



# ALLIANCE FOR MICROBICIDE DEVELOPMENT

**14 November 2008, Volume 9, Number 45**

The Alliance for Microbicide Development News Digest is an unedited compilation of:

- Media coverage of microbicides;
- Abstracts of published articles on microbicides and relevant science;
- Material on other reproductive health and HIV prevention technologies; and
- Matters of politics and policy with importance for microbicide research, development, and advocacy.

Its purpose is to:

- Raise awareness around the broadest possible range of opinions and information about microbicides disseminated in scientific journals and the media; and
- Provide an objective basis for decision-making and evidence-informed advocacy.

Articles included in the Digest do not necessarily reflect the views of the Alliance. No press releases are included, however when information from a press release is picked up by the media, that coverage is included. To suggest material for inclusion, please contact [digest@microbicide.org](mailto:digest@microbicide.org).

The Digest is produced in a web-based format. Readers can view complete issues of the Digest or search by keyword for individual articles at [http://www.microbicide.org/cs/weekly\\_news\\_digest](http://www.microbicide.org/cs/weekly_news_digest). If you would like to be removed from the Digest distribution list, please send an email to [digest@microbicide.org](mailto:digest@microbicide.org). We welcome comments, questions, and ideas about other microbicide-relevant topics we might cover, services we might provide, and better ways of providing them!

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## 1. MEDIA COVERAGE OF MICROBICIDES

### "HIV prevention gets £220m research fund"

**Date:** 12 November 2008

**Source:** *BMJ*. 12 November 2008;337:a2466.

**Author(s):** Helen Macdonald

[http://www.bmj.com/cgi/content/extract/337/nov12\\_1/a2466?maxtoshow=&HITS=2&hits=2&RESULTFORM AT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfullt ext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct](http://www.bmj.com/cgi/content/extract/337/nov12_1/a2466?maxtoshow=&HITS=2&hits=2&RESULTFORM AT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfullt ext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct)

The UK government has announced a £220m (270m; \$350m) research fund to develop technologies for the prevention of HIV, to help stop the worldwide epidemic spiralling "out of control."

The fund will be used to develop products for neglected tropical diseases, including tuberculosis and malaria, as well as drugs, vaccines, and **microbicides** for HIV.

The fund was announced at a conference in London on ways to accelerate preventive strategies for HIV infection.

At the conference, Gareth Thomas, the United Kingdom's development minister, quoted figures from Thailand's AIDS programme, showing that \$1 spent in the 1990s on HIV prevention saved \$43 a decade later.

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**EDITOR'S NOTE:** *The full text of this article is available with a subscription at the above website.*

## "Researchers investigate acceptability of potential HIV prevention device in Africa"

**Date:** 11 November 2008

**Source:** *Physorg.com*

<http://www.physorg.com/news145637818.html>

For some women in the poorest parts of the Kenyan capital of Nairobi, being paid for sex is one of the few ways they are able to feed themselves and their children. In a region hit hard by the HIV/AIDS pandemic, they are at very high risk for contracting the disease.

Georgia State University researchers recently investigated whether these women, and their male clients, would accept a potential method of preventing HIV/AIDS which allows women to take control of their own health.

The device, an intravaginal ring containing chemicals **microbicides**, has the potential to let women reduce their risk of contracting the disease in an environment where many of their clients refuse to use condoms.

"This group of women are really stressed, and are often supporting children," said Donna Smith, a research associate with the Georgia State Institute of Public Health. "These are not women who are making a decent living. They're just getting by and just one client walking away could be the difference between eating or not."

Working with colleagues such as Frances Priddy of Emory University, as well as Sabina Wakasiaka and the late Job Joab Bwayo of Kenya AIDS Vaccine Initiative, Smith and data coordinator Tina Hoang asked questions among female sex workers in the Nairobi slum community of Mukuru.

Scientists are working to develop **microbicides** which reduce the spread of HIV, and several types which could be used by women are in development. None have been found yet which have been proven effective in reducing the transmission of HIV/AIDS, but it is believed that an effective one will be developed in the future before a vaccine becomes available, Smith said.

An intravaginal ring, similar to the NuvaRing used currently for birth control in developed countries, could be used to release the **microbicide**, allowing women to potentially use the device without their partner becoming aware of it.

In the qualitative study published in the *Journal of Women's Health*, some women reported that they were comfortable with the idea of using the ring without letting their partner know, however, some of the male clients insisted on knowing that it was being used — and that if they became aware of the device, they would not pay or would pay less.

Overall, though, those participating in the focus group research, sponsored by the CDC Foundation, were open to the use of the ring.

"This should be your secret," one woman responded. "You don't need to tell him. You would be protecting yourself from those who want to infect you."

Smith and Hoang are also working on a six-month cohort study to track rates of STD infection among sex workers, which will help give future **microbicide** and vaccine researchers more knowledge about high-risk populations.

### "Local university spear heads HIV prevention"

**Date:** 08 November 2008

**Source:** *WKYC.com (Cleveland, OH)*

[http://www.wkyc.com/news/health/health\\_article.aspx?storyid=100210&catid=7](http://www.wkyc.com/news/health/health_article.aspx?storyid=100210&catid=7)

A first-of-its-kind trial at the Case Western Reserve University/University Hospitals AIDS Clinical Trials Unit will look at two different methods of female-controlled HIV prevention: daily use of a vaginal **microbicide** and pre-exposure prophylaxis (PrEP), which involves taking an anti-retroviral pill everyday.

The trial offers women living in the Greater Cleveland area a unique opportunity to help alter the course of the worldwide AIDS epidemic.

The development of female-controlled HIV prevention methods is a research priority around the world, as the number of HIV-infected women continues to increase dramatically. Of the estimated 33.2 million people infected with HIV globally, 15.4 million are women. In sub-Saharan Africa where the HIV epidemic is most severe, close to 60 percent of those living with HIV/AIDS are women and girls.

This trial will investigate the use of **microbicides** and PrEP as methods focused on giving women control of their own preventative medicine. **Microbicides** are topical treatments in the form of a gel, foam, or cream that could decrease or prevent the sexual transmission of HIV.

The trial will also investigate PrEP, an approach based on the premise that a pill a day with an antiretroviral drug commonly used for treating HIV will also help prevent HIV infection.

The clinical trial -- named MTN-001 -- is the first to be offered at CWRU through the National Institutes of Health-funded **Microbicide** Trials Network.

The safety trial is enrolling healthy, sexually active, HIV-uninfected women, age 18-45.

"Because MTN-001 is an earlier phase trial, we are not seeking women who are at high risk for HIV infection. Nor does participation in the trial place a woman at risk for HIV infection," said Robert Salata, M.D., Chief, Division of Infectious Diseases and HIV Medicine, University Hospitals, and Principal Investigator for the MTN-001 Study at the Case Western Reserve University/University Hospitals AIDS Clinical Trials Unit. "MTN-001 is looking at the absorption, acceptability and adherence of the **microbicide** and PrEP drug in the participants who will use them over specific periods of time, not how effective the methods are in preventing HIV infection."

MTN-001 will provide important information for a larger MTN clinical trial at several sites in Africa that will evaluate how effective the **microbicide** and PrEP drug are for preventing HIV infection in women.

"It is important to conduct some of the earlier phase clinical trials in the United States," said Salata. "We have the ability to perform more sophisticated laboratory testing of local and systemic drug absorption. It is also important to demonstrate to the women of Africa that American women in our studies are taking the same **microbicide** and PrEP drugs that we are asking them to take in studies taking place there. In Greater Cleveland, we are seeking women who are motivated by their wish to empower women to protect themselves from HIV, and who are able to meet the medical, time and effort requirements to complete the trial."

The most effective method currently available for the prevention of HIV infection is the consistent use of condoms. However, research has shown that many women do not have the power to require their husbands or male partners to wear a condom during sexual intercourse. This is especially true in the developing world, but is also true in economically developed countries such as the United States.

Effective **microbicides** and/or PrEP would put HIV prevention in the hands of women. There are currently no commercially available HIV **microbicides** or medicines approved for PrEP.

MTN-001 is only being offered at two United States clinical trials sites, the Case Western Reserve University/University Hospitals Clinical Trials Unit and a site at the University of Pittsburgh. In addition, several sites in South Africa and Uganda are taking part in MTN-001.

Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases, with co-funding from the National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the National Institutes of Health. Case is one of 18 MTN-affiliated clinical research sites in seven countries that are devoted to reducing the sexual transmission of HIV through the development and evaluation of products such as vaginal **microbicides** and PrEP.

All those interested in participating in this important research may contact the Case Western Reserve University/University Hospitals AIDS Clinical Trials Unit. The trial will last approximately 21 weeks, with 12 clinic visits during that period of time. Compensation is provided to participants. All clinic visits will be at the Clinical Trials Unit site at University Hospitals. For more information on HIV **microbicide** trials in Cleveland, call 216.844.AIDS (2437) or go to [www.clevelandactu.org](http://www.clevelandactu.org).

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## **2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC**

**"Highly potent, fully recombinant anti-HIV chemokines: Reengineering a low-cost microbicide"**

**Author(s):** Gaertner H, Cerini F, Escola J, et al

**Reference:** Proc Natl Acad Sci USA. 12 November 2008;Epub ahead of print.

<http://www.pnas.org/content/early/2008/11/12/0805098105.abstract?maxtoshow=&HITS=2&hits=2&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%252C+microbicides&and>

**Published Abstract:** New prevention strategies for use in developing countries are urgently needed to curb the worldwide HIV/AIDS epidemic. The N-terminally modified chemokine PSC-RANTES is a highly potent entry inhibitor against R5-tropic HIV-1 strains, with an inhibitory mechanism involving long-term intracellular sequestration of the HIV coreceptor, CCR5. PSC-RANTES is fully protective when applied topically in a macaque model of vaginal HIV transmission, but it has 2 potential disadvantages related to further development: the requirement for chemical synthesis adds to production costs, and its strong CCR5 agonist activity might induce local inflammation. It would thus be preferable to find a recombinant analogue that retained the high potency of PSC-RANTES but lacked its agonist activity. Using a strategy based on phage display, we set out to discover PSC-RANTES analogs that contain only natural amino acids. We sought molecules that retain the potency and inhibitory mechanism of PSC-RANTES, while trying to reduce CCR5 signaling to as low a level as possible. We identified 3 analogues, all of which exhibit in vitro potency against HIV-1 comparable to that of PSC-RANTES. The first, 6P4-RANTES, resembles PSC-RANTES in that it is a strong agonist that induces prolonged intracellular sequestration of CCR5. The second, 5P12-RANTES, has no detectable G protein-linked signaling activity and does not bring about receptor sequestration. The third, 5P14-RANTES, induces significant levels of CCR5 internalization without detectable G protein-linked signaling activity. These 3 molecules represent promising candidates for further development as topical HIV prevention strategies.

**"Chemokine analogues show suitable stability for development as microbicides"**

**Author(s):** Cerini F, Landay A, Gichinga C, et al

**Reference:** J Acquir Immune Defic Syndr. 04 November 2008;Epub ahead of print.

<http://highwire.stanford.edu/cgi/medline/pmid;18989226>

**Published Abstract:** New prevention strategies are urgently needed to slow the spread of the HIV/AIDS pandemic, and in the absence of an effective vaccine, there is hope that "**microbicides**"-HIV inhibitors applied to mucosal surfaces before sexual intercourse-may be able to make an impact. Because developing countries are at the center of the epidemic, affordability and stability during storage are key criteria for candidate **microbicides**. Furthermore, because formulation strategies that provide long-duration protection after a single dose may enhance acceptability and compliance, stability in the vaginal environment and in the presence of semen should also be considered. PSC-RANTES, a human chemokine analog, has shown promise as a candidate **microbicide**, but because it contains nonnatural structures that necessitate chemical synthesis steps, it is not suitable for production at a feasible cost and scale for general distribution in developing countries. We have recently developed 2 new fully recombinant chemokine analogs, 5P12-RANTES and 6P4-RANTES, which show equivalent anti-HIV activity to PSC-RANTES. In this study, we tested the stability of these molecules under conditions related to use as **microbicides**. Our results suggest that stability issues will not present a major obstacle to the further development of these promising molecules as **microbicides**.

### 3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

#### **"Excretion of human immunodeficiency virus type 1 through polarized epithelium by immunoglobulin A"**

**Author(s):** Wright A, Lamm ME, Huang YT

**Reference:** J Virol. 01 December 2008;82(23):11526-35.

<http://jvi.asm.org/cgi/content/abstract/82/23/11526?etoc>

**Published Abstract:** Human immunodeficiency virus (HIV) is transmitted primarily sexually across mucosal surfaces. After infection, HIV propagates initially in the lamina propria below the polarized epithelium and causes extensive destruction of mucosal T cells. Immunoglobulin A (IgA) antibodies, produced in the lamina propria and then transcytosed across the mucosal epithelium into the lumen, can be the first line of immune defense against HIV. Here, we used IgA monoclonal antibodies against HIV envelope proteins to investigate the abilities of polarized primate and human epithelial cells to excrete HIV virions from the basolateral to the apical surface via polymeric Ig receptor (pIgR)-mediated binding and the internalization of HIV-IgA immune complexes. African green monkey kidney cells expressing pIgR demonstrated HIV excretion that was dependent on the IgA concentration and the exposure time. Matched IgG antibodies with the same variable regions as the IgA antibodies and IgA antibodies to non-HIV antigens had no HIV excretory function. A mixture of two IgA anti-bodies against gp120 and gp41 showed a synergistic increase in the level of HIV excreted. The capacity for HIV excretion correlated with the ability of IgA antibodies to bind HIV and of the resulting immune complexes to bind pIgR. Consistent with the epithelial transcytosis of HIV-IgA immune complexes, the colocalization of HIV proteins and HIV-specific IgA was detected intracellularly by confocal microscopy. Our results suggest the potential of IgA antibodies to excrete HIV from mucosal lamina propria, thereby decreasing the viral burden, access to susceptible cells, and the chronic activation of the immune system.

#### **"Bacterial vaginosis in HIV-infected women induces reversible alterations in the cervical immune environment"**

**Author(s):** Rebbapragada A, Howe K, Wachihi C, et al

**Reference:** J Acquir Immune Defic Syndr. 04 November 2008;Epub ahead of print.

<http://www.ncbi.nlm.nih.gov/pubmed/18989228>

**Published Abstract:** BACKGROUND:: Bacterial vaginosis (BV) has been associated with increased HIV cervicovaginal shedding. We hypothesized that this might relate to BV-associated increases in mucosal activated CD4 T cells, which could enhance local HIV replication. METHODS:: Vaginal flora, cytokine/chemokine levels, and mucosal immune cell populations collected by cervical cytobrush were

analyzed in 15 HIV-infected Kenyan female sex workers, before and after BV therapy with oral metronidazole. RESULTS:: Therapy reduced the Nugent score in all but 1 participant, and BV elimination was associated with reduced genital levels of interleukin 1beta(IL1beta), interleukin 8 (IL-8), and Regulated Upon Activation Normal T-cell Expressed and Secreted (RANTES). In addition, BV elimination reduced the total number of cervical CD4 T cells, including those expressing the HIV coreceptor CCR5 and the activation marker CD69. CONCLUSIONS:: BV induces significant and reversible alterations in cervical immune cell populations and local inflammatory cytokines that would be expected to enhance local HIV replication.

**"Human domain antibodies to conserved sterically restricted regions on gp120 as exceptionally potent cross-reactive HIV-1 neutralizers"**

**Author(s):** Chen W, Zhu Z, Feng Y, et al

**Reference:** Proc Natl Acad Sci USA. 04 November 2008;105(44):17121-26.

<http://highwire.stanford.edu/cgi/medline/pmid;18957538>

**Published Abstract:** The antibody access to some conserved structures on the HIV-1 envelope glycoprotein (Env) is sterically restricted. We have hypothesized that the smallest independently folded antibody fragments (domains) could exhibit exceptionally potent and broadly cross-reactive neutralizing activity by targeting hidden conserved epitopes that are not accessible by larger antibodies. To test this hypothesis, we constructed a large (size  $2.5 \times 10^{10}$ ), highly diversified library of human antibody variable domains (domain antibodies) and used it for selection of binders to conserved Env structures by panning sequentially against Envs from different isolates. The highest affinity binder, m36, neutralized all tested HIV-1 isolates from clades A- D with an activity on average higher than that of C34, a peptide similar to the fusion inhibitor T20, which is in clinical use, and that of m9, which exhibits a neutralizing activity superior to known potent cross-reactive antibodies. Large-size fusion proteins of m36 exhibited diminished neutralizing activity but preincubation of virions with soluble CD4 restored it, suggesting that m36 epitope is sterically restricted and induced by CD4 (CD4i). M36 bound to gp120-CD4 complexes better than to gp120 alone and competed with CD4i antibodies. M36 is the only reported representative of a promising class of potent, broadly cross-reactive HIV-1 inhibitors based on human domain antibodies. It has potential for prevention and therapy and as an agent for exploration of the closely guarded conserved Env structures with implications for design of small molecule inhibitors and elucidation of mechanisms of virus entry and evasion of immune responses.

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#### **4. OTHER PREVENTION APPROACHES**

## **"Girls view HIV contraction as stigma"**

**Date:** 10 November 2008

**Source:** *The Times of India*

**Author(s):** Avanindra Mishra

<http://timesofindia.indiatimes.com/articleshow/3693392.cms>

It's one of the deadliest diseases and, of course, the most talked about one. Yes, you guessed it right, it's AIDS (acquired immuno-deficiency syndrome). But interact with them and most of the girls in the city could tell you the least about it. And the piloting slogan of almost all the anti-AIDS campaigns in the country is: 'Awareness is prevention'!

According to a survey conducted in three girls' colleges here, more than 50% students still believe that even a simple physical contact can lead to HIV transmission. What's more disheartening is the fact that 31% of them believe that the disease is a "cause of shame".

The survey, aimed at assessing the level of awareness regarding HIV/AIDS among college girls in the city, was conducted by two school girls from Delhi under the guidance of a lecturer in Parekh PG Girls' College.

During the survey, 600 girls in the age group of 15-19 years studying at Parekh PG Girls' College, International College for Girls and Maharani Girls' College in the city were approached between September 15 and October 15. Of them, 537 responded to the queries.

"Prevention of infection is an issue being addressed by the media and awareness-spreading voluntary organizations. But the information peters out at the stage of infection. There is minimal mention of treatment and post-diagnosis measures. The social problems arising with diagnosis are rarely addressed," reveals the study.

Even more disappointing is the fact that 22% of the respondents still believe that AIDS patients should be treated in isolation. Gender inequality and lack of availability of authentic sex education turned out to be the biggest challenges, though a rise in the awareness level was observed.

"It was discovered that the knowledge towards the disease is rising among the youth but when it comes to social and moral consequences of HIV infection, there still prevails a lot of confusion in their mind," said Nivedita Singh, one of the student surveyors.

"Our field strategy is structured with young women due to their higher responsiveness and ability to serve as more effective disseminators of information," she added.

Still a high school student, she, along with classmate and co-surveyor Niharika Singh, was motivated to conduct the survey and spread AIDS awareness after being appointed as a peer councillor in her school.

Commenting on the findings, a health official said that the awareness level about AIDS is increasing in the state but the study shows just how much more effort is required in this direction.

Jaipur being the state capital and a prominent education centre, students from all over the state with diverse economic backgrounds come here to pursue their studies at the city colleges. Hence, the city was chosen as a suitable place for the survey.

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## 5. POLITICS AND POLICY

### "More countries make spreading HIV a crime"

**Date:** 13 November 2008

**Source:** *Associated Press*

**Author(s):** Maria Cheng

[http://news.yahoo.com/s/ap/20081113/ap\\_on\\_he\\_me/eu\\_med\\_hiv\\_laws](http://news.yahoo.com/s/ap/20081113/ap_on_he_me/eu_med_hiv_laws)

An increasing number of countries worldwide are making spreading HIV a crime, according to a new report from the International Planned Parenthood Federation.

Health officials fear the trend could undermine gains made in fighting the AIDS pandemic and provoke a surge in cases. Globally, about 33 million people are thought to have HIV and nearly 3 million people are newly infected every year.

"If the law is applied badly, this could set us back and do incredible damage," said Paul de Lay, an AIDS expert at UNAIDS, who was not involved in the report.

De Lay said the laws could result in forced testing and drive the epidemic underground as people hide their HIV status, allowing the virus to spread unnoticed.

According to Planned Parenthood, 58 countries worldwide have laws that criminalize HIV or use existing laws to prosecute people for transmitting the virus. Another 33 countries are considering similar legislation.

Since 2005, seven countries in West Africa have passed HIV laws. In Benin, simply exposing others to HIV is a crime, even if transmission doesn't occur. And in Tanzania, intentional transmission of the virus can lead to life imprisonment.

Many of the laws in Africa were passed after a meeting in Chad in 2004 sponsored by the U.S. Agency for International Development, the world's biggest funder of AIDS programs, and attended by U.N. officials.

"The U.N. was definitely remiss to allow this to happen," said Kevin Osborne, a senior HIV adviser at IPPF and one of the report's authors.

De Lay said UNAIDS found out about the meeting only after it happened.

But poor countries aren't the only ones using these laws.

In the U.S., 32 states have laws criminalizing HIV transmission. Experts estimate that thousands of people have been charged across the country with spreading HIV.

Since 2001, 16 people in the United Kingdom have been prosecuted for spreading HIV.

In 2005, a woman in Canada was charged with criminal negligence and aggravated assault for passing HIV while pregnant to her baby.

She did not tell her doctors that she had HIV and did not receive the medications necessary to prevent the virus from infecting her child. She was sentenced to a six-month conditional sentence followed by three years of probation.

In countries like Britain, Canada and the U.S., which are major donors of efforts to fight AIDS in Africa, such cases are particularly unfortunate, many experts say.

"It sets a poor example in the sense that other countries may then think this is an appropriate or desirable way to deal with HIV," said Richard Elliott, executive director of the Canadian HIV/AIDS Legal Network.

While there might be exceptional cases where prosecuting people who are maliciously spreading HIV makes sense, experts said those were extreme cases.

"The criminal law is a blunt instrument," Osborne said. "If you put everyone in prison with HIV, then you think you've controlled it. But you haven't dealt with the issues around the intimate behaviors that spread HIV."

### **"Condoms trump abstinence in Obama global AIDS policy"**

**Date:** 10 November 2008

**Source:** *Bloomberg News*

**Author(s):** Jason Gale, John Lauerman

<http://www.bloomberg.com/apps/news?pid=20601087&sid=aKrlK33ovrk8&refer=home>

President-elect Barack Obama will reverse U.S. family-planning and AIDS-prevention strategies that have long linked global funding to anti-abortion and abstinence education, a public-health adviser said.

Public-health policies of President George W. Bush's \$45-billion PEPFAR program have brought AIDS drugs to almost 3 million people in poor countries such as Rwanda and Uganda, more than under any other president. Still, requirements that health workers emphasize abstinence from sex and monogamy over condom use have set back sexually transmitted disease prevention and family planning globally, said Susan F. Wood, co-chairman of Obama's advisory committee for women's health.

"We have been going in the wrong direction and we need to turn it around and be promoting prevention and family-planning services and strengthening public health," said Wood, a research professor at George

Washington University School of Public Health in Washington.

Bush on his first day in office, in January 2001, reinstated the so-called Mexico City Policy -- known to critics as the global gag rule. It bars U.S. family-planning assistance for organizations that use funding from any other source to provide counseling and referral for abortion, lobby to make abortion legal or more available in their country, or perform abortions except in cases of a threat to the woman's life, rape or incest.

Obama ``is committed to looking at all this and changing the policies so that family-planning services -- both in the U.S. and the developing world -- reflect what works, what helps prevent unintended pregnancy, reduce maternal and infant mortality, prevent the spread of disease," Wood said.

### *Gag Rule*

Wood resigned as the top U.S. regulator for women's health in 2005 in protest of the Food and Drug Administration's delay in clearing over-the-counter sales of the ``morning after" emergency contraceptive. Sale of the pill, called Plan B, without a prescription was held up for more than two years, after FDA staff recommended its approval in 2003.

Critics of the FDA have named Wood as among candidates they would like Obama to consider for the agency's next commissioner.

``A lot of the family-planning associations in Africa refused the terms of the gag rule and they lost funding, they lost technical assistance and they lost contraceptives," said Wendy Turnbull, a senior policy research analyst with Population Action International in Washington.

On the basis of that policy, Bush halted support for the United Nations Population Fund in 2002, saying it supported ``coercive" abortion programs in China -- an allegation the New York-based agency has denied. The directive cost the fund more than \$200 million in lost funding, said William Ryan, a Bangkok-based spokesman for the agency.

### *Condom Use*

Restrictions on education about condom use have hamstrung effective promotion, and the U.S. Centers for Disease Control and Prevention has had some condom information pulled from its Web Site, said Gill Greer, director general of the International Planned Pregnancy Federation in London.

``The U.S. administration has certainly succeeded in demonizing condoms rather than showing that they can be part of prevention of both unplanned pregnancy and sexually transmitted infections," she said in a telephone interview. ``I've always joked that the whole world should vote in the U.S. election because the whole world is so affected."

Under President Bush, the U.S. has provided more money to fight AIDS than during any other administration. Seven years ago, before the Bush program began with about \$15 billion, only about 200,000 people in poor nations got treatment, and few of them were in Africa.

### *Abstinence Success*

The emphasis on abstinence and fidelity "has been shown to have demonstrable success in Africa," said Valerie Huber, executive director of the National Abstinence Education Association in Washington. "It would be more than unfortunate if that policy was changed."

Both Republicans and Democrats have indicated support for the focus on abstinence and education that goes along with PEPFAR, which has also been shown to reduce the spread of HIV in countries such as Uganda, Huber said.

"If the president-elect wants to be science-based in foreign sex-education policies, it would be wisest to continue this way because it's shown to be effective," she said.

Calls to the office of Mark Dybul, coordinator for the Bush AIDS treatment program, weren't returned.

### *Prevention Quest*

The decision to focus on abstinence was "naïve and dangerous," and neglected prevention techniques with the most science behind them, said Mitchell Warren, executive director of the New York-based AIDS Vaccine Advocacy Coalition.

"Everyone pretty much expects we'll see a return to a true science-based response to HIV under Obama," he said in a telephone interview. "We've seen eight years of a focus on things we know don't work."

Without a vaccine, AIDS advocates are looking for ways to slow the spread of the HIV virus that currently infects about 33 million people worldwide. Treatment, even with cheaper versions of HIV drugs, is beyond the means of many patients in Africa, where about 24 million infected people live.

The U.S. has played an important role in bringing life-saving treatment to HIV patients who had been unable to get it, said Adel Mahmoud, a former head of Merck & Co. vaccines and professor in the department of molecular biology at Princeton University.

"But when the data says for every person we put on anti-retroviral therapy in Africa there are six new infections and we are doing nothing about it, it's absolutely mind-boggling," he said in a telephone interview. "Prevention is really the solution."

### *U.S. Influence*

Wood said that, in recent years, the U.S. government has influenced and "tightly vetted" international organizations to reflect its own policies.

Obama will bring "back a sense of balance and perspective and the use of good science and good medicine in these positions, and not just this narrow, political ideology," she said.

