IF NOT NOW, WHEN? THE PANDEMIC AND POLICY TRANSFORMATION BEYOND THE TIME OF COVID-19

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The sum of human actions that combine to write historical narratives cannot always be understood while still in the midst of crisis and shock. The COVID-19 pandemic's shock across all aspects of American life has inevitably led to the unveiling of systemic fractures in public health and social safety nets, creating an unprecedented challenge for elected officials across the country—and has resulted in a call for bold new policy making, coordination, and resources across all levels. While the pandemic is revealing long-standing systemic inequities, it remains to be seen whether the crisis will finally force us to radically rethink policy making and resource allocation, and transform our approach to global and domestic public health altogether. For veteran health justice activists, the current openness to consider and implement proposals previously labeled "radical" raises the question: if these policies are appropriate to address COVID-19, why not for other infectious diseases or chronic conditions? In a global crisis, what else is required to overcome partisanship, incrementalism, and nationalistic insularity?

The signs of a failing system have come into clear focus: The novel coronavirus's impact has not been felt equally. An inability to isolate—whether due to incarceration, performing so-called essential work (e.g. providing food, direct care, etc.), or poverty (lack of a permanent home or crowding in substandard housing)—significantly increases the risk of exposure and infection. Those who are incarcerated or in essential jobs are overwhelmingly the poorest and are disproportionately Black, Latinx, and Indigenous.[1, 2]As has been the case with other medical crises and conditions, innovations and medical breakthroughs have not been designed or delivered accessibly and affordably to all.

Almost immediately, increased risk was reframed around groups seen as disposable groups: older people and those with pre-existing conditions. Blame for viral transmission was cast along racial and ethnic lines, as experienced by Chinese American and Orthodox Jewish communities.[3,4] As the outbreak spun out of control, incomplete evidence and conflicting messages from public health officials led to the undermining of social distancing measures . A significant minority of Americans reject masks and other emergency measures altogether—sometimes violently—as assaults on individual freedom, opening a new front in partisan culture wars that overlapped frighteningly with the backlash against calls to end anti-Black structural oppression and police brutality.[5]

The worldwide loss of life, income, and livelihoods because of COVID-19 is arguably unprecedented in its sudden onset and breadth. Structural inequities have been exposed in the most brutal terms: the economic status quo underpays the labor force needed to sustain life and well-being, and provides neither protection nor rescue to those whose labor is deemed non-essential during the crisis. In the U.S., tens of millions were left to face unemployment with no functioning system to provide replacement income or food relief. In India, millions were sent on forced marches back to their places of origin in order to "shelter in place."[6] Private monopolists reaped billions, while pharmaceutical corporations received billions in public funds with limited or no oversight or conditions.[7,8] Promised free tests, treatments, and vaccines have not materialized, while "surprise" bills in the thousands hit Americans with health insurance, and lack of coverage keeps others away from testing and care.[9] Yet, as of this writing, in the U.S. no legislation to address the upstream drivers of high health care prices has been considered, and neither presidential candidate has affirmed the human rights to health care and the benefits of science.

While the devastating disruption to economic activity may be unique to COVID-19, the cycles of denial, fear, marginalization, polarization, and backlash are depressingly reminiscent of the early years of the AIDS pandemic. Not only have we seen a return to the ugly normalization of mass death for those deemed less worthy, but rather than apply the lessons of HIV and leading with honest, clear communication that seeks

to educate about the relative risks of different activities and empower people to protect their communities, law enforcement and public shaming formed the central pillars of the response. Predictably, this has deepened racial disparities, with the New York Police Department arresting Black people for not wearing masks in some city neighborhoods while handing out masks to White sunbathers in others (and with police routinely going without masks themselves).[10]

As the U.S. continues to allow structural disparities to disproportionately kill, the politicization of the crisis extends to research and development, manufacturing, and access to prospective treatments and vaccines. News reports of interference by executive branch authorities in all aspects of the COVID-19 response are too numerous to cite completely.[11] And as U.S. states and localities were left to battle among themselves for scarce resources, national leadership escalated a zero-sum game, pitting nation against nation. This patchwork application of policies continues to have limited effect in slowing the pandemic and will inhibit the global recovery. We see this starkly in the U.S.'s announced withdrawal from participation in and funding for the World Health Organization (WHO) (see Lovinger, p. 17), but it is also found in the U.S. government's prospective purchasing agreements with vaccine manufacturers, forgoing the WHO-led technology pool.[12]

Another particularly concerning undercurrent in the COVID-19 pandemic is a pattern of high-income countries leveraging public health research and development (R&D) investments that are meant for the common good to the exclusive benefit of their citizens. Instead, we need a systems approach that brings the world's diversity of experience to bear, rather than concentrating R&D and its fruits in rich countries. For all countries, the best national defense is a robust health and innovation system resourced to meet the needs of the people, including people beyond a country's borders.

Tuberculosis (TB) offers an important illustration: the U.S. government contributes 60 percent of public expenditures for R&D for TB, which kills more people every year than any other infectious disease.[13] This funding has led to game-changing tools, including shorter treatment for TB, the TB preventive therapy 3HP, the GeneXpert diagnostic platform, and bedaquiline treatment for antibiotic-resistant TB. Programs funded through the U.S. Agency for International Development (USAID) and the President's Emergency Plan for AIDS Relief (PEPFAR) implement these tools broadly in low- and middle-income countries in the name of "global health security," recognizing that supporting and coordinating with countries to help stem epidemics protects high-income countries of from experiencing emerging epidemics as well. This cooperative paradigm of shared health diplomacy has existed for years in global health, and it has been applied across a variety of infectious diseases.

During the current crisis, however, the U.S. and other high-income countries have invariably chosen nationalism over cooperation, flexing their fiscal power to hoard and pre-purchase scarce public health goods, without equitable allocation and affordable pricing for low- and middle-income countries. Many of these products and tools are underwritten by high-income countries, breeding a sense of entitlement to be "first in queue" to access emerging tools that are funded by their government and taxpayers.

COVID-19 has highlighted the routine reaping of private profits underwritten by public funds. One striking example is the U.S.-based diagnostic manufacturer Cepheid Inc.—maker of the above-mentioned GeneXpert diagnostic platform, which has set the price for its Xpert Xpress SARS-Cov-2 cartridge at an unaffordable $20 per test for 145 low- and middle-income countries. The company received $3.7 million in public funding through the U.S. government's Biomedical Advanced Research and Development Authority (BARDA).[14] The SARS-CoV-2 cartridge uses the company's existing diagnostic platform, which itself was scaled up and implemented in low- and middle-income countries using U.S. government support.

Negotiations through the WHO's Diagnostics Consortium have secured volume commitments for four months' worth of COVID-19 diagnostics supplies for low- and middle-income countries. However, Médecins Sans Frontières contends that companies such as Cepheid are not using the full extent of their manufacturing capabilities and that high-income countries are effectively cornering the market by buying up available supplies at the price set by the company.[15]

Despite long-standing and emerging structural and systemic inequities surfacing as a result of the pandemic, the opportunity remains to advance policy change. Governments must remake partnerships and bilateral aid to undo colonial power dynamics and build national public health sovereignty. Accountability and transparency must be attached to public investments received by private entities charged with developing public health tools. Communities should strategically advance the right to science and health; the "business as usual" approach has clearly not worked.

Table 1: Progressive U.S. Policymaking and Legislation to Address COVID-19

Bill Title and Number	Bill Summary	Proposed Improvements
Coronavirus Aid, Relief, and Economic Security Act (CARES Act), H.R. 748	▪ Provided critical funds to shore up public health programs and health systems in response to COVID-19. ▪ Included significant funding to Department of Health and Human Services research agencies, the National Institutes of Health/National Institute of Allergy and Infectious Diseases, and the Biomedical Advanced Research and Development Authority (BARDA) to pursue product development of medical countermeasures for COVID-19 and contract with the private sector in the development and production of tools.	▪ Add stronger accountability and transparency measures attached to federal grants and funding of therapeutics, diagnostics, and vaccines development and manufacturing issued to the private sector. ▪ Require a parallel true cost of goods analysis be submitted to the federal government detailing expenditures on products and manufacturing scale-up that uses funding from the CARES Act. ▪ Create additional backup measures such as invoking the Bayh-Dole Act to issue compulsory licensing in the case of unaffordable price-setting by product developers.
COVID Community Care Act, H.R. 8192 COVID-19 Health Disparities Action Act of 2020, H.R. 8203 and S. 4262	▪ These bills would provide emergency supplemental appropriations and grants aimed at implementing comprehensive public health programs to address COVID-19 in medically underserved communities hit hard by the pandemic. This would include testing and culturally competent care.	▪ Extend legislative provisions requiring publication of a comprehensive strategy toreduce health and health disparities related to COVID-19 across race, economic status, and other demographics to other infectious diseases, with targeted funding to alleviate these disease burdens.
Immediate COVID Testing Procurement Act, H.R. 6609 COVID-19 Emergency Production Act, H.R. 7018 COVID-19 Emergency Manufacturing Act of 2020, H.R. 7113 and S. 3847	▪ H.R. 6609 would require the government to issue purchase orders for necessary components and supplies to conduct COVID-19 testing under the Defense Production Act of 1950 (DPA). ▪ H.R. 7018 would allow the government to establish a "fair and reasonable price" for COVID-19 supplies produced under the DPA and for the federal government to coordinate distribution to states based on need. ▪ H.R. 7113 would establish an Emergency Office of Manufacturing for Public Health to coordinate manufacturing of key components for critical public health products for COVID-19, as well as to negotiate pricing with manufacturers.	▪ Create a mechanism for public health programs to report a broad and flexible list of vulnerable supply chains for other infectious diseases of public health concern, to rapidly authorize the use of the DPA to mitigate shortfalls and stockouts in critical public health products. ▪ Allow for fallback measures such as compulsory licensing if the private sector does not comply with DPA requests. ▪ Provide funding to scale up domestic manufacturing and supply chains for active pharmaceutical ingredients and other materials.
Taxpayer Research and Coronavirus Knowledge Act of 2020, H.R. 7288 and S. 4539	▪ This bill would establish a federal database of information detailing federal/public investment in and support for biomedical research and development for COVID-19 products. ▪ Information listed would include any funding received, tax benefits, incentives, patent filings, etc. for a range of products for treatment and prevention of COVID-19.	▪ Create stronger penalties for noncompliance in reporting information from private sector entities that are receiving public funds. ▪ Use this precedent to establish a similar database for other critically important drugs, diagnostics, and vaccines of public health significance that were also publicly funded, with future government contracts and incentives baked in requiring the disclosure of such information. ▪ Limit the application of "trade secrets" in the submission of such information. ▪ Establish and confirm policy mechanisms to reclaim any licenses or patents for noncompliance.
Make Medications Affordable by Preventing Pandemic Price Gouging Act of 2020, H.R. 7296 and S. 4439	▪ Would require any COVID-19 drug that has received federal support and public funding in its development to be affordable and accessible, with the aim of preventing monopolies and price gouging by private industry. ▪ Calls for nonexclusive licensing, with a "reasonable royalty" paid to the patent holder. ▪ Would require "reasonable pricing" to facilitate global access. ▪ Reporting requirements would include manufacturer expenditures on materials and manufacturing, R&D costs, total amount of government support received, and other federal benefits (tax credits, incentives).	▪ Amendments or other measures should be made to prevent monopolies and price gouging on additional medicines that are of public health interest, especially those in short supply. This bill should also encourage or require manufacturers to pledge their intellectual property and licenses to structures being set up globally, including the WHO COVID-19 product pool and the Access to COVID-19 Tools Accelerator's vaccine pillar (COVAX).

Old progressive policy ideas are new again and are being introduced at an increasingly fast clip in the U.S. and globally. Israel's health minister, for example, issued a compulsory license for lopinavir/ritonavir, an HIV antiretroviral medication for the purposes of treating COVID-19 after manufacturer Abbvie failed to commit quantities of its version, Kaletra, for the country. In a domino effect, other countries are following suit: Canada, Chile, Ecuador, and Germany are some of the few that are opening their patent policy to allow for compulsory license strengthening, particularly in the COVID-19 context.[16] The pandemic places the Australian government in a position to consider invoking the recently updated Crown Use Act, which its strengthened provisions authorizes the government to override patents for public health products.[17] Abbvie later suspended its intellectual property on lopinavir/ritonavir as a result of Israel's bold move.[18]

Policymakers are attempting to advance similar policies in the U.S. (see Table 1), where legislators are scrambling to strengthen health systems in testing and care, as well as to ensure the availability and affordability of COVID-19 therapeutics and vaccines that were publicly funded (predominately by the CARES Act and other stimulus bills). However, an important feature of these proposed progressive policies is that these measures are temporally specific to the current pandemic.

But the fact that policymakers are introducing concepts that have been historically called for by activists, particularly in the Access to Medicines movement, is a strong indication that policy makers may finally be receptive to these concepts and ideals, and breaking the partisan divide. It is up to us as a community of advocates and activists to make the case that these temporary fixes be made permanent, to transform public and global health responses for future pandemics and for the current HIV, TB, hepatitis C virus, and other infectious disease epidemics.

We cannot predict the next potential pandemic. But we can prepare the R&D pipeline and strengthen health systems now to better respond to outbreaks before they become pandemics. We know that the TB response helped with the HIV response, the HIV response helped with the Ebola response, and the Ebola response helped with the COVID-19 response. But we have to bring this learning to scale to make sure it reaches all countries, as well as the most vulnerable within each country. This takes bold, transformative policy making to counter rising nationalism in public health and to promote global good. We must identify the barriers that have slowed our response to previous pandemics and not repeat those hard lessons.

Transformation must penetrate multiple levels. Returning to the increased relative risks from COVID-19 because of comorbidities: in order to treat cardiovascular disease, for example, affordable access to primary care and medications is required. The food system, recreational spaces, air quality, and education all must be considered and remade in order to address cardiovascular disease in a South Side Chicago; a Bronx, New York; or a Southeastern Washington D.C. neighborhood. We can only end the COVID-19 pandemic, and be prepared for the next pandemic, when we use radical policy making to address the status quo that keeps us so vulnerable to so many other harms.

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