

Dear friends of TAG—

I am very proud to send you this fall 2006 edition of *TAG Update*. As you can see, this has been an exciting and productive year for the Treatment Action Group. This issue contains brief summaries of some of this year's highlights, including the release of TAG's *What's in the Pipeline?* report at the XVI International AIDS Conference in Toronto and TAG's *TB R&D Investments: A Critical Review* at the World Conference on Lung Health in Paris. There is also news about TAG's role in combating the outbreak of extensively drug resistant (XDR) TB in South Africa, about Hepatitis C Coinfection Project Director Tracy Swan's role in speeding up HCV drug development for HCV/HIV coinfecting persons, notes on Mark Harrington's meeting with Bill and Melinda Gates at the Toronto AIDS Conference, a profile of TAG's newest board member, Robert Pini, and an interview with TAG's new Editorial Director, Bob Huff. Finally there are brief updates on TAG's annual Research in Action Awards, and on our new Michael Palm Donor Circle.

Let me thank each of you for your ongoing and sustaining support for TAG's vital work.

Yours truly,

Barbara Hughes
President, Board of Directors

**2006 PIPELINE REPORT
TORONTO**

TAG's 2006 report, *What's in the Pipeline: New HIV Drugs, Vaccines, Microbicides, HCV and TB Therapies in Clinical Trials*, released at the XVI International AIDS Conference in Toronto in August 2006, reviewed and critiqued over 20 new anti-HIV drugs that are in experimental studies in humans, along with many potential anti-hepatitis C virus (HCV) drugs and a handful of new anti-tuberculosis (TB) drugs—the first in 40 years. The report also covered HIV vaccines, microbicides, and preventive pills, and provided information on future drug development. It was a collaborative effort by TAG staff members Rob Camp, Mark Harrington, Richard Jefferys, Tracy Swan, and Javid Syed, and was edited by Jen Curry and Bob Huff. Copies can be obtained from the TAG office or online at www.treatmentactiongroup.org/tagline/pipeline2006.pdf

**FIRST AFRICAN TB/HIV WORKSHOP
CAPE TOWN**

TAG's TB/HIV Project Director, Javid Syed, organized the first African TB/HIV Community Workshop, held in Cape Town, South Africa, in mid-June. The workshop was a collaborative effort by TAG and South Africa's Treatment Action Campaign (TAC). Over 70 African activists participated, highlighting the leading killer coinfection among people with HIV on the continent.

TB R&D REPORT

PARIS

TB R&D Investments: A Critical Review, by Cindra Feuer, edited by Javid Syed and Mark Harrington, was released at the 37th Union World Conference on Lung Health in Paris on November 3, 2006. The groundbreaking report established that the top 40 funders of TB research and development (R&D) spent only \$400 million on TB R&D in 2005—just 4% of what is spent on AIDS research, and far from what the Stop TB Partnership has estimated is needed. TAG presented its report at the conference and called for a five-fold increase in TB R&D to develop new diagnostics, drugs, and vaccines. The report is available from the TAG office or online at www.treatmentactiongroup.org/tbhiv/tbrandd.pdf.

HEPATITIS C VIRUS & HIV

SILVER SPRINGS

Tracy Swan, TAG's HCV/HIV Coinfection Project Director, has been appointed community representative to the FDA's Antiviral Drugs Advisory Committee (AVDAC) with special oversight over drug development for new drugs to treat HCV. Tracy attended her first hearing as FDA community representative in late October, where she asked industry and FDA to ensure that new anti-HCV drugs are studied expeditiously prior to approval in people living with HIV/HCV coinfection, a group that generally does not respond well to currently approved HCV drugs.

XDR-TB

SOUTH AFRICA, GENEVA, NEW YORK CITY

TAG played a key role in publicizing the alarming outbreak of extensively drug resistant (XDR) TB among HIV patients—many of them receiving antiretroviral treatment—at a rural hospital in KwaZulu-Natal, South Africa. The rapidly fatal form of TB is difficult to diagnose and even harder to treat. TAG's Mark Harrington interviewed Gavin Churchyard, director of Aurum Health Research, an institute providing treatment and research to South African gold miners, about the extent of XDR-TB in the gold mines; distributed the report to international activists and policymakers; and participated in the World Health Organization's Task Force on XDR-TB meeting in Geneva in early October. On November 10 in New York City, TAG, along with the Global Alliance for TB Drug Development, convened a meeting including Médecins sans Frontières (MSF), Partners in Health (PIH), and the CDC to discuss ways of accelerating the development of new TB drugs to address the crisis of multiple drug resistant (MDR) and extensively drug resistant (XDR) TB.

STUDY BY BRUCE SCHACKMAN FINDS HIV TREATMENT "GOOD INVESTMENT"

Cornell University researcher Bruce Schackman, an alumnus of TAG's Board, published a widely reported finding that people newly diagnosed with HIV can expect to live for decades.

HIV Drugs Extending Lives by 24 Years

Baltimore Sun / Associated Press

11 November 2006 — The average U.S. patient diagnosed with HIV today can expect to live 24.2 more years, more than triple the life span of those diagnosed with the AIDS-causing virus in the early 1990s, according to a new study.

But with HIV/AIDS patients living longer and taking more sophisticated drug regimens, a lifetime of treatment could cost more than \$600,000 per patient, straining the federal government's ability to provide for those in need.

Doctors involved in the study said a decade of treatment advances produced results that were once hard to imagine.

When the epidemic emerged in the early 1980s, survival was "measured in months or a few years," said Dr. Bruce Schackman, chief of health policy at Cornell University's Weill Medical College in New York. He is lead author of the paper in *Medical Care*, a journal published by the American Public Health Association.

Funding for treatment is "a very good investment, but it's an investment," Schackman said.

"If funding continues to be flat, a lot of people are not going to be effectively treated, and they're more likely to infect other people."

Feeding data from a national network of AIDS centers into a computer model, researchers estimated that patients today can expect to live 24.2 years after starting treatment, compared with 6.8 years for patients entering treatment in 1993.

HIV/AIDS

- Today, the average American diagnosed with HIV can expect to live 24.2 years. In 1993, life expectancy was 6.8 years.
- The average monthly cost of treating HIV, assuming optimal care, is \$2,100, up from \$1,500 in 1998.
- Care-cost breakdown: 73% for anti-retroviral medications, 13% for inpatient care, 9% for outpatient care and 5% for other HIV-related medications and laboratory costs.
- Patients typically enter care when they're about 39 years old.
- About 40,000 people are infected with HIV every year in the United States.
- Many HIV/AIDS patients eventually die of heart disease, stroke and other diseases of aging, rather than from opportunistic infections.
- The study could influence how much state and federal governments appropriate for HIV and AIDS care and prevention in the future, some HIV-policy experts said.
- Federal spending for HIV treatment more than tripled in the past decade, to \$11.6 billion in 2005. But with patients living longer and the federal government pushing for expanded testing, Schackman said, some patients could be left out unless the government increases its spending.



Activists from Georgia, Kenya, India, Tanzania, Ukraine, USA at TB/HIV Advocacy Workshop sponsored by TAG and Public Health Watch/Open Society Institute, Istanbul, September 2006.

MEETING WITH BILL & MELINDA GATES

INTERNATIONAL AIDS CONFERENCE – AUGUST 2006 – TORONTO

Five advocates were invited to meet with Bill and Melinda Gates at the International AIDS Conference in Toronto, including TAG's Mark Harrington. The couple had delivered the conference keynote address, focusing on the need for intensified research efforts focusing on new HIV prevention technologies, including microbicides, vaccines, and pre-exposure prophylaxis. Mark reported on their meeting:

On Monday morning at the AIDS conference I met with Bill and Melinda Gates along with four other advocacy grantees [AIDS Vaccine Advocacy Coalition, Center for Strategic & International Studies, Kaiser Family Foundation, and RESULTS], and with Gates Foundation staff. Each grantee had three minutes for their remarks, followed by an open discussion.

I told them the history of AIDS activism. In his plenary speech on Sunday night, Bill Gates called for volunteers in clinical trials. I told him of our work with FDA, NIH, and industry to speed AIDS drug development, increase research funding, restructure NIH, and support global scale-up of ART. I named names, laws, and budgets, and told them about the lymph node biopsies I underwent to shed light on where HIV lives in the body, before and after I started therapy ('92, '96, '98).

I articulated our vision for catalyzing alliances between activists and scientists to persuade the general population and political leaders to put more leadership and money in global killer diseases, how this worked with HIV/AIDS, and how it wasn't working yet with TB. I handed them the TB research mapping report, which Bill Gates examined closely, and explained that TB research gets four cents for every dollar spent on AIDS research, and that TAG estimates that TB research needs to quintuple.

Bill and Melinda Gates were very concerned about the failure of the tenofovir (TDF) pre-exposure prophylaxis (PrEP) trials due to activism. I said there was a need for rapid response to things some activists said which were demonstrably false. I said there was a need for strong research preparedness in countries where studies would happen. We talked about the hostile funding climate in DC to global health other than to PEPFAR, and the declining funding to NIH and CDC. I said we needed to think long-term about building up NIH to bring in young investigators and fertilize new science. I said that long term, strategic approaches to increase budgets for research worldwide, including in the US, are needed.

Melinda Gates stated her impression that AIDS activism in Africa needed to be stronger. I replied that groups such as the Treatment Action Campaign (TAC) are very strong indeed but that they are up against even stronger governments, not all of them well-intentioned. I stated that the Gates Foundation needed to adopt a new approach to support community-based activist groups in African and other

countries to promote research and treatment literacy, support scale up, and create demand for better programs today and research for better tools tomorrow.

They asked if TB was on the radar screen in Washington or elsewhere. I said it was barely on the radar in DC or with HIV activists either. I explained that much more must be done to highlight the need for immediate action on TB/HIV, which is affecting scale-up of antiretroviral treatment in the developing world.

I asked them to consider holding a high level meeting to link advocates working on global killer diseases, and to use their political prestige to meet with President Bush and other policymakers and call for much greater investment in global killer diseases. I asked that he emphasize that much of it must come from the public sector (which funds 70% of TB research), and to tell governments and other foundations that the Gates Foundation cannot solve these problems without much greater public, philanthropic, and private investment, and that investing in community advocacy is crucial to advancing these issues in rich and developing countries alike.

LETTER TO TAG

FROM BILL & MELINDA GATES

September 18, 2006

Mark Harrington
Treatment Action Group
611 Broadway, Suite 608
New York, New York 10012

Dear Mr. Harrington

Thank you for meeting with us at the International AIDS Conference. Learning about your experiences working on HIV and TB were particularly interesting, especially your thoughts on the clinical trials controversies.

There is such a great need for strong advocacy around these issues, and we appreciate the Treatment Action Group's hard work to overcome so many challenges, such as growing capacity, effective strategy building, and finding good advocates.

We look forward to a continued relationship between the Treatment Action Group and the foundation, and wish you great success.

Again, thank you for taking the time to update us in Toronto.

Sincerely,

Bill Gates and Melinda French Gates



INTERVIEW WITH TAG'S NEW EDITORIAL DIRECTOR, BOB HUFF

*Bob Huff is a long-time treatment activist. He worked with ACT UP/New York's Treatment + Data (T+D) Committee in the late 1980s, and made the film *Rockville is Burning!* covering ACT UP's 'Seize Control of the FDA' demo in October 1988. He was a founding member of the AIDS Clinical Trials Group (ACTG)'s Statistical Working Group, which brought together activists and scientists to work on designing clinical trials that could flexibly meet the needs of people with HIV while providing clear answers in a rigorous way. In the 1990s, Bob edited amFAR's Treatment Directory, studied biology at Columbia University, earned his Master of Fine Arts (MFA) at Bard College, and returned to AIDS treatment activism in the late 1990s. From 2001-2006 he was editor of GMHC Treatment Issues, at Gay Men's Health Crisis, New York.*

Why you? Why TAG? Why now?

I was drawn to ACT UP in 1987 by a sense of outrage and horror. It quickly became clear that the gaps in what we knew about the science of HIV were deadly. The activists that came together around that time caused dramatic change to occur in how the disease was studied and how treatments were developed. A lot of what we pioneered is now routine practice, but the amazing fact is, 20 years later, treatment activists are still helping to save lives.

Just because HIV treatments are incrementally better today than they were five years ago—and dramatically better than 15 years ago—doesn't mean we've reached the Promised Land. The greatest unmet medical need in HIV therapy today is for better first-line drugs that are more potent, more durable, and more tolerable. But even that is not enough. We need future drugs to be available on economic terms that bring all these benefits to every HIV-infected person in the world.

There has never been a better time to move towards reversing the worldwide death rate from AIDS. At long last the forces of opposition in South Africa have capitulated and that country is making dramatic monthly progress in bringing more people under care. We have new leadership in the U.S. Congress, which is an opportunity to assure that meaningful scientific research at the NIH can flourish. We're on the cusp of seeing a new generation of drugs approved that attack HIV in novel ways. Treatments for TB and hepatitis C virus, which have been stagnating, are poised for new breakthroughs. That said, thousands of people still die from HIV-related causes every day...and there is little we can directly do about it but continue to advocate for better tools and continue to demand that those who can do something—those in positions of power—work harder, go faster, and commit more resources. At TAG we feel a passionate urgency about this because we know what it's like to lose a loved one in the days and months before effective new treatments finally become available.

What is the role of the AIDS activist today?

To catalyze change, we need to know what is going on in every corner of AIDS research, and when we see connections that should be made, we can facilitate them. It's astounding how many good ideas don't move forward due to inertia or how many bad ideas get implemented because of ignorance.

Generally, the people we work with are smart and delightful. But we are not their friends and only provisionally are we colleagues. Like journalists, activists need to keep a critical distance, and as agents of change, keep an eye on the greater goals of progress and justice.

Even other activists should be taken to task if their actions are counterproductive. Nothing good comes without struggle; acting as critic is part of our role, but we do best when we help needed developments to move along faster, with better and more just outcomes for all people.

Is there an emerging issue in AIDS research that particularly concerns you?

Tuberculosis advocacy is now a field ripe for making a difference. It's similar to the early, uncharted days of AIDS activism when the path wasn't clear. The TB activists I've met are smart and committed but, until recently, haven't dared envision an ambitious plan for moving their field forward to respond to a changing epidemic. The TB world was accustomed to having too few resources and no new tools. Fortunately that's changing and TAG is primed to help make that happen in a smarter and more equitable way.

In addition, I think there may be some challenges in how we respond to success in treating HIV. With a wave of exciting new HIV drug approvals expected over the next year or so, we may finally see a dramatic reduction in the number of people with HIV who find themselves "unable to construct a viable regimen"; the classic definition of the so-called "salvage" patient who has developed resistance to nearly every available antiretroviral treatment option. This is a welcome situation that we've worked to achieve for a long time, but it has implications for future HIV drug development.

What do you hope to see TAG achieve?

I want policy and decision makers to immediately think of TAG whenever they need to know the latest and smartest thinking on questions about science and medical research in the lives of people living with HIV. I'm excited that TAG is planning to have a higher profile in Washington. This is a crucial time of change when new opportunities are opening up—these opportunities don't last forever and we need to be in DC influencing these decisions now.

As for the science, it's time to seriously evaluate where we are in relation to a cure. For a long time, viral eradication has seemed like a distracting fantasy but I think we are nearing a point when it deserves serious effort. It may never become practical to use on a worldwide scale, but curing HIV infection is a goal that must be pursued.



TAG'S NEWEST BOARD MEMBER

ROBERT PINI

Robert Pini is the Senior Vice President of Corporate Communications at New Line Cinema, the most successful independent film company. Previously he has worked at numerous corporate communications positions at various top media companies including ABC News, Conde Nast Publications, and Viacom/MTV Networks. A former Peace Corps volunteer, Robert witnessed the beginning of the AIDS epidemic in Cameroon, West Africa, a year or so after the first "gay cancer" story appeared in the *New York Times* in the early 80s.

When he returned from Cameroon after a 2 1/2 year stint, he felt he needed to become involved with the US AIDS fight. His first stop was "ACT UP" where he attended the group's second meeting and signed up to work on the media committee to promote and enlighten the media on the organization's activities. Later he oversaw the media relations for "Visual AIDS," a non-profit arts advocacy group that created "Night Without Light" and the iconic "Red Ribbon Project."

From his early days in the Peace Corps, Robert understood that HIV/AIDS would primarily afflict the poor, particularly individuals in developing countries. He is honored to serve as a board member for TAG, an organization that has sparked Robert's admiration for its grassroots efforts against AIDS in a time when the disease has been sidelined by the mainstream media and government. "TAG is one of the groups that keeps the flame burning," says Pini.

2006 RESEARCH IN ACTION AWARDS

HONORS TO AIDS POLICY ACTIVIST JUDITH AUERBACH, PEDIATRIC AIDS EXPERT DONNA FUTTERMAN, AND AWARD-WINNING PLAYWRIGHT TERENCE McNALLY

"We are honoring three heroes who have fought to keep AIDS in the public eye, through activism, medical care, and art," says Mark Harrington, executive director of TAG. "After twenty-five years of AIDS, TAG is committed to continuing the work laid out by these leaders until we have a cure, a vaccine, and full human rights for people with HIV/AIDS everywhere."

This year's honorees include Dr. Judith Auerbach, Deputy Executive Director for Science and Public Policy at San Francisco AIDS Foundation, also formerly Vice President for Public Policy and Program Development at amfAR; and Dr. Donna Futterman, Director of the Adolescent AIDS Program at Montefiore Hospital (one of the nation's leading programs providing comprehensive care for HIV positive and at-risk youth), also Professor of Clinical Pediatrics at Einstein College Medical Center.

Tony and Emmy award-winning playwright Terrence McNally will be honored as well for his compelling and provocative work in dealing with HIV/AIDS. Author of more than 40 plays, musicals, and screenplays, Mr. McNally's newest work "Deuce" will open on Broadway in April, 2007, starring Angela Lansbury and Marion Seldes. The RIAA Award will be presented to McNally by actor Nathan Lane, currently starring on Broadway in "Butley." Lane starred in several of McNally's ground-breaking productions.

ANTIRETROVIRAL UPDATE

On June 23, 2006, the U.S. Food & Drug Administration approved Tibotec's Prezista™ brand darunavir (formerly TMC-114), a new protease inhibitor, for use in extensively pre-treated persons. In October, Tibotec announced an expanded access program was opening for its new non-nucleoside reverse transcriptase inhibitor (NNRTI) etravirine (formerly TMC-125). Also in October, Merck announced an open-label safety/expanded access program for the first integrase inhibitor, MK-0518, and Pfizer is planning a similar program for its experimental CCR5 inhibitor, maraviroc. All three programs will target highly pre-treated individuals who need an experimental agent to increase their chances of achieving viral suppression. For more information visit www.clinicaltrials.gov.

TREATMENT INTERRUPTIONS & INTERMITTENT THERAPY RESEARCH LONDON

In mid-July, TAG, along with the NIH Office of AIDS Research, cosponsored a global research workshop on the future of clinical trials involving the interruption of antiretroviral therapy or intermittent treatment in light of the results of the SMART study, which demonstrated that this approach could be dangerous in certain situations. The workshop brought together activists and researchers from France, South Africa, Thailand, Uganda, the UK, the US, and elsewhere to discuss priorities for intermittent therapy research in adults, adolescents and children at various stages of HIV disease and to permit the safe investigation of new approaches to immune-based therapy and therapeutic vaccination, as well as the possible design of a global study of "when to start" ART. The report from the workshop can be read at: http://www.oar.nih.gov/public/NIH_OAR_STI_IT_Report_Final.pdf.

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INVOLVED**
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JOIN TAG'S BOARD

TAG is always looking for good board members. If you are looking for a great place to invest your time and talents, please call Barbara Hughes, TAG Board President, to learn more about Board opportunities at TAG. She can be reached at (212) 253-7922 or at barbarah@projectrenewal.org. Don't delay!

ABOUT TAG

Founded in 1992, the **Treatment Action Group**, or **TAG**, fights to find a cure for AIDS and to ensure that all people living with HIV receive the necessary treatment, care, and information they need to save their lives. TAG focuses on the AIDS research effort, both public and private, the drug development process, and health care delivery systems. We meet with researchers, pharmaceutical companies, and government officials to encourage exploration of understudied areas in AIDS research and speed up drug development, approval, and access. We work with the World Health Organization and community organizations globally, and strive to develop the scientific and political expertise needed to transform policy. TAG is committed to working for and with all communities affected by HIV.



MICHAEL D. PALM (1951-1998) *A LEGACY OF GENEROSITY*

In memory of Michael Palm, a great friend to TAG, we are honored to announce the launch of the **Palm Donor Circle** in recognition of major contributors to the Treatment Action Group.

Despite a long battle with AIDS, Michael considered his life to be one of great fortune and he in turn was generous with his professional success. In 1994, he established a foundation to provide funding for organizations working to advance the causes that were his passion. Over the next decade, The Michael Palm Foundation gave over ten million dollars toward the goals he set which include providing services for people living with HIV/AIDS, advancing gay and lesbian civil rights, and supporting a variety of artists, arts organizations, and cultural institutions.

Apart from monetary support, but every bit as valuable, Michael was generous with his time and intellect. He became actively involved with various organizations, serving on boards and providing strategic leadership, always with the same quiet, self-assured voice of reason that was uniquely his own. Many organizations were fortunate to have been the recipient of Michael's generosity in both forms and have honored him for the key role he played in the successful pursuit of their mission.

The Treatment Action Group is one of these very fortunate organizations to have been helped by Michael in so many ways.

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