

**The Well Project**

**presents a report of**

**The 5<sup>th</sup> Annual Meeting of  
The Women's Research Initiative on HIV/AIDS (WRI)**

**September 6-9, 2007**

**Deer Valley, Utah**

**Funding for this meeting and report provided through unrestricted educational grants from:  
Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences and the Office of AIDS  
Research (OAR/NIH). Tibotec Therapeutics provided funding for the creation and  
dissemination of summary reports of this meeting.**

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## **The Well Project Mission and the Women's Research Initiative on HIV/AIDS**

The Well Project (TWP) is committed to changing the course of the AIDS pandemic through a unique and comprehensive focus on women. Our goal is to improve prevention, treatment, and care for women with HIV. From the organization's inception, The Well Project has concentrated its efforts on overcoming the **three most significant barriers** to accelerating progress in these areas:

1. Communication of medical information on women is limited and not accessible to the patients and healthcare providers who need it most
2. Communities and caregivers most impacted by HIV lack capacity to effectively deal with the challenges of HIV
3. Research on women is inadequate, inefficient, and uncoordinated

The Well Project has focused its direct efforts on responding to the first and second barriers listed above through the creation of its global web portal and other educational/advocacy efforts such as the National Positive Women's Training Initiative (NPWTI). In addition, The Well Project designs, develops and implements continuing education efforts aimed at medical professionals on select issues to specifically address the second barrier.

To help overcome the barrier posed by inadequate research on women, TWP launched The Women's Research Initiative on HIV/AIDS (WRI) – formerly known as the Women and HIV Think Tank - in 2003. The WRI's mission has been to encourage, enable and coordinate efforts across disciplines and organizations to improve research related to HIV disease in women. The WRI is made up of over 75 experts from many fields and perspectives related to women's health and HIV. The membership includes academic, community and private practice clinicians, research scientists from academic, government, and pharmaceutical industry settings, HIV-positive women, and representatives of advocacy organizations. This group of experts has committed thousands of hours of volunteer time to this effort for which the organization remains grateful.

This report documents the 5th annual meeting of the WRI, our significant progress to date, and our major goals for the next five years.

## **Executive Summary: Six Themes for the Future**

Since 2003, the Women's Research Initiative on HIV/AIDS has involved more than 75 of the top thought and action leaders across disciplines of medicine, scientific research, community action, education, and advocacy related to women's health and HIV. The 5th annual meeting of The Well Project's Women's Research Initiative on HIV/AIDS (WRI) convened September 6-9, 2007 in Park City, Utah.

During the past five years, the WRI has focused on one major objective -- more, better, and faster research on HIV disease in women. This group has accomplished much towards this objective since its inception. This report updates many of the ongoing efforts of the WRI. However, to emphasize only these accomplishments would divert our attention from the key insights of this year's meeting. More than half of this year's meeting time was used to consider the next five years for women with HIV. The outcome of those deliberations was an imperative to continue the research mission of the WRI and to also begin tackling several other major issues including HIV stigma/ignorance, routine HIV testing and inadequate access to healthcare.

The WRI contends that our research advocacy mission is closely connected to these new goals. Until we make progress in overcoming these barriers, we will not have an environment in which we can make enough significant research progress. Stigma and inadequate healthcare access are two of the major reasons why many women do not know their infection or risk status and why the low enrollment of women in clinical trials continues.

This year's meeting was facilitated to allow open-ended creative thinking designed to forecast a greatly improved future for women vulnerable to, or infected with, HIV. Significant blocks of time were devoted to imagining what could evolve over the next five years. Six themes for the future emerged from this process; the major elements of change that we hope to see by 2012 are presented below.

- 1. The medical community is at the forefront of reducing HIV stigma by changing the way it thinks and talks about HIV.*

2. *HIV testing is a routine part of healthcare.*
3. *All people have access to treatment and care for HIV. This universal treatment approach not only saves lives but plays a significant role in preventing further transmission.*
4. *Women are educated and empowered through their communities to prevent transmission of HIV.*
5. *Women have access to microbicides, vaccines, and other preventive treatments which give them much more personal power in prevention.*
6. *All antiretroviral drug labels include full information on the use of each drug in women; the difference in pharmacokinetics, adverse events, and efficacy according to gender; how to use each drug in pregnant women and nursing mothers; and results of clinical trials powered to answer these questions in women.*

Since 2003, the WRI has aimed for more, better and faster research for women and this continues to be the focal point of The Well Project's efforts to accelerate research. Over the next five years (2008-2012), WRI efforts will expand to reduce HIV stigma by using education and improved messaging. We will also support efforts designed to increase potential HIV caregiver capacity and knowledge. To help overcome missed and late diagnoses, we will work to implement routine HIV testing for women through further educational efforts and by partnering with women's advocacy groups and medical professional organizations.

To bring these visions into reality, we have much work to do to continue to enhance the influence of the WRI and to establish relationships with stakeholders. The remainder of this report identifies some of the immediate next steps and longer-range plans to further this future vision. Thank you for being a part of this journey to improve women's lives.

## **Future Goals – Five Years and Beyond**

The WRI will continue its chosen mission of working for more, better and faster research efforts for women affected by HIV. During the 2007 meeting, we discussed our future intent in the following research-related areas:

### **Improve Treatment Information by Filling in the Research Gaps**

One of the main focuses of the WRI has been to assess and address gender-related biomedical research gaps in past and ongoing HIV drug trials. Treatment information can be improved by filling in these gaps. Current information is not only limited by a dearth of woman-related data but is also limited by the typically scattered organization of this information. We will foster efforts to develop concise and comprehensive treatment guides for use by women's healthcare providers in the future.

Two of our nearly completed projects (Antiretroviral Label Review and FDA Meta-analysis) are important first steps in bringing about this future reality. By the end of 2007, the WRI will have completed a paper which will summarize the results of their systematic review of FDA drug labels for all currently-approved antiretrovirals. The FDA's meta-analysis of their database for sex-based differences in safety and efficacy of antiretrovirals has also made significant progress toward maximizing safety and efficacy data for women with HIV. We intend to publicize and use the potentially persuasive information gained from the WRI's label review and the FDA's meta-analysis to improve disease management and guide future research priorities as related to HIV disease in women.

Additionally, we will work directly with the FDA and clinical trial sponsors to establish how to set clinical trial enrollment goals that achieve adequate safety and efficacy information for women. Ultimately, we want to have adequate representation of women in HIV clinical trials so that we can optimize future treatment information for women. We contend that it is critical to have a better understanding of how many women in a given trial is enough to produce clinically relevant answers rather than an arbitrary or even prevalence-based percentage applied universally.

### **Optimize and Encourage Best Practices for Women in Clinical Research**

The WRI will continue working with all of our partners (pharmaceutical industry, government, community, healthcare providers, clinical research professionals, and HIV-positive women and their advocates) to establish and implement the best research practices for enrolling, retaining and caring for women in HIV-related clinical trials. We advise training for clinical research site staff on a range of issues related to women. Using woman-centered best practices in clinical research can increase the level of commitment from study participants who are valued partners in the clinical research process. Having a well-researched enrollment goal in mind will be another important component of establishing best research practices. We will continue to highlight the negative impact healthcare provider bias can sometimes play on whether or not women are invited to consider being clinical research participants.

### **Encourage Development of Woman-Controlled HIV Prevention Methods**

We will help to facilitate the development of microbicides (both vaginal and rectal), pre-exposure prophylaxis, vaccines, and other woman-controlled HIV prevention methods. We will work with groups already doing this work to expand their reach and interest other gender equity groups in joining us to address the need for these prevention options. We will advocate for improved access to such products.

### **Improve Our Society's Future Response to HIV**

Over the next five years, we will focus on several big issues which we think will have a desirable impact on women living with HIV and will ultimately fulfill our mission of enhancing HIV-related research for women. These issues include HIV stigma, poor HIV education, and inadequate access to quality healthcare. Some of the improvements that we intend to work toward are presented below:

#### **Reduction of HIV Stigma: Find Effective Messaging and Consider Risk Language**

- Work through partnerships to create an environment where it is acceptable and expected to “know your status.”
- Examine successful elements of past campaigns used to reduce stigma for other conditions including teen pregnancy and breast cancer. Note failures of

past educational messages that have brought unintended results (e.g. increased smoking rates in response to anti-smoking ads).

- Advocate for the development of new universal messages with cross-cultural appeal to help normalize HIV testing. Connect to and enlist new spokespeople for this campaign who have broad appeal to youth and/or women.
- Recommend expanding locations of HIV education campaign billboards to a broader range of communities.
- Consult with the CDC about changing the risk language they use in their publicized materials. Encourage the CDC and other government agencies to minimize overuse of high risk category language which often serves to increase stigma.

#### **Routine and Normalized HIV Testing for Women as a Basic Healthcare Need**

- Educate women to expect and ask for HIV testing as part of their routine healthcare.
- Educate women's medical providers about the need to implement routine HIV testing. Inform providers that many cases of HIV in women are missed or diagnosed late.
- Provide healthcare providers education on how to best guide the next steps in patient care beyond a positive HIV test. Continue our message to women's healthcare providers about the pandemic's course in women, and how early diagnosis and treatment are important components of prevention within communities.
- Seek partnership with women's-health professional organizations (e.g. American Medical Women's Association) to educate their own members about HIV in women and the need for normalized testing.
- Form partnerships with women's advocacy organizations to assist with public information campaigns to encourage normalizing HIV testing for women.



- Choose appropriate partnerships to support legislative policy efforts designed to ensure adequate governmental and third party payer support for implementation of routine testing and appropriate linkages to care and support.
- Propose public messages aimed at women on National HIV Testing Day in June 2008.

### **Education of Healthcare Providers**

- Inform women's healthcare providers about what we do know about HIV in women, how much research data are lacking for women, and why/how they can encourage women's participation in clinical trials.
- Work with medical educators to incorporate women and HIV information into medical training curricula and to require competency testing in this for students.
- Guide the creation of educational tools which will equip non HIV-specialists with skills in HIV diagnosis, treatment and prevention in women. In conjunction with the federally sponsored network of Area Health Education Centers (AHEC), planning is underway to consider various options to produce a continuing education program aimed at rural healthcare providers in the southeastern United States. Proposed course content focuses on how to best supplement antiretroviral drug label information when making treatment decisions for HIV-positive women. Another possibility for course development is to use already-available educational resources that may have been under-utilized.

### **Education and Empowerment of Women**

- Encourage community-focused connections for women.
- Launch the National Positive Women's Training Initiative (NPWTI), a train-the-trainer program to provide peer educators throughout the U.S. The first phase of this is a reunion meeting in November 2007 for graduates of the former National HIV U Training Program (which was held each year from

1997-2000) that will help inform the design of the NPWTI program to be started in 2008.

- Communicate the personal value of clinical research. Educate positive women and their providers about the potential benefits of participating in clinical research which can include treatment access, more individualized patient management, access to state of the art diagnostic tools and a significant contribution to the greater understanding of HIV disease in women.

### **Improve HIV Education of U.S. public**

- Advocate for better and earlier health education in U.S. schools. How are we doing this?
- Raise public's awareness of the increasing number of women affected by HIV.
- Reframe risk messaging about HIV to convey that human behavior puts people at risk for HIV.
- Promote the message that knowing your status is the best way to protect yourself and others – and that HIV is a disease that can be managed.
- Convey the message that one can live with HIV.

## **Strategies and Actions: Reaching New Goals through New Partnerships**

The WRI's proposed efforts to reduce HIV-associated stigma, to improve HIV-related education, and to maximize healthcare access are ambitious in scope. We contend that we can have the most impact by partnering with other groups and different kinds of experts to carry this work forward. Examples of such partnerships and connections follow:

### **Use Pre-Existing Medical Community Connections –**

- Work to expand HIV education within medical professional organizations for all providers who commonly encounter women in their clinical practice. This would include clinicians in OB-GYN, internal medicine, family practice, emergency rooms and STD clinics. Specific groups to be targeted include America College of Obstetricians and Gynecologist (ACOG) and American Academy of Family Physicians (AAFP).
- Gain commitment of healthcare providers to help normalize HIV by offering HIV testing as a routine part of women's healthcare.

**Connect to Women's Advocacy Groups –** The WRI will form partnerships with professional and civic organizations who are involved in general women's advocacy for the purpose of making HIV testing a non-stigmatized and routine part of women's healthcare. We will seek to raise public awareness of the HIV pandemic in women.

**Encourage Community-Industry Communication To Foster Better Clinical Research Practices for Women –** We will disseminate lessons learned from a woman-focused clinical trial (GRACE study) to improve the participation of women in clinical research. This trial was designed, at least in part, in response to community pleas for adequate enrollment of women. The study sponsor aimed to be patient-centered, site-centered and flexible. While the study sponsor designed this trial to be women-focused, many of the learnings are applicable in all HIV studies. The success of this study is replicable and should become a benchmark for other clinical trials.

**Work with Committees to Improve Treatment Guidelines** – Several WRI members also serve on HIV/AIDS treatment guideline committees such as for the Department of Health and Human Services (DHHS) and International AIDS Society (IAS). We will advocate for concise, well-organized and complete treatment information references to use when providing healthcare guidance for women living with HIV.

**Encourage Novel Partnerships** – We will encourage novel partnerships between industry and government to help fund and guide research and development of women-controlled HIV prevention methods including microbicides (vaginal, rectal), vaccines (prophylactic and therapeutic), and other preventive therapies. We will also work through these partnerships to improve access to these technologies.

**Comparing Results: Women and HIV Surveys** – Several groups have recently completed surveys related to women and HIV. Two of these surveys were discussed at this meeting – one done by BI and the other by amfAR. The full results of these surveys will be available in the near future. Because one of these surveys was conducted in positive women and the other was conducted in the general public about positive women, the WRI is interested to see how a comparison of these results might impact our future choices of action, particularly in the areas of prevention/testing education and stigma reduction. The Well Project and WRI will work with both organizations to consider how these findings can help us set future goals and priorities.

**WRI Members Working with One Another** – WRI members have a valuable partnership with one another through involvement in this ongoing think-tank style initiative. We discussed the importance of working with one another as needed throughout the year and our intent to broaden the impact of the WRI by increasing its visibility. Members were encouraged to emphasize the WRI when they are listing their professional associations, memberships or volunteer work.

## Meeting Theme and Intent

The theme of the 2007 WRI meeting was “Designing the Future.” Intended external results of this meeting included:

- Building relationships among new and veteran WRI participants to enable and enhance our work
- Orienting and integrating new participants
- Reflecting on WRI successes and challenges during 2003-2007
- Generating big ideas and stories for the future direction of research and the WRI mission
- Identifying emerging issues to incorporate into the work of the WRI
- Accelerating progress in ongoing WRI working group activities
- Creating and designing the “Future Story” of the next five years of research on HIV/AIDS in women

## Meeting Overview

Since 2003, the Women's Research Initiative on HIV/AIDS has involved more than 75 of the top thought and action leaders across disciplines of medicine, scientific research, community action, education, and advocacy related to women's health and HIV. The WRI has identified gaps, challenges, and controversies in research on women and HIV. We have designed and launched an action plan for coordinating a multi-disciplinary effort to develop, track and enhance this research and have worked to accelerate the pace at which it is implemented.

The fifth annual meeting of The Well Project's Women's Research Initiative on HIV/AIDS (WRI) convened September 6-9, 2007 in Park City, Utah. Twelve new members of the WRI were present in the group of 36 participants. First-time participants were given orientation as a group on the afternoon before WRI veterans were to arrive. These new participants were introduced to one another and to the mission of the WRI. All were given an overview of the evolution and some of the past accomplishments of both The Well Project and The Women's Research Initiative. The particular combination of participants at annual meetings continues to change year to year to allow for new members and expertise. However, every person who has ever participated in an annual meeting continues as a valued member of the WRI network.

While the WRI meetings have always involved looking at past accomplishments and considering new directions, this year's meeting differed in several ways. The meeting participants were not required to join specific working groups and formulate specific action plans by the meeting's end. Instead, the meeting was facilitated to allow open-ended creative thinking designed to forecast a greatly improved future for women vulnerable to, or infected with, HIV. Significant blocks of time were devoted to imagining what could evolve over the next five years. Participants were encouraged to engage their full creative minds without pressure to fully commit to plans before evaluating what might be required. WRI members noted their success as active advisors in carrying out long-range, not short-term, plans where adequate time is given to developing team plans of action. Where specific action plans have been made during previous three-day meetings, it was noted that these action plans were often heavily revised later once participants had more time to create and refine achievable plans.

Delaying developing the details of action plans is practical for other reasons as well. The WRI now has a full-time Research and Program Manager to help coordinate efforts among WRI members and The Well Project staff. This fifth annual meeting was the first opportunity for WRI members to engage as a group with this new staff member. Consideration of TWP staff and WRI member time is a practical planning element that is best handled after, not during, the annual meeting so that The Well Project can be closely involved in initiating staff-driven actions designed to meet WRI goals. Additionally, our goals are likely to require the creation of new partnerships to move forward. Forming these strategically-chosen partnerships is a necessary and shorter-term goal that WRI members and their Research and Program Manager will focus on in the coming year.

In light of the shift in expected meeting outcomes, and in recognition of past success, this overall experience was designed to have the group emerge with a new vision of possibilities five years from now and of the role we might play in taking an integrated approach to making changes happen for women with HIV. Through creative brainstorming, the group set out to develop a desired set of hopeful and substantive changes that would affect the future of women and girls with HIV through the next five years. Strategies to focus and construct this future story included using individual reflection time, collecting written responses to forward-looking questions, developing creative forward-looking ideas in small groups, and full group discussions.

The meeting began with participants splitting into small groups and focusing on why they had chosen to continue as WRI members and what they believed to be the most important issues in women's research. The new members were asked what their advance expectations of this meeting were. These small group reflections were later shared with all meeting attendees as a way to start sorting through and choosing several achievable, desirable and persuasive goals for our future strategies.

The following session opened with Dawn Averitt Bridge (Co-Founder and Chair of the Board, The Well Project) reflecting on some of the past accomplishments of the WRI. She imagined for the group the future for the next five, ten, and twenty years. After absorbing Dawn's inspirational presentation, WRI members were prompted to spend individual time focusing on the following questions:

1. Looking out over the next 5 years, what do I want for the WRI?
2. I have a magic wand. What is the one thing I would do to change the course of the pandemic? Why?

Individuals submitted their written answers which were compiled into one list for all members to read. Small groups then met to consider this wish list in terms of what common themes emerged and where they noted crossover and synergy. Each group was instructed to select two ideas from the list and to discuss how these ideas might be accomplished. The full body of the WRI later responded to these chosen ideas, and came to a consensus that their list of wishes to change the pandemic fell into several broad areas.

1. Reduce stigma through improved messaging; change risk behavior language.
2. Normalize HIV testing. Educate and expect all women's healthcare providers to implement CDC recommendations to routinely offer HIV testing with competent follow-up. Focus on women/HIV medical education programs aimed at rural and non HIV-specialist healthcare providers.
3. Improve HIV prevention methods for women focusing on woman-controlled methods.
4. Educate women to ask for HIV testing as a routine part of healthcare. Educate community about the need to know HIV status. Offer better health education through schools.
5. Improve women's access to healthcare in general, and encourage third-party payers to cover routine HIV testing.

Our meeting culminated in a series of informal presentations designed to illustrate different future scenarios in which the world is vastly improved for women with HIV. Presentations were designed by six-person groups who used varied formats to showcase their ideas including White House press conferences, morning news and talk shows and press releases. Imagined accomplishments were accompanied by explanations addressing what barriers had been overcome to allow these



improvements. Presenters elaborated on change in society or government, for example, which would allow a climate in which all of these improvements can happen. Each group was assigned one of the following specific areas in which to forecast improvements via their presentations:

1. *HIV Stigma Reduction from a Medical Focus including Routine HIV testing*
2. *HIV Stigma Reduction using Community Focus on Leadership and Education*
3. *Universal Access to Treatment and Care*
4. *Prevention using a Community Focus on Education and Empowerment of Women*
5. *Prevention using a Medical Focus: Including development of Microbicides and Vaccines*
6. *Label Review of Antiretroviral Drugs: How to use these findings to advance the WRI mission of more, better and faster research on HIV treatments for women*

Full group discussions followed each of the presentations during which time many proposals were made as to potential steps that the WRI could take toward realizing these imagined futures. Many of these proposals are covered in an earlier section of this report (“Future Goals-Five Years and Beyond”).

WRI members departed the 2007 meeting feeling recharged and hopeful about what we intend to accomplish by our tenth anniversary in 2012. This year there was significant evolution in the WRI meeting process and in its expected outcomes. We examined our cumulative progress over the past five years and proposed what impact we intend to make within the next five. Many of our goals will be accomplished through working in partnership with others including the staff of The Well Project. A schedule of this year’s meeting and a list of the participants are included as appendices at the end of this report.

## **Accomplishments and Project Updates**

An essential part of each WRI is an overview of the accomplishments and project updates on ongoing WRI initiatives. This year, the WRI meeting was designed to commit the morning of Day 2 of the meeting to these updates. A quick accounting of past accomplishments and current projects follows.

### **Completed Review of Antiretroviral Drug Labels for Woman-Related Information –**

The objective review of woman-related safety and efficacy information available on FDA-approved antiretroviral drug labels has been completed. The purpose of this label review project has been to determine how well these drug labels inform healthcare providers in the use and selection of treatment regimens for their female patients. Each antiretroviral's drug label was assessed for information in eight woman-related areas such as interaction with oral contraceptives and safety for breastfeeding. The gaps and inconsistencies in woman-related information in these labels prevent HIV-positive women from receiving the full information they need to decide safest and most effective treatment regimens. More research on women and HIV is needed so that more information can be available for improving treatment decisions. The Label Review Subcommittee is working on a manuscript of their findings that will be submitted for publication.

**FDA Meta-analysis** – The FDA has been working on another WRI-influenced project started in response to the shortage of woman-specific data for many antiretrovirals which results in incomplete treatment information for women with HIV. The FDA responded to this shortage by obtaining funding for and planning a meta-analysis of data from past HIV drug studies many of which had enrolled only low percentages of women. One and a half years ago, the FDA began this meta-analysis of its clinical trials database; this project is now approximately two-thirds complete. WRI members are considering how to respond to possible findings in terms of information dissemination. Dr. Kimberly Struble from the FDA presented some of the preliminary findings of the meta-analysis to the full WRI group. She also explained that in the future these types of analyses can be less labor-intensive because the FDA has issued a guidance to pharmaceutical companies to submit their data in uniform formats.

**Developing Better Practices in Clinical Research** – The WRI helped develop new and better strategies to interest, enroll and care for women in clinical trials. The Gender, Race And Clinical Experience (GRACE) study (Tibotec Therapeutics), which is fully enrolled, is an example of such a women-focused trial. Dawn Averitt Bridge discussed strategies developed to support full enrollment of the GRACE Study. Customized and flexible funds for supplemental support at the site level were available through application. Patient tool kits were provided with a focus on patient education and study visits. Sites were provided with their own kits including items such as study posters and buttons, education materials and study criteria cards. Dr. Joe Mrus of Tibotec Therapeutics discussed the progress of enrollment to date. The study has subsequently completed enrollment. The WRI wants to build on this success by documenting best practices for future clinical research.

**Learning Directly from Women with HIV** - The Well Project served as consultants to Boehringer-Ingelheim (BI) in their plans for the recently completed national survey of women on their experiences and information needs at the time of HIV diagnosis and for the three years following. An overview of the range of survey questions asked was presented at the annual meeting. [NOTE: *A BI press release one month after our meeting indicated one of the main survey findings was that most women with HIV and their healthcare providers have not discussed how HIV might affect them differently than men. More than half of the respondents had never discussed how pregnancy can affect treatment options, or how those treatments can impact a pregnancy. Almost three-quarters of the women surveyed reported that HIV has caused struggle in managing their daily lives.*] The WRI members will use these final survey results to inform choices of future action especially in the area of best practices in clinical research and medical provider education.

**amfAR Survey** –Rowena Johnston of amfAR updated the group on their online survey of public perception and knowledge of women and HIV. She gave an overview of the kinds of questions that were asked and her plan to update the WRI when these results become available.

**“Ripple Effects”** – At the meeting’s outset, participants discussed why they continue to be part of the WRI and how the WRI meeting experience has impacted their lives. One of the key reasons given for returning each year was the sense of passion and connection gained through working with such a broadly experienced and dedicated

group of leaders. Reinvigorated WRI members take new ideas for action back to their home and work communities; this chance to inspire others to join our mission maximizes our potential impact. Many of the members gave personal examples of how the WRI has impacted them in ways that might not be obvious to others. One recounted how often she is influenced by the WRI perspective when she is reviewing articles or grant applications. Others said they take home new perspectives from each meeting or simply experience a renewal of energy for their work. Members pondered what the cumulative ripple effects of this group have been and how these ripples amplify as new members are added to the group. The collective ripple effects stemming from our annual brainstorming sessions are significant and continue to accumulate at this five-year point.

**Expanding Membership** – The WRI has expanded to include more than 75 participants from many different perspectives and backgrounds. Areas of expertise are many and include women’s health, HIV clinical medicine, academic and industry research science, government health agencies, community activism/education and medical education. Expanded membership translates to expanded impact and influence. (Appendices C and D list this year’s and past years’ meeting participants.)

**Being the Leading Voice for Prioritizing Research Needs for Women and HIV** – An overall goal of the WRI continues to be more, better and faster research for women with HIV. We are now recognized as leaders in improving research as a way of changing the course of the HIV pandemic for women.

## **Call to Action**

By 2012, we envision universal access to expert HIV healthcare, drastically reduced HIV stigma and effective health education in our schools. Empowered women will know their HIV status and will expect HIV testing to be a routine part of their healthcare. We believe these sweeping changes are achievable through our work and through our collective influence on the general public, healthcare providers, government leaders and educators. We invite researchers, advocates, government regulators, clinicians, pharmaceutical companies, and HIV-positive individuals to partner with us in achieving these goals.

## **Sponsors**

We appreciate the continuing support of our sponsors. The 2007 WRI Annual Meeting was sponsored by Boehringer-Ingelheim, Bristol-Myers Squibb, the Office of AIDS Research (OAR-NIH) and Gilead Sciences. The preparation of this meeting report was sponsored by Tibotec Therapeutics.

## Appendices

### *Appendix A: "What Do I Want for the WRI Five Years From Now?"*

In support of one of the meeting's first brainstorming sessions, members were given twenty-minutes of time alone to consider, write and submit answers to several questions including what their vision of the WRI five years from now was. An anonymous compilation of many of the written answers follows...

#### **"What do I want for the WRI five years from now?"**

"My hope is that WRI will continue to support, enrich and encourage the mission of advancing research for women and HIV. Having consumers, providers, NGO, pharma, funders (including Gates Foundation in the future) and Gov (FDA, NIH) and community around the table sharing ideas both in and out of the box is a wonderful opportunity to support The Well Project in their varied endeavors."

"To continue and expand its work to improve quantity and quality of research relating to women."

"To be a coalition on women and HIV/AIDS that is active, inclusive and has a clear policy/advocacy agenda."

"To be the vanguard and to refuse to accept the pace as it is and to imagine a future where AIDS becomes an uncommon and manageable disease – and make it so."

"To claim and occupy the leading edge of the movement toward a new status quo for HIV research and treatment of/for women. To act as the hub and resource for those engaged in changing - rather than modifying – the structure."

"To develop specific, detailed, practical and feasible "how to's" for recruitment and retention of women in clinical trials. This goal will achieve adequate representation of women in a given trial for the disease stage studied."

"To be a catalyst in launching a new "culture" in clinical trials for women that attracts more women."

"To influence all research entities to expand studies on women and HIV."

“To work with networks, organizations, communities and government to establish benchmarks for enrollment targets for women in trials. People are critical of companies who only enroll 13-15% women in a highly treatment-experienced study. But how do we know if this # is representative or not? Have realistic goals that reflect the epidemic.”

“To become the conduit and liaison between organizations/companies interested in women’s clinical research and sites (academic, community-based) interested in the same. Start first with sites in North America and then expand model globally. Partner with industry and health authorities to provide education to these sites to train them for clinical research.”

“To set a national and international best practices standard for enrolling and retaining women in studies.”

“Female-specific prevention agenda development.”

“Expand goals beyond clinical drug trials to include behavioral and psychosocial issues for women; this impacts women’s abilities to adhere to meds.”

“For us to continue to expand our focus beyond treatment issues, to include psychological/behavioral issues.”

“I’d like to see WRI have a significant impact on identifying all of the infected but unaware women and get them into care. To do so will involve a major educational change on providers and 3<sup>rd</sup> party payers and legislation, domestically and globally. If we can have public service announcements about blood pressure, diabetes, breast cancer, cervical cancer, prostate cancer, we should have them for HIV in a way that destigmatizes the disease. I want to continue working on efforts to eliminate racial and economic disparities in healthcare access.”

“Spearhead a program that brings newly diagnosed women together with other women from around the country. Establish policy and have influence and representation on government advisory boards.”

“To develop/expand information and support services for HIV-infected women.”



“Establish women’s centers for support and information throughout the country - connected regionally and locally as well as nationally. Support research, especially in prevention.”

“Partner with appropriate groups to get women tested for HIV.”

“Have formal linkages with women’s health organizations that can drive a research and healthcare agenda – like ACOG (American College of OB/GYN).”

“The global impact to reach women because if you affect women, you affect men, children and the world.”

“The formation of a treatment and research agenda that is translatable globally and accesses international bodies ... I think we have to link with international trade and policy bodies to affect change around treatment and prevention access “...

“Be concerned about the HIV healthcare workforce - many of my colleagues have died or are retiring. Not enough MDs and nurses are going into HIV care or even primary care. We need the National Health Service Corps to address the HIV epidemic and create positions in HIV clinics around the country, especially in communities hardest hit by the epidemic. After 2-3 years of service, providers would be trained and possibly committed to continuing in HIV care. It would also decrease their professional education loan indebtedness. Big problems require innovative and creative approaches to public/private partnerships. We can change the world if we work hard enough.”

“Make the WHICC (Women and HIV International Clinical Conference) the sounding board for WRI initiatives.”

“To be recognized as the leader in advocacy for HIV research in women.”

“For us to continue to meet yearly, because I think great things come out of these meetings.”

“To be the organization that brings together a multidisciplinary group that sets a national and international agenda for research on HIV/AIDS and related illnesses for women.”

## ***Appendix B: 2007 WRI Meeting Schedule***

**Stein Eriksen Lodge, Park City, Utah**

**September 6-9, 2007**

### **Thursday, September 6, 2007**

Arrivals throughout the day

3 – 6pm	Orientation for new WRI participants	Viking Room
7 – 10pm	Welcome reception for all WRI participants	Odin

### **Friday, September 7, 2007**

7:30 – 8:30am	Breakfast	Odin
8:30 – 9:45am	WRI Opening session	Alpine & Bronze
9:45 -10:00 am	Break	
10am -noon	WRI Full Group Session	Alpine & Bronze
Noon -1:15pm	Lunch	Odin
1:15-2:45pm	Breakout sessions	Suite 117-1 Suite 119-1 Alpine & Bronze
2:45 -- 3pm	Break	
3 – 4:30pm	WRI Full Group Session	Alpine & Bronze
4:30 – 6:00pm	Free time	
6:00 – 6:30pm	Cocktails	Plaza Terrace
6:30pm – until	Dinner	Plaza Terrace

**Saturday, September 8, 2007**

7:30 – 8:30am	Breakfast	Valhalla
8:30am – noon	WRI Program	Alpine & Bronze
Noon – 1:15pm	Lunch	Valhalla
1:15 – 3:30 pm	Future Story Breakout Groups	Suite 117-1 Suite 119-1 Alpine & Bronze
3:30 – 7:00pm	Free Time	
7:00	Shuttle departs to off-site Dinner	Arrival Lobby

**Sunday, September 9, 2007**

7:30 – 8:00am	Breakfast Buffet	Alpine & Bronze
8:00 – 10:30am	Future Story Presentations	Alpine & Bronze
10:30 – 11:00am	WRI Program Wrap Up	Alpine & Bronze

***Appendix C: List of 2007 WRI Meeting Participants*****Laura N. Armas-Kolostroubis, MD**

Clinical Director, TX/ OK AETC  
Staff Physician, HIV Women's Specialty Center,  
Parkland Hospital System

**Judith D. Auerbach, PhD**

Deputy Executive Director for Science & Public Policy  
San Francisco AIDS Foundation

**Richard Averitt**

Meeting Facilitator and Board Member  
The Well Project

**Julie Barroso, PhD, ANP, APRN, BC**

Associate Professor & Specialty Director,  
Adult Nurse Practitioner in Primary Care Program  
Duke University School of Nursing

**Dawn Averitt Bridge**

Co-Founder and Chair  
The Well Project

**Carol Brosgart, MD**

Vice President Public Health & Policy  
Gilead Sciences

**Gina Brown, MD**

Maternal-Fetal Specialist  
New York City Department of Health and Mental Hygiene

**Susan E. Cohn, MD, MPH**

Associate Professor of Medicine  
University of Rochester Medical Center  
Infectious Diseases Division

**Elizabeth Connick, MD**

Associate Professor of Medicine

University of Colorado at Denver and Health Sciences Center

**Terri Creagh, PhD**

Director of Research

Clinical and Epidemiologic Research

**Karine Dubé, MPhil**

Research and Program Analyst

amfAR, The Foundation for AIDS Research

**Judith Feinberg, MD**

Professor of Medicine

University of Cincinnati

**Monica Gandhi, MD, MPH**

Assistant Professor

University of California, San Francisco

**Kristy Grimm, PharmD**

Associate Director, Virology Medical Strategy

Bristol-Myers Squibb

**Debbie P. Hagins, MD, AAHIVS**

Clinical Director

Chatham County Health Dept.

**Sally L. Hodder, MD**

Executive Vice Chair, Director HIV Programs, Medicine

University of Medicine &amp; Dentistry of New Jersey

**Marcia McDonnell Holstad, DSN, RN-C, FNP**

Assistant Professor

Emory University

**Rowena Johnston, PhD**

Vice President, Research

amfAR – The Foundation for AIDS Research

**Sharon Lee, MD**

Director, Southwest Boulevard Family Health Care  
Kansas City, KS

**Joseph Mrus, MD, MSc**

Medical Director  
Tibotec Therapeutics

**Heidi Nass, JD**

Director, Education & Outreach  
UWHC HIV Clinic

**Cathy Olufs**

Education Director  
Center for Health Justice

**Tonia Poteat, MMSc, PA-C, MPH**

Physician Assistant  
Grady Infectious Disease Program

**Martell Randolph**

Community Health Educator  
Los Angeles, CA

**Laura Ray**

Research and Program Manager  
The Well Project

**Patricia Reichelderfer, PhD**

Microbiologist  
NIH/NICHD

**Alex Rinehart, PhD**

Senior Science & Research Liaison  
Tibotec Therapeutics

**Maura Riordan**

Executive Director

Women Organized to Respond to Life-Threatening Disease (WORLD)

**Deneen Robinson**

Owner

Savant Consulting Group

**Yolanda Rodriguez-Escobar, LMSW**

Executive Director

Mujeres Unidas Contra el SIDA

**Ellie Schoenbaum, MD**Professor Epidemiology & Population Health, OB-GYN & Women's Health and  
Medicine

Albert Einstein College of Medicine

**Stephen P. Storer, MD**

Senior Associate Director of Virology

Boehringer-Ingelheim Pharmaceuticals, Inc.

**Kimberly Struble, PharmD**

Medical Team Leader

Food and Drug Administration, Division of Antiviral Products

**Chris Turner, MSN, WHNP**

Feminist Women's Health Center/Private Practice

**Fulvia Veronese, PhD**

Health Scientist Administrator

Prevention Science Branch, DAIDS, NIAID, NIH, DHHS on detail from the NIH Office  
of AIDS Research**Ron Wilder**

Meeting Facilitator and Board Member

The Well Project

**Loreen Willenberg**

Advocate, Affected Community

Lake Elsinore, CA

**Carmen D. Zorilla, MD**

Professor, OB-GYN

University of Puerto Rico, School of Medicine



## ***Appendix D: Additional WRI Membership***

The WRI members below have participated in past meetings and continue to be in the expanding WRI network. Their listed affiliations and positions were current at the time of their last meeting attendance.

**Kathryn Anastos MD**

Montefiore Medical Center  
Albert Einstein College of Medicine

**Arlene Bardequez, MD, MPH, FACOG**

Associate Professor, Director HIV  
New Jersey Medical School, Dept of OB-GYN

**Karen Beckerman, MD**

Chair, Dept of OB-GYN  
Newark Beth Israel Medical Center

**Victoria Cargill, MD, MSCE**

Director of Minority Research  
National Institutes of Health

**Rebecca Clark, MD**

Associate Professor of Medicine  
LSU Health Sciences Center

**Robert Coombs, MD, PhD, FRCPC**

Professor, Laboratory Medicine and Medicine  
University of Washington

**Judith Currier, MD**

UCLA Care Center

**Rebecca Denison**

Executive Director  
Women Organized to Respond to Life-Threatening Disease (WORLD)

**Jeanne Dumestre, NP**  
LSU Health Sciences Center

**Ron Falcon, MD**  
Medical Director  
Tibotec Therapeutics

**Jane Hitti, MD**  
Dept of OB-GYN  
University of Washington Medical Center

**Katherine Hollinger, DVM, MPH**  
FDA / Office of Women's Health

**Tina Kanmaz, PharmD**  
Clinical Scientist  
Abbott Virology

**Veronica Miller, PhD**  
Director  
Forum for Collaborative HIV Research (FCHR)

**Levonne Mitchell-Samon, MD**  
University of Florida

**Karen Nielsen, MD**  
Associate Professor of Clinical Medicine  
Pediatric Infectious Disease  
University of California at Los Angeles

**Nancy Norman, MD, MPH**  
Medical Director  
Boston Public Health Commission

**Nancy Padian, PhD, MPH**  
Professor, Dept of OB-GYN and Reproductive Sciences  
University of California at San Francisco

**Andrew Pavia, MD**

Professor of Pediatrics and Medicine  
University of Utah

**Claire Rappaport**

Community Liaison  
International Network for Strategic Initiative in Global HIV Trials (INSIGHT)

**Star Seyedkazemi, PharmD**

Clinical Science Manager  
Abbott Laboratories, Virology

**Kathleen Squires, MD**

Director, Division of Infectious Diseases  
Thomas Jefferson University

**Melanie Thompson, MD**

Principal Investigator  
AIDS Research Consortium of Atlanta

**Jennifer Van Horn, MD**

Department of OB-GYN  
University of Utah