Transforming Health Crisis with Pandemic Therapies


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A Report of the CSIS Commission on Strengthening America’s Health Security
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About the CSIS Commission on Strengthening America’s Health Security

The Covid-19 pandemic has exposed deep and diverse weaknesses in U.S. global health security policy and infrastructure and has triggered massive health, economic, and social crises. The CSIS Commission on Strengthening America’s Health Security will drive discourse and develop concrete, pragmatic action agendas for U.S. health security policy in the Covid-19 era. The commission brings together a distinguished and diverse group of senior leaders and is advised by a group of preeminent subject experts. Initiated in April 2018, the commission will continue its efforts through the end of 2022.

The commission is directed by J. Stephen Morrison, senior vice president and director of the Global Health Policy Center. More information on the commission can be found on its dedicated microsite at https://healthsecurity.csis.org.
Acknowlegdments

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Overview

Nearly three years into the global Covid-19 pandemic, vaccines, tests, and therapies have made the work of preventing, diagnosing, and treating patients infected with SARS-CoV-2, the virus that causes Covid-19, much easier. Unprecedented collaboration in research and development has resulted in the availability and emergency use authorization or approval of new vaccines in record time. However, with Covid-19 vaccine and booster coverage in many low- and middle-income countries far below global targets, tests and therapies remain critical tools to reduce transmission of the virus among susceptible populations and prevent a surge in hospitalizations that could rapidly overwhelm fragile health systems.¹

The agenda to develop and advance global access to Covid-19 therapies is under threat. With so much early attention focused on vaccines, efforts to develop and equitably disseminate Covid-19 therapies have been modest and not well coordinated, hampered in many places by limited access to Covid-19 diagnostic tests.² While the United States and other wealthy countries may experience interruptions in disseminating Covid-19 tests and therapies, low- and middle-income countries face even more pronounced setbacks as financing, demand, and implementation capacity all remain highly problematic. As new mutations of SARS-CoV-2 threaten to undermine the efficacy of existing therapies, sustained investments in research and development are crucial to support continued innovation in next-generation treatments. Yet political will and national and international commitments fall far short of what is required to ensure equitable and timely access to Covid-19 therapies for the populations at greatest risk of severe illness.

The CSIS Commission on Strengthening America’s Health Security convened a working group on Covid-19 therapies in the fall of 2021 to develop policy recommendations aimed at strengthening U.S. leadership and global action to ensure development of, access to, and uptake of Covid-19 therapies.
worldwide. Drawing on insights gleaned through private meetings and roundtable discussions with pharmaceutical manufacturers, government officials, representatives of multilateral organizations, and nongovernmental organizations, and building on points raised in an interim report published in July 2022, the working group recommends in this final report the following:

1. **Continue research and development** into a diverse set of treatment options, ensuring innovative therapeutic products are designed with the intent of reaching populations in high-, middle-, and low-income countries at the same time.

2. **Accelerate U.S. leadership and diplomacy** to mobilize adequate new resources for global distribution of Covid-19 therapies.

3. **Prioritize the development of a global coordination mechanism** to finance, scale, and monitor the international mobilization for Covid-19 therapies and future pandemic rapid response.

4. **Intensify the focus on strengthening health systems**, including greater emphasis on primary health care, to improve the capacity of health facilities and health workers to diagnose Covid-19 infections and deliver innovative Covid-19 therapies.

5. **Accelerate the development of a comprehensive communications strategy** to combat misinformation; provide accurate, independent, and accessible information; and improve patients’ and providers’ understanding of the uses and benefits of Covid-19 therapies.

For people who remain at high risk of severe illness from coronavirus infection, new Covid-19 therapies have the potential to transform a health crisis into a manageable event. Prioritizing a process that ensures all populations benefit equally and at the same time from Covid-19 therapeutic innovations can create a platform for effectively distributing therapies in future pandemics.

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Since 2020, the search for new Covid-19 therapies has involved assessing older products for new uses while stimulating development of innovative therapeutic approaches. Yet even as repurposed and novel products have received emergency use authorization, or in some cases full approval, for treating Covid-19, the research and development process has faced multiple challenges that are further compounded by limited political will and financing. These challenges include inadequate infrastructure and capacity for carrying out clinical trials, complicated regulatory processes, gaps in access to healthcare, misinformation about the risks and benefits of Covid-19 therapies, and limited understanding among healthcare providers about how to assess the appropriateness of treatment options for patients at greatest risk of severe illness.

Early in the pandemic, research collaborations such as the World Health Organization (WHO) Covid-19 Solidarity Therapeutics Trial, the European Union’s Therapeutic Innovation Booster, and Accelerating Covid-19 Therapeutic Interventions and Vaccines (ACTIV), led by the National Institutes of Health (NIH), were launched to coordinate and accelerate development and testing of promising new products. The Bill & Melinda Gates Foundation and Wellcome Trust, in cooperation with Mastercard, supported the Covid-19 Therapeutics Accelerator (CTA) to provide rapid and flexible funding for testing and development of new Covid-19 therapies. In China, universities and research consortia have also introduced promising antiviral treatment candidates.
Combination Therapy for Covid-19: Lessons from HIV/AIDS and Hepatitis C Virus

As deaths from HIV/AIDS increased in the 1980s, researchers assessing older drugs for new uses determined that azidothymidine (AZT), originally studied for treating cancer, could prevent the human immunodeficiency virus (HIV) from replicating in the body, prolonging the lives of people infected with the virus. As researchers identified other drugs that worked in ways similar to AZT, healthcare providers began prescribing several different medications to patients, establishing the combination therapy that came to be known as highly active antiretroviral therapy (HAART). Since early versions of HAART required patients to take numerous pills per day, providers observed significant risk of medication nonadherence and loss to follow-up. In 1993, to facilitate clinical trials and expedite development of combination antiretroviral therapy, Pfizer, Merck, GlaxoSmithKline, and other biopharmaceutical companies that had developed the primary therapies included in HAART joined forces via the Inter-Company Collaboration for AIDS Drug Development (ICC). By coordinating sharing of proprietary data, collaborating to determine shared benchmarks for assessing drug combination efficacy, and sharing compounds among corporate competitors, the ICC helped expedite effective drug development and regulatory approval processes.

Given the emergence of coronavirus variants—and the possibility that one or more could prove resistant to existing Covid-19 treatments—providers may need to offer patients combination therapies. Important lessons may be gleaned from the ICC and other initiatives, such as the Hepatitis C Drug Development Advisory Group (HCV DRAG) Drug Resistance Working Group, which brought biopharmaceutical companies together to work collaboratively on product development and testing. Such lessons include coming together voluntarily, formalizing a legal framework for sharing sensitive or proprietary data, soliciting input and feedback from affected communities, and engaging with government regulatory agencies as a group in order to facilitate testing, review, and approval of jointly developed products.

In the United States and elsewhere, new oral tablet antiviral preparations—Merck’s Lagevrio (molnupiravir) and Pfizer’s Paxlovid (nirmatrelvir/ritonavir)—have received emergency use authorization. The U.S. Food and Drug Administration (FDA) also approved Gilead’s Veklury (remdesivir) for treatment of Covid-19. The drug, which must be administered through infusion, was developed in cooperation with the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and evaluated for use against coronavirus diseases such as SARS, and Middle East respiratory syndrome (MERS), as well as Ebola viruses. While several monoclonal antibody treatments have received emergency use authorization, new sublineages of the SARS-CoV-2 Omicron variant have rendered some of these treatments ineffective, resulting in removal of authorization.
Sustaining a research agenda also depends on streamlined and integrated regulatory processes. In the United States, the FDA established the Coronavirus Treatment Acceleration Program (CTAP) to facilitate the availability of Covid-19 drugs and provide guidance and priority review for Covid-19–related products. In the European Union, the EU Strategy on Covid-19 Therapeutics outlines an approach for ensuring accelerated review, flexibility in packaging and labeling requirements, and conditional marketing authorizations. Under the strategy, the European Medicines Agency (EMA) works closely with member countries' regulatory authorities to secure approval for clinical trials. At least 20 Latin American and Caribbean countries use regulatory reliance to adopt marketing authorizations from the FDA, EMA, and Health Canada. Others in the region also rely on regulatory guidance from Argentina, Australia, Brazil, Chile, Japan, Mexico, and Switzerland. In sub-Saharan Africa, the WHO prequalification process has somewhat improved the region's fragmented approach to drug authorizations. The African Medicines Agency, which was established in 2021 after a two-year ratification process, is also scaling up operations with a focus on strengthening member countries’ regulatory systems and ensuring harmonization in product registries across the continent.

Overcoming regulatory hurdles does not guarantee that authorized products will be easily manufactured or made available to all countries in a transparent or equitable fashion. In 2021 U.S. president Joe Biden and EU president Ursula von der Leyen launched a joint Covid-19 manufacturing and supply chain task force with plans to link investments in research and development with manufacturing capabilities. In April 2021, Merck announced bilateral voluntary licenses with several generics manufacturers, followed in October by the announcement of a licensing agreement with the Medicines Patent Pool (MPP) to authorize production of molnupiravir in more than 100 countries. The MPP has also negotiated with 36 generics producers to manufacture generic versions of Pfizer’s Paxlovid to be sold in 95 low- and middle-income countries, with UNICEF committing to procure four million doses for country procurement. In May 2022, the Clinton Health Access Initiative (CHAI)
Katherine E. Bliss and J. Stephen Morrison announced it had also formalized agreements with generics suppliers to make a treatment course of generic Paxlovid available to high-risk patients in low- and middle-income countries at less than $25, a fraction of the $530 that the U.S. government had paid per course for domestic distribution.\textsuperscript{17}

However, recent analyses in the \textit{New York Times} and elsewhere have suggested that, as of early 2022, the vast majority of Paxlovid and Lagevrio purchases were from high-income countries. This raises the likelihood of repeating with Covid-19 therapies the inequities and delays seen with Covid-19 vaccines and HIV/AIDS treatments decades prior.\textsuperscript{18} Affordability questions, weak testing capacity, limited demand by governments that have not prioritized therapeutics in their pandemic response, and manufacturing complexities that make it difficult for some generics producers to enter the market all point to the importance of an integrated approach to research and development, production, and distribution.

\textbf{Figure 2: Voluntary Licensing under the Medicines Patent Pool}

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\end{center}

Note: This map depicts countries where producers have signed agreements to manufacture molnupiravir (Merck) and nirmatrelvir (Pfizer) under voluntary licensing agreements with the Medicines Patent Pool. Nirmatrelvir is the novel component of the co-packaged therapy sold under the brand name Paxlovid.

Source: See the endnotes for complete references.

Several developments have increased political momentum for making Covid-19 tools available worldwide, but obstacles remain. In May 2022, President Biden hosted the second Global Covid-19 Summit, with an emphasis on galvanizing global engagement and commitments in support of equitable distribution of Covid-19 therapies.\textsuperscript{19} The summit secured more than $3 billion in new funding pledges, but those focused on Covid-19 therapies totaled a mere $122 million and did not advance greater global coordination in planning for or expediting delivery of Covid-19 treatments to the most vulnerable communities. Notably, the United States announced an investment of $20 million in American Rescue Plan Act funds to join with the Global Fund to Fight AIDS, Tuberculosis and Malaria; Unitaid; and FIND to pilot Covid-19 test-and-treat strategies in up to eight countries.\textsuperscript{20} Merck and Pfizer committed to making courses of their antiviral medications available for distribution in low- and middle-income countries at reduced prices.\textsuperscript{21} The recently launched Financial Intermediary
Fund (FIF) for Pandemic Prevention, Preparedness and Response at the World Bank will offer countries long-term financing to strengthen their capacity to address disease outbreaks, including through distribution of therapeutic products. While not yet fully funded or focused specifically on Covid-19 therapies, the FIF promises to help countries make delivery of pandemic therapies an important element of future planning efforts.

Modest U.S. commitments toward global distribution of Covid-19 therapies reflect tension between domestic and foreign priorities and, importantly, Congress’s inability to pass additional essential resources for the domestic and overseas Covid-19 response. In July 2022, Democrats in the U.S. Senate proposed a $21 billion emergency supplemental funding bill, with $16 billion to support ongoing Covid-19 vaccine, testing, and treatment programs. In early September 2022, the Biden administration requested $22.4 billion in emergency funds for Covid-19 activities, $4 billion of which was to be devoted to global programs to “contain and treat the pandemic.” However these and other recent proposals for supplemental Covid-19 funds to support domestic and international programs have failed to gain broad bipartisan support. As a result, the Biden administration shifted $10 billion in funds meant for Covid-19 tests and protective gear to purchase 170 million new bivalent vaccine boosters and 10 million courses of Paxlovid. Without significant new financial commitments, U.S. leadership—and the ongoing response at home and abroad—will remain heavily constrained.

Medical Oxygen: Renewed Focus on a Time-Tested Treatment

The Covid-19 pandemic has underscored the importance of ensuring a sustainable supply of medical-grade oxygen for treating respiratory infections in clinical settings. Even before the pandemic, oxygen shortages in many low- and middle-income countries undermined efforts to prevent the deaths of an estimated one million children and adults experiencing a variety of respiratory ailments and breathing disorders. Because patients suffering from severe Covid-19 who receive oxygen have a greater likelihood of survival, difficulties securing medical-grade oxygen from pressure swing adsorption plants, maintaining oxygen-delivery equipment, and training health workers to properly administer oxygen therapy have led to higher death rates in many places.

Since 2020, several groups have focused on strengthening access to oxygen as a critical therapeutic intervention. In early 2021, the Access to Covid-19 Tools Accelerator (ACT-A) set up the Oxygen Emergency Taskforce, which included private, public, and multilateral agency members, to increase “access to liquid oxygen, oxygen plant repairs, and critical parts” in low- and middle-income countries. By October of that year, the task force had developed a strategic plan to identify priority countries, secure financing for plant maintenance and technical support, and address obstacles to efficient global distribution of liquid oxygen. In June 2022, the Global Fund, in collaboration with the Skoll Foundation, Unitaid, and Germany, committed to increasing support for oxygen supplies in eligible countries. To date, at least $800 million in donor funding has supported global oxygen supplies, but an estimated $1 billion in additional funds is needed to support treatment of Covid-19 patients and prepare for future health crises.

Ensuring people can—and want to—make use of Covid-19 medicines as they become available is a final challenge. One necessary step is ensuring supply meets demand. As recently as June 2022, there was a mismatch in the United States between the locations of reported Covid-19 cases and the
availability of antiviral and monoclonal antibody therapies. In some places, monoclonal antibodies, which require infusions, are not easily delivered because of limited clinical space or a dearth of health workers trained to administer them. WHO guidance on using monoclonal antibodies continues to evolve in response to the emergence of new variants resistant to existing preparations. Although oral antivirals are much simpler to administer in places where health systems are fragile, limited diagnostic capabilities, fragmented health systems, and poor access to healthcare at the community level can make it difficult for the most vulnerable patients to receive the care they need.

At the same time, communications about how and when to use Covid-19 therapies have been weak, leading to considerable confusion among healthcare providers about use of these therapies. Because of limited information about treatments, misinformation about unproven “cures” for Covid-19, such as ivermectin and hydroxychloroquine, has found a receptive audience, creating a new set of communications challenges that will stretch well into the future.

### Misinformation and Conspiracy Theories Related to Ivermectin

In June 2020, as Covid-19 cases mounted amid ongoing research into vaccines and effective antiviral therapies, claims that the antiparasitic drug ivermectin could successfully treat coronavirus began circulating on the internet. Reports of an Australian study that showed ivermectin to be effective in blocking replication of SARS-CoV-2 in a laboratory setting fueled intense public interest in the drug. The FDA and EMA warned against using ivermectin to treat Covid-19, noting that the dosage required to treat respiratory ailments would be dangerous to human health. Nevertheless, some physicians began prescribing ivermectin to patients with coronavirus infection. Other patients began purchasing ivermectin without a prescription through businesses catering to the livestock industry, which uses the drug for treating parasites in animals. Meanwhile, websites promoting ivermectin for preventing and treating Covid-19 proliferated, and social media pages touting its uses garnered thousands of likes. Podcasts disparaging vaccines and promoting ivermectin abounded.

As interest in ivermectin skyrocketed in the United States and internationally, the NIH included the drug in randomized clinical trials assessing the effectiveness of existing drugs in mitigating severe Covid-19. Studies published in 2022 concluded that ivermectin does not reduce the risk of hospitalization or recovery time. With multiple health authorities recommending against using ivermectin to treat Covid-19, the drug has become the subject of conspiracy theories positing that the U.S. government, in collaboration with multinational pharmaceutical companies, discourages uptake of ivermectin and other relatively inexpensive preparations, such as hydroxychloroquine, to promote newer, costlier drugs. As recently as September 2022, posts circulated on social media falsely claiming the NIH had quietly and suddenly added ivermectin to a list of antiviral medications it recommends. Many social media posts rejecting Covid-19 vaccines in favor of ivermectin claim that efforts to discourage its use are meant to bolster uptake of new, expensive drugs.
Recommendations

1. Continue research and development into a diverse set of treatment options, ensuring innovative therapeutic products reach populations in high-, middle-, and low-income countries at the same time.

To develop therapies that help prevent surges in infections that could overwhelm health systems, researchers, the private sector, governments, and nongovernmental organizations should be mindful of the barriers to equitable access to these products within low-, middle-, and high-income countries. From the beginning of the research process, they should prioritize development of treatment options suitable for use in diverse settings, endeavoring to make innovative products available across populations in a variety of contexts simultaneously. In addition to scaling up access to oral treatments, these groups should emphasize finding ways to deliver monoclonal antibody therapies more efficiently and affordably to populations with fewer resources.

Even as populations develop resistance to Covid-19 through immunization or prior infection, it remains important to strengthen incentives for companies to assess how therapeutic products from different manufacturers can be used in combination or prophylactically to support vulnerable populations that remain at high risk of serious illness. It is also important to continue streamlining regulatory processes through use of new regional approaches, such as the African Vaccine Regulatory Forum (AVAREF), the African Medicines Agency, and, critically, the WHO prequalification process, to accelerate the availability of new medicines and quality-assured generics that meet the criteria of global procurement organizations such as UNICEF and the Global Fund. Continued effort to modernize regulatory approaches and strengthen communications across regulatory agencies can help ensure a more rapid response in future pandemics.

At the global summit convened by the White House in May 2022, several U.S. agencies, along with Merck, Pfizer, and CHAI, announced commitments to make treatments for Covid-19 available at lower prices for low- and middle-income countries. But subsequent global meetings, such as the G7, have failed to prioritize Covid-19 therapies, with foreign ministers’ and leaders’ statements focusing almost entirely on vaccines.\textsuperscript{40} The White House and Congress will need to move beyond ad hoc emergency funding packages to reach consensus on major additional U.S. financial commitments for domestic and global Covid-19 efforts, including procurement and distribution of the full range of therapies. The Biden administration’s report on the first year of the American Pandemic Preparedness Plan offers a vision of steps that, with sufficient funding, can be taken to respond to Covid-19 and future pandemic threats.\textsuperscript{41}

Assertive U.S. diplomatic outreach is essential to win greater commitment from other countries to support globally equitable access to Covid-19 therapies. The G20 meetings to be hosted in November 2022 by Indonesia and the G7 summit to be hosted by Japan in May 2023 offer opportunities to highlight the importance of continued investment in global access to therapies.

3. Prioritize the development of a global coordination mechanism to finance, scale, and monitor the international mobilization for Covid-19 therapies and future pandemic rapid response.

As of September 2022, there was no global equivalent of COVAX, the global vaccine access program, to finance and oversee the equitable global distribution of Covid-19 therapies. Instead, the field appears fragmented, populated by pilot projects and efforts to assess the scalability of various products in a small set of countries. The ACT-A therapeutics pillar, co-led by Wellcome Trust, the Global Fund, and Unitaid, has focused on improving low- and middle-income countries’ access to medical oxygen and steroid treatments.\textsuperscript{42} ACT-A is now reportedly overseeing country readiness assessments to determine needs and capabilities for distributing oral antivirals, including Paxlovid, which secured strong recommendation from the WHO in April 2022, and molnupiravir, which received conditional recommendation.\textsuperscript{43} ACT-A could potentially be modified and its mission expanded to oversee the large-scale distribution of Covid-19 therapies. However, in the face of considerable funding gaps and uncertainty as to what form the various ACT-A pillars will take after the end of 2022, it will be important to explore other options to replace or complement this work through integration of public, private, philanthropic, and government efforts.\textsuperscript{44} Given the strong roles the Africa Centres for Disease Control and Prevention and the Pan American Health Organization (PAHO) have played in procuring commodities for the Covid-19 response, regional networks are well positioned to play a larger role in financing and distributing therapies as they become more readily available.

The United States should play a leading role in convening an ad hoc consortium of countries focused on coordinating and advancing access to innovative Covid-19 therapies worldwide. Several U.S. agencies are well positioned to contribute to this coordination effort. Within the U.S. government, this would involve achieving better unity of efforts across different agencies. The U.S. Agency for International Development (USAID), which is leading bilateral efforts to support countries in distributing Covid-19 therapies, could incorporate funding for such activities into its existing Covid-19 response strategy. In doing so, it should work in coordination with the U.S. Department of Health and Human Services (HHS) and other federal agencies. The U.S. Biomedical Advanced Research and Development Authority (BARDA) should continue to lead U.S. efforts to accelerate testing and treatment development and support, expanding
the industrial base for manufacturing in the United States. Meanwhile, the CDC could play a key role in working with ministries of health and other partner organizations to research, standardize, and promote appropriate testing in countries around the world to ensure effective use of therapies.

PEPFAR has considerable experience delivering antiviral therapies. It leads U.S. representation on the board of the Global Fund, which currently finances more nonvaccine Covid-19 interventions for low- and lower-middle-income countries than any other organization and recently signed an agreement with Pfizer to provide six million courses of Paxlovid for distribution to low- and middle-income countries starting in late 2022. This points to PEPFAR’s prominent role in ensuring that U.S. bilateral approaches to Covid-19 testing and treatment complement multilateral agencies’ strategies.45

4. **Intensify the focus on strengthening health systems, including greater emphasis on primary health care initiatives, to improve the capacity of health facilities and health workers to diagnose Covid-19 infections and deliver innovative Covid-19 therapies.**

Outside high-income countries, demand for purchasing antivirals remains lukewarm. This may be because there has not been an advanced market commitment for therapies as there has been for vaccines through the COVAX Facility, or because government procurement agencies in low- and middle-income countries may not prioritize Covid-19 therapies over the other health needs of their populations.46 Underresourced health systems may not be capable of ensuring that patients are diagnosed and begin treatment within the five-day window following symptom onset. New initiatives, such as the COVID Treatment Quick Start Consortium, aim to assess what it will take to increase distribution of therapies in 10 low- and middle-income priority countries.47 Led by Duke University, CHAI, Americares, and the COVID Collaborative, with support from Open Society Foundations, the Hilton Foundation, and Pfizer, the consortium can shed light on the factors that hamper or encourage successful distribution and uptake of therapeutic approaches. As interest in therapies increases, actors including the U.S. government, UNICEF, and other global procurement organizations such as the Global Fund could serve as large-volume buyers to ensure production, particularly of quality-assured generic products from generics licensees.

The U.S. government is already working to support health systems strengthening activities through several ongoing and recently announced programs. The Global Health Worker Initiative, proposed by President Biden in May 2022, calls for $1 billion to support the recruitment, training, professional development, and retention of public healthcare workers.48 The Action Plan on Health and Resilience in the Americas, announced in June 2022, establishes the Americas Health Corps, which will train half a million health workers throughout the Latin America and Caribbean region.49 Directing these and other related bilateral efforts in support of primary health care and progress toward universal health coverage can support distribution of Covid-19 therapies in countries worldwide and pave the way for enhanced response in future health crises.

5. **Accelerate the development of a comprehensive communications strategy to combat misinformation; provide accurate, independent, and accessible information; and improve patients’ and providers’ understanding of the uses and benefits of Covid-19 therapies.**

Since early 2020, misinformation about Covid-19 treatments has confused patients and providers, diverting resources to unproven products and causing harm to people who have taken potentially dangerous remedies instead of being vaccinated or treated with tested products. Scientific agencies have responded by posting accurate and evidence-based information on their websites, but when the
resources are highly technical or academic in nature, they may be difficult for the general public to understand. Working with mainstream and social media to limit dissemination and amplification of misinformation and intensify circulation of accurate, evidence-based information about Covid-19 therapies that is accessible to a nonspecialist audience could help improve trust and patient outcomes.

Given the challenges of misinformation, it is critical that trusted independent messengers communicate the benefits, eligibility criteria, and uses of novel products so providers feel confident prescribing new products and patients feel comfortable using them. There has been considerable confusion, both domestically and globally, about who is eligible for Covid-19 therapies and how best to administer them. In the United States, the NIH and the CDC both provide clinical guidance for the use of Covid-19 therapies, while the WHO maintains a “living guideline” on various therapeutics for Covid-19. Finding ways to share best practices and messages across countries and sectors will help address uncertainties and create greater trust in and demand for lifesaving therapeutic products.

The CDC is currently undertaking an internal reform effort to improve the way it works with other elements of the federal government, collaborates with state and local authorities, and communicates with the American people regarding public health issues. As it examines failures in messaging regarding global health threats and considers steps to ensure timely, accurate, and meaningful communications, the CDC can take the lead domestically and share lessons learned with international partners grappling with the challenges of misinformation, disinformation, and regaining the trust of an uncertain public.
Conclusion

In the nearly three years since the first cases of Covid-19 were reported, international collaboration in research and development, as well as product distribution, has led to a wide range of options to treat patients at high risk of severe illness. New antiviral preparations, along with monoclonal antibodies, are broadly available in many high-income countries, but access and uptake in low- and middle-income countries lag. Without concerted international financial and political commitments to ensure greater global access to and uptake of these important Covid-19 innovations, the effort to end the Covid-19 pandemic could regress. Without sufficient financing, commitments to ongoing research and development, or communications to combat misinformation and help providers and patients understand the uses and benefits of Covid-19 therapies, infrastructure for developing new therapies could be in disarray or decline when a dangerous new subvariant emerges.

Several processes that are underway offer opportunities for reinvigorating and accelerating progress in providing globally equitable access to Covid-19 therapies. These include the ongoing discussions of the Intergovernmental Negotiating Body, which oversees the process of drafting an international agreement on pandemic prevention, preparedness, and response; the ongoing reforms at the CDC; and the recently launched FIF, among others. Within the United States, bipartisan collaboration to secure financing for domestic and international efforts will help galvanize broader global engagement to advance an international coordination mechanism to distribute therapies to low- and middle-income countries, strengthen health systems to effectively deliver Covid-19 therapies, and communicate the uses and benefits of therapeutic interventions for current and future pandemics to providers and the public at large.

Therapies have grown significantly during the most recent phase of the pandemic as a strategically important tool across all geographies. Given the expectation that large waves of Covid-19 infection
will persist, vaccines will not be—nor should they be seen as—the single dominant solution. Demand for testing and treatment options will continue to increase. The race to develop diverse new therapies, to partner them with expanded testing capacity, to solve the riddle of deep inequities in access, and to predict emergent drug-resistant viral variants will remain a priority. Success will not come easily given widening complacency, financial and political impasses, momentary lapses in market demand for therapies, and the exhaustion and institutional depletion from almost three years of the pandemic. But there is no option for turning away. As such, this report provides specific, concrete, realistic, and meaningful steps that can move the global response to both Covid-19 and future pandemics forward.
This report conveys a majority consensus of the signatories who are participating in their individual capacity, not as representatives of their respective organizations. No expert is expected to endorse every single point contained in the report. In becoming a signatory to the report, experts affirm their broad agreement with its findings and recommendations. Language included in this report does not imply institutional endorsement by the organizations that participants represent.

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About the Authors

**Katherine E. Bliss** brings her expertise in the social sciences, Latin American studies, and international relations to her work analyzing U.S. government support for health programs in low- and middle-income countries. She is particularly interested in how political and cultural perspectives shape approaches to such global health challenges as HIV/AIDS; vaccine-preventable diseases; and access to safe drinking water and sanitation. Trained as a historian, Katherine spent the early part of her career teaching at the university level and publishing books and articles on gender relations and public health in twentieth-century Mexico. A Council on Foreign Relations International Affairs Fellowship enabled her to shift her focus to global health policy, placing her at the U.S. Department of State, where she worked on environmental health issues and the development of foreign policy approaches to pandemic preparedness.

At CSIS, Katherine has previously served as deputy director and senior fellow within both the Americas Program and Global Health Policy Center, where she oversaw a multi-program project on the influence of the BRICS countries on the global health agenda and directed the Project on Global Water Policy. Her recent work has examined the health situation in the context of the Venezuelan political crisis and the challenges facing immunization programs within fragile or disordered settings. Katherine received her AB in history and literature, *magna cum laude*, from Harvard College and her PhD in history from the University of Chicago. She completed a David E. Bell Fellowship at the Harvard Center for Population and Development Studies.

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Endnotes


“COVID-19 Therapeutics,” Launch & Scale Speedometer.


Figure 1


Figure 2


