2001

annual report

OF THE TREATMENT ACTION GROUP

TREATMENT ACTION GROUP
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MISSION STATEMENT

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 and the world'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.

ANTIVIRAL PROJECT

New antiviral drugs. TAG's Antiviral Project, focuses on new antiviral drugs, treatments for salvage therapy, Federal HIV treatment guidelines, long-term effectiveness research, and structured treatment interruptions (STIs). In 2001, we met with many drug companies, including Abbott, Agouron (now merged with Pfizer), Boehringer-Ingelheim, Bristol-Myers Squibb, DuPont (now merged with BMS), Gilead, GlaxoSmithKline, Roche, Schering-Plough, Tibotec, Triangle, and Trimeris, to discuss new anti-HIV drugs in development. 2001 also saw FDA approval for Gilead Sciences' Viread brand tenofovir DF, a potent once daily nucleotide analogue for treatment of HIV. Also in 2001, Roche/Trimeris opened a limited access program for the HIV binding inhibitor T-20 (Fuzeon brand entfuvirtide). TAG held negotiations with Bristol-Myers Squibb on a broad (15,000 person) expanded access program for its new once daily protease inhibitor, atazanavir. We continue to follow many other new drugs in development including FTC (emtricitabine), tipranavir, and others.

HHS Treatment Guidelines. TAG Executive Director Mark Harrington serves on the HHS Panel on Clinical Practices for Treatment of HIV Infection in Adults and Adolescents. For many years he led a group on the Panel which advocated for a more cautious approach to initiating HAART which, despite its clear benefits in advanced disease and its ability to dramatically reduce viral load at all stages of HIV infection, carries with it serious risks of long-term toxicity, as well as high cost, inconvenience, adherence problems, and the emergence of drug resistance and cross-resistance. In June 2000 he coauthored an article in *The Lancet* recommending that treatment be deferred until the CD4 count was below 350 and the viral load over 50,000. In 2001, TAG won a major victory with a major impact on clinical care and the cost of HIV care, with the release of revised recommendations on when to start HAART. Whereas the original Guidelines in 1997 called for HAART initiation when the CD4 count dropped below 500 cells/mm3 or HIV RNA rose above 10-20,000 copies/mL, the revised Guidelines now call for therapy initiation when the CD4 count drops below 350 or the viral load rises above 55,000. Mark Harrington wrote a cover story on the new Guidelines for GMHC's *Treatment Issues* in May 2001. The Guidelines changed again in early 2002, eliminating the recommendation that all people with acute primary HIV infection (PHI) be treated.

Long-Term Effectiveness Research. TAG is a forceful advocate of the need for strategy trials designed to look at the long-term safety and effectiveness of HAART, including differing approaches to when to start, when to switch, and whether to interrupt therapy. After an extended campaign, in 2001 the NIH began funding for some of the first such strategy trials, including the Community Programs for Clinical Research on AIDS (CPCRA) SMART (Strategic Management of Antiretroviral Therapy). Other studies in this area are looking at which drug combinations of therapy to start with, and how to manage drug-resistance in a rescue therapy population.

Structured Treatment Interruptions (STIs). Since 1999 TAG has cosponsored three scientific workshops on Structured Treatment Interruption research. The third took place in February 2002, bringing together over 60 researchers world-wide focused on the use, safety, and efficacy of STIs and intermittent therapy in primary, chronic, and advanced HIV infection, to stimulate the host immune response to HIV, to reduce viral drug resistance, and to reduce drug exposure and toxicity. TAG's report on the 3rd International STI Workshop is now up on our website. STI research may have dramatic implications for the cost and feasibility of HAART use in developing countries.

BASIC SCIENCE & VACCINE RESEARCH

Basic Science Program. TAG has always believed that the ultimate solutions for the HIV pandemic - *a cure and a vaccine* - must come from intensified, expanded basic research on HIV infection. In 2001, TAG hired Richard Jefferys, our first full time Basic Science Project Director. Richard formerly headed the Access Project at AIDS Treatment & Data Network (ATDN), where he created a database of AIDS Drug Assistance Programs (ADAP); later he was a senior writer for the International AIDS Vaccine Initiative (IAVI).

Pathogenesis Project. For TAG's Pathogenesis Project, Richard Jefferys is interviewing over fifty leading researchers to elucidate the unanswered questions about HIV pathogenesis. Key issues include the evolving understanding of HIV pathogenesis since the advent of highly active antiretroviral therapy (HAART), the role of the thymus and T cell homeostasis in immune reconstitution, the role of antigen-presenting cells (APCs), early events in primary HIV infection, the role of HIV-specific immunity in exposed uninfected persons and long-term non-progressors, and the role of genetic and immune factors in progression of and resistance to HIV disease. TAG's report will synthesize the views of leading researchers in the field and point the way forward.

Vaccine Development. Despite recent optimism and some concrete gains in retroviral vaccine development, we are still many years away from having a safe and effective vaccine ready for deployment. Richard Jefferys writes frequently on the work being done to find an AIDS vaccine.

Immune-based therapies. Despite over a decade of research, no immune-based therapies are approved for strengthening the immune system to control HIV. TAG works with researchers and biotechnology companies to explore innovative immune-based approaches to HIV therapy, including therapeutic vaccines and intermittent HAART.

ONCOLOGY, INFECTIONS & CO-INFECTIONS

Opportunistic infections. TAG's Oncology & Infections Project focuses on the opportunistic complications of AIDS, including co-infections such as hepatitis B and C virus (HBV, HCV) infections and tuberculosis (TB). In 2001, TAG played a critical role in accelerating the development of valganciclovir, the first effective oral drug for the treatment of cytomegalovirus (CMV) retinitis. TAG testified for approval of the drug at the FDA in early 2001, and the drug was later approved. Hepatitis and HIV co-infection. In the post-HAART era, hepatitis and liver disease have risen to become the most common killers of people with HIV in the USA.

Hepatitis & HIV co-infection. In 2001, TAG distributed thousands of copies of *The Hepatitis Report A Critical Review of the Research and Treatment of Hepatitis C Virus (HCV) and Hepatitis & HIV Coinfection*, which has also been downloaded from our website over 10,000 times.

Tuberculosis and HIV co-infection. Tuberculosis (TB) is the leading killer of people with AIDS worldwide. TAG started its TB/HIV Coinfection Project in 2001. In spring 2002, we planned the first International TB/HIV Coinfection Education & Community Mobilization Workshop, held in Montreal in October. Twenty-nine people attended the workshop, among them 18 from developing countries in sub-Saharan Africa, Latin America, Eastern Europe and India. TAG's report on the TB/HIV workshop is now up on our website.

FEDERAL AFFAIRS

NIH AIDS research budget. TAG was among the first to call for a doubling of the entire NIH biomedical research budget, as long ago as 1992. NIH support for AIDS research has increased by over 200% since TAG was founded, from $800 million in 1991 to $2.7 billion in 2003. Since 1997, Congress and the Executive Branch have agreed to double the entire NIH research budget by 2003. TAG will continue to advocate for healthy growth for NIH. Particular foci include increasing resources for basic science, vaccine, microbicide, and international research.

AIDS Drug Assistance Program (ADAP) funding crisis. Despite the fact that more Americans are living with HIV than ever before, U.S. support for AIDS Drug Assistance Programs has not kept pace with the need. TAG is working with key allies around the country to push the administration and Congress to fully fund the extra $162 million to ensure that no person with AIDS goes without needed life-saving drugs.

US funding for international AIDS activities. Two years ago TAG recommended that the US significantly increase its support for international AIDS activities. While inadequate, the Administration has committed $500 million (over two years) to the new Global Fund for AIDS, Tuberculosis and Malaria (GFATM). We are working with allies in Washington and around the country to continue pressing for dramatic increases in U.S. support to fight AIDS internationally.

COMMUNICATIONS & COMMUNITY PROGRAMS

TAGline. We continue to publish ten issues of *TAGline* in English and Spanish each year. We also publish a more user-friendly *TAG Update* and *Annual Report* once each year. TAG's website, www.treatmentactiongroup.org/ www.aidsinfonyc.org/tag receives over 25,000 hits/month.

NATAF. TAG continues to cosponsor the North American AIDS Treatment Action Forum, which took place at Vancouver, British Columbia, in December 2001. Over 500 advocates from around the continent attended. TAG staff presented at over ten workshops.

AIDS Treatment Activists Coalition (ATAC). In 2001, TAG helped to found a new national treatment advocacy alliance, the ATAC, focused on broadening the circle of effective AIDS treatment activists around the country. ATAC held its first two workshops in February and July 2002.

INTERNATIONAL PROGRAMS

U.S. trade and drug patent protection. Flexible implementation of international trade accords is essential in order to let developing countries deal with the health crises posed by HIV, TB and other infectious diseases. To address these issues, TAG is working in coalition with Health GAP Coalition, Médecins sans Frontières (MSF), Treatment Action Campaign (TAC), and many others to ensure that developing countries can access the cheapest high quality life-saving medications - whether brand-name or generic - regardless of patent status. In April 2001, TAG Senior Policy Director Mark Harrington was the sole representative of the AIDS treatment advocacy community to attend the World Health Organization/World Trade Organization (WHO/WTO) workshop on Differential Pricing & Financing of Essential Medicines, held at Høsbjør, Norway - one of a number of events which helped lead to a new consensus at the WTO ministerial conference at Doha, Qatar, in November, which allowed developing countries ten more years of flexibility (through 2016) to bring their patent regimes in line with WTO treaties. In spring 2001, TAG also met with the Office of the U.S. Trade Representative (USTR) and the Pharmaceutical Research & Manufacturers Association (PhRMA) to pressure the U.S. and the private sector to change their policies regarding global HIV drug access. Reports on these meetings are on the TAG website. We also participated in the UN General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001, where we met with representatives of many PWA organizations from around the world to coordinate our advocacy efforts.

WHO/UNAIDS Accelerating Access and Treatment Guidelines. Patent flexibility is useless without an intensified commitment to reducing drug prices, developing infrastructure in developing countries, and providing simplified treatment guidelines for using antiretrovirals there. In February 2001, TAG instigated a global sign-on letter to GlaxoSmithKline calling on them to stop interfering with developing countries' rights to access cheap generic antiretrovirals. Over 600 organizations worldwide signed on. In April 2001, GSK and Merck capitulated to worldwide pressure, reduced prices on their antiretrovirals, and forced PhRMA/South Africa to drop its suit against the South African government. In May 2001, Mark Harrington attended a WHO meeting at Geneva on antiretroviral therapy in resource-poor settings, leading to the publication of preliminary WHO ART guidelines in spring 2002. TAG will work closely with others to push for increased funds for the Global Fund to Fight AIDS, TB, and Malaria.

Treatment Action Campaign, South Africa
Following our successful 3-day workshops with Treatment Action Campaign in Johannesburg, Durban, and Cape Town, South Africa, in November 2001, TAG supported several TAC initiatives in 2001, including five issues of TAC's newsletter, *Equal Treatment*, and eleven hour-long treatment literacy training videos made in several of South Africa's languages including material from the TAC/TAG workshops. TAC distributed tens of thousands of copies of *Equal Treatment* across South Africa.

International Conference on AIDS in Asia & the Pacific (ICAAP). Based on the success of the TAC/TAG workshops, TAG funded and cosponsored a one-day workshop for treatment advocates from Asia and the Pacific just before the 6th ICAAP held at Melbourne, Australia, in October 2001, supporting travel and training for over 50 treatment advocates from across Asia.

2001 CONTRIBUTORS

$100,000 and above
The Royal S. Marks Foundation

$50,000 to $99,999
Newman's Own, Inc.
Roche Laboratories Inc.

$25,000 to $49,999
Agouron Pharmaceuticals, Inc.
GlaxoSmithKline Inc.
Merck & Co. Inc.

$10,000 to $24,999
Boehringer Ingelheim Pharmaceuticals Inc.
The Paul Rykoff Coleman Foundation
DuPont Pharmaceuticals Co.
Gilead Sciences
The Mathilde and Arthur B. Krim Foundation, Inc.
Richard Lynn and Joseph Evall
The Office of AIDS Research
The Michael Palm Foundation
UNAIDS

$5,000 to $9,999
Mark O'Donnell
ViroLogic, Inc.

$2,500 to $4,999
M. Lee Garrison
Albert Maccarone, Jr.
Vincent McGee
The Overbrook Foundation

$1,000 to $2,499
Franklin Berger
Ross Bleckner
Frank Bove
Lynne and Tony Brown
David Corkery
Constance D'Aurizio
Lynda M. Dee, esq.
Paul Dietz
Randall Drain
Mario Egozi
Gene Falk and Tim Savin
Michael Giordano
Steven Gluckstern
Judith and Richard Harrington
Christina and Kenneth Hecht
Paul Kennedy
Barry Margolin
Karen K. Smith McCune and Mike McCune
Mark Melchior
Sally Morrison
Elizabeth Powell and Steven Frank
Walter Rieman
Bruce Schackman
Evan Schwartz and Robert Fitterman
The Sexton-Wallace Fund
Matthew Singer
Jeffrey Soref
James Stepp and Peter Zimmer
W. Kirk Wallace and Mark Sexton
Terry Watanabe Charitable Trust
Robin Weiss and Allan Wimer
The Zacks Family Foundation

$500 to $999
The Altman Stiller Foundation
Christine and Benjamin Anagnos
Norbert Buller
Matthew Collins
Sarah Donovan
Joy Episalla
Michael Field
James McKay Harcus
Lloyd Hoffman III
Douglas Holtquist
Richard Hooper
James C. Hormel
Thomas Keane
Tim Lotfus
Michael MacElhenny
Terrence McNally
Ana Oliveira
James Pepper
William St. Clair Pugh
Karen and Jerome Radwin
David Rosenauer and Rex Walker
Paul Sack
Jane Silver
Grant Stitt and Alan Shapiro
Sarah Wright

$250 to $499
James Allman
Katherine and Thomas Ash
David Barr
John Beach
Thomas Berger
Roger M. Bloom Hulley Memorial Fund
Richard Buxbaum
Charles C. J. Carpenter
Marshall Coburn
The Martha Collett Mellon Trust
Randall Cooper
Andrea Dailey
Peter Diffly
Eve Ensler
Howard Grossman, M.D.
Samuel Grubman, M.D.
Mark Harrington
Lawrence Hoskins
Michael Katovitz
Horace Kenney III and Jeffrey Kolch
Kenneth Monteiro
Donna Pauldine
Judith Peabody
James Porcarelli and Scott Gerst
Daniel Scheffey
Steven Schroko
Andrea Sessler
Edward Sikov
Janis Spire and Trish Karlin
Peter Staley
Mary Tokar
Joseph Viana and Raymond Baker
Carrie Yamaoka
William Zwart and David Berchenbriter

THANK YOU.

TREATMENT ACTION GROUP, INC.
STATEMENTS OF FINANCIAL POSITION

ASSETS

	Years ended December 31, 2001	2000
Current assets:		
Cash and cash equivalents	$ 222,869	$ 248, 099
Investment-donated marketable securities, at market	4,889	11,695
Prepaid expenses	13,524	10,622
Unconditional promises to give - Unrestricted	47,240	30,555
Total current assets	288,522	300,971
Property and equipment - net of accumulated depreciation	19,430	11,692
Security deposits	2,650	2,250
Total assets	$ 310,602	$ 314,913

LIABILITIES AND NET ASSETS

Current liabilities:	$ 11,239	$ 21,027
Accounts payable and accrued expenses		
Total liabilities	11,239	21,027
Net assets:		
Unrestricted	208,760	188,643
Restricted	90,603	105,243
Total net assets	299,363	293,886
Total liabilities and net assets	$ 310,602	$ 314,913

STATEMENTS OF CASH FLOWS

Cash flows from operating activities:		
Increase in net assets	$ 5,477	$ 169,860
Adjustments to reconcile increase in net assets		
to net cash provided by operating activities:		
Unrealized (gain) loss on marketable securities	2,124	(3,416)
Realized loss on sale of marketable securities	132	615
Loss on sale of fixed assets	–	–
Depreciation	6,205	5,781
Donation of marketable securities	(955)	(3,455)
(Increase) Decrease in current assets:		
Prepaid expenses	(2,902)	(10,622)
Unconditional promises to give	(16,685)	(15,354)
Security deposits	(400)	150
(Decrease) Increase in current liabilities:		
Accrued expenses	(9,788)	8,756
Net cash provided by operating activities	(16,792)	152,315
Cash flows from invvesting activities:		
Proceeds from sale of marketable securities	5,505	324
Proceeds from sale of fixed assets	–	–
Purchases of property and equipment	(13,943)	(835)
Net cash used in investing activities	(8,438)	(511)
Net increase in cash balance	(25,230)	151,804
Cash, beginning of year	248,099	96,295
Cash, end of year	$ 222,869	$ 248,099

TREATMENT ACTION GROUP, INC.
STATEMENTS OF ACTIVITIES

	Years Ended December 31,	
Changes in unrestricted net assets	2001	2000
Revenue and support		
Bequests	$ 955	$ 650
Direct mail	47,674	42,463
Donations	40,762	32,258
Grants	447,539	486,045
Special event income	72,097	47,265
Travel reimbursement	6,314	6,795
Interest and dividend income	4,368	1,210
	619,709	616,686
Net assets released from donor restrictions	14,640	74,757
Total unrestricted revenue and support	634,349	691,443
Expenses		
Program services		
Antiviral Project	96,176	76,941
OAR Project	30,578	75,785
Pathogenesis Project	20,316	38,006
Infections and Oncology Project	70,250	61,757
Community Outreach	38,808	41,316
TAGline	60,939	39,870
International Programs	113,477	146,855
	430,544	480,530
Supporting services expenses		
Management and general	120,051	60,751
Fundraising	61,381	88,346
Total services expenses	611,976	629,627
Other income (expenses)		
Realized loss on sale of marketable securities	(132)	(615)
Unrealized gain (loss) on marketable securities	(2,124)	3,416
Loss on sale of fixed assets	–	–
Total other income (expenses)	(2,256)	2,801
Increase in unrestricted net assets	20,117	64,617
Temporarily restricted net assets		
Grants revenue		180,000
Net assets released from restrictions	(14,640)	(74,757)
Increase in temporary restricted net assets	(14,640)	105,243
Increase in total net assets	5,477	169,860
Net assets, beginning of year	293,886	124,026
Net assets, end of year	$299,363	$293,886