



Forum for Collaborative HIV Research

Summary of the Executive Committee Retreat March 18-19, 2003 Washington DC

Summary

The Forum convened this retreat to reconfirm the participation of and support from all its constituents, review its mission and goals, the direction of its program, the funding plan and necessary changes to its structure. Agreement on the continued need and support for the continuation of the Forum as a unique, independent entity that addressed critical issues through a creative, collaborative approach not conducted elsewhere in the HIV field was expressed across all sectors and constituencies present. The proposed mission statement was revised as follows: The Forum for Collaborative HIV Research is an independent public/private partnership including government agencies, the pharmaceutical industry, HIV researchers and clinicians, and the HIV patient advocacy community. The qualities that make the Forum unique and have contributed to its success will be essential for future work. The Forum's approach is needed in the areas of health services research and prevention. Recommendations were to place more emphasis in these areas in addition to the biomedical areas and to continue to carefully explore issues in global HIV/AIDS. This will require an increase in capacity. Some adjustments to the EC will be required. The choice of which projects to take on will depend on the greatest need for the Forum application; the unifying theme of *research* will help to focus the projects. Equipose and equity in funding between the public and private sectors need to be reestablished. Unrestricted core funding from both sectors will be essential for the Forum to be able to continue its work as an independent and neutral body.

Objective for the Retreat

The Forum convened this Retreat with Executive Committee (EC) members plus additional advisors (see Appendix A) to take stock of where the Forum has evolved to and to consider where we are headed. This is a timely discussion, since the Forum is developing a program and funding plan for the next period. The Forum sought to take advantage of this opportunity to review our mission and goals, the direction of our program, as well as to explore the potential for new partnerships. Specifically, the Forum asked the constituents to confirm their participation and support for the next period. The EC members and advisors were also asked to consider what opportunities and needs for the unique Forum application exist and which new partners we need to engage. The EC members were asked to discuss the need for balance of public and private sponsorship, seeking funding from as yet untapped sources (non US agencies, foundations) and structural/operational changes.



Forum History

Bopper Deyton, former Executive Committee member and one of the original founders of the Forum provided an overview of how and why the Forum was established six years ago¹. At that time, while all of the various interest groups wanted and needed to have several critical research questions addressed, none had the specific mission or the mechanism to fulfill this goal. As a result the establishment of a public/private partnership, in the form of an independent entity to catalyze appropriate stakeholders to address critical research needs resulted in the creation of the Forum. The characteristics of the Forum were

- collaboration
- ownership (by each stakeholder)
- independence (not run by any ONE stakeholder)
- credibility
- productivity (no duplication of other work)
- accountability (to stakeholders)
- accessibility

Criteria for success included the continued financial support from participants, improved collaboration among existing research systems, new research catalyzed through Forum activities and translation of the results of Forum catalyzed research into benefit for patients. How we define success -- now or in the future – will be integrally related to the agenda that we set for the Forum.

Other founding Forum members added comments. Industry representatives emphasized the achievement of the Forum in that it was able to bring individual industries together in a collaborative and trusting fashion. The fact that some of the initial issues included the role of health care financing and the role of public and private payors was reiterated.

The Forum Today

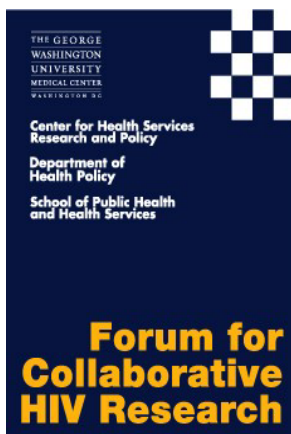
Mission statement

The proposed mission statement was discussed and revised as follows:

The Forum for Collaborative HIV Research is an independent public/private partnership including government agencies, the pharmaceutical industry, HIV researchers and clinicians, and the HIV patient advocacy community.

Our mission is to enhance and facilitate HIV Research

¹ The Keystone Dialogue Report is available on request



Current Status

The Forum's work, outlined in a graph distributed to all participants, has increasingly expanded in the number and scope of projects. Changes to the Forum also have included the size and composition of the Executive Committee, expanded partnerships with other stakeholders and experts in projects, increasing follow-up to projects with outcomes assessments, distribution of products, and increasing visibility of the Forum's work. The Forum has not changed in terms of its basic structure, including elements of the public/private partnership such as a mix of funding sources for and participation in projects. The Forum also continues to catalyze advances in research rather than carry out or conduct research.

Forum Project Selection

The process whereby projects are selected and prioritized, and the criteria for prioritization have not changed essentially over time. Projects may be brought to the Forum by EC members, other Forum partners, or the community at large. Some projects grow out of previous projects. The project themes are discussed and prioritized by the EC. Once agreement is reached, the decision to start a project depends on financial and human resources. The prioritizing criteria for project selection are as follows:

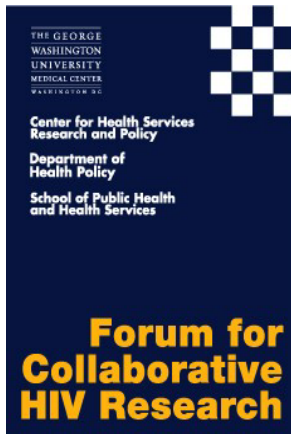
- How will the unique function of the Forum contribute to this issue?
- Does the issue require the unique Forum structure for progress to be made?
- Is it the issue at the forefront of HIV research?
- Are other organizations or groups looking at this issue?

Projects need to have clear and achievable objectives. Although our scope is broad, individual projects need to be very specifically focused.

Forum Function

The six steps of the Forum's function were outlined, and each discussed briefly with examples from recent projects; the types of outcomes for each function that are looked for and tracked in terms of the Forum's function were also listed. The six functions are:

- Assess current knowledge
- Identify gaps
- Provide mechanisms to meet, discuss and synthesize
- Recommend steps to fill the gaps
- Actively catalyze stakeholders
- Facilitate strategy development and propose new mechanisms



The Forum disseminates its products through website publications, peer reviewed publications, feedback meetings with individual constituents, and conference activities (e.g. Symposia, Summary Lectures).

Outcome Assessment

Outcomes of Forum activities that are relatively easy to track include background review papers, reports, publications in peer reviewed journals, research agendas, new collaborations, new funding within existing mechanisms or new mechanisms, new clinical studies and new standardization and/or consensus. Examples of these types of outcome are summarized in Table 1.

How do we attribute credit to the Forum when many advances are made because of converging influence of multiple steps and/or events? This important aspect of the Forum's work is more difficult to track quantitatively. These outcomes include increased levels of engagement, interactions that occur in a Forum setting, conversations that require the independent and neutral meeting ground. There are challenges to evaluating this type of outcome: the Forum interaction product can lead to new thinking for an individual stakeholder, but this is an evolution, not a single event. Nevertheless, there have been clear examples of Forum activities that have led to "the field moving forward" (Table 1).

Role of the Forum

There is not doubt that the qualities which make the Forum unique and have contributed to its success in the past will continue to be essential in the Forum's future. Changes in any one of these would compromise the ability of the Forum to fulfill its mission. Phrases such as "agent for change", "level playing field", "translating science into action" and "nexus between science and policy" were used. Being a primary mover in developing new programs through virtue of its relationship with the stakeholders will provide the legitimacy for the Forum's existence.

Qualities that make the Forum unique

- Independent and unbiased entity
The Forum provides a platform for "unconstrained debates and discussion" on issues at the interface of research and action, or research and policy. For some the Forum represents a very important unique opportunity to discuss in an open setting not normally available to them because of restrictions through regulations. For others, the Forum has provided a unique window on the perspectives and views of other sectors that they would not normally have had a chance to experience and this has resulted in changes in their approach. The neutrality of the Forum is very closely tied to its credibility.
- Public/private partnership
The value of public/private partnerships is seen increasingly in public health.



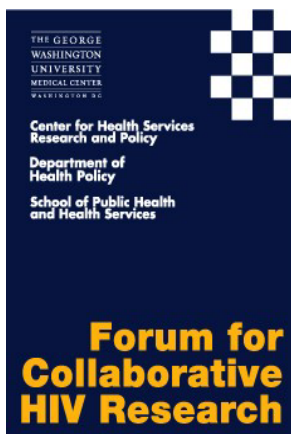
The Forum is an example of truly functioning industry/government collaboration. It is important that government and industry are on equal footing; this allows questions to be asked within the Forum that cannot be asked by individual stakeholders.

- Collaborative approach
A unique aspect of the Forum is the ability to bring all voices to the table. It is the independence and neutrality which allows the individual “voices” to participate in collaborative efforts. A multi-institutional neutral group is needed, along with additional players to address the issues in HIV both domestically and abroad.
- Leadership
An important ingredient is the credibility of the stakeholders. The Forum provides leadership in identifying “gap” areas rather than being a passive recipient for projects. An important aspect of the Forum’s work is the bridging of expertise from within and without the HIV field. We can learn from other diseases and apply those lessons to HIV. Reciprocally, what happens in HIV may have an impact on other diseases; this is true both for the clinical issues as well as for policy. The Forum is unafraid to ask difficult questions in a manner that brings people to the Forum.
- Flexibility
Flexibility and the ability to move quickly and pragmatically on projects sidestepping bureaucratic hindrances are key to our function and set us apart from other organizations. Not only does this allow us to tackle problems expeditiously, it also determines the nature of the projects which we take on.
- Function
The Forum’s important role in identifying research gaps and organizing collaborative discussions among recognized experts to analyze, assess, and, when appropriate, make recommendations for filling those gaps. It is not so much the identifying of gaps in knowledge or gaps in research that is important (many organizations identify gaps) but helping to initiate action in areas where the gaps are not being addressed. The Forum provides an opportunity to address the gaps with “out of the box” thinking by bringing together individuals that would not normally interact.

Questions regarding the Forum’s role in HIV/AIDS research

Is the Forum needed today? What is the “value added”?

Strong consensus from all constituencies was expressed for the continued need for the Forum as a unique, independent entity that can address critical issues through a creative, collaborative approach not conducted elsewhere in the HIV field. Every government and major organization involved in HIV has called for a multisectorial approach. Many of the issues identified back in 1996 are still there. The *fundamental*



qualities (see above) of the Forum help support for our work; these qualities need to be maintained as we move into the next phase.

The Forum will be needed as long as the Forum can remain in an “uncomfortable, tense” atmosphere, at the “edge of comfort”. The value of the Forum is seen in the “managed interaction” with stakeholders. In the Forum settings, individuals are allowed to drop their guard. The product of this interaction has been a window into other people’s priorities and this “product” has influenced the thinking of individual stakeholders (e.g. industry).

Where do we place our future emphasis?

The broad context within which the Forum has conducted and will conduct its work and contributes toward advancing HIV research was discussed. Participants were asked how HIV/AIDS has changed over the last five to seven years, as well as what the key substantive HIV/AIDS research issues are in the near future.

Changes in HIV/AIDS and issues for the future are listed in Table 2. The challenge for the Forum is to find which of these it has the capacity and mandate to address.

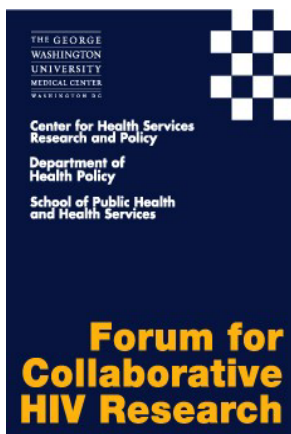
What are some specific projects that the Forum should consider?

Recommendations for specific project areas that the Forum should consider getting involved in flowed from the discussion on where the issues in HIV/AIDS lie. These are summarized in Table 3.

How do we choose a direction for our program?

Much discussion ensued around the issue of how we chose a direction for our program. This could be done thematically, or categorically.

- Greatest need
One way to streamline our direction is to look for where the greatest *need* is for which the Forum’s structure and capacity will allow the greatest impact. These will be needs that require a multisectorial approach – when a need is defined, all voices must be heard. One of the major criteria for deciding on tackling a certain area is to ask the question: what can the Forum uniquely contribute? Staffing capacity will be a prime determinant in selection of specific directions. A cautionary note against slipping into an advocacy role was expressed: the implications of “agent for change” in this regard were discussed. Our role as a *catalyst* is very important. The participants confirmed that the criteria set up for prioritizing and choosing specific projects was valid (see above).
- Research
A helpful unifying theme is “*research*” – this was broadly supported by the group. We can view research as the “vehicle”, then the question becomes: what to we apply



it to? For example, when looking at treatment access in the developing world, our remit is not to fix the problem, but rather, to catalyze research that will lead to increased access. The research discussion needs to occur within the context of our collaborative nature. By focusing on the research questions, we can set clear parameters for our scope. The issue then becomes to choose problems where we can actually achieve the outcome that we set our goals and objectives on. This clarification will take care of much of the tension of the “domestic vs. global” discussions.

- Domestic, International and Global
The Forum has begun to move along two dynamic lines characterized by the poles of “domestic vs. global” and “biomedical vs. policy and health services research”. Clearly, there will be more movement back and forth between these poles. The unifying themes outlined above will help to maintain focus and balance. *Not* becoming involved in the global setting is not really an option anymore. Many instances where the issues “here and there” were characterized as being very similar were raised (see Table 2 and Table3) and this applies to biomedical, health services and prevention research. Several recommendations were made as to handle this without completely changing our structure.
 - Add to the currently working structure rather than shifting to a completely new one
 - Seek guidance from those “on the ground” in the affected areas
 - Develop a “slightly modified” structure, and maintain the goal to focus on specific research issues, with a portion of the effort addressing issues important at the global level (e.g. our Transfer of Laboratory Technology project).

A single “ideal global Forum” will be difficult, if not impossible, to build. From a global perspective (both geographically as well as thematically) the issues are too complex, there are too many players and the issues are too overwhelming.

What is the Forum’s role in “identifying gaps”?

The Forum does not pretend to have the monopoly or the insight to uncover the gaps that no one else has seen. Rather, it examines the reason why these sometimes very obvious gaps exist and persist-- what needs to be done to correct the situation, what new programs need to be set up -- through discussion and analysis by a broad cross-section of professionals and stakeholders. Frequently, the problems will lie in areas in which leadership by other organizations is lacking. However, the Forum will never be in a position to become a substitute for the other legitimate organizations. The outcome goals will need to include the incorporation of the Forum’s recommendations by whatever “legitimate” group has the acknowledged leadership in this area.

How much restructuring of the Forum is necessary at this point?



The Forum has shown by its past performance that not every expertise needs to be represented on the EC or within the staff in order for us to do meaningful work. The additional expertise (frequently from outside the HIV field) or additional stakeholders are brought into each Forum project as needed. One suggested model included the present EC structure, accompanied by a series of theme specific advisory boards (one for prevention, one for health services/policy, etc) and increased staffing (quantity and expertise) as needed.

Funding the Forum

The original Forum model was based on equal core funding contributions from the public and private sectors; contributions were capped to avoid the perception of dominance of any one group. Over time, special project funding was introduced. The conclusions of the EC discussions were that core funding, and equipoise and equity within that structure, is essential to the carrying out of our mission. An increased base for the core funding was strongly recommended. The ANRS (France) offered this agency's support for specific projects that fall within their agenda.

Questions for Future Discussion

- A parallel effort is needed for the developing world -- "*a* Forum". Could it be "*this* Forum?"
- Are all the appropriate stakeholders at the table? (E.g. economists, generic industries, developing world practitioners, private insurers)
- How well does the current composition of the EC (e.g. the European representation) cover the current challenges?
- How can we engage leaders and funding bodies to act globally without losing interest locally?

Concluding Comments

Agreement on the need and support for the continuation of the Forum was expressed across all sectors and constituencies present. It was not possible to resolve all issues; additional time will need to be spent discussing the identified issues. The Forum may reconvene smaller groups of advisors to gain more insight into these.

This represents the first time since the inception of the Forum that an outside group of advisors has been included in the deliberations of the Executive Committee. The advice and insight offered will be extremely valuable as we proceed to face the challenges of the next phase. It is hoped that this level of close interaction with the Forum and insight into how we work will result in stronger partnerships with the individuals and the institutions and organizations they represent.

Table 1
Examples of Outcomes of Forum Activities



Outcome	Examples	Reference
Background Review Papers	Most recent: <ul style="list-style-type: none"> • Knowledge, Experience and the Quality of Health Care: A Literature Review and Synthesis • Linking of Testing, Prevention and Care • Immune-based Therapies: A Review of Clinical Endpoints Used in Trials of Selected Immunologic Agents 	www.hivforum.org/publications/publications.htm
Meeting Reports	Most recent: <ul style="list-style-type: none"> • STI Roundtable Discussion: Moving the Agenda Forward • What Defines Lipodystrophy? • Transfer of HIV Diagnostic and Monitoring Technologies Into Resource Poor Settings 	www.hivforum.org/publications/publications.htm
Peer Review Publications	<ul style="list-style-type: none"> • Importance of Antiretroviral Drug Concentrations in Sanctuary Sites and Viral Reservoirs • Monitoring of Long-Term Toxicities on HIV Treatments: an International Perspective 	<ul style="list-style-type: none"> • AIDS Research and Human Retroviruses 19:167-176; 2003 • AIDS (Invited Editorial Review, in press)
Research Agendas	<ul style="list-style-type: none"> • Research Agendas constitute a major section of each meeting report 	www.hivforum.org/publications/publications.htm
New Collaborations and Collaborative Networks	<ul style="list-style-type: none"> • FRAM Study • CD4 Working Group and • Viral Load Working Group (Transfer of HIV Diagnostic and Monitoring Technologies Into Resource Poor Settings) • Joint grant application to Doris Duke Charitable Foundation • Collaborative studies on transport of patient samples and storage effects 	
New Funding Available to Research	<ul style="list-style-type: none"> • Doris Duke Charitable Foundation Clinical Research Award 	



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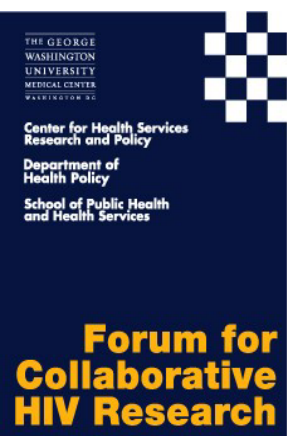
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Community		
New Clinical Studies	<ul style="list-style-type: none"> • FRAM study 	
Standardization and Consensus	<ul style="list-style-type: none"> • Integral part of many meeting reports • Standardization of assays for immune-based therapies (NCCLS) 	
“Moving the field forward”	<ul style="list-style-type: none"> • New approach to clinical studies in the salvage treatment setting as a result of discussions with agencies (regulatory/research), industry and other Forum constituents 	

Table 2
HIV/AIDS Issues Facing the HIV Community



Theme	Issues
Challenges in Treatment Strategies	<ul style="list-style-type: none"> • Management of disease more complex; multiple decisions required • Shift in clinical management without appropriate research to guide decision • Need to clarify long term treatment issues: <ul style="list-style-type: none"> ○ HIV infection or treatment related? • Need to understand natural history of drug resistant virus • Lessons to be learned from other chronic disease models • Understanding the role of clinical research in quality care
Global epidemic	<ul style="list-style-type: none"> • Acknowledgment of global epidemic is positive, but from the perspective of the USA, this has meant a shift rather than a widening of our views • “Unprecedented mobilization of resources” but the gaps in our understanding of the epidemic have continued to widen • Translation of “what we know” into affordable care • Assessment and identification of the role of generics • Urgent need for the coordination of the myriad of “pilot projects” being set up; assessment of uptake of these programs • Changes in who controls the agenda: from scientists to patent experts, trade and commerce representatives
Prevention Behavioral Vaccine Research Microbicides Research	<ul style="list-style-type: none"> • Prevention and care need to be intimately linked, both domestically and globally • Social complacency • Individual level complacency • Challenges for prevention work brought about by treatment success • Increasing skepticism and impatience surrounding prevention programs
Immune system	<ul style="list-style-type: none"> • Harnessing the immune system to benefit patients • Therapeutic vaccines
Genomics and Proteomics	
Disparities in Health Care	<ul style="list-style-type: none"> • Health care disparities are widening • Similarities between resource poor settings in Africa and in South East Washington DC • Large gaps in health care delivery
Health Services Needs	<ul style="list-style-type: none"> • Shift from death and dying model to chronic disease model has not been accompanied by sufficient gains in knowledge regarding care delivery, effective systems of care, financing and integration of prevention • Lack of infrastructure and plan for health services research • Increased need for social and medical services, behavioral and mental health services, treatment of

	<p>addictive disorders, but a management model is lacking</p> <ul style="list-style-type: none"> • Domestic “system” for serving individuals with HIV consists of little programs, many of which are being dismantled • Interest in HIV medicine lagging behind the need for expertise • Stigma is a major issue domestically and globally
Regulatory Environment	<ul style="list-style-type: none"> • Additional rules make it difficult to operate effectively • Backdrop of changed civil rights <i>vis a vis</i> the Disabilities Act
Role of Industry	<ul style="list-style-type: none"> • Industry has leadership in clinical research infrastructure • Changes due to mergers between companies and loss of smaller companies • Potential impact of this on which drugs (vaccines) get developed and what research is supported

Table 3
Projects That the Forum Should Consider



Broad Theme	Topics	Specific questions
Global HIV/AIDS	Access to treatment and care	<ul style="list-style-type: none"> • Is the “perfect getting in the way of the good”? • Health care delivery
	Treatment strategies	<ul style="list-style-type: none"> • What is the impact of specified drug regimen vs. free choice of combinations? What is significant resistance at the population level?
	Population questions	<ul style="list-style-type: none"> • Intersection of population genetics and viral genetics • Population genetics in relation to toxicity
	Prevention	<ul style="list-style-type: none"> • Opportunities for secondary prevention as individuals are brought into treatment • Planning of prevention services • Interface prevention in health care delivery settings (Opt out vs Opt in) • Post-natal transmission
	Clinical research in developing countries	<ul style="list-style-type: none"> • Ethical issues • Infrastructure needs • Support for clinical research and grant writing workshops
	Modeling the epidemic	<ul style="list-style-type: none"> • Assessing the impact of interventions
	Regional Forums	<ul style="list-style-type: none"> • Platform for interactions of all the players active in a given region: academic, government, industry, foundations
Health Services Research (US)	Financing	<ul style="list-style-type: none"> • Financing and the health care system for delivery of care • Changes in public policy and their impact on HIV care delivery
	Access to care	<ul style="list-style-type: none"> • Enhancing access to diagnosis and care: addressing the “accessing care too late” problem • Health disparities
	Prevention	<ul style="list-style-type: none"> • Prevention models in primary care setting
	Research platform	<ul style="list-style-type: none"> • Facilitating the development of a research platform for health services research
Biomedical	Genomics	<ul style="list-style-type: none"> • Maximizing benefit to patients • Ethical and confidentiality issues in HIV



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		<ul style="list-style-type: none"> • Coordination of approaches among the various constituencies
	Drug Development	<ul style="list-style-type: none"> • Ethical and scientific clinical trial design issues in pre-approval drug trials
	Treatment strategies	<ul style="list-style-type: none"> • Reducing drug exposure: implications for prevention and risk behavior; implications for policy
	Vaccines research	<ul style="list-style-type: none"> • Phase III trials
	Microbicides research	<ul style="list-style-type: none"> • Moving the agenda forward

Appendix A – Attendees

Participant	Affiliation	EC member
Braun, James	Physician's Research Network, New York, NY	✓
Cargill, Victoria	Office of AIDS Research, National Institutes of Health, Bethesda MD	✓
Cheng, Ben	Forum for Collaborative HIV Research	
Clayden, Polly	HIV-1 Base, London, UK	✓
Cohen, Calvin	Harvard Vanguard Medical Associates, Boston, MA	✓
Daniels, Elaine	Agouron Pharmaceuticals, Inc	
Delph, Yvette	Social and Scientific Systems	
Deyton, Lawrence	US Department of Veteran Affairs, Washington DC	
Differding, Virginia	Clinical Trials Partnership, Amsterdam, Netherlands	
Dilley, Abby	Resolve, Washington DC	
Dionne, Tom	CCG, CPCRA, USA	✓
Donnelly, Anne	Project Inform, San Francisco, CA	✓
Dooley, Sam	National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention, Atlanta GA	
Gulick, Roy	Weill Medical College of Cornell University, New York NY	✓
Haverkamp, Gert	PharmAccess International, Amsterdam, Netherlands	
Hodder, Sally	Bristol-Myers Squibb, Plainsboro NJ	✓
Holloway, Joan	HIV/AIDS Bureau, Health Resources and Services Administration, Rockville, MD	✓
Jones, Angela	Resolve, Washington DC	
Kagan, Jonathan	Division of AIDS, NIAID, NIH, Bethesda MD	✓

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Kazatchkine, Michel	Agence Nationale de Recherches sur la SIDA, Paris, France	
Kuritzkes, Daniel	Partners AIDS Research Center, Cambridge MA	✓
Lane, Clifford	National Institute for Allergies and Infectious Diseases, NIH, Bethesda MD	
Levi, Jeffrey	George Washington University, Washington, DC	
Manion, Douglas	GlaxoSmithKline, Research Triangle Park, NC	✓
Marlink, Richard	Harvard AIDS Institute, Boston, MA	
Miller, Veronica	Forum for Collaborative HIV Research, Washington DC	✓
Munk, Bob	New Mexico AIDS Infonet, Arroyo Seco, NM	
Murray, Jeffrey	Food & Drug Administration, Rockville, MD	✓
Nass, Heidi	CCG, Adult Clinical Trials Group, USA	✓
Palen, John	George Washington University, Washington, DC	✓
Parrish, Blaine	Forum for Collaborative HIV Research, Washington, DC	
Pizzuti, David	Bristol-Myers Squibb, Princeton NJ	
Powderly, William	Washington University School of Medicine, St Louis, MO	
Rosenbaum, Sara	George Washington University, Washington DC	
Safrit, Jeff	Elizabeth Glaser Pediatric AIDS Foundation, Santa Monica CA	✓
Valdiserri, Ron	National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention, Atlanta GA	
Wertheimer, Wendy	Office of AIDS Research, National Institutes of Health, Bethesda, MD	
Wilson, Phill	African American AIDS Policy and Training Institute, Los Angeles, CA	✓