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TAG
Treatment Action Group

tagline

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

Cure Research Momentum Accelerates

By Richard Jefferys

The research effort to discover a cure for HIV infection continues to gain momentum, with several important developments having occurred since the last issue of *tagline*.

In July, the National Institute of Allergy and Infectious Diseases (NIAID) announced the award of three multimillion dollar five-year grants under the aegis of the Martin Delaney Collaboratory, a program named in memory of the longtime AIDS activist and founder of Project Inform, who died in 2009. The awards represent a significant expansion of the original plan, which reflects a number of factors: the commitment of NIAID to the goal of curing HIV; the activism of community-based groups such as TAG, AIDS Policy Project, amfAR, and Project Inform; and the quality of the requests for funding that were submitted by researchers.

Grantees include the Fred Hutchinson Cancer Research Center in Seattle, where coprincipal investigators Keith R. Jerome and Hans-Peter Kiem are overseeing five projects, including a collaboration with Sangamo Biosciences on the use of hematopoietic cell transplants to create HIV-resistant immune cells (Kiem has developed a macaque model for evaluating this type of approach). Jerome is also pursuing the potential use of proteins called endonucleases to excise the HIV genome from latently infected cells.

Principal investigator David Margolis at the University of North Carolina at Chapel Hill is leading the largest of the groups, consisting of 15 scientific projects at nine different academic research centers throughout the U.S. Merck Research Laboratories is a key part of this team, but will not be receiving funding from the National Institutes of Health (NIH). The major goals are to improve the understanding of HIV persistence despite antiretroviral therapy and to develop therapies to target and eliminate viral reservoirs.

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A Golden Decade of Antiretroviral Drug Development

Success rate for new ARVs entering phases II–III surpassed 32%
U.S. ADAP Prescribing Practices Closely Match Recent ARV Guidelines

By Polly Clayden and Mark Harrington

As we were putting together the 2011 Pipeline Report this summer, we decided to look back at the previous years' reports on anti-HIV drug development. Treatment Action Group (TAG) has been covering the antiretroviral (ARV) drug pipeline since our founding; in the past two years we have joined forces with HIV i-Base (UK) to deepen and broaden our coverage.

To preface this year's Pipeline, we decided to look at the series of detailed pipeline reports since 2003. We wanted to examine several questions:

- Whether the HIV drug pipeline is drying up;
- What the success rate is for new ARV drugs entering phases II–III to assess the likelihood

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Lastly, a triumvirate of principal investigators—Steve Deeks and Mike McCune at University of California, San Francisco, and Rafick-Pierre Sekaly at the Vaccine and Gene Therapy Institute of Florida—are overseeing seven projects aiming to delineate where HIV reservoirs are located in the body and how they are created and maintained, with the ultimate goal of developing therapies that can eliminate reservoirs without causing excessive immune activation.

The announcement of the Martin Delaney Collaboratory grants occurred just a week ahead of the 2011 International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Rome, at which the IAS launched "The Rome Statement for an HIV Cure" calling for an acceleration of cure research. The statement was initiated by members of an IAS Advisory Board working to develop a global scientific strategy for the field, and lists three key objectives:

- Recognizing the importance of developing a safe, accessible, and scalable HIV cure as a therapeutic and preventive strategy against HIV infection and to help control the AIDS epidemic.
- Committing to stimulating international and multi-disciplinary research collaborations in the field of HIV cure research.
- Encouraging other stakeholders, international leaders, and organizations to contribute to accelerating HIV cure research through their own initiatives and/or by endorsing this statement and supporting the alliance that the Advisory Board is building.

The online version of the statement currently has 4,479 signatories. You can sign it here: http://www.iasociety.org/Default.aspx?pageId=583. The conference itself offered further evidence of the increased profile of HIV cure research, with multiple sessions and satellite meetings addressing the topic.

Another research funding development came from amfAR, which announced a second round of grants—albeit of far smaller amounts than those bestowed by NIAID—under its amfAR Research Consortium for HIV Eradication (ARCHE) program. The funding will support several scientists who are already part of ARCHE and two new additions to the group: Adriana Andrade at Johns Hopkins and Una O'Doherty at the University of Pennsylvania. Andrade is conducting a small clinical trial of the FDA-approved alcoholism treatment disulfiram (Antabuse), following up on work by ARCHE researcher Bob Siliciano suggesting that the drug might be able to awaken latent HIV reservoirs. O'Doherty plans to compare different approaches to evaluating the size of the HIV reservoir, in hopes of identifying the most accurate and practical methods.

O'Doherty's study addresses important questions identified at a workshop on cure-related HIV research that took place in Baltimore in April, sponsored by AIDS Policy Project, amfAR, Project Inform, and TAG. A full report and list of recommendations from the workshop will be posted online soon. For a frequently updated list of resources on HIV cure research, including links to articles, scientific papers, and clinical trials, see TAG's website: http://www.treatmentactiongroup.org/cure/resources.

The *i-Base/TAG 2011 Pipeline Report* also contains a section describing the current status of cure-related clinical research, available online at: http://www.treatmentactiongroup.org/pipeline-report/2011.

Finally, a group of community-based organizations sent a letter to the NIH and the U.S. Food and Drug Administration (FDA) asking them to convene a national dialogue on how best to move forward with AIDS cure research. The letter is printed below.

9 August 2011

Jack Whitescarver, Ph.D.
Associate Director for AIDS Research, National Institutes of Health (NIH)
Director, Office of AIDS Research, NIH

Margaret A. Hamburg, M.D.
Commissioner, U.S. Food and Drug Administration (FDA)

The undersigned organizations are writing to request that the NIH and FDA collaborate to convene a workshop on clinical trials and regulatory issues pertaining to HIV cure research. We are keenly interested in anticipating and overcoming obstacles to moving cure research forward at the fastest pace that is justified in the context of both science and safety concerns, and believe that interagency discussions on the subject—perhaps similar to those that have taken place regarding stem cell research—can play a vital role.

At a recent community-sponsored meeting on HIV cure-related clinical research, a number of key issues were identified that we believe could form the basis for a productive, non-product-specific dialogue involving appropriate officials from your two agencies.

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These include:

- The need for interagency discussions to broaden knowledge and awareness of the current status of HIV cure-related research
- Appropriate pre-clinical milestones to justify advancing approaches into clinical trials
- Evaluating and prioritizing assays with the potential to be used as trial endpoints
- The use of analytical treatment interruptions—and exploration of valid alternatives—to evaluate the effects of interventions, and appropriate parameters for ensuring participant safety
- Methods of improving uptake of gene-modified cells in clinical trials
- Appropriate trial populations for the different types of interventions under consideration
- Facilitating cross-trial comparisons and specimen sharing
- The level of risk that is appropriate for trials where the potential benefits to individual participants may be negligible but the benefits to advancing the science—and therefore to the wider community of HIV-positive people—may be significant
- Ethics and informed consent
- Educational initiatives for institutional review boards and community advisory boards
- The need for government agencies to actively engage the diverse array of stake-holders, including and especially people with HIV/AIDS, in decision-making about research ethics and access to clinical trials

We envision that such a workshop would be the first of an ongoing series of steps to engage the FDA with NIH, researchers, and community representatives in dealing with the regulatory, scientific, and ethical issues related to cure research.

Thank you for your consideration,

AIDS Policy Project
amfAR
Project Inform
Treatment Action Group •

What We Need to Cure AIDS?

By Mark Harrington

A cure for HIV is possible: one man, the so-called Berlin patient, has already been cured of chronic HIV infection with an immune system transplant with cells genetically resistant to HIV. After four years, the man remains free of detectable HIV, and his HIV antibodies are disappearing. However, this approach is dangerous (potentially fatal), costly, and not scalable to the 34 million people currently living with HIV.

A cure for HIV is necessary: 34 million people worldwide are living with HIV, and 25 million more will be infected in each of the coming decades (a total of 300 million by 2100). The lifelong treatment of these 334 million people would be logistically difficult, expensive, and could result in drug resistance, treatment failure, and onward transmission of drug-resistant HIV—a public health nightmare without end.

Five things are needed to cure HIV:

1. Scientific commitment. The U.S. National Institutes of Health, the French National AIDS Research Agency, the Foundation for AIDS Research (amfAR), and a handful of drug companies including BMS, Gilead, Johnson & Johnson, Merck, and Sangamo are all committed to AIDS cure research; some of the smartest experienced and younger scientists are working tirelessly to discover and develop a safe, effective, feasible, and scalable HIV cure.

2. Scientific resources. Curing HIV will require a massive investment of scientific resources including grant money, animal models, laboratory tests, and expensive and long-term clinical trials. Experts estimate that over $800 million a year will be needed to fully fund the most promising opportunities in AIDS cure research. Currently less than $100 million per year is available for this effort. Full funding for the NIH and its AIDS research budget, overseen and coordinated by the NIH Office of AIDS Research, will be necessary to achieve a cure for AIDS.

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3. An informed, educated, and motivated community of participants for HIV cure clinical trials. Currently, many people with HIV are interested in enrolling in cure-related clinical trials. However, to ensure their continued willingness to engage in studies that will be long-term, high-risk, and may involve deferring, interrupting, or going off highly effective antiretroviral therapy, continued community education, involvement, and participation in cure research at all levels (planning, implementation, evaluation, community outreach and education, resource mobilization, and advocacy) will be required.

4. A flexible, rigorous, and inclusive regulatory approach to cure-related clinical trials. Just as the U.S. Food and Drug Administration (FDA)—after many activist demonstrations and interventions—created a flexible regulatory environment that allowed the rapid study of anti-HIV drugs, accelerated their approval based on changes in so-called surrogate markers such as CD4 cell counts and HIV-RNA levels (viral load), and expanded access to experimental agents for those lacking valid therapeutic options, so HIV cure research will require coordinated, flexible, and scientifically advanced regulatory oversight by the FDA working across departments involving drugs, therapeutic vaccines, monoclonal antibodies, and cell and gene therapies.

5. Public understanding and commitment to curing AIDS. The HIV cure research effort will be long-term, high-risk, and will include many failed studies and approaches before it succeeds in discovering and delivering a safe, effective, feasible, and globally scalable HIV cure. Public support and understanding of this effort are essential to secure the research funding and political support that will be required for this effort to succeed. •

A Golden Decade Continued from page 1

that current candidates will progress toward approval; and

- How rapidly which new drugs and combinations enter practice in one industrialized country, the United States.

The global ARV treatment market is estimated at $13 billion in market volume this year, with most of the profits made in industrialized countries, while most of the people in need of treatment live in developing ones.

The past decade has indeed been a golden age of ARV drug development. Of the 30 new chemical entities approved by the U.S. Food and Drug Administration (FDA) to treat HIV infection since 1986, half (15/30) were approved in the years since 2003. Thirty-seven drugs and fixed-dose combinations (FDCs) are FDA-approved for sale in the United States; a further 132 drugs and FDCs (including adult and pediatric formulations) are tentatively approved under the FDA's generic registration program to facilitate global access through programs such as the President's Emergency Program for AIDS Relief (PEPFAR). Please see the data series from the TAG ARV pipelines dating from 2003 to the present (See Table 1 on page 5).

The success rate for new ARV drugs and FDCs that have entered phase II or further studies since 2003 is an astonishing 32.6% (15/46). Most recently, in 2011, the FDA approved rilpivirine (Edurant), extended-release nevirapine (Viramune XR), and the FDC rilpivirine/TDF/FTC (Complera).

In the first quarter of 2012, Gilead is expected to file with regulatory authorities for approval of the integrase inhibitor elvitegravir, the pharmacokinetic booster cobicistat, and the FDC elvitegravir/cobicistat/TDF/FTC ("Quad"), with regulatory action likely later in 2012, which, if it leads to approval, would bring the success rate to 39.1% (18/46).

So much for those who say investing in HIV treatment is a bad bet.

Rapid implementation and uptake of new therapies provides rapid return on investment.

Another remarkable feature of the HIV treatment landscape is the rapidity with which new drugs and combinations are incorporated into the standards of HIV care in developed countries. In the United States, this process has been facilitated since the late 1990s by the establishment of the standing Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents and the Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children (http://aidsinfo.nih.gov/Guidelines/Default.aspx).

The Adult and Adolescent Guidelines Panel meets monthly by teleconference, once yearly in person (usually at the annual retrovirus conference CROI), and issues updated online treatment recommendations at least annually, with changes highlighted in yellow to make navigating the ever-changing treatment landscape easier. A review of data generously provided by the U.S. National Association of State and Territorial AIDS Directors (NASTAD) demonstrates the astonishing fidelity of U.S. AIDS Drug Assistance Program (ADAP) prescribing practices in 2009 to the most recent iteration of the U.S. HIV treatment guidelines (See Table 2 on page 6).

Among the many striking features of the 2009 ADAP reported data on ARV usage are:

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TABLE 1. HIV Treatment Pipeline 2003–2011

Class	Drug name	Generic name	Brand name	Sponsor	2003	2004	2005	2006	2007	2008	2009	2010	2011
NRTI	SPD 754, AVX754, DOT	Apricatibine		Shire Biochem, Avexa		I	Ib	Ib	II	II	II	discontinued	
NRTI	D-D4FC, DPC-817	Reverset		Pharmasset/Incyte	I	I	II	discontinued					
NRTI		Racivir		Pharmasset			Ib	Ib	II				
NRTI	ACH-126,443	Elvucitabine		Achillion	II	II	II	Ib	II				
NRTI	DAPD	Amdoxivir		Gilead, Emory, RFS Pharm	IIb	to Emory	to RFS II		II	II	II	discontinued	
NRTI	MIV-310, FLT	Alovudine		BI, Medivir, Beijing Mefuvir	II					to Mefuvir			
NRTI	AG1549	Capravirine		Agouron/Pfizer	III	III	discontinued						
NRTI	FTC	Emtricitabine	Emtriva (2003)	Triangle/Gilead	approved								
NRTI	PMPA, GS-7340 (TDF prodrug)			Gilead									II
NRTI	OBP-601	Festinavir		BMS									II
NNRTI	DPC-083, AI-183			BMS	II	discontinued							
NNRTI		Calanolide A		Advanced Life Sciences/Sarawak MediChem	II		II						
NNRTI	TMC-125	Etravirine	Intelence (2008)	Tibotec	II	II	II	III	III	approved			
NNRTI	GSK-2248761/IDX889			GSK/Idenix							II	II	II
NNRTI	TMC-278	Rilpivirine	Edurant (2011)	Tibotec			I	II	III	III	III	III	approved
NNRTI	BILR 355/r BS			Boehringer Ingelheim				Ib	II				
NNRTI			Viramune XR (2011)	Boehringer Ingelheim									approved
NNRTI	UK-453,061	Lersivirine		Pfizer							II	II	II
PI	TMC-114	Darunavir	Prezista (2006)	Tibotec	I/II	II	III	approved					
PI	VX-175/GW-433908	Fosamprenavir	Lexiva (2003)	Vertex/GSK	approved								
PI		Tipranavir	Aptivus (2005)	Boehringer Ingelheim	III	III	approved						
PI		Atazanavir	Reyataz (2003)	BMS	approved								
PI	GSK-640385	Brecanavir		GSK			Ib	II	discontinued				
FI	T-20	Enfuvirtide	Fuzeon (2003)	Trimeris/Roche	approved								
CCR5RI	SCH-C, SCH 351125			Schering-Plough	I/II	stopped							
CCR5RI	SCH D, SCH 417	Vicroviroc		Schering-Plough		I	II	II	II	III	III	stopped	
CCR5RI	UK-427,857	Maraviroc	Selzentry (2007)	Pfizer	I	I	II	III	approved				
CCR5RI/CCR2RI	TAK-652, TBR-652	Cenicriviroc		Takeda/Tobira				I				I	II
II	MK-0518	Raltegravir	Isentress (2007)	Merck				III	approved				
II	GSK-1349572	Dolutegravir		GSK/Shionogi/ViiV							II	II	III
II	GSK-1265744			GSK/Shionogi							II		
II	GS-9137/JTK-303	Elvitegravir		Gilead			I	II	II	III	III	III	III
Anti-CD4 Mab	TNX 355, Hu5A8	Ibalizumab		Tanox, Biogen, Taimed	I	Ib	II	II	II	II	II	II	II
AI	PRO 542			Progenics	II								
AI	PRO 140			Progenics			Ib	Ib			II		
AI	BMS663068			BMS								II	II
MI	PA-457, MPC-4326	Bevirimat		Panacos, Vitex, Myriad		I	Ib	II	II	II	II	discontinued	
PK booster	GS 9350	Cobicistat		Gilead							II	III	III
PK booster	SPI-251			Sequoia								III	
FDC	ABC/3TC		Epzicom (2003)	GSK	approved								
FDC	FTC/TDF		Truvada (2004)	Gilead		approved							
FDC	EFV/FTC/TDF		Atripla (2006)	BMS/Gilead				approved					
FDC	RLV/FTC/TDF		Complera (2011)	Gilead/Tibotec								III	approved
FDC	ELV/CBS/FTC/TDF	Quad		Gilead								III	III

Sources: Camp 2003–2006; Huff 2007; TAG 2008; Huff 2009; Collins 2010–2011.

LEGEND
NRTI = nucleoside reverse transcriptase inhibitor; NNRTI = non-nucleoside RTI; PI = protease inhibitor; FI = fusion inhibitor; CCR5RI = CCR5 receptor inhibitor; CCR2RI = CCR2 receptor inhibitor
II = integrase inhibitor; AI = attachment inhibitor; MI = maturation inhibitor; PK booster = pharmacokinetic booster; FDC = fixed-dose combination

TABLE 2. U.S. ADAP Antiretroviral Market Share by Drug in 2009

Sponsor	Brand name	Generic name	Abbreviation	Class	2009 ADAP reported expenditures	2009 expenditures adjusted for missing	% of total	Year FDA approved
Gilead	Atripla	efavirenz/emtricitabine/tenofovir	EFV/FTC/TDF	NNRTI+2NRTIs	$348,729,057	$376,753,577	26.96%	2005
Gilead	Truvada	emtricitabine/tenofovir	FTC/TDF	2NRTIs	$236,929,054	$255,969,116	18.31%	2004
BMS	Reyataz	atazanavir	ATV	PI	$147,703,662	$159,573,405	11.42%	2003
Abbott	Kaletra	lopinavir/ritonavir	LPV/r	PI	$72,149,642	$77,947,727	5.58%	2000
Merck	Isentress	raltegravir	RAL	II	$51,950,133	$56,124,943	4.02%	2007
Tibotec	Prezista	darunavir	DRV	PI	$44,983,885	$48,598,874	3.48%	2006
Gilead	Viread	tenofovir DF	TDF	NRTI	$35,870,178	$38,752,794	2.77%	2001
BMS	Sustiva	efavirenz	EFV	NNRTI	$28,472,290	$30,868,413	2.21%	1998
Gilead	Emtriva	emtricitabine	FTC	NRTI	$1,563,801	$1,689,471	0.12%	2003
All recommended first-line ARV drugs subtotal					**$968,351,702**	**$1,046,278,320**	**74.86%**	
GSK	Epzicom	abacavir/lamivudine	ABC/3TC	2NRTIs	$69,922,861	$75,541,993	5.41%	2004
Abbott	Norvir	ritonavir	RTV	PI	$53,948,036	$58,283,402	4.17%	1996
GSK	Combivir	lamivudine/zidovudine	3TC/AZT	2NRTIs	$49,600,002	$53,585,951	3.83%	1997
GSK	Trizivir	abacavir/lamivudine/zidovudine	ABC/3TC/AZT	3NRTIs	$31,622,256	$34,163,481	2.44%	2000
GSK	Lexiva	fosamprenavir	APV	PI	$30,610,979	$33,070,934	2.37%	2003
BI	Viramune	nevirapine	NVP	NNRTI	$20,823,184	$22,496,574	1.61%	1996
Tibotec	Intelence	etravirine	ETV	NNRTI	$13,510,660	$14,597,402	1.04%	2008
Pfizer	Viracept	nelfinavir	NFV	PI	$13,024,714	$14,071,404	1.01%	1997
GSK	Ziagen	abacavir	ABC	NRTI	$10,735,553	$11,598,282	0.83%	1998
GSK	Epivir	lamivudine	3TC	NRTI	$8,218,373	$8,878,817	0.64%	1995
Roche	Invirase	saquinavir	SQV	PI	$6,189,161	$6,686,533	0.48%	1995
Roche	Fuzeon	enfuvirtide	T-20	FI	$5,323,713	$5,751,537	0.41%	2003
Pfizer	Selzentry	maraviroc	MVC	CCR5RI	$4,401,282	$4,754,977	0.34%	2007
BMS	Zerit	stavudine	d4T	NRTI	$1,983,721	$2,094,520	0.15%	1994
BI	Aptivus	tipranavir	TPV	PI	$1,650,208	$1,782,822	0.13%	2005
Merck	Crixivan	indinavir	IDV	PI	$1,526,234	$1,648,885	0.12%	1996
BMS	Videx/Videx EC	didanosine	ddI	NRTI	$1,146,738	$1,238,892	0.09%	1991
GSK	Retrovir	zidovudine	AZT	NRTI	$831,340	$898,148	0.06%	1987
Pfizer	Rescriptor	delavirdine	DLV	NNRTI	$191,901	$207,323	0.01%	1997
All other ARV drugs subtotal					**$325,260,916**	**$351,351,877**	**25.14%**	
All ADAP drugs 2009 total					**$1,293,612,618**	**$1,397,630,197**	**100.00%**	

Source: NASTAD

A Golden Decade Continued from page 4

1. 75% of sales were for drugs recommended as preferred first-line antiretroviral therapy (ART) regimens in the federal guidelines;
2. Of the nine drugs and FDCs included among the U.S. first-line recommendations, eight were approved by the FDA in the past decade; just one (efavirenz) was approved in the 1990s;
3. Two drugs approved in 2006 and 2007—darunavir and raltegravir, respectively—were approved by the FDA for first-line indications less than two years after initial recommendation in salvage patients;
4. Both of those drugs soon after were included by the U.S. guidelines panel among the preferred recommended regimens for antiretroviral-naive patients; and
5. Prescribing practice rapidly evolved to incorporate the newest data on the newest drugs.

These data demonstrate the effective interaction of research, regulation, normative guidelines, practice, and implementation in the United States, despite its highly fragmented health care system and the fact that those receiving treatment through ADAP are, by definition, not rich.

However, the fact that 8,785 individuals in 10 states are currently on waiting lists to receive treatment through ADAP reveals that the United States continues to be a global disgrace when it comes to universal access or health equity.

In any case, it is clear that HIV therapeutics has room for considerable improvement, and that improvements will be rapidly diffused and their investors will enjoy a substantial return on their investment.

We urge the World Health Organization (WHO) as well as national guidelines-defining groups in countries affected by HIV to urgently implement such forward-looking practices to ensure that people living with HIV everywhere have access to the best possible treatment options.

In next year's Pipeline we look forward to documenting further progress. •

Ending the Neglect of Childhood TB

By Claire Wingfield

It is estimated that of the nine million new cases of tuberculosis (TB) each year, one million occur among children under the age of 15. Yet advocacy for prevention, diagnosis, and treatment of TB in children has been largely absent from the global public health agenda. In fact, the true global burden of TB in children is unknown because of the lack of child-friendly diagnostic tools, and inadequate surveillance and reporting of childhood TB cases. National TB programs and research efforts have ignored TB in children for a variety of reasons, among them that children are less likely to spread disease. However, the stark reality is that children with TB infection today represent the reservoir of TB disease tomorrow.

If TB is going to be eliminated, research needs to address the unique aspects of childhood TB. Children are more susceptible than adults to advancing from TB exposure to infection and to disease, yet none of the current clinical trials evaluating new or existing drugs in TB disease include children. The reasons cited for not including children in drug trials are numerous, but they tend to range from insufficient funding to lack of childhood TB expertise to concern about confirming TB diagnosis. Despite this, we still have a moral obligation to more proactively address these challenges and include children in TB research to ensure that they also benefit from scientific advances.

Thanks in part to the efforts of TAG, childhood TB is finally getting some attention from the scientific community. Protocols are being developed for studies that would evaluate the safety and pharmacokinectics—how drugs are absorbed, distributed, metabolized, and eliminated in the body—of two TB drugs in infants and children. Institutions like the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. National Institute of Allergy and Infectious Diseases (NIAID) in collaboration with several academic institutions and an industry partner are taking the first steps to initiate TB treatment trials in children.

Confirming a TB diagnosis in a child can be very challenging and is therefore a major complication for pediatric TB treatment trials. Current methods of diagnosis using microscopy and culture produce mediocre results at best. But there has been some recent progress on improving diagnosis in children. In December 2010, the World Health Organization (WHO) recommended the Xpert MTB/RIF—a new rapid diagnostic test—be used in place of the most common TB diagnostic tests in cases of suspected HIV-associated and drug-resistant TB in adults.

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The Xpert MTB/RIF has the potential to significantly improve TB diagnosis and get patients onto appropriate treatment more quickly. At the time of the WHO's announcement, there were no data on how best to use this new technology in children. However, in July 2011, the first study providing evidence that Xpert MTB/RIF was reliable in diagnosing TB in children was published. Hopefully, this one study will pave the way for more data-gathering to increase the number of children receiving timely and accurate TB diagnoses.

Given the historical and systematic neglect of children affected by TB, there is a need for urgent action from all who are committed to reducing the global burden of TB. New evidence must be generated on how best to prevent, diagnose, and treat TB in children. To that end, researchers must include children in high-quality basic, clinical, and operational research. Lastly, but most importantly, advocates and community members must continue to sound the alarm about the challenges of childhood TB and demand greater support and resources for these efforts. •

2011 Research In Action Awards

TAG's annual **Research in Action Awards (RIAA)** honors activists, scientists, philanthropists, and creative artists who have made extraordinary contributions in the fight against AIDS. RIAA is a fundraiser to support TAG's programs, and provides a forum to honor heroes of the epidemic. Now in its fifteenth year, the 2011 RIAA will be held on Sunday, December 11, from 6 to 8pm at the MidTown Loft, NYC.

This year's Awardees are:

- **John Benjamin Hickey**, Winner of the 2011 Tony Award for best featured actor in a play for his performance in the revival of Larry Kramer's *The Normal Heart*;
- **Dr. Polly Harrison**, Founder of the Alliance for Microbicide Development; and
- **Dr. Robert F. Siliciano**, Medical Investigator at the Howard Hughes Medical Institute and Professor of Medicine at the Johns Hopkins University School of Medicine.

To purchase tickets or to sponsor this year's RIAA, please go to:

www.treatmentactiongroup.org/riaa

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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TAG
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