o end hiv/aids, hepatitis c, and tuberculosis



'THE STRUGGLE OF A LIFETIME' (CONTINUED)

"Ours is not the struggle of one judicial appointment or presidential term. Ours is the struggle of a lifetime, or maybe even many lifetimes, and each one of us in every generation must do our part." –U.S. Representative John Lewis (1940–2020)¹

By Mark Harrington and Erica Lessem

hen we opened TAGline with the words above one year ago, we could not have remotely predicted either the specifics or the scale of struggles of the year to come. These struggles continued to be against alltoo-predictable evils: the utter failure of governments around the world to respond adequately to crises; blatant disregard for human life; unconscionable institutionalized violence, racism, sexism, and classism; the prevailing of political assertions over fact; and the prioritization of power and profit over people. During the ongoing, still growing, and out-ofcontrol COVID-19 pandemic, "essential workers" continue to be treated as expendable. Banks and airlines receive huge bailouts and titans of industry and big corporations turn record profits, while old people are left to die isolated and alone in institutional settings, people experiencing homelessness are more vulnerable and stigmatized than ever-including by New York Gov. Andrew Cuomo²-and incarcerated people are sitting ducks in prisons and jails, where large outbreaks have infected over 242,000 people and killed at least 1,400 (likely a vast underestimate given low testing coverage).³

At the time of writing, over 2 million human beings who were alive in January 2020–including courageous Chinese whistleblower Dr. Li Wenliang, HIV researcher Gita Ramjee, and many of our loved ones–have died from COVID-19 and the lack of appropriate government preparation for and response to it. This year–as throughout U.S. history–police violence, racism, and transphobia have ended so many Black lives, so many trans, Latinx, and Indigenous lives. In recent months, we have lost activists, pioneers, and national leaders: performing artist Nashom Wooden, aka Mona Foot (1970– 2020); harm reduction activist Elizabeth Owens (1959– 2020); Representative John Lewis himself (1940–2020); Representative Elijah Cummings (1951–2019); Supreme Court Justice Ruth Bader Ginsburg (1933–2020); and the courageous Timothy Ray Brown (1966–2020), the first person ever to be cured of HIV infection. Working within and for the struggle until they died, these people gave more than their example, work, or lives—they give us inspiration, lessons learned, strategies and tactics, and hope. We dedicate this issue of TAGline to <u>all</u> of them.

n the U.S., we continue to struggle with the vicious and violent forces that go back to the country's origins, when colonists seized land from Indigenous nations and entrenched the institution of slavery. The parameters of the struggle have morphed over the years, taking different such as genocide, slavery, massacres, lynching, Jim Crow, the confinement of Native Americans to reservations, the confinement of people of color-particularly Black Americans-by the carceral state, redlining, the war on people who use drugs, and voter suppression and disenfranchisement. Yet these various presentations harbor a continuous underpinning of vigilante and police violence and other forms of political, economic, and social discrimination and segregation. o overcome these and other injustices, movements were formed, grew, expanded, fragmented, and branched throughout American history. These movements had a range of focuses: Native American rights and survival, abolition, labor, anti-war, women's rights, LGBTQ+ rights, civil rights, the Movement for Black Lives, the #MeToo movement, and movements for the rights of immigrants, prisoners, and people who use drugs.

TAG's particular struggle—the movement against AIDS and its deadliest coinfections—centers on the intersection of human rights, public health, and social justice. Our struggle, both scientific and political, is inherently intersectional, multidimensional, and multigenerational. Our movement builds on the legacy and intersects with the past, present, and future of these historic movements toward justice, liberty, and equality for all.

These movements have achieved so much, but gains can be taken away. The Supreme Court gutted the Voting Rights Act;⁴ the Affordable Care Act has been under attack for the past 10 years; abortion rights continue to be eroded and could be further curtailed by the determined fiat of a reactionary Supreme Court. Progress has been far from linear. Labor movements grew in strength from the mid-1800s to the mid-1960s but are now significantly weakened (with the notable exception of police and prison worker unions). And many of the touted gains along the way belied insidious injusticeseven in its strength, the labor movement usually recapitulated the racism of broader society. Before the Civil War, slavery abolitionists and suffragists formed an alliance; this movement fragmented as Black men-but not women of any color-got the vote, and racism pervaded parts of the women's suffrage movement, denigrating Black men and leaving Black women behind and invisible.

s we prepare to emerge from one of the most fraught election cycles in U.S. history, we reflect on what this means for sustaining and gaining progress in our movement. Elections themselves do not solve problems, they only reposition them, raising new sets of issues and reframing the injustices of history. The role that elections are supposed to play–one of national catharsis, because they symbolize the chance to achieve closure in one political cycle and begin another—is belied by the persistent obstacles and inequities in access to the simple right to vote. Back in 2008, some were quick to conclude that the election of President Barack Obama signified the U.S.'s transition into a post-racial state. The persistence of widespread racism in this country under both his tenure and the four years of the current presidency clearly and painfully proves the untruth of this proposition.

Instead, what history shows us is that—as the Honorable John Lewis wisely noted—struggles last for generations and pass through multiple cycles of presidents, Senate and congressional sessions, and Supreme Courts. The reality is that the changes we are trying to enact are extremely difficult no matter who is in office.

What history shows us is that [...] struggles last for generations and pass through multiple cycles of presidents, Senate and congressional sessions, and Supreme Courts. The reality is that the changes we are trying to enact are extremely difficult no matter who is in office.

he most productive and lasting changes are instigated, led, and supported by popular movements and are raised to national attention and action at critical times when the political configuration of the national government allows for substantive change. This was true in the wake of the Civil War, when radical Republicans dominated Congress because the Southern states that seceded had yet to regain representation, and during the New Deal, when President Franklin D. Roosevelt's coalition had supermajorities in both houses of Congress (though many New Deal programs, excluded Black Americans from their benefits, whether in access to federal home loans or participation in Social Security). Similarly, after President John F. Kennedy's assassination and Lyndon B. Johnson's landslide victory in 1964, Congress was able to pass historic civil rights, housing, and education legislation-not to mention establish

Medicare and Medicaid–which set the stage for a juster America. Tragically, the promise of Johnson's Great Society was destroyed by the national conflagrations that ended the 1960s, including assassinations, urban uprisings, and the seemingly endless Vietnam War. Even the more moderate advances of the Obama-era Affordable Care Act were only possible because the Democrats controlled both houses of Congress for a brief period ending in the 2010 midterm elections.

This issue of TAGline exemplifies and extends the continued struggle for everything we've already won and the things we have yet to win– and the wisdom that government institutions and initiatives can only work with full ownership of the People.

This edition of TAGline delves into how to effect these profound changes through systems built for and by the people, starting with Annette Gaudino, Suraj Madoori, and Matt Rose's visionary <u>article</u> on how the U.S. and governments around the world must transform to better prevent and respond to pandemics, and how communities must hold them to account. We see evidence for this community power–as well as the stubborn structural and social barriers and gaps–in Edric Figueroa's <u>interviews</u> with community leaders working to end HIV in the U.S. Their work and that of the ACT NOW: END AIDS coalition brings community power to influence the implementation of the federal Ending the HIV Epidemic plan for equitable, meaningful, community driven progress. This need for community ownership and involvement extends to the research sphere. Richard Jefferys and Lindsay McKenna parse how <u>research equity</u> is fundamental for gender and racial equity in the response to COVID-19 and other conditions. And finally, Elizabeth Lovinger and Anthony D. So broaden our focus to the <u>global level</u>, illustrating how community participation, and U.S. support and participation, are essential for an effective coordinated global health response by the World Health Organization.

his issue of TAGline exemplifies and extends the continued struggle for everything we've already won and the things we have yet to win–and the wisdom that government institutions and initiatives can only work with full ownership of the People. As James Baldwin wrote in 1963, "The future is going to be worse than the present if we do not let the people who represent us know that it is our country. A government and a nation are not synonymous. We can change the government, and we will."⁵

As we enter the next phase of the struggle to cross the bridge from the injustices of our history and today's society to achieve the vision of a just, equitable world, we close with words again from the Honorable John Lewis of his legendary participation in the 1965 voting rights march across the police-blocked Edmund Pettus Bridge in Selma, Alabama:

"We were beaten, we were tear-gassed. I thought I was going to die on this bridge. . . We cannot give up now. We cannot give in. We must keep the faith, keep our eyes on the prize."

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

By Matt Rose, Annette Gaudino, and Suraj Madoori

he 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.

Almostimmediately, increased risk was reframed around groups seen as disposable groups: older people and those with preexisting 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

he 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 highincome countries have invariably chosen nationalism over cooperation, flexing their fiscal power to hoard and prepurchase 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 lowand 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.

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).

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

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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THE END FALLS ON US: ELEVATING THE CONTINUED NEED FOR COMMUNITY LEADERSHIP IN ENDING THE HIV EPIDEMIC

by Edric Figueroa

Interview with community leaders Angel Fabian, Venton Hill-Jones, and Evany Turk

On Feb. 5, 2019, President Trump announced a federal plan to End the HIV Epidemic (EHE). EHE will invest financial resources in 57 of the highest-HIV-incidence cities, counties, and states in the U.S. in order to ramp up testing, prevention, treatment, and related services. The ultimate goal is to end the domestic epidemic by 2030.1 Communities of people living with HIV and those invested in addressing the societal inequities that increase HIV transmissions in these jurisdictions have been mobilizing for accountable, effective, and inclusive EHE planning and implementation since the announcement. Now, more than halfway through 2020-a year of debilitating impacts of COVID-19-meeting the goals of EHE requires revitalized local action and the political will to sustain safety nets for the communities most affected by both viruses. TAGline interviewed three community leaders for their perspectives; they pointed to several key themes surrounding COVID-19's impact on progress to end HIV in the U.S.

The contemporaneous challenges and commitments to survival

"In the era of COVID, many of the same detrimental policy issues to ending the HIV epidemic are at play: poverty, systemic racism, lack of expanded Medicaid, and the need for universal healthcare and economic justice," says Evany Turk, national field organizer at the Positive Women's Network (PWN). Still, there is a heightened attention to survival among PWN members.

"We have lost members ... our members have lost family, friends, and employment. We are first and foremost trying to support our base," Turk said. PWN is offering up to \$250 to



Angel Fabian: Advocacy Coordinator, Fijate Bien Mpact Global

its members for assistance with basic needs and is maintaining a virtual support group to combat the sense of isolation. "Our members understand that no one is going to advocate for us, women living with HIV, so we have to do it."

Even before the COVID-19 pandemic, Angel Fabian, Fijate Bien advocacy coordinator at MPact, was organizing listening sessions and advocacy trainings at the U.S.-Mexico border, in Puerto Rico, and across the Central Valley of California. They reported that HIV was not a high priority for most of the Latinx gay and bisexual men and transgender people they had met with. Instead, access to basic needs such as food, housing, and income took precedence.

Fabian grew up in California's Central Valley, which is a site of mainly migrant agricultural communities. In this area, there is only one community health center (CHC) that provides services to over 1,000 low-income and/or uninsured community members living with HIV. California currently has a \$54 billion

budget deficit as a result of COVID-19.² Fabian worries that without the right advocacy, the first programs to get cut will be safety-net programs such as Medicaid, Medicare, emergency rooms, food stamps, and CHCs. "People who depend on the AIDS Drug Assistance Program and other Ryan White HIV/ AIDS programs get all their services from this one source. If this clinic shuts down or is forced to reduce services, I can't imagine the consequences this will have on people living with HIV and on the HIV epidemic in the Central Valley."

"Black communities have always been in a state of emergency when it comes to public health disparities in the South," says Venton C. Hill-Jones, founder and chief executive officer of the Southern Black Policy and Advocacy Network (SBPAN). "When we are dealing with any epidemic in this country, Black communities are the first to feel its full impacts." Hill-Jones said that the higher death rates in communities of color from COVID-19 and HIV are about social justice: "In addition to biomedical strategies to fight these epidemics, we need strategies to address anti-Black racism in health departments in the South."

The need to build and actualize local and collective power

COVID-19 has limited the capacity of health departments to offer necessary HIV care and prevention services.³ Engaging the community members who are at risk of HIV because of a lack of access to resources for feedback on EHE plans has become a harder, but still crucial, task. A task that is also a requirement under two major EHE funding sources for public health departments and qualified health centers, the Centers for Disease Control and Prevention (CDC) notice of funding opportunities PS19-1906⁴ and PS 20-2010⁵.

Fabian moves sensitively through the larger Latinx community: "In many of these communities, individuals have never heard of a federal plan to end the HIV epidemic." Fijate Bien conducts trainings, largely for recent immigrants and monolingual Spanish speakers, which center the value of community-led solutions. Fabian hopes leaders will walk away ready to create their own processes to effectively address HIV prevention, care, treatment, and advocacy.

At PWN, many members are part of planning coalitions for ending the HIV epidemic. Turk reports hearing that members



Evany Turk: Field Organizer, Positive Women's Network

across different states don't believe that their community of women living with HIV (the majority of whom are Black and women of color) is being listened to. As a result, PWN leaders continue to advocate for leadership from women living with HIV in EHE. Through monthly policy updates and member engagement in local coalitions, PWN is raising its community voices when it comes to EHE and other policy issues affecting women living with HIV.

When founding SBPAN in 2018, Hill-Jones did not want to duplicate efforts already taking place in the South. "We brought in women, Black gay men, young people, adults over 55 living with HIV, faith leaders, and trans communities into a Southern Black HIV/AIDS Network," he said. Hill-Jones created the network to advance the capacity of its members to affect federal, state, and local HIV policy, programs, and research. SBPAN was activated immediately after the announcement of the first EHE funding opportunity, PS19-1906. When health departments finally submitted EHE plans on behalf of their communities in December 2019, many SBPAN members had not seen the draft plans. As a result, over 20 members in nine Southern states sent a letter to the CDC and the Department of Health and Human Services calling for the inclusion of Black Southern voices in EHE. The CDC provided feedback to the EHE plans submitted by health departments and extended deadlines for revisions thanks in part to the advocacy of groups like SBPAN.

An increase to national-level consciousness demands equally profound commitments to human rights

Since its inception, PWN has been committed to advancing racial justice and unlearning racism, but the Black Lives Matter (BLM) movement warranted deeper conversations on anti-Black racism. PWN supported its Black staff members to establish a day that celebrates and honors Black women living with HIV, and in 2021 the organization will launch a series of inaugural events that will educate and honor Black women living with HIV. The first #CelebrateAndHonorBlackWomenDay will be March 12, 2021.

PWN has also maintained fervent advocacy on molecular HIV surveillance, a key feature of the "Respond" EHE pillar.¹ Molecular HIV surveillance is genetic sequencing of viral fragments of HIV, which indicates their variation in ways that can be used to track and intervene in clusters of new HIV transmissions. Like many activists, Turk cautions that putting this data into a larger data assemblage that could make determinations about transmission directionality may have criminalizing implications for communities that are already experiencing disproportionate burdens of stigma and racism.⁶ Through the support of its members and in collaboration with other HIV advocacy organizations, PWN launched the Health Not Prisons Collective in direct opposition to implementing methods like molecular HIV surveillance without assurances that such data will not be shared with the criminal justice system. The collective serves to highlight the ways that carceral solutions to public health issues cause unnecessary harm and to invest in community-led solutions to undo structural harms.

"The Black Lives Matter uprisings revealed what HIV advocates already knew ... there is a strong need to address racism, transphobia, and homophobia, particularly in the South, where the full consequence of not addressing these issues can be seen," Hill-Jones said. "An increasing number of HIV criminalization cases, more targeted attacks to communities of color, and less political will from leaders to improve conditions" are just a few of the implications of the institutionalized prejudices he names. "As we have conversations around the preservation of Black lives in the context of policing, we also have to have it about public health ... so many Black lives have been lost due to COVID-19⁷, HIV, and other preventable illnesses."

In February of 2020, SBPAN launched an HIV Advocacy Needs Assessment: Health Policy and Advocacy Opportunities for Black Communities in the South. Hill-Jones hopes that "no matter their previous advocacy experience, communities will find it useful for developing a more informed and better equipped engagement of systems affecting HIV health outcomes for diverse Black communities in the South."



Venton C. Hill-Jones: Chief Executive Officer of the Southern Black Policy and Advocacy Network

The rising rates of HIV in Black and Latinx communities in the South are also no surprise to Fabian, who says that the living conditions and the socioeconomic challenges are similar in both communities.⁸ "The BLM uprisings illuminated the prejudice overlooked for too long in the Latinx community," Fabian said. "We have been forced to have conversations around racism ... with our grandparents, parents, and even with the Spanish media that perpetuates anti-Blackness." Fabian hopes this moment will help communities focus on how to better show up for each other and build intentional coalitions. For Fabian, making the links between HIV and the human rights violations occurring in migrant communities across the U.S. is critical. "The administration is not helping EHE and is using the COVID-19 pandemic as a scapegoat to violate international law by deporting asylum seekers back to their countries of harm." These deportations are in direct contradiction to what experts say will help stop the global spread of COVID-19: a suspension of all deportations.⁹

Preparing for all possible scenarios

PWN has "known for a long time how to end the epidemic," Turk said. "A big part of our successes is that members tell their personal stories of how structural barriers have prevented them from accessing key services as a tool for interpersonal and systemic change." Turk said that the work of PWN has always been to prepare its base for whatever is ahead, even if it is resistance. Of course, she said, PWN would love to have an administration that's willing to work with them. Either way, Turk said, they are "ready to do the work."

"We have a very important role ... to make sure that our ideas are included with intention and ensure that EHE plans have the strong foundation necessary to be successful," Hill-Jones said. "Hopefully, what this moment in history has taught us is to understand the specific approaches necessary to end HIV in diverse communities." For Hill-Jones, such an approach must go beyond just listening to Black communities and toward advancing advocacy that dismantles the anti-Blackness embedded in U.S. institutions.

"This moment is an opportunity for everyone to ask themselves how they can become better allies to each other's struggle," Fabian said. Whether it is the current or a new administration, U.S. leadership must use this sentiment as a guide and engage meaningfully with the community leaders whose input is critical to achieving the 2030 EHE goal. Evany Turk is national field organizer at the Positive Women's Network. Angel Fabian is advocacy coordinator for Fijate Bien at MPact Global Action for Gay Men's Health and Rights. Venton C. Hill-Jones is founder and chief executive officer of the Southern Black Policy and Advocacy Network.

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ACCELERATING THE DEVELOPMENT OF COVID-19 VACCINES AND THERAPEUTICS FOR EVERYONE

By Richard Jefferys and Lindsay McKenna

he COVID-19 pandemic has spurred a massive global research effort to develop therapeutics and biomedical prevention interventions (particularly vaccines, because they're believed to be the best hope for curtailing the pandemic and returning society to normalcy). The U.S. government is investing heavily through the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private research partnership and the puerilely named "Operation Warp Speed" program, which aims to accelerate vaccine development. The urgency has prompted implementation of novel adaptive clinical trial designs intended to rapidly weed out ineffective therapies, along with widespread use of concertinaed vaccine research timelines that combine typically discrete phases, leading to an abundance of phase I/II and II/III studies.

As more candidates enter the latter stages of efficacy testing, it's increasingly important that trial participants reflect the diverse populations that will need interventions. This is a necessary step—along with work on pricing, distribution, and accessibility—toward ensuring that rollout can happen rapidly for all people who stand to benefit.

Who is most at risk?

he increased susceptibility of older people and people with comorbidities to worse outcomes from COVID-19 is well described. In the U.S., studies have shown that there is a disproportionate risk of COVID-19 among Black and Latinx people, and while the data are more limited, this might also be the case for American Indian, Alaska Native, and Pacific Islander populations.¹ (For more on these disparities, see Madoori, et al. p. 15) Recent evidence indicates that racial disparities are even greater among young people,² and while this is a group at lower risk for severe disease and mortality, studies have found that a proportion of younger people with COVID-19 require hospitalization and mechanical ventilation.³

Overall, women face a lower risk of morbidity and mortality from COVID-19 than men, likely because of sex differences in immune responses.⁴ However, evidence indicates that pregnant women face significantly higher risks than nonpregnant women (see textbox p. 15).

Ensuring inclusion

n example of advocacy to ensure broad representation in COVID-19 research is the recent response to exclusion of people with HIV from vaccine efficacy trials conducted by Moderna and Pfizer. After the circulation of sign-on letters and statements from community activists (including TAG) and professional medical organizations, both companies amended their protocols to allow the participation of people with HIV.⁵ In Pfizer's case, this involved expanding its trial from 30,000 to 44,000 participants to facilitate inclusion of people with HIV, hepatitis B, and hepatitis C.⁶

Updates on enrollment in several vaccine efficacy trials have included information on participant diversity. At the time of writing, Moderna had reported that 28,043 people have joined its study, approaching the 30,000-person target. While the company notes that 33% are from "diverse communities," the most recently available breakdown is far from optimal: 72% of participants are white, 16% Hispanic or Latinx, 7% Black or African American, 3% Asian, 1% more than one race, 0.4% American Indian or Alaska Native, and 0.2% Hawaiian or other Pacific Islander.⁷ The COVID-19 Prevention Network (CoVPN), which is collaborating with Moderna, is undertaking initiatives aimed at improving participant diversity.⁸ Enrollment trends by week suggest that these efforts are having a positive impact.⁷

Pfizer has enrolled 36,576 participants, including at sites outside the U.S. The company notes that about 42% have diverse backgrounds (28% in the U.S.): 28% Hispanic or Latinx, 9% Black, 4% Asian and 0.6% Native American.⁹

Persistent gaps

Neither company appears to provide a breakdown of participants by sex and/or gender identity, and a recent analysis (not yet peer reviewed) has found that this is a common problem in COVID-19 research. Among 2,484 trials registered in ClinicalTrials.gov, only 16.7% cited sex/gender as a recruitment criterion and 4.1% made reference to sex/gender in their descriptions of planned analyses. Of the 11 clinical trials with published results as of June 2, 2020, none reported results disaggregated by sex/gender. The authors of the paper write: "Given the biological relevance and the potential risks of unwanted side effects, we urge researchers to focus on sex-disaggregated analyses already at the planning stage of COVID-19 trials."

Among a multitude of therapeutic trials, two major randomized controlled studies have demonstrated reductions in recovery time or mortality in hospitalized people with COVID-19. The antiviral drug remdesivir was associated with an improvement in recovery time of five days on average,¹¹ while the immune-suppressive corticosteroid dexamethasone reduced 28-day mortality in people receiving either invasive mechanical ventilation or oxygen alone.¹² Information on the demographics of participants in these trials is shown in Table 1. No information on race/ethnicity of participants was provided for the dexamethasone study, which was conducted in the UK, but the published results note that a prespecified subgroup analysis by race will be forthcoming when data collection is completed.

Relatively few COVID-19 clinical trials are including children. An early review of research conducted in China found only three studies enrolling people under 16 years old (out of 63 evaluating conventional therapies).¹³ Researchers have issued a call for more pediatric trials, with a set of recommendations including central coordination and an emphasis on multicenter studies to increase sample sizes.¹⁴ Gilead Sciences, the manufacturer of remdesivir, has launched a pediatric study,¹⁵ and an expert panel has made preliminary recommendations on the use of the drug in this population.¹⁶

Similarly, inclusion of children in COVID-19 vaccine trials is limited. AstraZeneca is assessing the safety of its candidate in the 5 to 12 age group. Based on information in online registries, two studies in China allowed enrollment of people as young as 6 months (no data have yet been presented), and one study in India has a lower age bound of 12.¹⁷

Table 1: Demographics for participants enrolledin major randomized controlled studies of therapeuticsfor COVID-19

	remdesivir (U.S.)	dexamethasone (UK)	
Total # of participants	1062	6425	
Women	378 (35.6%)	2338 (36.4%)	
Race			
American Indian or Alaska Native	7 (0.7)	N/A	
Asian	135 (12.7)	N/A	
Black or African American	226 (21.3)	N/A	
Multi-Racial	3 (0.3)	N/A	
Native Hawaiian or Other Pacific Islander	4 (0.4)	N/A	
White	566 (53.3)	N/A	
Unknown	121 (11)	N/A	
Ethnicity			
Hispanic or Latinx	250 (23.5)	N/A	
Not Reported/ Unknown	57 (5,4)		

Conclusion

As scientific research progresses toward the goal of effective therapies and biomedical prevention options for COVID-19, there is clearly much work to do to ensure that there is robust information on the effects of candidate interventions in diverse populations. To chart the path forward, it's essential that there be maximal transparency regarding plans for generating the data necessary for rapid approval and distribution for all. A regrettable component of the emerging maelstrom of information related to COVID-19 is limited disclosure of new trial results via press release. TAG concurs with researchers who have outlined a minimum set of requirements for the disclosure of new study results, including participant demographics.³³

SPOTLIGHT: ETHICAL INCLUSION OF PREGNANT PARTICIPANTS IN RESEARCH

In 2019, 1.9 billion women were of childbearing age (15-49 years old) globally.¹⁸ Surveys in the United States have found that nearly 50 percent of women age 15-44 expect to have a child in the future and that from 2011 to 2015, 85 percent of women 40-44 reported ever having given birth.^{19,20} In fact, there are nearly 4 million births every year in the U.S.²¹ Many women of childbearing potential are part of the essential workforce, including healthcare workers. A disproportionate share of lowwage essential jobs are held by Black and Latinx women, populations that also have higher rates of pregnancy conditions such as gestational diabetes and hypertension, both risk factors for COVID-19related complications.^{22,23}

An analysis of surveillance data collected by the U.S. Centers for Disease Control and Prevention (CDC) found that Hispanic and non-Hispanic Black pregnant women were disproportionately affected by SARS-CoV-2 infection during pregnancy. Further, among women of childbearing age with SARS-CoV-2 infection, those who are pregnant are more likely to be hospitalized, be admitted to the intensive care unit, and receive mechanical ventilation compared with nonpregnant women.^{24,25} Yet, 65 percent of COVID-19 therapeutic clinical trials²⁶ and 100 percent of COVID-19 vaccine clinical trials exclude pregnant people.²⁷

In many ways the exclusion of pregnant people from COVID-19 clinical research is the legacy of decades of researchers misguidedly seeking to protect pregnant people and fetuses from research, rather than through their participation in research. Still, it's inexcusable, especially when considering that for some of the therapeutic interventions under investigation for COVID-19 (e.g., chloroquine/ hydroxychloroquine, lopinavir/ritonavir), safety data exist in pregnancy from use for other indications. Additionally, a number of platforms under investigation for COVID-19 vaccines have been tested previously and found safe in studies of pregnant animals (e.g., ChAdOx1 for Rift Valley fever disease in pregnant sheep, gorilla adenovirus-vectored vaccines for Zika virus in pregnant mice).^{28,29,30}

To ensure that all populations can benefit from ongoing research efforts, developmental and reproductive toxicology (DART) studies necessary to include women of childbearing potential and pregnant people in clinical trials must be an urgent priority, especially ahead of phase III trials. Developers of vaccines and therapeutics should be transparent about their plans to conduct DART studies and assess their candidates in pregnant people.

Following people enrolled in trials who become pregnant is another important way to capture data; the efficacy trial protocols for the Moderna and Pfizer COVID-19 vaccines have recently been disclosed publicly, and both include guidance on reporting and following any cases to capture outcomes.^{31,32}

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ENSURING GLOBAL HEALTH SOLIDARITY AND ACCOUNTABILITY BY INVESTING IN THE WORLD HEALTH ORGANIZATION

by Elizabeth Lovinger and Anthony D. So

Introduction

n July 6, 2020, the Trump administration gave a formal, one-year notice of its intention to end the United States's membership from the World Health Organization (WHO).¹ The WHO is the United Nations agency responsible for issuing public health guidance, mobilizing funding for global health efforts, coordinating public health responses and initiatives, collecting and disseminating data, and advocating for the importance of health as a human right. Despite the outsized importance of such a global health coordinating organization during a pandemic, President Trump had been signaling his desire to withdraw U.S. support for the WHO for months-and had been repeating claims about the WHO's mismanagement of the COVID-19 response and undue influence from China within the institution.² However, in order to respond most effectively to the COVID-19 pandemic and to prepare the global community for future public health challenges, the U.S. must fulfill its existing funding commitments and invest in holding the WHO accountable to member states, civil society, and communities.

According to Trump, the WHO had failed to exert pressure on the Chinese government both to share information about the novel coronavirus and stop its spread beyond Hubei province.³ Trump acknowledged that COVID-19 was "more deadly" than seasonal influenza as early as February, in a taped interview with journalist Bob Woodward.⁴ Later the president said he intentionally downplayed the severity of the pandemic to avoid public panic. Missteps in China did hamper the global response.⁵ Local officials in Wuhan withheld information from national government officials in China,⁶ and this resulted in delays in confirming human-tohuman transmission in China and by the WHO.⁷ However, these actions in China cannot fully account for the magnitude and difficulty of the COVID-19 pandemic; other factors come into play when a disease is airborne and easily transmissible by the asymptomatic. Nor do these actions negate the need for a well-resourced, multilateral public health body. Whatever fault might lie with the WHO's leadership and early actions, they do not warrant U.S. withdrawal from the institution itself.

To respond most effectively to the COVID-19 pandemic and to prepare the global community for future public health challenges, the U.S. must fulfill its existing funding commitments and invest in holding the WHO accountable to member states, civil society, and communities.

n fact, withdrawal only makes influencing reform less likely, as evidenced by the U.S.'s own efforts toward reform through the Group of Seven (G7) process.⁸ Soon after the U.S. announcement of withdrawal from the WHO, Germany and France rebuffed U.S. efforts to lead WHO reform talks at the G7, instead floating their own proposal to strengthen both funding and the ability to call out member states that fail to be transparent in their reporting of future disease outbreaks.⁹ The United Kingdom has also stepped in to fill the void, boosting its contribution by 30 percent, which will make it the largest donor to the WHO after the U.S. leaves.¹⁰ As a member-based multinational institution, the WHO is only as effective as its member states enable it to be.¹¹ The U.S. government pays the largest member state share of assessed contributions, but it has remained in arrears on these payments in 2019 and 2020.¹² In the past, U.S. presidential administrations have leveraged their outsized impact on WHO budgets to advance foreign policy

In order to best utilize the WHO's strengths and enact necessary reforms, the U.S. must immediately reverse its decision to withdraw from membership. This must include paying all owed arrears and increasing voluntary contributions to meet the urgency of the COVID-19 response.

objectives such as the Global Health Security Agenda.¹³ Working with the WHO, the U.S. has advanced this agenda to encourage countries to undertake the Joint External Evaluation and assess their pandemic preparedness.

In order to best utilize the WHO's strengths and enact necessary reforms, the U.S. must immediately reverse its decision to withdraw from membership. This must include paying all owed arrears and increasing voluntary contributions to meet the urgency of the COVID-19 response. With this restored position of leadership, the U.S. could play a key role in enacting necessary reforms to make the agency more fully responsive and accountable to the member states collectively, civil society organizations, and the communities it aims to serve.

One such reform could include reserving seats on external policy advisory committees and expert consultations for civil society organizations as key non-state actors. These opportunities to give voice to communities should extend to, and prioritize, the people most directly affected by the particular health issues being addressed. Civil society has already played a critical role in shaping global health initiatives that helped lay the groundwork for the COVID-19 response, including the Pandemic Influenza Preparedness Framework¹⁴ and the WHO's work on antimicrobial resistance (AMR);¹⁵ an AMR-specific indicator to monitor the UN Sustainable Development Goals;¹⁶ and the goal of "triple elimination" of HIV, viral hepatitis, and sexually transmitted infections.¹⁷ Furthering civil society's involvement in policy-making deliberations at the WHO would strengthen the organization.

n order to enact these reforms and monitor their progress, greater funding is needed to ensure that policy and normsetting processes have the capacity to take the voices of civil society and communities into their deliberations. In turn, the WHO would benefit from an engagement with these constituencies that would protect its continued role in global health governance among member states. Most important, the U.S. government must recognize that time is of the essence. If we are to safeguard the future of multilateral public health work and prevent future pandemics, the integrity of global health governance through the WHO must be secured and restored immediately. In a pandemic, the cornerstone to global health security is ensuring that the countries of the world have a place to shape collective action and response. This place can only fulfill its promise with sufficient resources and partnership with civil society and communities.



Figure 1: WHO Assessed Contributions by Member State, 2018–19¹⁸

Figure 2: WHO Voluntary Contributions by Member State or Contributor, 2017¹⁹



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Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus.

TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

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