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TAG
Treatment Action Group

tagline

NEWS ON THE FIGHT FOR BETTER TREATMENT, A VACCINE, AND A CURE FOR AIDS

A Global Plan to End AIDS Everywhere But at Home

The bold, aggressive new plan released by Hillary Clinton once again wildly surpasses in ambition what U.S. officials dare attempt in this country.

This article was first published on December 1, 2012, in theAtlantic.com.

by Mark Harrington

On Thursday, outgoing Secretary of State Hillary Clinton released the Obama administration's *Blueprint for an AIDS-Free Generation*, fulfilling a commitment she made at July's International AIDS Conference for next-level global strategy to fight AIDS.

Unlike the earlier domestic U.S. National HIV/AIDS Strategy, released in 2010, the global *Blueprint* makes a bold scientific case, based on the latest science and buttressed by substantial progress from the field, that investments in high-quality combination HIV prevention efforts and treatments can dramatically reduce new HIV infections and HIV deaths, while saving millions of lives and billions of dollars.

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On the Edge: Uncertainty Grows over HIV Budgets

The HIV community is bracing for impact as acrimonious federal budgetary battles rage on.

by Coco Jervis

The eleventh hour "fiscal cliff" deal reached by Congress and the Obama administration on New Year's Eve leaves much to be desired. By postponing the sequestration process until March 1, 2013, millions of dollars in funding for critical HIV research initiatives are still at stake, and potentially devastating cutbacks to lifesaving HIV treatment, care, housing, and prevention programs

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Grief Is a Sword: A Eulogy for Spencer Cox

A brilliant HIV treatment activist, Spencer Cox directed TAG's Antiviral Project from 1994-1999. He died of AIDS on December 18, 2012. Peter Staley delivered this eulogy at his memorial gathering in New York City on January 20, 2013. http://vimeo.com/m/58035151

I want to remember the activist. I first met Spencer when he started showing up at ACT UP meetings in the fall of '88. We were all so young. I was younger than most, but he was seven years my junior.

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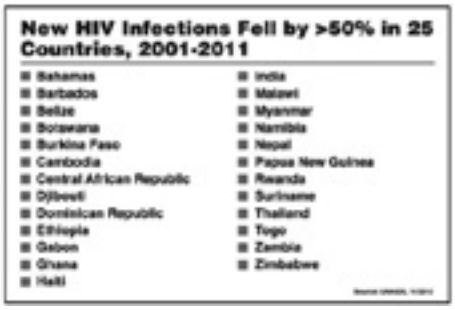
The *Blueprint* even includes a mandate for research to *end* the epidemic, something lacking in less optimistic earlier plans.

The ambitious international goals set by the Obama administration on World AIDS Day 2011 appear likely to be met. The plan to use the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria to support ongoing treatment of 6 million people with antiretroviral therapy (ART) by the end of 2013, including 1.5 million pregnant women, is on track. Already 5.1 million people are on ART thanks to PEPFAR, of the 8 million total receiving these effective anti-HIV treatments globally. And in the past year alone, 750,000 pregnant women have received ART to prevent mother-to-child transmission of HIV, resulting in the births of 230,000 HIV-free babies.

What's more, huge drops in the cost of generic drug manufacturing and improvements in health-care delivery systems meant that in 2012 PEPFAR was able to support twice the number on ART, 5.1 million, as it could just three years earlier with the same investment of approximately $5 billion.

The report also reveals that—thanks to the Global Fund, PEPFAR, and increasing local investment—many countries have reduced their number of AIDS deaths by over 50 percent, including Botswana, Burundi, Cambodia, Côte d'Ivoire, Dominican Republic, Ethiopia, Guyana, Kenya, Namibia, Peru, Rwanda, Surinam, Zambia, and Zimbabwe. South Africa now has the world's largest HIV treatment program, half of which is paid for with internal funds.



Some countries are even definitively putting the epidemic in reverse. Botswana, Ethiopia, Zambia, and Zimbabwe each put many more people on ART than were newly infected.

Other countries, such as Uganda, which have rising HIV infection rates, could achieve similar results by implementing high-quality combination prevention efforts (such as those focused on preventing mother to child transmission and encouraging voluntary medical male circumcision and condom use) and earlier treatment of those who are infected.

These results can be achieved in years, not decades.

Over the past decade, global HIV treatment has scaled up 200-fold, from 100,000 on ART in 2002 (mainly in Brazil), to over 8 million today. UNAIDS estimates that 14 million life-years have been saved globally by HIV treatment in the past decade, and almost 900,000 deaths averted this year alone.

Here at home, however, the epidemic is at a stalemate. New HIV infection rates have hovered around 50,000 per years for two decades—long before the introduction of effective HIV treatment. And the Obama administration is still committed to an under-resourced National HIV/AIDS Strategy. Not only is the U.S. plan not on track to achieve its goals, but they are themselves far less ambitious than what has already been achieved in the past decade in some of the world's poorest countries, such as Cambodia, Ethiopia, or Zambia.

At a White House briefing which followed Clinton's festive *Blueprint* launch, a diverse group of administration and community speakers discussed the domestic epidemic, but there were no new announcements save for Health and Human Services Secretary Kathleen Sebelius' relatively anodyne tribute to the promise of the Affordable Care Act and its potential to help push forward the U.S. strategy, known by its acronym, NHAS:

"Consistent with the goals of the NHAS, the ACA makes considerable strides in advancing equality for and helping people living with HIV/AIDS get the health insurance and care they need and deserve. When fully implemented, insurers will be prohibited from denying cover-

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age to anyone or imposing annual limits on coverage—an important protection for people living with HIV/AIDS....most private health plans must now cover HIV testing without a co-pay for adults and adolescents at higher risk and HIV testing and counseling for sexually active women. Medicare also covers certain recommended preventive services, including HIV screening for individuals at increased risk, without cost-sharing or deductibles. These preventive measures help people living with HIV/AIDS stay healthy while preventing the spread of HIV.... Because of the ACA, a series of investments to help providers support patients with chronic disease like HIV/AIDS are available. Under the law, states can receive extra federal funding to support high-quality coordinated care through Health Homes for Medicaid beneficiaries with chronic health needs. The goal of a Health Home is to treat the whole person, coordinating all their care from primary and acute care to behavioral health and long-term services.

Today, I am proud to announce that we will be issuing a rule to explicitly include HIV/AIDS on the list of chronic conditions that every state may target in designing effective Health Homes. This will make it easier for states to provide coordinated care for people living with HIV/AIDS."

Because the Supreme Court decision upholding the ACA turned Medicaid expansion from a mandate into a state option, the state-by-state struggle for equitable HIV treatment access will continue.

At the White House all speakers—Valerie Jarrett, Secretary Sebelius, PEPFAR's Eric Goosby, and NIAID AIDS supremo Tony Fauci—expressed obvious relief that the election was over and that ACA implementation could proceed. Agreeing but broadening the point, a diverse and motivated group of community representatives spoke for young black women, young black gay men, Latinos, researchers, and providers. They cautioned that ACA implementation would not cover the needed housing, mental health, and other essential services required to deliver high quality HIV services.

It was good to be among a group of people committed to ending AIDS. But no one from the administration mentioned drug users. The ban on federal funding of needle exchange continues. No one mentioned the urgent upcoming need to reauthorize PEPFAR or the Ryan White Care Act, which will provide vital services, especially in states which decline to provide full HIV coverage under the ACA, and to provide community support, housing, and other services unlikely to be covered by insurance exchanges.

In the United States, only 25 percent of the 1.2 million HIV positive people are on effective ART with an undetectable viral load. Only 33 percent are retained in care. Only 82 percent even know their HIV status—a number that's much lower among young people with the virus.

We can do much better. In nine years, Massachusetts has brought down its HIV infection and AIDS death rates by over 50 percent. Hospital costs dropped steeply over the same period.

On my way out of the gathering I ran into CDC Director Tom Frieden, who helped lead New York's successful response to the HIV-associated, drug-resistant tuberculosis outbreak in the 1990s. I told him that with TB rates at a historic low in the United States, we were in danger of making the same mistakes which led to its outbreak in 1989—excessive funding cuts, stockouts of first- and second-line TB drugs, inadequate political attention, funding and support. "TB is close to my heart," he said. "You need to put it higher up on your agenda," I replied.

Each year Obama has been president, he's cut funding to the CDC and to the TB program.

It's well past time for the administration to hold its own HIV/AIDS strategy to the same high standards that it expects from the scores of countries that have benefited from American generosity, and from their own increasing investments, to turn back the HIV pandemic in this decade.•

Data Deluge at AASLD

by Tracy Swan

It is difficult not to be dazzled by cure rates of up to 100% from interferon-free hepatitis C virus (HCV) trials presented at the American Association for the Study of Liver Diseases (AASLD) meeting in November 2012.

Here we provide a glance at some key interferon-free trials data from AASLD. A comprehensive review of clinical trials data is now available through the *TAG/i-Base Pipeline Report* web portal: www.pipelinereport.org/toc/HCV/dec-treatment-pipeline-update.

Genotype 1 Treatment Update

Cure rates in treatment-naive people receiving interferon-free regimens remain impressive, yet HCV subtype (1a vs. 1b) and IL28B genotype (CC vs. non-CC) may impair efficacy of certain regimens. This was the case in a pair of phase II trials: Abbott Laboratories' AVIATOR (combining ABT-450/r, a ritonavir-boosted protease inhibitor, and ABT-267, an NS5A inhibitor, either with or without ABT-333, a non-nucleoside polymerase inhibitor, or ribavirin) and Boehringer Ingelheim's SOUND-C2 (combining faldaprevir, a protease inhibitor, and BI 201127, a non-nucleoside polymerase inhibitor, with or without ribavirin).

In contrast, neither HCV subtype nor IL28B genotype had an impact on treatment outcomes in a BMS/Gilead phase II trial combining daclatasvir (an NS5A inhibitor) and sofosbuvir (a nucleotide polymerase inhibitor), or in ELECTRON, which combined sofosbuvir and GS-5885 (an NS5A inhibitor).

AASLD also brought good news for treatment-experienced people with HCV genotype 1, notably null responders (those with minimal response to peginterferon and ribavirin). In AVIATOR, 89% to 93% of null responders maintained undetectable HCV levels for 12 weeks (SVR-12) after completing 12 weeks of all-oral treatment. In Gilead's ELECTRON, three of three null responders given 12 weeks of sofosbuvir, GS-5885, and ribavirin reached the SVR-12 milestone.

Adding oral drugs to peginterferon and ribavirin also significantly boosted SVR among null responders in Roche's MATTERHORN trial and BMS's QUAD trial, AI447-011.

Genotypes 2 and 3

Encouraging results from peginterferon-free trials in treatment-naive and treatment-experienced people with HCV genotypes 2 and 3 were presented at AASLD. But recent results from Gilead's POSITRON study—issued by press release in late 2012—underscore the importance of larger trials in more "real-life" populations. POSITRON included interferon-ineligible, -intolerant, and -unwilling participants starting treatment for the first time. After 12 weeks of sofosbuvir and ribavirin, SVR was only 61% in genotype 3—no better than with 24 weeks of peginterferon and ribavirin (in treatment-naive people).

Interferon-free regimes offer huge advantages: improved tolerability, safety, and convenience for treatment-naive people with HCV genotypes 2 and 3. Yet high prices will make these drugs unappealing to payers without a clear demonstration of improved efficacy and the potential to fill unmet therapeutic needs.

Although the future of HCV treatment—interferon-free, effective, safe, tolerable, and convenient regimens—holds great promise for people living with hepatitis C, more information is needed about these regimens in people coinfected with HIV; liver transplant candidates and recipients; people with renal impairment; and people with cirrhosis (especially those who are treatment-experienced)—in other words, people with the greatest immediate need of a safe and highly effective cure.•

Beyond ARVs: Advocacy for Non-AIDS Disease Management

by Tim Horn

Fact: If we're going to make headway in preventing and treating non-AIDS-related health complications among people with HIV, which are very much on the rise and a serious risk to disease-free survival, we're going to need the full-on cooperation of pharmaceutical companies manufacturing and developing drugs for non-HIV diseases.

Enter Micardis (telmisartan), a drug produced by Boehringer Ingelheim (BI) to treat high blood pressure. Because telmisartan possesses unique anti-inflammatory properties, the AIDS Clinical Trials Group (ACTG) is interested in studying the drug to better understand the causes and treatment of aging- and inflammation-related comorbidities that are rapidly on the rise among people with HIV, notably cardiovascular disease, diabetes, and cancers. And because of its potential safety- and drug-interactions advantages over similar agents, its evaluation is a high priority.

Much to the ACTG's dismay, BI informed the study investigators of its unwillingness to provide free or low-cost telmisartan, along with matching placebo—despite the study's small population (54 anticipated volunteers) and short duration (48 weeks). A great deal of communication between the researchers and BI ensued, but to no avail.

In early November, TAG rose to the challenge by drafting and promoting a sign-on letter urging BI to reconsider its decision. The final letter, with more than 100 signatures, was submitted to the company on December 3. In addition to being the direct-advocacy work TAG should be involved in, it is a teachable issue for newer activists, as it embodies a number of key research priorities: the comprehensive study of anti-inflammatories for HIV disease and cure research; clinical trials drug procurement and design challenges; and exposing the conflict and competition between clinical trials networks and the pharmaceutical industry.

The response was not what we hoped. The company said its negative decision was non-negotiable, citing a slew of regulatory and legal reasons. Regulatory concerns—notably the demonstration that drugs such as Micardis are being eyed precisely because they will potentially fill an "unmet medical need"—are easy for activists to challenge. It is the myriad legal issues that tend to stop dialog in its tracks, ranging from fears of off-label promotion, violating anti-kickback legislation, and product liability that tend to stop dialog in its tracks.

The end result is disappointing for the ACTG. To move forward with the study, it must now pay for the drug at market price, estimated to be $70,000 for all patients randomized to receive treatment. It will also need to abandon the control arm, as significant financial resources and time will be required to develop a matching placebo from scratch.

For TAG, however, this is just the beginning. Next steps involve discussion with the U.S. Food and Drug Administration and the Office of the Inspector General to better understand the laws that we depend on to prevent pharmaceutical companies from engaging in unethical marketing tactics, but that shouldn't be cited as deterrents when it comes to needed research.

Negative decisions from companies being asked to provide non-HIV drugs to HIV clinical trials investigators are becoming increasingly commonplace—decisions we can no longer afford to accept.•

TB Zeroes Campaign Achieves Big Win

by Erica Lessem

The world has recently called for zero new TB deaths, infections, and suffering, and that voice has been heard. Treatment Action Group (TAG), along with other activists, researchers, clinicians, implementers, policy makers, and foundation and government staff began calling in May 2012 for a new global TB strategy focusing on ending TB deaths, new infections, suffering, and stigma.

The Zeroes Campaign: Differences from the World Health Organization (WHO) Stop TB Strategy

	Zeroes Campaign	Stop TB Strategy
Goal	• End TB deaths, infections, suffering, and stigma as soon as possible	• Halt and begin to reverse the incidence of TB by 2015 • Eliminate TB as a public health problem by 2050 • TB control
Country ownership	• Essential: countries need to determine their own timeframes and strategy for getting to zero	• Minimal: targets are set by WHO globally
Civil-society involvement	• Essential: stems from calls for changes to the status quo from advocates and activists as well as scientists and policy makers • Civil-society involvement will also be crucial to engaging and maintaining political will globally and in-countries	• Mediocre: calls for advocacy, communication, and social mobilization; and community participation in TB care, prevention, and health promotion • However, civil-society groups were not meaningfully engaged in the drafting of the Stop TB Strategy nor in ongoing efforts to implement that strategy
Importance of research	• Essential: calls for increased investment in research for development of new TB drug regimens, diagnostic tests, and vaccines	• Essential: calls for research to be enabled and promoted
Mentality	• Optimistic • Patient-centered • Adaptable • Integrated with other health areas	• Unambitious • Geneva-centered • Rigid • Vertical: TB is in a silo

Just six months later, these demands have been endorsed by one of the leading global structures fighting TB, the Stop TB Partnership (www.stoptb.org/news/stories/2012/ns12_073.asp).

Indeed, since its inception in May 2012 and introduction in the fall 2012 issue of TAGline, the Zeroes campaign has made remarkable progress in changing the way the world addresses TB. The Zeroes campaign—with the support of TAG, the Stop TB Partnership, Partners In Health, the Sentinel Project on Pediatric Drug-Resistant TB, and the Harvard Medical School Department of Global Health and Social Medicine—hosted a symposium on November 13, 2012, in Kuala Lumpur, Malaysia. Speakers—including survivors of TB, researchers, and care providers—urged the over 100 attendees, and the world, to get to zero for TB quickly, and explained both how this is possible and what is required. Videos from the symposium are available online at: www.treatmentactiongroup.org/tb/advocacy/zero-symposium.

With clear public support and emerging political will, the Zeroes campaign will continue to forge forward with foundational work to map and model what it would take in terms of case finding, prevention, treatment, diagnosis, care, metrics, and economics to reduce new TB deaths, infections, stigma, and suffering as rapidly as possible. Please join these efforts by signing on to the Zeroes declaration, and demanding zero TB deaths, infections, and suffering where you live! •

TAG Welcomes the FDA Approval of the First New Drug for TB in 40 Years

by Erica Lessem

December 28, 2012, was a historic day for the one million people around the world with strains of tuberculosis (TB) that are particularly difficult to treat. For the first time in forty years, the United States Food and Drug Administration (FDA) approved a new drug, bedaquiline for TB. This approval follows the first ever public hearing to review a new drug for TB, in which the expert panel unanimously found the drug effective at fighting multidrug-resistant (MDR) TB. (MDR-TB is defined as a strain of *Mycobacterium tuberculosis* that is resistant to at least isoniazid and rifampicin, two of the four first-line drugs that are used to treat TB.) Currently, MDR-TB patients have to endure up to two years of treatment with toxic existing drugs, only to have just a fifty percent chance of surviving. The FDA's decision sets both a precedent around the world for other regulatory authorities, and the tone for the future of the TB drug pipeline.

New drugs are urgently needed in order to get to zero deaths, new infections, and suffering from TB (see page 6). Less than five percent of the million people with MDR-TB receive appropriate treatment. Among the tiny proportion able to access care, fewer than half are cured. Even treatment success can mean hearing loss, liver damage, and psychosis.

In the past decade, after years of stagnation, TB drug research has undergone a renewal. Bedaquiline (also known as TMC207, or by its trade name, Sirturo) is the first novel drug candidate coming out of this renewal to be approved. Based on results from early-and middle-stage research studies in people with MDR-TB, combining bedaquiline with existing TB drugs clears the bacteria more quickly than existing drugs alone. This means that including bedaquiline could make MDR-TB treatment shorter and more effective.

There is, however, some concern about the drug's safety. As such, Mark Harrington, the Executive Director of Treatment Action Group (TAG), urged the FDA advisory committee in his public testimony, "Be bold. Make history. But do it stringently." The FDA has granted accelerated approval for bedaquiline (meaning before results from larger, phase III trials are available), and therefore must require bedaquiline's sponsor to carry out a phase III trial quickly, as well as conduct other necessary studies into the drug's safety, suitability in children and people with HIV, and potential for use along with other novel drug candidates such as delamanid, which is following closely on bedaquiline's heels.

In order for a real renaissance in TB treatment to occur, the world needs more than just one new FDA-approved drug. Other countries need support and urging to build their infrastructure to approve and introduce new drugs such as bedaquiline in a timely fashion, and to make them available for urgent cases on a pre-approval basis. Additionally, only with other safe and effective new options to fight TB can we ensure new drugs' effectiveness in the long-term by preventing resistance, and stop unnecessary suffering from current toxic and ineffective drugs. However, as illustrated by TAG's recently released *2012 Report on Tuberculosis Research Funding Trends, 2005-2011*, TB drug research still faces a shortfall of nearly half a billion dollars. By not only approving bedaquiline but also ensuring that proper follow-up studies are completed soon, the FDA could demonstrate to MDR-TB patients and providers that they matter, signal to other regulatory authorities around the world that TB is a priority, encourage developers and investors that there is a market and clear approval pathway for TB drugs, and ultimately herald a new era in TB treatment.•

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that have saved and enriched the lives of countless individuals here and abroad remain a significant risk.

The deal, titled the "American Taxpayer Relief Act of 2012," reduces tax breaks for many high-income households, extends unemployment insurance benefits, and imposes a delay on mandatory across-the-board sequestration cuts—temporarily offset by a limited number of new discretionary spending cuts and tax policies. More worrisome, however, is the looming triple threat of the federal government hitting the debt ceiling, the expiration of the current continuing resolution, and the reset of sequestration cuts—all of which will unfold over the next two months.

Considerable Consequences

It's difficult to overstate the potential impact of sequestration or other entitlement-program cuts on the health and well-being of those living with, and at great risk of, HIV infection. In places where there are a high percentage of poor people, any decline in federal funding for much-needed community and family services often has rippling and catastrophic effects on people's lives. For example, states that rely heavily on AIDS Drug Assistance Program (ADAP) monies for their patient populations could see a rise in ADAP waiting lists again. Additionally, beleaguered community-based organizations (CBOs) have much to be concerned about, with tightening of the CDC's HIV prevention budgets and political un-certainty over the Ryan White program reauthorization, which provides critical safety-net funding for wraparound and supplemental services for people with HIV or those vulnerable to infection. What's more, many CBOs will need to transform their infrastructure and services to accommodate the era of expanded health care coverage for millions of Americans under the Affordable Care Act.

It's difficult to overstate the potential impact of sequestration or other entitlement-program cuts on the health and well-being of those living with, and at great risk of, HIV infection.

The U.S. response to the global HIV/AIDS epidemic will also likely be affected. If the sequester is allowed to happen, non-security discretionary spending will likely be subjected to a 5.1% across-the-board cut. In terms of global health funding allocated in the State and Foreign Operations bill, this could mean about $482 million being slashed—a great percentage of which would affect PEPFAR, Global Fund, and Blueprint for an AIDS-Free Generation funding.

Finally, if the sequester goes through, a reduction of around $181 million in AIDS research funding is expected for National Institutes of Health (NIH) AIDS research programs. Any further cuts to NIH will have the clear and devastating effects of undermining our nation's leadership in health research and our scientists' ability to take advantage of the expanding opportunities to advance health care.

A Budgetary Mess

The lead-up to sequestration began anticlimactically on May 16, 2011, when the United States reached a debt ceiling of $14.3 trillion dollars. As a result, congress and the Obama administration spent the summer tortuously hammering out the Budget Control Act of 2011 (BCA), which raised the debt ceiling temporarily and outlined a budget-reduction framework of $2.3 trillion over ten years. Congress implemented $1.2 trillion in discretionary spending cuts and commissioned the 12-member bipartisan, bicameral "Super Committee" tasked with identifying an additional $1.2 trillion in deficit reduction through tax and entitlements reform. The Super Committee's failure to develop a deficit-reduction plan by their November 2011 deadline triggered the ticking sequestration-process time clock. Mandatory across-the-board spending cuts to most federal programs were slated to begin in January 2013 if an alternative compromise could not be reached.

Throughout 2012, lawmakers bickered and thwarted every opportunity to come up with a

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compromise that would have averted sequestration—punting all negotiations until after the election. This culminated in the dramatic December march to the fiscal cliff. Republicans sought deep budget cuts to discretionary spending along with massive entitlements reform; Democrats demanded discretionary cuts balanced with revenue hikes. The compromise, finally reached on New Year's Eve, only partially resolved the fiscal-cliff crisis by extending some of the Bush-era tax cuts and postponing the sequestration process until March 1, 2013, all the while failing to substantively address fundamental issues of debt control and federal spending. Further, congressional inaction on sequestration has delayed other aspects of the federal budget including the release of the president's FY 2014 budget request—which now won't take place until after March 1.

As deadlines for these ongoing budget negotiations draw nearer, the precarious financial position of the HIV community has come into sharper focus, particularly while so many of the National HIV/AIDS Strategy goals remain elusive. A strong financial commitment, not sweeping cuts to research and programming, is needed if we are to succeed in reducing HIV incidence, increasing access to care and optimized health outcomes, and curtailing HIV-related health disparities. There are over 1.2 million people living with HIV in the U.S., the highest number in the epidemic's 30-year history, and more than 50,000 Americans become infected every year—a rate that has remained fairly stagnant over the past 20 years.

For HIV activists, the near-term challenge is to capitalize on the two-month delay of sequestration to hammer home the advocacy messages to lawmakers about the impact these cuts will have on the millions of people living with HIV here and around the world who rely on lifesaving HIV treatment, care, and prevention programs. The reality is that blind, indiscriminate, across-the-board cuts, made regardless of program demands or effectiveness, is poor, shortsighted policy—it would harm our public-health efforts to reduce HIV incidence nationally, and undermine progress and investments already made in the domestic and global HIV fight. •

Help Support Inclusion of Pegylated Interferon on the World Health Organization's Essential Medicines List

The current standard of care for HCV is pegylated interferon (PEG-IFN) and ribavirin. Yet in most countries, this treatment is unaffordable to all but the wealthiest people. **In order to stimulate price reductions and increase access**, Médecins Sans Frontières (MSF) has submitted an application to include PEG-IFN on the WHO's Essential Medicines List (EML).

The WHO EML is considered a global standard. Many governments refer to the EML when making decisions on health spending. A drug on the list may be more likely to be prioritized for coverage under a national health care scheme.

TAG has created a simple guidance for organizations to write a letter of support for this important effort. Organizations such as patient groups, professional associations, regional or global adovcacy networks, governmental agencies, or national research institutes can submit. Deadline for submission is mid-February 2013. The letter should highlight the HCV epidemiology in your country/region, and how inclusion of PEG-IFN on the EML would increase treatment access and impact the epidemic. The WHO committee is technical, and responds to evidence-based information rather than political arguments.

More background information and sample letters are online at: www.treatmentactiongroup.org/hcv/pegifn-who-eml-support-letter.

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Spencer started by joining ACT UP's most intimidating committee. The Treatment & Data gang was a pack of know-it-all divas who expected new members to climb the learning curve fast, and burn their own paths. He did both in short order, and quickly earned the respect and friendship of these self-taught expert activists. It didn't hurt that he was one of the few who could outsmoke Mark Harrington, or that he provided a constant soundtrack of dark humor to our often depressing work.

But it's when our activism started to pivot that Spencer really began to shine. AIDS treatment activism began with fury, and blind hope, that if we just pushed hard enough, we could force the system to find the cure or near-cures that were surely out there. But they weren't, and a simple bureaucratic fix wasn't going to save us.

Spencer and the other science geeks led this pivot. We could no longer take shortcuts around the tenets of scientific discovery. We must instead devise new and creative methods to use those basic tenets for our ultimate goals. Spencer, in particular, became almost religious about this new science-driven activism.

He and the other geeks started the pivot by challenging the hard-fought and hard-won orthodoxy of gay men threatened by AIDS from our politically active enclaves in New York and San Francisco, from neighborhoods like Greenwich Village, Chelsea, and the Castro. We demanded and got our quick FDA approvals. We used our often gay and truly heroic HIV specialists, becoming experts together, custom-tailoring novel regimens from approved and unapproved treatments alike. Over time, we got more AZT knockoffs approved, with less and less applicable info on how to use them to actually save lives.

That's when the science geeks made their courageous play. Spencer slammed the status quo. He testified before the FDA about the accelerated approval of the third AZT knockoff, d4T, saying:

The approval of therapies based on inadequate, ambiguous, uninterpretable or incomplete data offers severe and potentially insurmountable difficulties in the future evaluation of new treatments. This is the deck with which the current therapeutic house of cards was built.

It was a wonder watching him wow the FDA, and in meetings with the biggest names in AIDS research, like Anthony Fauci. He earned the respect, and the love, of his fellow science geeks, and those of us lower down the learning curve. We were family, albeit one with lots of incest happening.

Spencer played a key role when TAG launched an audacious campaign challenging Hoffmann-La Roche's blatant attempt to get their protease inhibitor, saquinavir, approved without providing the necessary real-world data on how to use it. I remember having my doubts at the time. Should TAG really go out on a limb like this, infuriating most of the other AIDS groups that sought to defend our hard-won regulatory reforms?

Spencer patiently walked me through the arguments for challenging the self-help orthodoxy we ourselves had help build. He made his case not with science or statistics, but with ethics. This was about moving beyond a status quo that provided the illusion of serving only a privileged few. This was about serving the greater good. This was about health care for all, built on a democratization of data, not just drugs. We needed answers, not just access. We needed clinical trial data that could be used for standards of care in all resource settings, so that the guessing would end, and clear treatment guidelines would save the greatest number of lives.

He was right of course. And today we have highly detailed treatment guidelines, backed by interpretable data, and adjusted for resource settings around the world. Eight million people on standardized regimens. Eight million lives saved.

It's a stunning legacy, and so bittersweet. How could that young gay man, confronted with his own demise, respond with a level of genius that impacted millions of lives, but

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failed to save his own?

This death hit us hard. We have grappled to make sense of it. Why did he stop his meds? What role did his struggle with crystal meth play? Was this a failure of community? Are there lessons we can learn?

These aren't just nosy questions by idle bystanders. There are thousands of survivors of the plague years who in small ways and large feel damaged and vulnerable. All of us have felt the pain and helplessness of watching a friend struggle with meth.

The details of Spencer's own struggle with it, or even if there was a struggle this past year, remain shrouded in the wildly divergent opinions of those who knew him. I saw him after his return to New York, and he was the Spencer of old: campily dismissive of almost everything and everyone, cutting in his humor, and with grand plans for the future, including walking the red carpet at the Oscars. He shined at the premiere of *How to Survive a Plague*; comforted Sarah Jessica Parker after a screening a few weeks later; and wowed a crowd of health care workers at St. Luke's Hospital during a post-screening panel we did together just a few weeks before he died.

What we do know for sure is that a great deal of his life came crashing down in 2008 because of his struggles with addiction, and he was still far from rebuilding that damage.

The debate that has ensued since his death between frustrated community activists and harm reductionists is worth having. We need to find some common ground that is neither complacent nor stigmatizing.

Given Spencer's activism, his treatment interruptions were confounding. There were at least three over the last decade, all resulting in dangerous hospitalizations. When asked why, he would evade, probably realizing that the answers would be too painful to explain.

His last burst of activism was explanation enough. He spoke out forcefully about the depression and PTSD that the surviving generation of gay men from the plague years often suffered from, regardless of HIV status. While many of us, through luck or circumstance, have landed on our feet, all of us in some way have unprocessed grief, or guilt, or an overwhelming sense of abandonment from a community that turned its back on us, and increasingly stigmatized us, all in an attempt to pretend that AIDS wasn't its problem anymore.

That is Spencer's call to action, and we should take it on.

Maybe we've overanalyzed his death. The *whys* might be better explained by this young man's complexities, his genius and wit, and the flip side of that coin, his very human imperfections. The larger issues his death raised for our community should be explored, but not manipulated, from what was, in the end, a man's uniquely beautiful, courageous, and fallible life.

It is his activism I will remember.

In Paul Monette's *Last Watch of the Night: Essays Too Personal and Otherwise*, he writes of his lover's death from AIDS and his own imminent one in the essay "3275," which is the plot number of Monette's gravesite with his lover's on Revelation Hill at Forest Lawn Cemetery:

We queers on Revelation Hill, tucking our skirts about us so as to not touch our Mormon neighbors, died of the greed of power, because we were expendable. If you mean to visit any of us, it had better be to make you strong to fight that power. Take your languor and easy tears somewhere else. Above all, don't pretty us up. Tell yourself: None of this ever had to happen. *And then go make it stop, with whatever breath you have left. Grief is a sword, or it is nothing.*

Spencer Cox's family and friends are honored to announce the establishment of three memorial funds in his name:

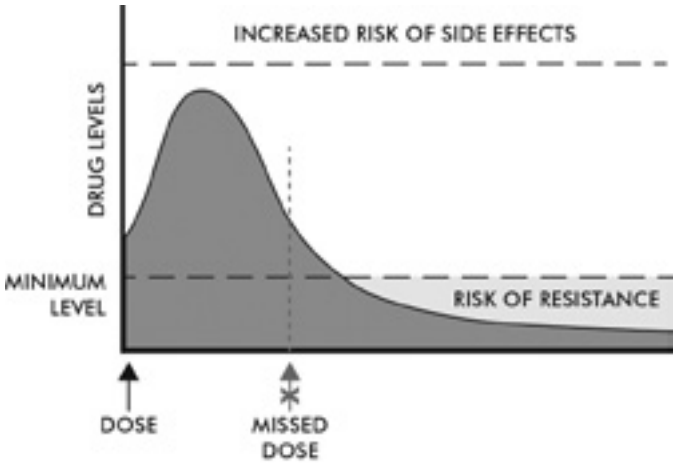
Broadway Cares/Equity Fights AIDS
www.broadwaycares.org/donate

Ali Forney Center
www.aliforneycenter.org/index.cfm?fuseaction=donorDrive.personalCampaign&participantID=1642

HeavenSent Bulldog Rescue
http://www.heavensentbulldogrescue.com

GUIDE TO CLINICAL TRIALS FOR PEOPLE WITH HEPATITIS C

SECOND EDITION NOW AVAILABLE



Tracy Swan's popular guide for people who are deciding to participate in a clinical trial for new hepatitis C treatment has been updated. This guide is avialable in both English and Spanish. To download PDFs or request printed copies by mail, free of charge, go to: www.treatmentactiongroup.org/hcv-clinical-trials-guide.

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Supporting TAG is a wise investment in AIDS treatment advocacy. With a small but well-organized and highly respected staff of professionals, every donation to TAG brings us one step closer toward better treatments, a vaccine, and a cure for AIDS .

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www.treatmentactiongroup.org/donate

About TAG

Treatment Action Group is an independent
AIDS research and policy think tank
fighting for better treatment, a vaccine, and a cure for AIDS.

TAG works to ensure that all people with HIV 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 AIDS .

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