Ending the Epidemic

Progress in the Fight for Better Treatment, a Vaccine, and a Cure for AIDS

2016 Annual Report

TAG
Treatment Action Group

June 12, 2017

Dear Friend of TAG:

I'm so proud to share with you Treatment Action Group's 2016 Annual Report. As you will see, TAG's passionately dedicated, deeply informed staff have been unstinting in their efforts to speed up research and high-quality prevention, treatment, and care programs for people living with HIV, hepatitis C virus (HCV), or tuberculosis (TB), and for those most at risk of acquiring these infections.

Today, more than ever, TAG's work is vital. We are living in an unprecedented political era. Every day brings a new outrage and gathering threats to our work promoting research, prevention, and treatment.

Everything TAG has fought for over the past three decades to defeat HIV/AIDS and end the TB and HCV epidemics is at risk.

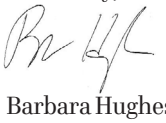
Our progress towards ending these epidemics with extremely effective new tools for prevention, treatment, and cures will be in vain if people don't have comprehensive coverage to ensure access. TAG's vital work needs your support now more than ever:

- TAG is leading community efforts to end AIDS as an epidemic in New York State by the close of 2020 by strengthening HIV, STD, and sexual health programs for those most affected
- TAG is expanding its Ending the Epidemic work to southern states where the HIV/AIDS epidemic continues at its worst
- TAG is leading efforts to build on existing law and regulation to control drug costs
- TAG is leading efforts to defend key National Institutes of Health AIDS research agencies and their budgets from brutal cuts proposed by the new administration
- TAG is fighting efforts to greatly weaken the U.S. Food and Drug Administration and its ability to ensure that safe and effective new drugs are studied properly, available with expanded access when necessary, and approved quickly when evidence merits it

I'm pleased to report that TAG's strong financial health and commitment to accountability and transparency have earned it a 4-star rating for the second year in a row from Charity Navigator. Charity Navigator awards only the most fiscally responsible organizations a 4-star rating.

We're so grateful to you for your dedicated support of TAG's work, and we ask that you continue to sustain that support for the struggles ahead.

Yours truly,



Barbara Hughes
President, Board of Directors

Project Updates

HIV Project

TAG's HIV Project spent the last year advancing its research and policy priorities against a backdrop of significant shifts in the federal political climate and continued to push activism and policy aimed at effectively ending HIV as an epidemic in the U.S. – and ultimately, around the world. Building on the community-driven initiative to end AIDS in New York State, TAG is laying the groundwork to support and strengthen community partnerships in three southern states to chart their own epidemic-ending strategies.

TAG's work over the past year led to the publication of *Community Mobilization: An Assessment of Mechanisms and Barriers at Community-Based and AIDS Service Organizations in Nine U.S. Metropolitan Areas* in January 2017, which elucidates the mechanisms, facilitators, and barriers of HIV community mobilization in 10 high-prevalence jurisdictions. The HIV Project completed its two-year Advocacy Education Initiative, a series of online educational materials, webinars, and capacity-building workshops designed to strengthen regional advocacy and policy engagement regarding comprehensive HIV prevention service delivery needs, including post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) scale up. TAG published in the *Journal of the International AIDS Society* its ground-breaking primary and secondary HIV prevention continuum model for the U.S. as a conceptual framework for local health departments to identify key steps in reducing HIV incidence and improving health outcomes among those vulnerable to, as well as those living with, HIV infection.

In tandem with these efforts, the HIV Project continued to uphold its long-standing commitment to accelerate the development of novel treatment options for people living with and vulnerable to HIV infection. A critical extension of this work—essential for strategies to end AIDS and sharply curtail HIV incidence—is an increase in project activities that challenge outrageously high treatment costs, particularly for HIV medications priced well beyond what the market can bear, and many public and private insurers instituting cost-control measures increasingly out of alignment with evidence-based recommendations.

U.S. and Global Health Policy

TAG's Washington D.C.-based policy and advocacy staff spent 2016, which will go down in history as a watershed election year in American politics, fighting for favorable research, treatment access, and regulatory policy and funding, which are critical in the fight against HIV, TB, and HCV.

In 2016, TAG's policy staff were instrumental in launching a coalition dedicated to building a national framework to end the epidemic in the U.S. We led efforts to include a community-driven HIV policy and research agenda in the Presidential candidates' election platforms. TAG worked with coalition partners to craft policy statements and participated in meetings with both the Clinton and Sanders campaigns, bringing national attention to coalition efforts to end the epidemic. In addition to pressuring the campaigns to outline specific policy commitments to support HIV/AIDS efforts, we were able to secure a speaker at the Democratic National Convention—Daniel D. Driffin, a young, black, gay, HIV-positive Ph.D. student and activist.

TAG expanded our federal advocacy against tuberculosis (TB), particularly for TB Research & Development (TB R&D) spending. Senior Health Policy Officer Suraj Madoori, who joined TAG in April 2016, collaborated extensively with TAG's TB/HIV team and partner organizations to support and set an ambitious advocacy agenda and spending targets for TB R&D in the U.S. and other donor countries. Suraj calculated the budget shortfall from years of underfunding TB R&D, and used this analysis to push for new advocacy for budget appropriations in Congress and among global health partners, publishing two policy briefs, entitled *Breathing Life into Flatlined U.S. Government Funding for Tuberculosis Research: FY 2017–2020 Allocations and Recommendations* and *Breakthrough: Catalyzing R&D to End TB*. These briefs were used to educate both domestic and global community advocates and organizations, funders, and policymakers such as the U.S. Congress and the Global TB Caucus.

At the end of 2016, several political and policy shifts posed new challenges for TAG's ongoing advocacy work. Despite a two-year-long fight led by TAG and other activists, President Obama signed the hotly contested 21st Century

Left to right, NYS Senator Brad Hoylman, Board Member Joy Episalla, RIAA Honoree and TAG's Board President Barbara Hughes, and Board Member David Sigal.

Cures Act into law, which contains provisions that weaken the U.S. Food and Drug Administration's (FDA) safety standards for future drugs and devices. TAG successfully launched *Act Now: End AIDS*—a national coalition dedicated to organizing local networks to develop and implement plans to end HIV epidemics—but our momentum was challenged by the unexpected election results. The new administration has pushed a deluge of undermining proposals to end the Affordable Care Act (ACA); drastically cut federal spending for research at the National Institutes of Health (NIH); curtail public health and global health programs at the Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID); and severely roll back the regulatory capabilities of the FDA.

Despite the challenges and new battles that lie ahead, TAG remains committed to resisting major losses in research, public health, health care, and global health infrastructure, protecting these programs and expanding them through increased collaborative and cutting-edge advocacy. The focus of our policy work in 2017 remains unchanged as we move forward with our steadfast vision to end the HIV, HCV, and TB epidemics globally.

Basic Science, Vaccines, and Cure (BSVC) Project

The BSVC Project organized and co-sponsored the annual Pre-CROI Community HIV Cure Research Workshop. Over 70 attendees gathered in Seattle to hear presentations from both scientists and activists, and to participate in discussions. The event also recognized and celebrated Timothy Ray Brown reaching his tenth year since being cured of HIV infection.

TAG continued to regularly update its listing of ongoing and completed clinical trials related to HIV cure research, featured on the TAG website, as well as other web-based resources, such as links to community-based articles and open-access scientific papers on the subject.

Using TAG's Cure Research Media Monitor webpage, we responded to the widely circulated claim that a Nigerian researcher had developed a cure for HIV. The BSVC Project alerted the Nigerian National Health Research Ethics Committee of the Federal Ministry of Health about the claim, contributing to the initiation of an investigation into what appears to have been a profoundly unethical clinical trial that was conducted without the approval of Nigerian regulators. As part of TAG's ongoing work to improve the accuracy of media coverage of HIV cure research, the BSVC Project contacted *The Independent* about a misleading headline that stated that participants in a research study had become "HIV free"; the editors acknowledged the problem and corrected the headline.

Rosie Perez, 2016 RIAA Honoree.

Richard Jefferys collaborated with Deputy Executive Director of HIV and HCV Programs Tim Horn and Community Engagement Coordinator Jeremiah Johnson to develop and distribute a community survey on the use of PrEP in clinical trials of biomedical prevention interventions. This is an important emerging issue because the efficacy of PrEP in preventing HIV infection raises complex ethical questions regarding how it should best be provided to participants in clinical trials of other biomedical prevention approaches, such as vaccines. A report describing the survey results will be released in July 2017 at the International AIDS Society Conference in Paris.

Hepatitis C Virus (HCV) Project

In 2016, TAG and our allies continued to fight locally, nationally, regionally, and globally to secure universal access to affordable HCV prevention, diagnostics, and treatment. TAG worked to build and strengthen our hepatitis C coalition; share information about advances in diagnostics and treatment with advocates; document research and treatment access progress and barriers; advocate for sound epidemiological, biomedical, and implementation research; and use available information to promote policies for universal access to affordable HCV prevention, diagnostics, care, and treatment, as well as the removal of structural barriers.

This year, the HCV Project successfully recruited two dynamic new HCV Project co-directors, Annette Gaudino and Bryn Gay. Thanks to their extensive knowledge and organizing experience on treatment access, the HCV Project developed and implemented several global campaigns to address HCV elimination at the statewide, national, and global levels, as well as high drug pricing, drug decriminalization, and harm reduction. TAG continued to confront exorbitant drug prices that act as a major barrier to patients' access to direct-acting antivirals (DAAs), including those that treat all genotypes. We fought through 2016 for the removal of non-evidence based barriers to the broadest possible access to HCV curative therapies.

TAG led local partners in advocating for the inclusion of DAAs on the New York State AIDS Drug Assistance Program (ADAP) formulary, which resulted in

Karyn Kaplan presents the 2016 Research in Action Award to Daniel Lee, Executive Director of the Levi Strauss Foundation.

drugs from almost all manufacturers being made available to HIV/HCV co-infected New Yorkers. TAG engaged in community consultations and advocated for people who are most at risk and most underserved to be involved in HCV planning and policy-making processes, particularly community forums with people who are HIV/HCV co-infected.

The HCV Project shared campaign strategies and advocacy tools with partners domestically and in low- and middle-income country settings. We launched the global hepCoalition website and community of practice; the mapCrowd data tool and summary reports with our partner, Doctors of the World; and developed the Pharma Greed Kills network to help mobilize activists. Recent campaigns that we organized emphasized harm reduction approaches as being central to curbing the HCV epidemic, and our efforts included supporting the establishment of supervised injection facilities and safe consumption spaces.

TB/HIV Project

From advocating for early stage research through access, TAG's TB/HIV project work in 2016 was data driven, rights based, and especially energetic.

Ensuring Research Responds to Community Needs and Leads to Access

TAG's TB/HIV project launched its Right to Science portfolio. In an article in *Health and Human Rights*, a joint submission to the UN Secretary General's High-Level Panel on Access to Medicines; Senior TB/HIV Project Officer Mike Frick's plenary talk at the International AIDS Society TB2016 pre-conference; and the Fall *TAGline* edition, TAG invoked the Right to Enjoy the Benefits of Scientific Progress, articulating the responsibilities of governments and companies with regards to TB research and access.

The two TB-focused community groups that TAG supports, the Global TB Community Advisory Board and the Community Research Advisors Group, gave input into several clinical trial protocols and presented on common omissions at the TB2016 conference.

To ensure ethical inclusion of pregnant women, TAG drove the establishment of a TB and Pregnancy Research Working Group, which, under Senior TB/HIV Project Officer Lindsay McKenna's leadership, developed an observational study.

TAG led a coalition for the sound development of the new TB drug sutezolid, which resulted in an open development license that is expected to allow the drug's development in optimal new regimens.

Creating Conditions for Access at the Global Level

To ensure that the fruits of research are accessible to all, TB/HIV project staff:

- participated in updating global guidance on drug-susceptible TB, bedaquiline and delamanid, and ethics in the TB response;
- updated *An Activist's Guide to TB Drugs* to support advocacy to close research and access gaps;
- helped launch the TB Procurement and Market-Shaping Action Team to improve TB product supply security and affordability. TB/HIV Project Director Erica Lessem was nominated Vice Chair;
- along with the TB CAB and other partners, TAG called for a model list of essential diagnostics, which the WHO has now initiated efforts to establish.

Supporting Country-Level Access

TAG supported activists in India, the country with the most TB cases and deaths, in holding their government accountable for its failed TB response. The #BrokenTBPromises campaign drove social media and press attention through daily tweets and a demonstration at the Union World Conference on Lung Health. In addition to legal victories against the government for failure to provide access to medicines, this advocacy helped to drive the recent announcement of national bedaquiline scale-up.

TAG and the TB CAB called for better global support for the TB response in Papua New Guinea, which resulted in a monitoring mission that urged the use of new tools and paved the way for community engagement—including through a new national activist group, Treatment Access Network PNG.

Activism for TB Research Funding

The 2016 *Report on Tuberculosis Research Funding Trends*, a cornerstone of the TB/HIV project, documented an alarming decrease in TB research funding. At the World Health Organization (WHO) Global TB Symposium and the BRICS (Brazil, Russia, India, China, and South Africa) health ministers meeting, TAG and partners called for these high-burden, upper-middle-income countries to triple research funding to fight TB.

2016 Contributors

$100,000 or more

Bill & Melinda Gates Foundation
Gilead Sciences
Elton John AIDS Foundation
Open Society Foundations
Veterans Affairs Medical Center of Washington, D.C.
ViiV Healthcare

$50,000 - $99,999

Ford Foundation
Janssen Therapeutics
Levi Strauss Foundation
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$25,000 - $49,999

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amfAR, The Foundation for AIDS Research
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INPUD, the International Network of People Who Use Drugs
Merck & Co.
The New York Community Trust
The Elizabeth Taylor AIDS Foundation
TB Alliance
World Health Organization

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Barbara Hughes
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Richard M. Lynn and Joseph Evall
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$500 - $999

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$250 - $499

Peter Allen "in honor of Bruce Schackman"
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Ivy Arce "in honor of Richard Jefferys, Tim Horn, Lei Chou, Annette Gaudino, and Jeremiah Johnson"
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Jonathan Bank
Alvin H. Baum Jr.
Amy and Peter Blauzvern "in honor of Monte Steinman"
Frank and Meredith Bove
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Howard Brown Health Center
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Plus donations from an additional **338** contributors as well as support from the United Way

We would also like to thank the following for their generous in-kind donations of services and goods:
Blueprint NYC
Rosalind Fox Solomon
SPOTCO

as well as the following donors of items for TAG's Silent Auction:
Almond Restaurant
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Kiehl's Since 1851
KleinReid Porcelain Gallery
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Osteria Morini
NBC Universal "Late Night with Seth Meyers"
Stuart Thompson Productions

TAG Financials

Balance Sheet

	2016	2015*
Assets		
Cash and cash equivalents	$ 1,978,688	$ 2,971,378
Contributions receivable	73,871	171,984
Prepaid expenses and other current assets	31,826	24,928
Donated artwork	404,500	381,000
Security deposits	72,463	43,015
Property and equipment — net	30,870	17,666
Total Assets	**$ 2,592,218**	**$ 3,609,971**
Liabilities and Net Assets		
Liabilities		
Accounts payable and accrued expenses	$ 74,083	$ 20,734
Net assets		
Unrestricted	1,355,999	1,649,386
Temporarily restricted	1,162,136	1,939,851
Total net assets	2,518,135	3,589,237
Total Liabilities and Net Assets	**$ 2,592,218**	**$ 3,609,971**

** FY15 Assets reflect a $1,070,138 pre-payment from the Bill and Melinda Gates Foundation for program expenditures in FY16 and the first quarter of FY17.*

Statement of Cash Flows

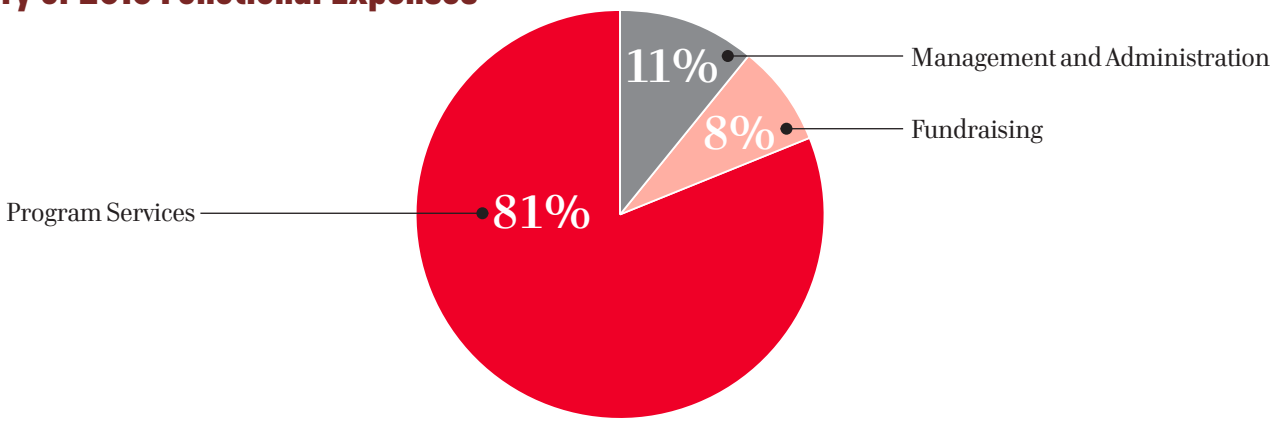
	2016	2015
Cash Flows From Operating Activities		
Change in net assets	$ (1,071,102)	$ (191,480)
Adjustments to reconcile change in net assets to net cash provided (used) by operating activities		
Depreciation	7,246	8,464
Donated artwork	(23,500)	(38,500)
Loss on disposal of fixed assets	4,745	3,166
Decrease (increase) in assets		
Contributions receivable	98,113	1,991,131
Prepaid expenses and other current assets	(6,898)	(797)
Security deposits	(29,448)	
Increase (decrease) in liabilities		
Accounts payable and accrued expenses	53,349	(9,789)
Net cash provided (used) by operating activities	**(967,495)**	**1,762,195**
Cash flows from investing activities		
Purchases of fixed assets	(25,195)	(3,782)
Net change in cash and cash equivalents	**(992,690)**	**1,758,413**
Cash and cash equivalents — beginning of year	**2,971,378**	**1,212,965**
Cash and cash equivalents — end of year	$ 1,978,688	$ 2,971,378

Statement of Activities

		2016		
		Unrestricted	Temporarily Restricted	Total
Revenues and Other Support				
Contributions and grants		$ 334,641	$ 1,055,972	$ 1,390,613
Special events income	$ 294,745			
Less direct costs of special events	(91,952)	202,793		202,793
Other income		28,381		28,381
Interest income		1,885		1,885
Net assets released from restrictions		1,833,687	(1,833,687)	
Total Revenues and Other Support		**2,401,387**	**(777,715)**	**1,623,672**
Expenses				
Program services				
HIV Project		508,856		508,856
Cure Project		144,777		144,777
Hepatitis C Virus Project		345,198		345,198
TB/HIV Project		1,155,069		1,155,069
U.S. and Global Health Policy Project		15,404		15,404
Total program services		**2,169,304**		**2,169,304**
Supporting services				
Management and general		304,774		304,774
Fund raising		215,951		215,951
Total Supporting Services		**520,725**		**520,725**
Total Operating Expenses		**2,690,029**		**2,690,029**
Change in net assets before loss on disposal of fixed assets		(288,642)	(777,715)	(1,066,357)
Loss on disposal of fixed assets		(4,745)		(4,745)
Change in net assets		(293,387)	(777,715)	(1,071,102)
Net assets — beginning of year		1,649,386	1,939,851	3,589,237
Net Assets — End of Year		**$ 1,355,999**	**$ 1,162,136**	**$ 2,518,135**

See independent auditor's report. The accompanying notes are an integral part of these statements.

Summary of 2016 Functional Expenses



TAG Limited Art Editions

Each year at its annual Research in Action Awards, TAG presents a new, limited edition work of art, generously donated by a highly regarded visual artist. Past artists include Joy Episalla, Kate Shepherd, Nan Goldin, Robert Gober, Bill Jacobson, Donald Moffett, Tony Feher, Carrie Yamaoka, and David Armstrong.

TAG retains an inventory of many of the editions for sale to the public. All proceeds benefit TAG in support of programmatic work.

If you are interested in purchasing an edition or learning more about the available editions, detailed information can be found at http://www.treatmentactiongroup.org/limited-art-editions.

Contribute

TAG welcomes donations from individuals who want to see the research agenda remain responsive to the needs of all people living with HIV, HCV, and TB. Make a tax-deductible gift now: www.treatmentactiongroup.org/support.

Does your company have a matching gifts program? If so, you can double or even triple your donation. Just complete the program's matching gift form and send it in with your donation to TAG.

When you shop on Amazon, enter the site at smile.amazon.com. Choose TAG Treatment Action Group as your designated charity, and 0.5 percent of the price of your eligible purchase will benefit TAG.

Save the Date!

November 16th, 2017 at 6:00 pm
Research in Action Awards
Celebrating TAG's 25th Anniversary

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About TAG

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.

We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

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