



## 2005 Women and HIV Think Tank

November 10-13, 2005  
The Biltmore Estate  
Asheville, North Carolina

*Funding for this meeting and report provided through unrestricted educational grants from:  
Abbot Virology, Boehringer Ingelheim, BMS Virology, Gilead Sciences, and the Office of AIDS Research.  
Tibotec Therapeutics provided funding for the summary reports in preparation for the 2005 meeting.*

# Table of Contents

<b><i>2005 Women and HIV Think Tank Executive Summary</i></b> .....	<b>3</b>
<b><i>2005 Women and HIV Think Tank Meeting Report</i></b> .....	<b>6</b>
<i>Evolution of the Women and HIV Think Tank Initiative</i> .....	6
<i>Priorities for 2006</i> .....	7
<b><i>Call to action: Accelerating research on women and HIV/AIDS</i></b> .....	<b>10</b>
<b><i>Appendices</i></b> .....	<b>11</b>
<i>Guide to Working Group Reports and Action Plans</i> .....	11
<i>Appendix A: Centers of Care and Research Working Group</i> .....	12
Report on 2005 .....	12
Action plan for 2006 .....	15
<i>Appendix B: Standards of Treatment and Care Working Group</i> .....	16
Report on 2005 .....	16
Action plan for 2006 .....	18
<i>Appendix C: Policy Agenda (formerly Coalition) Working Group</i> .....	20
Report on 2005 .....	20
Action plan for 2006 .....	21
<i>Appendix D: Community Engagement Working Group</i> .....	23
Action plan for 2006 .....	23
<i>Appendix E: Research Tracking and Search Technology (TWP Initiative)</i> .....	24
Report on 2005 .....	24
Action plan for 2006 .....	25
<i>Appendix F: Living Research Agenda (TWP Initiative)</i> .....	26
<i>Appendix G: Information and Awareness Dissemination (TWP Initiative)</i> .....	26
<i>Appendix H: Women and HIV Think Tank 2005 Meeting Design</i> .....	27
The Well Project Mission.....	27
Think Tank Program Mission.....	27
Think Tank 2003 Meeting Background .....	27
Think Tank 2004 Meeting Background .....	27
Think Tank 2005 Meeting Intent .....	27
Think Tank 2005 Desired Results.....	28
Women and HIV Think Tank 2005 Detailed Agenda .....	29
<i>Appendix I: Women and HIV Think Tank 2005 Participants</i> .....	30
Participants .....	30
Meeting Staff .....	32

## **2005 Women and HIV Think Tank Executive Summary**

The 2005 Women and HIV Think Tank convened November 10-13, 2005 in Asheville, North Carolina. This year, the meeting participants included thirty individuals representing research institutions, clinics, government agencies, advocacy organizations, and pharmaceutical companies. Overall, the ongoing Think Tank body is made up of nearly sixty experts across disciplines and sectors.

As the Think Tank Initiative enters its fourth consecutive year, there is a considerable amount of progress and momentum to report. In an effort to provide the most relevant information, we will summarize activities and discussions in the body of this report and provide access to working group materials in the appendices.

In order to understand the work and evolution of the Think Tank over time, it is important to understand its core mission: to promote and facilitate expedience and efficiency in research about HIV disease in women by producing a coordinated effort across disciplines and organizations. In support of this mission, The Well Project (TWP) has established a unique, ongoing collaborative process of dialogue, brainstorming, prioritization, and action. Over the past few years, we have convened a remarkable group of leaders from academia, industry, government, and community advocacy. This group has devoted countless hours and energy at our annual meetings and during the year through working groups on behalf of the women we all serve. By engaging this diverse group of thought-leaders in a rigorous process of brainstorming in both full group and breakout group formats, a strong consensus has emerged on the future direction of this initiative and specific plans to proceed.

A significant topic for discussion at this year's meeting was the evolution of the Think Tank Initiative. As proclaimed by the members of the Think Tank -- "the name 'Think Tank' suggests a lot of theory and talk, but no action. We are committed to action and we *are* achieving real results." This year's meeting marked a key milestone in the maturity of the Women and HIV Think Tank and also of The Well Project (TWP) as an organization. Based on the evolving needs of the Think Tank body for ongoing leadership and infrastructure as described below, both the Think Tank body and The Well Project believe it makes sense for TWP to provide these functions as part of the core mission of TWP.

In that spirit, we have decided to officially change the name of the Women and HIV Think Tank to accurately reflect the real work of this group, to convey our ongoing

commitment to tangible and measurable results in the management of HIV disease in women, and to establish TWP's role in providing sustained leadership for this effort. The name we have chosen is "The Well Project's Women's Research Initiative on HIV/AIDS" (WRI). We will use this name throughout this report and in future communications.

The most significant outcome of this year's meeting is the unequivocal consensus that emerged that increasing the participation of women in research is the most tangible mechanism for improving HIV treatment and prevention efforts for all women over the long term. We identified seven critical initiatives by which The Well Project and the WRI could work to increase participation of women in HIV research. These initiatives are:

- Improve research standards to ensure adequate representation of women
- Evaluate clinical trials networks' research agendas with respect to women
- Engage HIV+ women in research through a national community advisory network and other mechanisms
- Advance public policy with regards to women and HIV
- Create and disseminate a living research agenda to direct research into gaps
- Enhance search mechanisms and facilitate tracking of unpublished and preliminary scientific research via the Internet (e.g. conference abstracts)
- Distribute information to affected women, their clinicians, and researchers

Based on additional discussion of the role of TWP in leading the Women's Research Initiative, the participants elected to form three working groups to pursue initiatives in 2006:

1. Standards of Treatment and Care
2. Policy Agenda
3. Community Engagement

TWP agreed to take lead responsibility for the remaining initiatives merged into these three topic areas:

1. Living Research Agenda
2. Information Dissemination and Awareness Expansion
3. Research Tracking and Search Technology

Each of the detailed Action Plans of these working groups and The Well Project initiatives are described in detail in the body and appendices of this report.

The Well Project is committed to providing leadership and support for the ongoing work of the Women's Research Initiative. We are actively and aggressively seeking additional financial support for this role, which would encompass: guiding strategy for the work, preparing multi-year plans, facilitating and supporting working groups, and convening future WRI events as well as the annual WRI meeting.

## **2005 Women and HIV Think Tank Meeting Report**

Building on the work of the 2003 and 2004 Think Tanks, the intent of the 2005 meeting was to *assess, update, and accelerate our action plan* for coordinating a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women. To accomplish this overall intent, we identified four critical results to achieve during the meeting:

- *Review, assess, and discuss activities from existing Think Tank working groups*
- *Prioritize critical and emerging issues to identify most appropriate target initiatives for 2006*
- *Develop a process to facilitate, track, and report on ongoing initiatives of working groups*
- *Build out action plans for existing and newly-identified working groups*

The 2005 Think Tank included thirty of the nearly sixty individuals involved in this initiative. Following our multidisciplinary focus, the participants represented research institutions, clinics, government agencies, advocacy organizations, and pharmaceutical companies.

### **Evolution of the Women and HIV Think Tank Initiative**

This year's meeting marked a key milestone in the maturity of the Women and HIV Think Tank and also of The Well Project (TWP) as an organization. Based on the evolving needs of the Think Tank body for ongoing leadership and infrastructure as described below, both the Think Tank body and The Well Project believe it makes sense for TWP to provide these functions as part of the core mission of the organization.

In 2003, The Well Project initiated and organized the first Women and HIV Think Tank meeting to bring together thought leaders in the field of women and HIV. The 2003 meeting identified the gaps and controversies in research on women and HIV and developed a prioritized research agenda. TWP's primary role was to serve as a convener and facilitator of these conversations.

In 2004, the role of the Women and HIV Think Tank evolved as significant infrastructure and policy obstacles were identified which impede research progress.

As the group identified gaps in knowledge, they also identified a significant lack of coordination and infrastructure needed to address these gaps in knowledge. This was the starting point for the work of the 2004 Women and HIV Think Tank.

Over a three-day period in 2004 we explored the critical challenges, identified solutions, and established ongoing working groups to address these needs. During the 2005 calendar year, TWP provided organizational support to these initial Think Tank Working Groups. With extremely limited organizational resources, TWP worked to maintain the focus and momentum of the working groups. As we planned for the 2005 meeting, we believed it essential to reassess and reprioritize the working group initiatives and to develop a more sustainable model to facilitate the work of these groups. At the 2005 annual meeting, representatives from each working group presented a progress report which is summarized later in this document.

Based on the evolving needs of the WRI body for ongoing leadership and infrastructure, both the Think Tank body and The Well Project believe it makes sense for TWP to provide these functions as part of the core mission of TWP. The mission of the WRI supports TWP's overall mission and complements TWP's other focus areas of information, education, awareness and advocacy. As we move into 2006, the Think Tank will become a core initiative of The Well Project under the name "The Well Project Women's Research Initiative on HIV/AIDS" (WRI).

The Well Project will guide the strategy for the Women's Research Initiative on HIV/AIDS, facilitate and support working groups, and convene future meetings to develop a living agenda for research and policy. To fulfill this role, resources will be required to fortify, resource, and staff the initiative. The Well Project team continues to be inspired by this work and is committed to finding the funding to provide this leadership and put this much-needed infrastructure in place. With the help of the "Call to Action" (see appendix) letter and support of all of our partners and participants, we are confident that we will meet this challenge.

## **Priorities for 2006**

After reviewing the progress to date, the participants focused on completing intensive brainstorming about critical and emerging issues. Over forty potential action items and initiatives were identified.

Through this discussion, we agreed that increasing the participation of women in research is the most tangible mechanism for improving HIV treatment and prevention efforts for all women over the long term. We identified seven critical initiatives by which The Well Project and the WRI could work to increase participation of women in HIV research. These include:

- Improve research standards to ensure adequate representation of women
- Evaluate clinical trials networks' research agendas with respect to women
- Engage HIV+ women in research through a national community advisory network and other mechanisms
- Advance public policy with regards to women and HIV
- Create and disseminate a living research agenda to direct research into gaps
- Enhance search mechanisms and facilitate tracking of unpublished and preliminary scientific research via the Internet (e.g. conference abstracts)
- Distribute information to affected women, their clinicians, and researchers

Based on additional discussion of the role of TWP in leading the Women's Research Initiative, the participants elected to form three working groups to pursue initiatives in 2006:

1. Standards of Treatment and Care: Enhance the base of research knowledge on women and HIV and how this knowledge is communicated to the community of patients and treatment/care providers
2. Policy Agenda: Increase the visibility of and response to women and HIV-related issues
3. Community Engagement: Engage HIV-positive women in all aspects of research, treatment, and care by proactively developing a network of positive women as advisors and formally gathering the input of HIV-positive women through a national study

TWP agreed to take lead responsibility for the remaining initiatives:

4. Living Research Agenda: Assemble, publish, and maintain a 'Women and HIV Research Agenda' as prioritized by this group of experts and others
5. Information Dissemination and Awareness Expansion: Collaborate with WRI members to broadly recruit new users to the web portal



and to increase general awareness as an ongoing effort to advance the common understanding of HIV disease in women

6. Research Tracking and Search Technology: Seek innovative partners to apply emerging technologies to make past and present research initiatives more broadly accessible to the research community

Each of the detailed Action Plans of these working groups and The Well Project initiatives are described in detail in the appendices of this report.

## **Call to action: Accelerating research on women and HIV/AIDS**

*The text below was adopted by the members of the Women's Research Initiative on HIV/AIDS as a summary and call to action:*

The *Women's Research Initiative on HIV/AIDS* consists of leaders from academia, industry, government, and community advocacy (See [participant list](#)). This group met in November 2005 to discuss the challenges related to advancing research on HIV and women.

We collectively agreed that HIV/AIDS increasingly impacts women in the US as well as worldwide. HIV/AIDS is now a general health issue for all women. Unfortunately, HIV-positive (and at risk) women are not sufficiently represented in clinical research. This is a major obstacle to our ability to address critical scientific research questions to optimize women's health. For example:

- How do we design optimal treatment strategies for women? (e.g. better understanding of sex-specific ARV efficacy, pharmacokinetics, and toxicity)
- How do we design optimal prevention strategies for women and girls?

We agreed that increasing the participation of women in research is the highest priority for improving HIV treatment and prevention efforts for all women. We identified critical initiatives by which The Well Project and the WRI could work to increase participation of women in HIV research. These include:

- Improve research standards to ensure adequate representation of women
- Evaluate clinical trials networks' research agendas with respect to women
- Engage HIV+ women in research through a national community advisory network and other mechanisms
- Advance public policy with regards to women and HIV
- Create and disseminate a living research agenda to direct research into gaps
- Enhance search mechanisms and facilitate tracking of unpublished and preliminary scientific research via the Internet (e.g. conference abstracts)
- Distribute information to affected women, their clinicians, and researchers

We\* whole-heartedly support The Well Project in these initiatives. We hope that you will join us in lending your support as well. \*(See attached list of names and affiliations of 2005 Think Tank participants).

## Appendices

### Guide to Working Group Reports and Action Plans

The appendices that follow will present more detailed information on the activities of the Women's Research Initiative. The table below summarizes the status of each working group and the information contained in each relevant section.

<u>Appendix</u>	<u>Initiative</u>	<u>2005</u>	<u>2006</u>
A	Centers of Care and Research Working Group	Working group report	Ongoing work is TWP internal
B	Standards of Treatment and Care	Working group report	Working group action plan
C	Policy Agenda (formerly Coalition)	Working group report	Working group action plan
D	Community Engagement Working Group		New working group action plan
E	Research Tracking and Search Technology	TWP report on "Links" project	TWP initiative for 2006
F	Living Research Agenda		New TWP initiative for 2006
G	Information and Awareness Dissemination		New TWP initiative for 2006

Appendices H and I provide the detailed agenda and participant list for the 2005 meeting.

## **Appendix A: Centers of Care and Research Working Group**

### **Report on 2005**

The Women's Centers of Care and Research group, one of four working groups to evolve from the 2004 meeting, grew out of an identified need to explore appropriate and effective mechanisms to insure sufficient numbers of women in clinical trials. This interest in enhancing women's participation in research spawned a working group to discuss ideas about incorporating research into care.

The working group members decided to research existing models of comprehensive women's health services to further explore the integration of clinical care and research. Aware of the program but unfamiliar with its mandates, the working group members decided to investigate the Centers of Excellence in Women's Health program sponsored by the Office of Women's Health (OWH). Kate Robert, an intern for The Well Project from Duke University, detailed the Centers of Excellence model in a twenty page report – a summary of which follows.

#### *Centers of Excellence in Women's Health (CoE)*

The overarching mission of the CoE program is to improve the health status of diverse women across the life span, while the central goal of the CoE program is to end the fragmentation that has characterized women's health care. The CoE program provides university-based women's health centers with national recognition and financial resources to unite five core components: leadership development, professional training and education, community outreach, clinical care, and gender-based research. The CoE model hinges on reciprocal relationships: clinicians are expected to become more involved in research, and researchers are expected to help translate their findings into practical applications.

Although all CoEs share the same five core components and philosophy towards women's health, each CoE differs in environment and structure. While some CoEs provide comprehensive services within one facility and reflect a "one-stop shopping" approach to women's health, others are "centers without walls" that offer networked services at a variety of clinical sites. While cardiovascular disease, diabetes, cancer, and HIV/AIDS are often cited in literature from the OWH as particular threats to women's health, the CoE model does not require CoEs to focus on any one of these diseases. Moreover, the Office on Women's Health does not require CoEs to measure whether women's health outcomes improve or whether their satisfaction increases with the introduction of the CoE model.

As part of the five core components, CoEs are required to maintain or expand a comprehensive, integrated clinical care center for women. CoEs are also required to conduct new high quality gender-based research that includes basic, preventive, population-based, clinical, and/or multidisciplinary studies, especially those targeting cardiovascular disease, diabetes, cancer, and HIV/AIDS. In addition, CoEs must recruit underrepresented individuals, including women and minorities, to participate in research studies and clinical trials.

#### *Centers of Excellence Interview Process and Results*

After reviewing the background report, circulating a preliminary program survey to CoE administrators and compiling the responses, the working group members decided to further investigate the CoE comprehensive model by interviewing various CoE Medical Directors. The goal of the interview process was to determine the overall benefits and challenges inherent in this model of comprehensive care. A cross-section of CoE institutions were selected with an effort to represent both institutions that were veterans of the CoE program and institutions that were newly appointed Centers of Excellence. An interview guide was drafted by the working group and loosely followed by those who conducted the first round of interviews.

Several themes emerged from the first round of interviews:

- Individual institutions typically apply for CoE designation for one of two reasons: as a natural progression from a preexisting internal comprehensive women's health care program or to elevate women's health as a priority within an institution not already recognizing it as such.
- Nearly all interviewees noted that the award grant from the Office of Women's Health is insufficient funding to meet the program mandates; this therefore asserts the need for institutions to leverage funds.
- The greatest benefits of the CoE program were described as (a) the multidisciplinary approach to care, (b) prestige of the national designation and its ability to both elevate women's health within the institutional system and assist in building community relationships, and (c) collaboration between like institutions and the resulting 'hub' for women's health research.

It was clear following the initial interviews that within each institution there are a group of clinicians and faculty that are dedicated to multidisciplinary comprehensive care. The challenge then is to convince those with decision-making power of the benefits of comprehensive women's health care and to convince them to provide additional funding for the initiative. Aside from the obvious financial challenges to the OWH CoE structure, those intimately involved with a CoE program praise the model and its five components.

After the first round of interviews and review of common themes, the working group decided to move forward in the following ways:

- A follow-up interview would be conducted with select institutions to gather more concrete examples of how HIV integrates into care, research, and other components of the CoE mandate.
- Explore the role of collaborative centers to determine if 'successful' CoEs were working in collaboration with another center/model, and if this collaboration fragmented care.
- Contact the Office of Women's Health and Gallup regarding any internal and/or external evaluation of the CoE program. (Although multiple attempts were made to gather this information, the working group received no response.)

In-depth conversations were had with CoE representatives at Brown University, Harvard Medical School, Fenway Community Health, Magee Women's Hospital, the UCLA CARE Center, and the University of California San Francisco. These follow-up conversations further emphasized the individuality of each Center of Excellence, both in structure and programming. While some of the institutional CoEs are addressing HIV disease as a high priority, others work collaboratively with outside HIV centers and clinics to meet the care and clinical trials needs of the HIV-positive women's population. The extent of 'collaboration' varies with each example. There seems to be a loose collaboration and referral system between the Harvard hospitals and Fenway Community Health, and UCLA's CoE and CARE Center. In contrast, Brown University and Magee Women's Hospital go to much greater lengths to integrate care and research and have established a more comprehensive structure to facilitate this coordination. A description of each follows:

- Within the Brown University system, HIV-positive women receive clinical care at one of two hospitals – Miriam Hospital for adults or the Women and Infant hospital. The Brown University AIDS Program recruits trial participants from both hospitals and regularly informs doctors, allied medical personnel, and the community of on-going and upcoming trials via a monthly newsletter and on-site bimonthly programs. There is good communication between staff members and a sense of fluidity between the physically separate hospitals/centers – there has been no known 'loss to follow-up' due to what some may consider fragmented care. Dr. Cu-Uvin duly noted that follow-up rates in Rhode Island are excellent, partially due to the small size of the state and lack of alternative care options.
- Magee Women's Hospital is known as an integrated health center combining medicine and Ob/Gyn care. Clinical care of HIV-positive women is provided at

either the HIV Care Clinic or in the Ob/Gyn department of the hospital. The Magee staff seems to recognize the historical fragmentation of women's care and works to address the barriers in everyday practice. For example, if a patient needs to be seen by both a generalist and a gynecologist, the doctors are moved between facilities, not the patient. In addition, the Microbicides clinical study is housed in the Ob/Gyn department at Magee. If a woman is seen in the HIV Care Clinic and is interested in the microbicides trial, her doctor will physically accompany her to the Ob/Gyn department to obtain further information and/or assist her in enrolling in the study.

### *Conclusions*

Over a two-part interview process, telephone and e-mail conversations were had with ten individuals working as CoE Medical Directors or as the director of a collaborating agency. After speaking with the various individuals, it is clear that the CoE program by itself, though comprehensive in theory, does not guarantee the delivery of comprehensive care and research opportunities in the field of HIV. The closest operational examples can be found at Magee Women's Hospital and Brown University where good communication exists between collaborating hospitals and care clinics.

Despite the CoE program's good intentions, existing literature fails to provide evidence that the program has been successful in achieving its stated goals. Although anecdotal evidence suggests that CoEs may have initiated some programs to improve leadership development, enhance professional training and education, extend community outreach, and encourage gender-based research, the success of these initiatives has yet to be evaluated. Empirical evidence does suggest that CoEs provide higher quality care than other health care settings; however more research needs to be conducted to isolate which aspects of the CoE model produce this effect. [Note: For a detailed review of the literature related to evaluation of care received at a Center of Excellence, please ask to be sent a copy of Kate's comprehensive program overview).

### **Action plan for 2006**

The Centers of Care and Research working group has completed their research and has turned next steps over to TWP. The Well Project is submitting the CoE research for a non-abstract driven session at the International AIDS Conference in Toronto. TWP is considering writing of white paper on the AIDS-related activities of the CoE highlighting the finding that not enough is done to address the need of at risk and HIV-infected women.

## **Appendix B: Standards of Treatment and Care Working Group**

### **Report on 2005**

The purpose of the “Standards” group identified in 2004 was to enhance research participation of women. This working group identified several goals in support of this purpose:

- Identify standards needed to ensure adequate enrollment of women and adequate data collection to support research efforts
- Ensure that drug development and clinical research adequately reflect the population affected by HIV, in particular women, and that such specific issues as safety and efficacy in women are investigated; ensure that women-specific issues are explored
- Identify incentives or policies needed to establish these standards of care in pharmaceutical industry research

### *Key Activities in 2005*

The major activities of the “standards” working group included an introductory working meeting with FDA representatives at CROI in February, 2005. A second working meeting with FDA representatives in July 2005 led to several ideas:

- Drug label review
- Best practices in clinical trials document
- Meta-data analysis

This group took on two projects: drug label review and a review of existing best practices documents. These efforts are summarized below:

### *Drug Label Review Project: The Case for Better Drug Labeling*

A study by the FDA highlighted in an article in the Yale Health Policy, Law and Ethics Journal<sup>1</sup> arguing for better and more sex and gender analysis in clinical research made a strong case for better drug labeling. The study examined the labeling for new drugs approved between 1995 and 1999.

- Of the 185 product labels analyzed for this study, twenty-two percent of the labels stated that there were sex differences for the drug.

---

<sup>1</sup> Sarah K. Keitt, MPH. “Sex & Gender: The politics, policy, and practice of medical research.” Yale Journal of Health Policy, Law, and Ethics III-2 (2003), pp. 101-125.



- Ten percent stated that no studies were performed, studies were inadequate, retrospective review showed no differences, or that the product was not indicated in a specific gender.
- Thirty-two percent of the labels had no statements about sex.
- Of the forty-one products for which the labels did describe sex differences, most (ninety percent) were pharmacokinetic.
- Twelve percent were safety differences and five percent were related to efficacy.
- Of all 185 products reviewed, not one reported a change in dosage based on sex differences—despite the fact that thirty-seven of these products had known sex differences in their PK properties.

Given this background context on drug labels, this working group seeks to answer a key question: How well do drug labels for HIV drugs address women’s issues?

To address this question, the group created a matrix questionnaire and evaluated 26 HIV drug labels for information about women. Our examination found:

- Varying degrees of inclusion, information and relevance
- No ability to compare/contrast impact on women based on label with any accuracy and reliability
- Drug label does not serve purpose for women – it is difficult to know from the label what is critical

We identified several options for improvement that may be considered:

- Change/standardize label format and information
- Create supplement document separate from label
- Evaluate European label approach

#### *Best Practices Review Project*

This project seeks to answer a key question: What are best practices in clinical trials design, recruitment, and retention for women in HIV?

Although this question has been discussed at previous Think Tanks, during our first meeting with the FDA, the agency indicated a need for a “best practices” document to support women’s involvement in clinical research. The agency encouraged TWP’s interest in this activity and welcomed our efforts to identify or create a best practices document.

To begin this effort, the group gathered several existing best practices documents for clinical trials (including 2 meeting summaries, 1 journal article, 1 internal policy

guideline document, and 1 handbook; only one of these documents was HIV-specific). A preliminary review by TWP found:

- The case for sex-based research and the need to not just “involve” women in clinical research is strong.
- The “best practices” for developing women-friendly or women-centered research are largely based on the successful women’s cohort model.
- The most comprehensive document is an NIH guide in the form of a PI notebook for the inclusion of women and minorities in clinical research.
- Of the documents reviewed, no comprehensive “best practices” document was found.

A more comprehensive document covering the best practices review will be circulated to this working group and the larger group. Based on the input from this group, we will determine specific recommendations to present to FDA to influence the direction for women’s HIV trial design, recruitment, enrollment, and retention.

#### *Meta-analysis on women and HIV*

During the group’s meetings with the FDA, the FDA raised the possibility of conducting a meta-analysis to identify issues pertaining to women and HIV. This analysis could provide insight on how HIV impacts women. The FDA suggested that the WRI working group could potentially assist in generating ideas to scope and structure this meta-analysis research. The working group determined that numerous questions and issues around how to approach this work must be considered and elected to defer this work to 2006.

#### **Action plan for 2006**

Based on input from the overall WRI, the standards group identified three specific goals and actions for 2006:

- Goal 1: Complete label review to recommend possible label modifications to FDA
  1. Review labels of HIV drugs for information on women
  2. Generate reports
  3. Define expectations for improved label and patient information  
Pursue concept of “living label” with easier updates
  4. Define implementation roadmap with agency, researchers, networks, and pharmaceutical industry

5. Timeline: Report to FDA at CROI in February 2006; present label review findings at Toronto in July 2006
- Goal 2: Establish external review of clinical trials networks
    1. Identify group (e.g. OAR) to conduct an annual review of clinical trial networks to assess performance with respect to women's participation with the goal of making these reviews public
    2. Timeline to be determined
  - Goal 3: Establish "meta-analysis" questions for FDA
    1. Identify initial group from FDA and industry to scope possible meta-analyses
    2. Timeline to be determined

## **Appendix C: Policy Agenda (formerly Coalition) Working Group**

### **Report on 2005**

The 2004 Think Tank identified several needs in the policy arena related to women and HIV. These needs include:

- A collective voice for and about women with HIV
- Ability to shape and disseminate information on women and HIV to assure accuracy and integrity of science
- Lobbying for expansion of research and care for HIV-positive women

Based on these needs, the “coalition” working group was formed to establish a coalition of professional and advocacy organizations to ensure the accuracy and integrity of public information and to increase the visibility of HIV disease in women.

### *Key Activities*

Initial working group calls in December 2004 and April 2005 identified an amfAR-initiated coalition as a possible solution and collaborated on initial efforts. This initiative, called the Women and HIV/AIDS Coalition (WHAC) held initial meetings in January 2005 and a steering committee meeting in April 2005. The first steering committee meeting was co-chaired by amfAR and TWP and hosted by the Kaiser Family Foundation. This meeting brought together 25 national and international organizations to frame the mission and objectives of WHAC. A second steering committee meeting was held in November 2005.

### *WHAC Statement of Purpose*

“The Women and HIV/AIDS Coalition exists to create a climate where women get what they need to live safe, healthy, and fulfilling lives. Our vision is to create a coordinated effort to raise awareness and advocacy around the invisible epidemic among women in the U.S. and around the U.S. government’s HIV/AIDS-related policy as it affects women globally.”

### *WHAC Objectives*

The WHAC steering committee developed several objectives in support of its mission:

- Provide supporting infrastructure for coordination, information sharing, networking, and learning
- Develop broad-based message and message-delivery strategy
- Develop leadership capacity among women most significantly affected by HIV/AIDS

- Promote science-based approach to policy
- Mobilize constituency with political capacity to drive change

#### *WHAC Action Items*

The WHAC steering committee developed several initial action items in support of its mission:

- Working group to develop statement of principles (policy agenda)
- Develop materials to inform broader WHAC membership
- Working group to design leadership development activities (e.g., education and lobby day)

#### **Action plan for 2006**

The WRI generated substantial discussion on whether and how the mission and policy objectives of the WRI are consistent with those of the amfAR-led WHAC coalition. The WRI determined that a specific policy agenda promoting increased research on women is required and that WHAC is pursuing a broader policy agenda domestically and internationally. The Policy Agenda working group formed to specifically focus on research policy issues.

HIV/AIDS is now a general health issue for all women. Unfortunately, HIV-positive (and at risk) women are not sufficiently represented in clinical research in part due to stigma, lack of community, and other real and perceived barriers. Health Policy can be a significant obstacle to women's participation in research as well. The Policy Agenda working group formed out of the need to increase the visibility and response to women and HIV. At Think Tank 2005, the policy agenda working group identified a broad overall goal and several areas of possible activity, which we have grouped into two categories.

Overall goal: Increase the visibility of and response to women and HIV to normalize HIV Disease with the intention to facilitate the involvement of women in HIV research.

This working group's initial work will be to define a specific policy agenda to accelerate research. The first steps are:

- Define specific messages
- Identify specific "ask"
- Conduct ongoing policy research

Once the policy agenda is articulated, the group will establish a specific action plan with measurable goals and objectives. Some initial ideas from brainstorming sessions include:

- Promote public awareness (science exhibits, speakers, PSAs)
- Identify champions at federal, state, and local levels
- Identify leverage points between pharma and government

Timeline: first working meeting to occur in December 2005 or early 2006.

## **Appendix D: Community Engagement Working Group**

### **Action plan for 2006**

Increasing women's participation in HIV research requires the active involvement of HIV-positive women in all levels of clinical trial design and implementation. A working group was formed to better engage women in defining research needs. Two goals were identified:

- Goal 1: Conduct a national survey of HIV-positive women regarding treatment, care, and research
  1. Seek funding for focus group surveys to define parameters of a national survey
  2. Conduct the focus groups
  3. Define requirements and seek funding for a national survey
  4. Conduct the national survey
  5. Timeline:
    - a. Develop initial proposal for focus groups by January 2006
    - b. Secure multi-company funding for first phase of survey study design by February 2006
    - c. Conduct Focus groups and Expert Advisory Board by Spring 2006
    - d. Develop and submit an abstract for presentation for the International AIDS Conference in Toronto in July 2006 to generate interest and financial support for National Survey to be conducted in 2007
- Goal 2: Establish a national community advisory board
  1. Work with TWP to define needs and funding sources to facilitate a national advisory board of women infected and affected by HIV
  2. Timeline to be determined

## **Appendix E: Research Tracking and Search Technology (TWP Initiative)**

### **Report on 2005**

The 2004 Think Tank concluded that it is difficult to easily and reliably track research and that no single, practical mechanism exists to serve this purpose. The group envisioned a “Universal Database” to track research progress. Given the cost and complexity of such an undertaking, the Think Tank identified an intermediate goal called the “Links” project which would establish an online directory of existing research sources. TWP took the lead in completing this project during 2005.

#### *“Links” Project: Universal DB Concept*

The “links” project starts with a vision for the creation and maintenance of a comprehensive, searchable online database to house current and future research on HIV disease in women. This database would house data from government, industry, private research organizations, foundations, and others sources. Such a database would reduce duplication of research efforts, promote collaboration and interdisciplinary research, and accelerate dissemination of research findings.

#### *“Links” Project: Key Activities*

To begin with a smaller scale project, the “links” project involved several activities:

- Survey of Think Tank Members to identify frequently-used online resources
- Research into existing alternatives (Scanned over 20 existing sites)
- Designed and Implemented ‘Clinical Research Links’ page on The Well Project Web portal

#### *“Links” Project: Key Learnings*

We identified two sites that provide important insight into how a universal database might be designed. The first is the industry-sponsored International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) database launched in 2005. This site searches and pulls from ClinicalTrials.gov and CenterWatch.com. As such, in its current design, the IFPMA Web site only publishes information from Pharma-sponsored studies which already exists elsewhere online. Therefore, the IFPMA database is inadequate for tracking research and adds no significant value to the existing efforts since all ‘data’ accessible on the database is available on other Web sites.

The second site is the government-sponsored Computer Retrieval of Information on Scientific Projects (CRISP). This site covers all government-sponsored research on



human subjects since 1972. The search results display abstract, PI name and contact information, grant FY, project start and end date. This site is the best example of a database showcasing clinical research; however it is limited to government-sponsored research.

Based on the preliminary research and analysis of the “links” project implementation, The Well Project has concluded that no universal database exists that combines information from government and industry-sponsored studies. The Universal Database concept remains an unmet need for the research community.

To view the “links” project ‘Clinical Research Links’ page on The Well Project Web portal, please visit this url:

[http://www.thewellproject.org/Treatment\\_and\\_Trials/Clinical\\_Trials/Clinical Research Links.jsp](http://www.thewellproject.org/Treatment_and_Trials/Clinical_Trials/Clinical_Research_Links.jsp)

Next steps for this project are to solicit feedback from users and research on the value of this directory and key requirements for improvement.

#### **Action plan for 2006**

Capitalizing on the previous work to build a resource of research links, TWP will identify possible technology approaches to developing a more comprehensive capability to search and track HIV research.

## **Appendix F: Living Research Agenda (TWP Initiative)**

The first Think Tank meeting in 2003 focused on identifying the gaps and controversies in research on women and HIV and developing a prioritized research list. TWP will develop a mechanism to publish and disseminate this information while working to identify resources to support an ongoing scientific advisory group to maintain a “living” research agenda.

## **Appendix G: Information and Awareness Dissemination (TWP Initiative)**

All participants agreed that increasing the visibility of TWP’s core website and mission is a critical initiative. TWP will work to secure funding to promote the website as an information resource to patients, caregivers, and researchers.

## **Appendix H: Women and HIV Think Tank 2005 Meeting Design**

### **The Well Project Mission**

The Well Project is committed to reducing the total human cost of the HIV/AIDS pandemic through a unique and comprehensive focus on women.

### **Think Tank Program Mission**

The Women and HIV Think Tank, first convened in 2003, is committed to encouraging expedience and efficiency in research about HIV disease in women by producing a coordinated effort across disciplines and organizations.

*Our aim is to enable more, better, and faster research that yields improved prevention, treatment, and care for women.*

### **Think Tank 2003 Meeting Background**

The initial meeting in 2003 focused on identifying the gaps and controversies in research on women and HIV, developing a prioritized research agenda.

### **Think Tank 2004 Meeting Background**

The 2004 Think Tank meeting focused on the *design and launch of an action plan* for coordinating a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women.

### **Think Tank 2005 Meeting Intent**

Building on our work in 2003 and 2004, the intent of the 2005 Think Tank is to *assess, update, and accelerate our action plan* for a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women.

### **Think Tank 2005 Desired Results**

By 12:00 noon on Sunday, November 13, 2005, we will:

- *Review, assess, and discuss activities from existing Think Tank working groups*
- *Prioritize critical and emerging issues to identify most appropriate target initiatives for 2006*
- *Develop a process to facilitate, track, and report on ongoing initiatives of working groups*
- *Build out action plans for existing and newly-identified working groups*

## Women and HIV Think Tank 2005 Detailed Agenda

### *Thursday, November 10, 2005*

- 12:00 pm – 7:00 pm Optional pre-meeting activities (hike, swim, spa, massage, etc)  
7:00 pm – 10:00 pm Welcome Reception and Dinner ..... *Vanderbilt A and Balcony*

### *Friday, November 11, 2005*

- 7:00 am – 7:45 am Breakfast ..... *Inn Dining Room*  
7:45 am Shuttle to Lioncrest Ballroom..... *Outside Inn*  
8:00 am – 9:15 am Welcome, introductions, and meeting overview..... *Lioncrest Ballroom*  
9:15 am – 9:45 am Recap of 2003 and 2004 Think Tanks ..... *Lioncrest Ballroom*  
9:45 am – 10:00 am Break  
10:00 am – 12:00 pm Update from 2004 Think Tank working groups ..... *Lioncrest Ballroom*  
12:00 pm – 1:15 pm Lunch and Break ..... *Lioncrest Chestnut Patio*  
1:15 pm – 2:45 pm Identify critical and emerging issues ..... *Lioncrest Ballroom*  
2:45 pm – 3:00 pm Break  
3:00 pm – 4:45 pm Identify critical and emerging issues (cont'd)..... *Lioncrest Ballroom*  
4:45 pm – 5:00 pm Reflections on the day ..... *Lioncrest Ballroom*  
5:00 pm Shuttle to Inn ..... *Outside Lioncrest*  
6:45 pm Shuttle to the Horsebarn ..... *Outside Inn*  
7:00 pm – 10:00 pm Dinner ..... *Historic Horse Barn*  
10:00 pm Shuttle to Inn ..... *Outside Horse Barn*

### *Saturday, November 12, 2005*

- 7:00 am – 7:45 am Breakfast ..... *Inn Dining Room*  
7:45 am Shuttle to Lioncrest Ballroom ..... *Outside Inn*  
8:00 am – 8:30 am Day 2 kickoff session ..... *Lioncrest Ballroom*  
8:30 am – 9:45 am Improving Think Tank effectiveness ..... *Lioncrest Ballroom*  
9:45 am – 10:00 am Break  
10:00 am – 12:00 pm Defining 2006 Priorities ..... *Lioncrest Ballroom*  
12:00 pm – 1:15 pm Lunch and Break ..... *Deerpark Restaurant*  
1:15 pm – 3:00 pm Working Group Sessions ..... *Lioncrest Ballroom*  
3:00 pm Shuttle to Inn ..... *Outside Lioncrest*  
3:00 pm – 6:00 pm Rest, reflect, re-energize  
6:00 pm Shuttle to the Candlelight Christmas Tour ..... *Outside Inn*  
8:00 pm – 9:30 pm Candlelight dinner ..... *Stable Café*  
9:30 pm Shuttle to Inn ..... *Outside Stable Café*

### *Sunday, November 13, 2005*

- 7:00 am – 8:45 am Breakfast ..... *Inn Dining Room*  
8:45 am Shuttle to Lioncrest Ballroom ..... *Outside Inn*  
9:00 am – 10:15 am Working Group Action planning ..... *Lioncrest Ballroom*  
10:15 am – 10:30 am Break  
10:30 am – 11:30 am Presenting Action Plans ..... *Lioncrest Ballroom*  
11:30 am – 12:00 pm Meeting Close ..... *Lioncrest Ballroom*  
12:00 pm Shuttle to Inn ..... *Outside Lioncrest*  
12:30 pm Lunch at Leisure; Depart ..... *Library*

## **Appendix I: Women and HIV Think Tank 2005 Participants**

### **Participants**

**Judith D. Auerbach, PhD**

Vice President, Public Policy and Program Development  
amfAR

**Dawn Averitt Bridge**

Founder  
The Well Project

**Gina Brown, MD**

Medical Director  
Cicatelli Associates, Inc.

**Susan Ellen Cohn, MD, MPH**

Associate Professor of Medicine  
University of Rochester

**Jenna Conley**

Senior Manager  
Gilead Sciences

**Robert W. Coombs, MD, PhD, FRCPC**

Professor, Laboratory Medicine and Medicine  
University of Washington

**Terri Creagh, PhD**

Clinical and Epidemiologic Research

**Ron Falcon, MD**

Medical Director, Virology  
Tibotec Therapeutics

**Judith Feinberg, MD**

Professor of Medicine  
University of Cincinnati

**Becky Griesse**

Research Assistant  
Forum for Collaborative HIV Research

**Jane Hitti, MD**

University of Washington Medical Center

**Beri Hull**

Global Advocacy Officer: Access to Care, Treatment and Support  
The International Community of Women Living with HIV and AIDS (ICW)

**Ben Kozub**

Product Manager, HIV  
Boehringer Ingelheim Pharmaceuticals

**Sharon Lee, MD**

Director  
Family Health Care

**Heidi Nass**

Coordinator, Treatment Support and Education Program  
HIV Care Program, University of Wisconsin Hospital and Clinics

**Nancy Norman, MD, MPH**

Medical Director  
Boston Public Health Commission

**Cathy Olufs**

Education Director  
CorrectHELP – The Corrections HIV Education and Law Project

**Nancy Padian, PhD**

Professor  
UCSF

**Andrew Pavia, MD**

University of Utah

**Kristy D. Porter, PharmD**

Associate Director, Virology Medical Affairs  
Bristol-Myers Squibb

**Tonia Poteat, PA-C**

Grady Infectious Disease Program

**Patricia Reichelderfer, PhD**

Microbiologist  
NIH/NICHD

**Star Seyedkazemi, PharmD**

Clinical Science Manager, Abbott Virology  
Abbott Laboratories

**Kathleen E. Squires, MD**

Director, Division of Infectious Diseases  
Thomas Jefferson University

**Stephen Storfer, MD**

Associate Director, Virology  
Clinical and Scientific Affairs  
Boehringer Ingelheim Pharmaceuticals, Inc.

**Melanie Thompson, MD**

Principal Investigator  
AIDS Research Consortium of Atlanta

**Fulvia Veronese, PhD**

Health Science Administrator  
NIH, Office of AIDS Research  
Etiology and Pathogenesis and Microbicide Section

**Meeting Staff**

**Megan Raspa, MPH**

Project Manager  
The Well Project

**Facilitators**

**Richard Averitt**

Chief Operating Officer  
The Well Project

**Ron Wilder**

President  
Aligned Action, Inc.



**Meeting Planners**

**Debbie Cooke**

VP, Chief Operations Officer  
Meeting Masters, Inc.

**Tina DeRenzis**

President  
Meeting Masters, Inc.