



# annual report

O F T H E T R E A T M E N T A C T I O N G R O U P

## A Note from the Board President

I'm very proud to share with you the Treatment Action Group's 2003 Annual Report. It was a year of growth and exciting accomplishments:

- TAG expanded our staff, bringing on a new Antiviral Project Director, Rob Camp, and a new Coinfection Project Director, Tracy Swan.
- TAG fought to protect the AIDS research budget from cuts and to increase funding for treatment at home and abroad.
- We helped secure FDA approval of four new antiretroviral drugs and pushed drug companies to do a better job gathering data on side effects and drug interactions.
- We published important reports on two deadly killers of people with HIV – tuberculosis and hepatitis C.
- TAG staff helped U.S. and global experts write new anti-HIV treatment guidelines based on the latest data.
- We held our Second International TB/HIV Community Workshop in the fall, which was an enormous success.

The board and staff of TAG are so grateful for your support, which makes our work possible and which contributes to treatments that benefit people today and to AIDS research that will benefit them tomorrow.

Yours in the struggle,

Barbara Hughes  
Board President

## 2003 at a glance

### JANUARY

**Rob Camp** joins TAG as our new Antiviral Project Director. Rob and Mark attend the Houston AIDS Treatment Activists Coalition (**ATAC**) meeting to develop stronger national coalition, then the DC **Federal AIDS Policy Partnership** to plan policy for the year. We hear warnings of coming assaults on Medicaid and Medicare. Rob, Mark, and **Richard Jefferys** meet with officials from the **Office of AIDS Research** (OAR) and the NIAID **Division of AIDS** (DAIDS) in Bethesda to discuss National Institutes of Health (NIH) AIDS research. We mourn the death of philanthropist **Irene Diamond**, a supporter of TAG. President Bush proposes \$15 billion **Emergency Plan for AIDS Relief**; however, just \$2.5 billion will be appropriated this year.

### FEBRUARY

Space shuttle **Columbia** breaks up over Texas. Researchers find that an HIV-1 antibody blocks **vaginal infection** in monkeys, lending support to the search for an HIV **microbicide**. TAG publishes **Daniel Raymond's** report on TAG's first international **TB/HIV community workshop**. TAG sponsors a **HCV/HIV** roundtable at the 10th Retrovirus conference in Boston and publishes HCV consultant **Tracy Swan's Research and Policy Recommendations for HCV/HIV infection**. Basic Science Project Director, **Richard Jefferys**, meets with **Aventis** to discuss its **ALVAC** vaccine, still in clinical trials after many setbacks. **VaxGen** issues a misleading press release on failed phase III **AIDSVAX** HIV prevention trial.

## MARCH

**Rob Camp** publishes a TAG position paper supporting approval for Roche's **Fuzeon** brand **enfuvirtide (T-20)**. TAG cosponsors the first **International Treatment Preparedness Summit** in Cape Town, a global meeting of 125 treatment activists, to plan treatment education and advocacy programs in countries where HIV drugs are soon to be scaled-up. We witness the start of the U.S. war in **Iraq**. The Food and Drug Administration (**FDA**) approves **Fuzeon**. South Africa's **Treatment Action Campaign (TAC)** starts a civil disobedience campaign for universal antiretroviral treatment access.

## APRIL

**Baghdad** falls to U.S. forces. The Centers for Disease Control and Prevention (**CDC**) issues new guidelines to broaden access to HIV screening and approves the **rapid HIV test**.

## MAY

**Rob Camp** testifies at the FDA hearing in favor of approving Bristol-Myers Squibb's **Reyataz** brand **atazanavir**, the first once daily protease inhibitor. Artist and longtime activist **Joy Episalla** joins the TAG board. Mark Harrington attends an HIV **operational research** meeting. Two research groups publish discovery of a new human **HIV-blocking protein**, known as **APOBEC3G** or **CEM15**, presenting a new pathway for **drug development**.

## JUNE

TAG is asked to testify at the NIH/NIAID meeting on the **future of HIV clinical trials** in Bethesda. **Mark Harrington** attends the 3rd World Health Organization (WHO) tuberculosis (**TB**)/HIV Working Group meeting. The CDC clamps down on San Francisco's **Stop AIDS Project**. The FDA approves Reyataz (**atazanavir**).

## JULY

Fundraiser and longtime activist **Jason Osher** joins the TAG board. The FDA approves Gilead's **Emtriva** brand **emtricitabine (FTC)**. TAG participates in the 2nd International AIDS Society (IAS) conference on pathogenesis and treatment in Paris. New U.S. **antiretroviral treatment guidelines** are published on-line.

## AUGUST

Mark Harrington meets with **Department of Health and Human Services** policy staff in Washington to discuss how the Administration could improve research and treatment. **NYC faces a startling blackout**. **Rob Camp** attends a **microbicide** meeting in DC and sets up a meeting with drug companies developing new HIV **entry inhibitors**. The **South African** government announces its decision to provide **antiretroviral** treatment through the public sector.

## SEPTEMBER

TAG hires **Tracy Swan** as its **Coinfection Project Coordinator**. Mark participates in the WHO **TB/HIV** meetings in France, the Netherlands, and South Africa. TAG starts planning its 2nd international TB/HIV community workshop.

## OCTOBER

**Rob Camp** writes a TAG position paper on GSK/Vertex' **Lexiva** brand **fos-amprenavir**, a protease inhibitor subsequently approved by FDA. Mark works on a WHO committee to revise **Antiretroviral Treatment Guidelines for Resource-Poor Settings**. TAG sponsors its 2nd International **TB/HIV community mobilization workshop** at the 34th World TB Congress, attended by 50 activists representing 25 countries.

## NOVEMBER

Treatment activist and long-term AIDS survivor **Carlton Hogan** dies in Minneapolis. Second VaxGen **AIDSVAX** gp120 vaccine trial is conducted in Thailand, but also fails to protect from HIV. Undeterred, the NIH/Department of Defense begins enrollment in a **phase III study** of canarypox/**AIDSVAX** prime-boost vaccine trial in Thailand. Rob Camp organizes an activist meeting in Bethesda with **FDA, Tibotec, and Pfizer**. The FDA asks TAG for earlier input on drug approval recommendations. Newly re-revised U.S. **treatment guidelines** are published on-line.

## DECEMBER

The World Health Organization releases its **"3x5" plan** to treat 3 million HIV positive people with antiretrovirals by 2005. WHO also publishes its **ARV treatment guidelines** for use in **resource poor settings**, with input from Mark. TAG participates in the **ATAC Strategy Summit** in New York City and the **North American AIDS Treatment Action Forum** in Phoenix. Researchers discover another human **HIV-blocking protein**, known as **Murr1**. TAG holds its **Research in Action Awards**, honoring activist **Martin Delaney and Project Inform**, dancer and choreographer **Bill T. Jones**, immunologist and ex-OAR Director **William E. Paul**, and former amfAR Public Policy Director and current Irene Diamond Fund President **Jane Silver**.

## JANUARY 2004

Congress finally passes the **2004 budget**, four months after fiscal year begins. The **NIH** gets an increase of \$1 billion, 3.7%, to \$27.98 billion, with \$2.7 billion for AIDS research. International AIDS, TB and malaria programs get \$2.5 billion. HIV prevention research is protected from cuts.

### **TAG IN THE NEWS** – some highlights of our recent media coverage

[TAG board member] Lynda Dee, a member of the Maryland AIDS Drug Assistance Program advisory committee, said that many assistance programs not only provide drugs directly to low-income patients, but they reimburse drug co-payments to patients with private insurance. As Norvir's price rises, those co-payments will probably go up, too, she said. "Nobody's saying they shouldn't have a reasonable profit, but to raise a drug's price like this seven years after they've already made a fortune is unconscionable," Ms. Dee said. "Nothing has united the AIDS community like this in years."

– "Price of AIDS Drug Intensifies Debate on Legal Imports"  
The New York Times, 14 April 2004

Mark Harrington, executive director of the Treatment Action Group, which lobbies for better AIDS treatment, welcomed [FDA approval of] the new [fast saliva] test but warned that it could be abused. "What if they started using it on every immigrant at every airport?" Mr. Harrington asked. "I'd see that as a violation of human rights." He also said he worried that the test would make

it easier for the police or prison guards to give tests without consent, or for health authorities to test outside nightclubs or gay bars when patrons were too drunk to give legitimate consent or to be helped by counseling if the tests proved positive.

– "Fast Saliva Test for H.I.V. Gains Federal Approval"  
The New York Times, 27 March 2004

An AIDS activist organization called Treatment Action Group is also critical of the [Federally-funded Thai AIDS vaccine] medical trials. Executive director Mark Harrington says the vaccine [trial] isn't worth its \$119 million price tag. "The question many of us are asking is why are we putting so many resources into a really failed package of vaccine candidates when there [are] better products which are ready to move forward," said Mr. Harrington. This trial will be the third attempt so far to develop an AIDS vaccine. Mr. Harrington and the authors of the commentary in Science say that if this one fails, it will be harder to find volunteers for the next one.

– "US-backed Controversial HIV/AIDS Vaccine Trial Starts on 16,000 Thai Volunteers"  
Voice of America, 30 January 2004

The study has divided AIDS activists as well as AIDS scientists. [Richard Jefferys of the] Treatment Action Group, which regularly analyses the U.S. government's AIDS research portfolio, said there is "little hope this vaccine combination will be able to offer any protection against HIV" and called the trial "a waste of human and financial resources."

– "U.S.-Backed AIDS Vaccine Trial  
in Thailand is Questioned"  
The Washington Post, 19 January 2004

Treatment Action Group in New York issued a statement declaring that scarce resources should be devoted to "newer and more potent" vaccines. It said the design of this trial would make it impossible to know whether it was the combined vaccines, or ALVAC alone, that had a protective effect if one should be found.

– "AIDS Researchers Question Value  
of Costly Vaccine Trial"  
The San Francisco Chronicle, 16 January 2004

New cases of infection continue in the U.S. at a rate of about 40,000 each year -- and the disease is taking a devastating toll in Africa and elsewhere around the world. In addition, the drugs have major limitations. They're expensive and usually complicated to take. Over years of use, they cause potentially life-threatening side effects. And they're being outwitted by the virus, which is developing mutations that enable it to evade the drugs. Existing treatments "are reaching their limit," says Rob Camp, antiviral project director at the Treatment Action Group.

– "Barring the Door Against AIDS"  
Business Week, 24 November 2003

NIAID, which is expected to spend \$1.3 billion on AIDS research this year, is already working with host countries to improve their ability to deliver care, says Mark Harrington of Treatment Action Group, an AIDS advocacy organization. Harrington says the policy will push countries—some awaiting money from Bush's \$15 billion AIDS initiative or from the Global Fund—to create treatment programs. "It's moving but it's not moving so fast that there isn't time to get it right," Harrington says.

– "U.S. to Limit Trials in Developing Nations"  
Nature Medicine, June 2003

[At the FDA hearing on BMS's atazanavir] Rob Camp of the Treatment Action Group commented that atazanavir labelling should make clear to patients that the drug's favourable effects on lipids are not proven to extend to lipodystrophy.

– "Atazanavir Approval Recommended in U.S."  
AIDSMap (UK), 14 May 2003

Dr. Henry Heimlich, inventor of the famous anti-choking manoeuvre, is working with doctors in several African countries to begin human tests of a controversial AIDS therapy in which patients are deliberately infected with malaria. ... "This comes up periodically, but malaria has never worked for anything... If Heimlich is really doing this, he should be put in jail," said Mark Harrington, executive director of Treatment Action Group, an AIDS research advocacy organisation. ... "Malaria kills three million people every year, and there seems to be evidence that malaria worsens HIV...these are huge, huge ethical issues," Harrington said.

– "Heimlich Announces Plans to Test Malariotherapy on  
HIV-positive Patients in Several African Nations"  
Reuters, 14 April 2003

Most of the large pharmaceutical companies were slow to make price concessions until confronted by organized campaigns that shamed them into doing so, said James Love, who directs the Consumer Project on Technology, an offshoot of a center started by consumer activist Ralph Nader. The Gilead effort is "both responsible and smart. It is good management," said Love. "We would rather see companies do the right thing rather than have to go after them." Mark Harrington, executive director of the Treatment Action Group, noted that the company started its [global] price reduction program just 18 months after Viread was approved for marketing in the United States. "They are a small biotech company and they came out faster with an offer than the large drug companies did when they got drugs approved, so they have to be praised," Harrington said.

– "Gilead Unveils AIDS Drug Plan"  
San Jose Mercury News, 4 April 2004

**TREATMENT ACTION GROUP, INC.  
STATEMENTS OF FINANCIAL POSITION**

**A S S E T S**

	<b>Years ended December 31</b>	
	<b>2 0 0 3</b>	<b>2 0 0 2</b>
Current assets:		
Cash and cash equivalents	\$ 261,075	\$ 329,254
Investment-donated marketable securities, at market	7,832	4,687
Due from vendor	3,937	-
Prepaid expenses	924	820
Unconditional promises to give - Unrestricted	47,115	52,074
Total current assets	<u>320,883</u>	<u>386,835</u>
Property and equipment - net of accumulated depreciation	18,272	16,405
Security deposits	<u>2,756</u>	<u>2,756</u>
Total assets	<u>\$ 341,911</u>	<u>\$ 405,996</u>

**LIABILITIES AND NET ASSETS**

Current liabilities		
Accounts payable and accrued expenses	\$ 8,690	\$ 17,343
Total liabilities	<u>8,690</u>	<u>17,343</u>
Net assets		
Unrestricted	333,221	388,653
Total net assets	<u>333,221</u>	<u>388,653</u>
Total liabilities and net assets	<u>\$ 341,911</u>	<u>\$ 405,996</u>

**STATEMENTS OF CASH FLOWS**

Cash flows from operating activities:		
Increase in net assets	\$ (55,432)	\$ 89,290
Adjustments to reconcile increase in net assets to net cash provided by operating activities:		
Unrealized (gain) loss on marketable securities	(1,440)	202
Realized loss on sale of marketable securities	-	(216)
Depreciation	5,651	5,804
Donation of marketable securities	(1,705)	(2,816)
(Increase) Decrease in current assets:		
Due from vendor	(3,937)	-
Prepaid expenses	(104)	12,704
Unconditional promises to give	4,959	(4,834)
Security deposits	-	(106)
(Decrease) Increase in current liabilities:		
Accrued expenses	<u>(8,653)</u>	<u>6,104</u>
Net cash (used in) provided by operating activities	<u>(60,661)</u>	<u>106,132</u>
Cash flows from investing activities:		
Proceeds from sale of marketable securities	-	3,032
Purchases of property and equipment	<u>(7,518)</u>	<u>(2,779)</u>
Net cash (used in) provided by investing activities	<u>(7,518)</u>	<u>253</u>
Net (decrease) increase in cash balance	(68,179)	106,385
Cash, beginning of year	<u>329,254</u>	<u>222,869</u>
Cash, end of year	<u>\$ 261,075</u>	<u>\$ 329,254</u>

**TREATMENT ACTION GROUP, INC.  
STATEMENTS OF ACTIVITIES**

	<b>Years ended December 31</b>	
	<b>2 0 0 3</b>	<b>2 0 0 2</b>
Changes in unrestricted net assets		
Revenue and support:		
Bequests	\$ 1,705	\$ 2,816
Direct mail	40,694	32,514
Donations	8,167	7,728
Grants	508,309	565,805
Special event income	105,590	93,028
Travel and other reimbursement	5,190	3,457
Interest and dividend income	<u>2,467</u>	<u>3,682</u>
	672,122	709,030
Net assets released from donor restrictions	<u>-</u>	<u>90,603</u>
Total unrestricted revenue and support	672,122	799,633
Expenses		
Program services		
Antiviral project	97,377	69,904
Federal Affairs/OAR project	19,916	23,911
Basic Science project	95,291	88,869
Coinfection project	33,066	52,731
Community outreach	67,092	53,442
TAGline / Website	73,549	51,744
International projects	<u>178,114</u>	<u>115,281</u>
	564,405	455,882
Supporting services expenses		
Management and general	101,771	100,288
Fundraising	<u>62,818</u>	<u>63,584</u>
Total services expenses	<u>728,994</u>	<u>619,754</u>
Other income (expenses)		
Realized gain (loss) on sale of marketable securities	-	216
Unrealized gain (loss) on marketable securities	<u>1,440</u>	<u>(202)</u>
Total other income (expenses)	1,440	14
(Decrease) Increase in unrestricted net assets	<u>(55,432)</u>	<u>179,893</u>
Temporarily restricted net assets		
Net assets released from restrictions:	-	<u>(90,603)</u>
Decrease in temporary restricted net assets	-	<u>(90,603)</u>
(Decrease) Increase in total net assets	<u>(55,432)</u>	<u>89,290</u>
Net assets, beginning of year	<u>388,653</u>	<u>299,363</u>
Net assets, end of year	<u>\$ 333,221</u>	<u>\$ 388,653</u>



**\$100,000 or more**

The Bill & Melinda Gates Foundation

**\$50,000-99,000**

Merck & Co.  
Paul L. Newman  
The Office of AIDS Research  
Hoffmann-LaRoche, Inc.  
The Elizabeth Taylor AIDS Foundation

**\$25,000-\$49,999**

Bristol-Myers Squibb Virology  
JP Morgan Private Bank  
Terry K. Watanabe

**\$10,000-\$24,999**

Agouron Pharmaceuticals, Inc.  
Boehringer Ingelheim Corporation  
Broadway Cares/Equity Fights AIDS  
Gilead Sciences, Inc.

**\$5,000-\$9,999**

The Canary Charitable Foundation  
Richard M. Lynn & Joseph Evall  
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THANK YOU.

## TAG MISSION STATEMENT

Founded in January, 1992, the Treatment Action Group, or TAG, is the first and only AIDS organization dedicated solely to advocating for larger and more efficient research efforts, both public and private, towards finding a cure for AIDS.

The Treatment Action Group (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 our nation's health care delivery systems. We meet with researchers, pharmaceutical companies, and government officials, and resort when necessary to acts of civil disobedience, or to acts of Congress. We 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.

TAG is a non-profit corporation with 501c (3) status. Contributions are tax deductible to the extent allowed by law.

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