

REGIME CHANGE IN AMERICA: TRACKING TAG'S WORK ACROSS EIGHT NATIONAL ELECTION CYCLES

By Erica Lessem and Mark Harrington

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.

—Congressmember John Lewis, Across that Bridge: Life Lessons and a Vision for Change

2020 marks the eighth U.S. presidential election cycle since Treatment Action Group's founding in 1992. A hallmark of our activism has been to prepare for each presidential and congressional election cycle strategically, to ensure that whoever is elected, and whoever controls the House and the Senate, is informed about the best scientifically grounded research and policy and research programs.

1992–2000

When TAG was founded in 1992 by members of ACT UP/New York's Treatment + Data (T+D) Committee, the U.S. HIV epidemic was at its worst; AIDS incidence was at an all-time high.¹ ACT UP had achieved some significant gains in drug approval and access since 1988, including the parallel track program for pre-approval access to promising new treatments; the accelerated approval pathway for HIV drugs; and expedited U.S. Food and Drug Administration

(FDA) approval of several early treatment options. Still, though, available treatments for HIV infection did not durably suppress the virus, delay or prevent progression, or significantly lengthen survival.

To address this crisis, TAG focused on three priorities:

- Accelerating basic science on HIV infection to better understand how HIV destroys the immune system and how best to block it;
- Accelerating clinical trial designs that combined access with answers to expedite the discovery, development, and approval of safe, effective therapies; and
- Expanding funding for the AIDS research programs at the U.S. National Institutes of Health (NIH) and reforming NIH's AIDS research program to be more effective.

After the election of Bill Clinton in November 1992, TAG pushed for the incoming Congress and the new administration to pass sweeping reforms to the NIH AIDS research program. Senator Ted Kennedy and Representative Henry Waxman included TAG's reforms in the 1993 NIH Revitalization Act, which passed both chambers of Congress and was signed by President Clinton in June 1993. The bill strengthened NIH's Office of AIDS Research and gave it the power to move money in accordance with a prioritized scientific research agenda.

Over the next decade, the NIH budget more than doubled, with AIDS research funding rising to over \$3 billion per year.²

TAG worked relentlessly from its inception to accelerate and improve the FDA approval process for the newest two classes of anti-HIV drugs, the protease inhibitors and the non-nucleoside reverse transcriptase inhibitors. TAG played a key role in forcing the manufacturers of protease inhibitors to create more reliable study designs to prove these drugs worked. The FDA approved the protease inhibitor saquinavir in late 1995 and the breakthrough protease inhibitors ritonavir and indinavir in March 1996, ushering in the treatment revolution that has led to millions of lives saved and infections prevented.³

By 1996, advances in HIV science and clinical trials led to the approval and distribution around the country of combination antiretroviral therapy (cART), which included powerful new drugs such as protease inhibitors, taken in combination with two AZT-like drugs. With the advent of powerful triple cART, AIDS deaths in the U.S. were halved from 1995 to 1997; similar declines were seen in other high-income countries.

TAG's first eight years were focused on accelerating HIV research and treatment access in the U.S. and helped lead to the breakthrough discovery of effective cART. As the new millennium approached, however, the global dynamics of the HIV pandemic came into clearer focus, and with them the need for dramatic increases in access to effective HIV prevention and treatment in developing countries, where the vast majority of the world's 24 million people with HIV were living (and dying).⁴ ACT UP Philadelphia members fought back, forming Health Global Access Project (Health GAP) to "challenge conventional wisdom that AIDS drugs were too expensive, too difficult to administer, and too low on the priority list to afford access to people in the global South."⁵ TAG and others in the movement began conducting international treatment literacy workshops, at the invitation of partners in the Global South.

2000–2008

Mobilization for treatment access globally increased. During the Durban International AIDS Conference in July 2000, a global movement for HIV treatment access coalesced.

While the U.S. dealt with a post-election crisis from November to December 2000, TAG was in South Africa conducting massive treatment education workshops with the South African Treatment Action Campaign (TAC) in Durban, Johannesburg, and Cape Town. The South African activists were in the midst of their titanic struggle to obtain government-sponsored access to HIV treatment for the over 5 million South Africans living with HIV.

In this spirit of addressing inequities globally, TAG began working on tuberculosis (TB). This expansion of focus came in response to activist needs from Brazil to South Africa to Thailand—and in recognition of TB's position as the leading cause of illness and death for people with HIV globally. These efforts included both treatment literacy as well as high-level policy influence to close wide research gaps. Simultaneously, TAG spearheaded viral hepatitis research activism. TAG pointed out resource needs; over time, this activism led to huge breakthroughs for hepatitis C virus (HCV) and incremental advances in TB.

TAG fought pharmaceutical companies' attempts to keep global AIDS drug prices high. Working with Health GAP, TAC, and others, TAG pushed successfully for high-quality, low-cost generic HIV drugs to be made accessible worldwide through the Global Fund to Fight AIDS, Tuberculosis and Malaria starting in 2002 and through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) starting in 2003. Today, over 23 million of the world's 37.9 million people living with HIV are receiving cART.⁶

2009–2016

TAG fought tirelessly for effective new HIV prevention interventions, such as pre-exposure prophylaxis (PrEP), to be studied in all affected populations. Proof that PrEP worked led to FDA approval of Truvada (tenofovir disoproxil fumarate and emtricitabine) for PrEP in 2012.

TAG's advocacy for clinical trials to determine the most effective time to start cART led the NIH to conduct the START study, whose results—released in 2015—showed that starting cART immediately after HIV diagnosis was the most effective strategy. Alongside the HIV Prevention Trials Network 052 study showing that early HIV treatment prevented transmission of HIV to an uninfected partner by 96 percent,⁷ these studies led to a revolution in HIV treatment and prevention, with cART being recommended for all people living with HIV.

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During the Obama presidency, the White House issued the first National HIV/AIDS Strategy (NHAS) for the United States. TAG was critical of the NHAS for its unambitious targets for reducing new HIV infections and increasing treatment success and viral load suppression. To prove how HIV treatment and PrEP could be used together to radically reduce new HIV infections, increase viral suppression, and save lives, TAG teamed up with Housing Works and the New York State and City Health Departments to create the New York State Ending the Epidemic (EtE) strategy, which aims to reduce new HIV infections by 75 percent from their 2010 level by the end of 2020. New York Governor Andrew Cuomo responded to community demands by detailing a plan to bring New York closer to ending the HIV epidemic.⁸ Implementing the strategy has sharply reduced new HIV infections among most

key groups, including men who have sex with men, in New York State, though further progress is required to achieve the 2020 EtE target.⁹

As New York scaled up its EtE strategy, TAG began working with partners in the hardest-hit regions of the U.S.—including the Deep South—to help community organizations, people with HIV, and health departments collaborate to develop their own local and state EtE plans and strategies.

This period saw an explosion in hepatitis C treatment options. By 2014, clinical trials were focused on injectable-free regimens of just 12 weeks, with cure rates reaching 95 percent.¹⁰ In just a few years, several of these miracle cures received FDA approval, changing HCV into an easily curable condition.

Renewed investment in TB research began to bear fruit after more than a decade. Initiated under the Bill & Melinda Gates Foundation and spurred by TAG's advocacy since the early 2000s, increases in investment were substantial, but started from a baseline of almost zero (with the exception of the investments of the U.S. government under the Centers for Disease Control and Prevention's Tuberculosis Trials Consortium). But two major advances occurred. First, the serendipitous discovery in a Janssen lab of bedaquiline, a new drug in a new class very active against TB in 2004 led eight years later to the first FDA approval of a TB drug from a novel class in five decades (though the phase II trials were inadequate to demonstrate how to use the drug in optimal combinations). GeneXpert MTB/RIF, the first rapid test to diagnose TB as well as resistance to one of the most common drugs used to treat it, entered the global market in 2010—thanks in part to early investments in the platform from the Bush administration's overreaction to anthrax scares.

2016–2020

Recent policy decisions relating to HIV and the social and economic constructs that affect it have been a roller coaster. After dismantling the Presidential Advisory Council on HIV/AIDS and trying to end the Affordable Care Act, the current administration unexpectedly picked up the HIV movement's rhetoric on ending the HIV epidemic with a State of the Union announcement of a new initiative for 57 jurisdictions. Many people who

were involved in this iteration were involved in PEPFAR, so perhaps unsurprisingly, the initiative resembles a mini-PEPFAR for the domestic context. And that's why it both offers unprecedented resources crucial to the fight and is fundamentally inadequate. As it's designed to address HIV in only 57 jurisdictions, it will not end our nation's HIV epidemic. Furthering our concern, recent policies have undermined women's health, immigrant rights, rights for LGBTQ people, and pro-access drug pricing, and will stymie this initiative.

But as our history shows, we will not give up the fight, and victories can be achieved in any political climate. We are working with partners of the Act Now: End AIDS coalition to pass enabling legislation to

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fully support efforts to eliminate HIV and its syndemics, including sexually transmitted infections. We know that because of long research timelines, the seeds we planted two administrations ago will keep bearing fruit, and we must be on the lookout for when an unexpected scientific advance happens to be ready to take it to scale as quickly as possible. And we have to call now for research on the many remaining questions that will propel us forward in future administrations.

Regardless of which party controls the White House, the Senate, and the House of Representatives, TAG's policy work is relentless and unflinching. As history shows, and as you'll see from this issue of TAGline, political

will to end AIDS is not about endorsing or vilifying any specific candidate. Huge advances and devastations have occurred regardless of which party holds executive office. Rather, this issue aims to invigorate the activist community and sensitize all political candidates to ensure that HIV and related health and social justice issues are prioritized in the lead-up to 2020 and beyond. Annette [Gaudino and Elizabeth Lovinger's](#) piece shows us how to build this needed community power. [Richard Jefferys](#) shows us the science that's at stake. And [Bryn Gay](#) goes deep on the need for a harm reduction approach in future administrations. [Jeremiah Johnson and Suraj Madoori](#) close with insights from leaders in the movement. We hope this issue helps mobilize activists and allies to keep our eyes on the long haul even as we fight daily in the trenches.

A luta continua!

Notes

1. U.S. Centers for Disease Control. HIV and AIDS – United States, 1981–2000. <https://www.cdc.gov/Mmwr/preview/mmwrhtml/mm5021a2.htm> 2001. MMWR June 1. 50(21);430-4.
2. Congressional Research Service. National Institutes of Health (NIH) Funding: FY1994-FY2020. 2019 Apr 4. <https://fas.org/sgp/crs/misc/R43341.pdf>
3. U.S. Food & Drug Administration. HIV/AIDS historical time line 1995–1999. 2018 Aug 14. <https://www.fda.gov/patients/hiv-timeline-and-history-approvals/hivaids-historical-time-line-1995-1999#95>
4. UNAIDS. HIV estimates with uncertainty bounds 1990-2018. 2019. <https://www.unaids.org/en/topic/data>
5. HealthGAP. "About us." <https://healthgap.org/about/>
6. UNAIDS. HIV estimates.
7. Cohen MS, Gamble T, McCauley M. Prevention of HIV Transmission and the HPTN 052 Study. *Annu Rev Med.* 2019 Oct 25. doi: 10.1146/annurev-med-110918-034551.
8. New York State Department of Health. Ending the AIDS Epidemic in New York State. https://www.health.ny.gov/diseases/aids/ending_the_epidemic/
9. New York State. Governor Cuomo Announces New Data Showing Largest Decrease in HIV Diagnoses Since New York's "Ending the Epidemic" Initiative Began, State is on Track to End the AIDS Epidemic by End of 2020. 2019 Oct 2. <https://www.governor.ny.gov/news/governor-cuomo-announces-new-data-showing-largest-decrease-hiv-diagnoses-new-yorks-ending>
10. Swan T. Hepatitis C pipeline: BONANZA! The gold rush is under way. New York: Treatment Action Group; July 2014. <http://www.treatmentactiongroup.org/pipeline-report/2014/hcv-pipeline>.