutional and legal infrastructure supporting vaccine development and commercialization is increasingly problematic. Creating dedicated public-private partnerships is a step in the right direction to address the problem of insufficient funding for vaccine development. But if countries are unwilling to explore the full range of legal and policy tools available to make vaccines affordable, many populations across the globe will be deprived of access to critical public health tools.

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