



ALLIANCE FOR MICROBICIDE DEVELOPMENT

15 June 2007, Volume 8, Number 23

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

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

Its purpose is to:

- Raise awareness around the range of opinions and information about microbicides disseminated in the press and scientific journals; and
- Provide a neutral, objective basis for decision-making and evidence-based advocacy.

The *News 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/publications/>. If you would like to be removed from the *Digest* distribution list, please send an email to 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. ALLIANCE UPDATES AND COMMUNITY NEWS

The Alliance welcomes our new Writer/Research Associate

The Alliance is pleased to welcome our new Writer / Research Associate, Stephanie Tillman. Stephanie holds a BA in Global Health from the University of Michigan - Ann Arbor, where she also earned a minor in Medical Anthropology. Stephanie's academic background focused on sexual identity and empowerment, male and female reproductive health, and health disparities from both public health and social work perspectives. During her studies, she worked as a Sexual Health Educator and helped to pilot Michigan's two-time award winning peer health advocacy student group, PULSE, which reached out to all communities on campus through confidential peer-support interactions and informative programming. Stephanie also worked extensively abroad in both the developing and developed world. Her

work in Malawi focused on sexual health education and behavior modification, specifically with youth, village chiefs and commercial sex workers. Stephanie also assisted with research into the Safe Motherhood Initiative's immediate impact on maternal health in rural Honduras while providing doula support in a birth center. In Budapest, Stephanie compared sexual health education, contraceptive access, and support for the LGBTQ community in Hungary's transitioning healthcare system to that of the current American system. Other long-term research projects included maternal nutrition and breastfeeding, women's agency in sexual decision making in developing nations, birth in lesbian and gay communities, and international and domestic family planning education.

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2. MEDIA COVERAGE OF MICROBICIDES

"Funding and support needed for microbicides"

Date: 14 June 2007

Source: *RH Reality Check*

Author(s): Dawna Cornelissen

<http://www.rhrealitycheck.org/blog/2007/06/14/funding-and-support-needed-for-microbicides>

Over the last 20 years, researchers and activists have taken interest in a product that could be the most important innovation in reproductive health since the pill: **microbicides**. Like the pill, **microbicides** are being promoted as a woman-controlled or initiated prevention method. But, unlike the pill, **microbicides** go beyond just preventing pregnancy to preventing sexually transmitted infections (STIs) as well. In fact, at this point the prevention of STIs, with an emphasis on Human Immunodeficiency Virus (HIV) prevention, makes up the majority of **microbicide** research, development, and advocacy. Although they are not yet available, it is hoped that **microbicides** will greatly reduce the transmission of HIV worldwide.

Generally, an ideal **microbicide** would be odorless, colorless, tasteless, non-irritating, fast-acting, long-lasting, inexpensive to manufacture and purchase, and available in contraceptive and non-contraceptive forms. **Microbicides** come in a variety of forms, including gels, creams, films, suppositories, pre-loaded diaphragms or cervical caps, sponges, vaginal rings, etc. Although most **microbicides** are designed to be applied topically to the vagina, there are some baseline studies being done on rectal **microbicides**.

The woman-controlled strategy employed by **microbicide** advocates is in response to both social and biological factors uniquely affecting women. Social factors like gender inequality and violence against women have led to the feminization of HIV. Biological factors affecting women include women being more likely than men to contract HIV after just one exposure. Worldwide there are now more adult women (15 years or older) than ever before living with HIV. According to UNAIDS, the 17.7 million women living with HIV in 2006 represents an increase of over one million compared with 2004. Clearly, **microbicide** research and development is greatly needed.

A key factor in getting **microbicides** available to the public is adequate funding. One way that advocates of **microbicides** are attempting to increase U.S. government funding is through legislation that would establish and coordinate units specifically designed for **microbicide** research and development. One piece of legislation that attempts to do this is the **Microbicide** Development Act (MDA). It is hoped that with this bill, **microbicide** funding will soon become the priority it should be in the federal government's budget to combat HIV/AIDS. Versions of the MDA have been introduced seven times since 2000, but none have ever passed. It was most recently introduced again in both the House and the Senate on March 8, 2007 (International Women's Day). The Senate version currently has 18 cosponsors and the House version has 54 cosponsors; both versions are in committees.

Although the U.S. government has appropriated some funding, it has not been adequate to produce an effective **microbicide** for public use. According to the Global Campaign, barely 3% of the U.S. budget for HIV/AIDS research is spent on **microbicide** research and development. Passing the MDA would help to secure the funding needed by coordinating **microbicide** research and development efforts within the three U.S. federal agencies already involved in HIV/AIDS research. It is unclear why exactly the MDA has not received adequate support from Congress in the past. I would hope that curbing and hopefully stopping not only the spread of STIs, but also the HIV/AIDS pandemic is important to the United States. To learn more about what you can do to support the MDA, visit the Global Campaign for **Microbicides**.

"Improving the outlook for women-initiated dual protection"

Date: 14 June 2007

Source: *RH Reality Check*

Author(s): Maggie Kilbourne-Brook

<http://www.rhrealitycheck.org/blog/2007/06/14/improving-the-outlook-for-women-initiated-dual-protection>

Despite the success of family planning programs worldwide, more than 120 million couples who do not want to get pregnant lack access to contraceptives to delay or space births. Consequently, women in many regions continue to experience high rates of unintended or unwanted pregnancies, with high rates of pregnancy-related morbidity and mortality.

Women also represent a disproportionate percentage of people living with AIDS. Sexually transmitted infections (STIs) represent the second most prevalent cause of poor health in women, especially young women. Almost two decades ago, women identified their need for more options to protect themselves against pregnancy and STIs. PATH, an international nonprofit organization based in Seattle, has developed two new technologies to improve women's options for protection from pregnancy and STIs.

The SILCS diaphragm is a single-size, reusable cervical barrier that provides a new option for dual protection. Standard diaphragms are difficult to supply in low-resource settings because they come in many sizes and require a trained provider to fit them. The SILCS diaphragm's single-size design overcomes these obstacles and offers discreet protection for women whose partners cannot or do not want to use a male or female condom.

Women evaluated hundreds of prototypes during the design process to enable PATH researchers to refine the features of the SILCS device. The result is a design that is easy to use, comfortable, and acceptable for both women

and their partners. The benefit of this user-centered design process is that acceptability is built in at every step. Couples participating in studies in South Africa, Thailand, the Dominican Republic, and the United States reported that the SILCS diaphragm was easy to use and acceptable, even when women had no previous diaphragm experience.

Clinical studies have also shown that the SILCS device fits most women and performs as well as a standard diaphragm. The large clinical study to evaluate contraceptive effectiveness of the device will be launched later this year in the United States. The SILCS diaphragm could be approved for marketing as a contraceptive by the United States Food and Drug Administration (USFDA) by 2010.

Now PATH and others are interested in evaluating the SILCS diaphragm as a **microbicide** delivery system. Using a **microbicide** with the SILCS device would enhance the partial effectiveness of both methods for increased protection. Plus, using the SILCS diaphragm to deliver a **microbicide** could reduce messiness of a gel alone and allow women to insert gel in advance of sexual intercourse - a real advantage for those who want to be spontaneous.

Female condoms are another important product that offers dual protection. Recent international declarations have identified access to female condoms as an integral component to ensuring universal access to HIV prevention, treatment, and care. However, in most countries male condoms still are the only method available for HIV/AIDS prevention. Wider access to female condoms, as well as male condoms, is needed to deliver on our commitment to protecting women's health.

The Female Health Company currently produces the only globally available female condom providing dual protection against unwanted pregnancy and STIs including HIV. The FC Female Condom™,® was approved by the USFDA and has been introduced in nearly 100 countries. In 2005, Female Health Company launched its second-generation product, the FC2, which offers the same product characteristics but with a potentially lower cost.

Based on a decade of women's experience with the first female condom (FC Female Condom™,®), and working closely with women in Mexico, South Africa, Thailand, and the United States, PATH developed an improved female condom. The PATH Woman's Condom is easy to handle and insert, stays stable in the vagina during use, and is comfortable for both partners - all improvements over the existing product that users asked for.

The design was completed in 2003, and the Woman's Condom was tested by couples in three countries in 2004 for acceptability. Over 90 percent of these couples, including nearly half who had no previous female condom experience, were satisfied with its performance for ease of use, stability, comfort, and sensation. Additional independent trials of the PATH Woman's Condom in 2005 confirmed good acceptability and easy use and showed women's preference for the PATH condom over the FC Female Condom™,® by about 2 to 1. PATH is planning for the clinical trials required for market approval. The product could be available in one or more countries within the next three to four years.

No single product will meet the needs of all couples for protection across their lifetime. Couples need access to a choice of barrier protection products to find the ones that will be acceptable and appropriate in different relationships and at different stages of life. However, products that are easy to use, broadly acceptable, and introduced as part of a comprehensive dual-protection program will lead to higher levels of protected sex. The women-centered design process used for both the SILCS diaphragm and the Woman's Condom helped PATH develop products that are easy to use, widely acceptable, and have broad cultural relevance. The next steps are to identify the commitment to bring these products to market and invest in comprehensive programming to ensure product availability.

These products were developed with funding from the United States Agency for International Development (USAID) through the CONRAD program, and also with support from the Bill & Melinda Gates Foundation, The Lemelson Foundation, and other donors.

"Spanish government contributes 1 Million euro for AIDS vaccine development"

Date: 14 June 2007

Source: *PRNewswire*

<http://www.prnewswire.co.uk/newsindex.shtml?/news/bydate.shtml>

The International AIDS Vaccine Initiative (IAVI) and the Spanish AIDS NGO grupo de Trabajo sobre tratamientos del VIH (gTt) are grateful to the Spanish government for their one-year contribution of one million Euro to IAVI for the development of an AIDS vaccine. Leire Pajin, the Secretary of State for International Cooperation, made the announcement about the new appropriation during an international seminar on AIDS vaccines in Madrid. This is first grant from the Spanish government to IAVI.

"We are very grateful to the Spanish government for making such as an important contribution to our organization," said Frans van den Boom, Vice President of IAVI's European Programme. "It strengthens Europe's leading role with now eight governments and the EU supporting the development of an AIDS vaccine."

Despite efforts to control the AIDS epidemic, every day another 12,000 people become newly infected with HIV. The vast majority of these people live in developing countries, and many are women and girls.

The development of AIDS vaccines is an essential component in the global response to the AIDS pandemic. Access to available treatment and care is vitally important, but with the same urgency investments are also required in new AIDS prevention technologies, such as vaccines and **microbicides**.

The support from the Spanish and other governments allows IAVI to address some of the most critical questions in AIDS vaccine science, to continue clinical testing of promising AIDS vaccine candidates, to build infrastructure for research and development in India and African countries and to prepare communities for larger-scale AIDS vaccine clinical trials.

"This announcement is the result of joint advocacy efforts by Spanish AIDS and development NGOs, members of parliament and IAVI that have been sustained over the past years," said Joan Tallada, General Coordinator of gTt.

"We are very proud that the Spanish government is making funds available to IAVI for the development of an AIDS vaccine. It is our hope that Spain will continue to partner with us over the long-term in our efforts to find a vaccine."

History has shown that vaccines are extremely effective in controlling infectious diseases, and an AIDS vaccine, once available, will have a major impact on the AIDS epidemic. Estimates suggest even a partially effective AIDS vaccine distributed to just 30% of the population would cut 17 million new infections over the course of 15 years, an important step to eradicating AIDS over the coming decades.

"A new, female UN voice for AIDS in Africa"

Date: 12 June 2007

Source: *CanWest News Service*

Author(s): Kate Heartfield

<http://www.canada.com/victoriatimescolonist/news/comment/story.html?id=6e27e7de-11b5-4cd9-b08e-02f861134d4f>

Asking stupid and rude questions is part of my job. So I make no apologies for asking Elizabeth Mataka, who has replaced Stephen Lewis at the United Nations, whether she has personal experience with AIDS.

There's a pause at the other end of the phone line to Zambia, then: "My dear, in this part of the world, there is not a single person." She starts again, with a little less exasperation. "I am speaking as a person who has lost relatives, who has lost workmates, who has had to feed people who have HIV/AIDS. So yes, it is a personal epidemic."

It is a personal epidemic for almost everyone in Sub-Saharan Africa, especially for the women who are dying and nursing the dying, and that's what people in Canada just don't get. That's why Lewis was adamant that his successor be an African woman. Lewis was, until the end of last year, the UN Special Envoy for AIDS in Africa.

Mataka was born in Botswana and lives in Zambia. She is not only an African woman, but also an African grandmother -- a member of a group the Stephen Lewis Foundation champions. Not that those are her only qualifications. She is a social worker and has policy experience with the epidemic, having been a member of AIDS organizations in Zambia. She is vice-chairwoman of the board of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Ban Ki-moon, who became UN secretary general in January, took his time with many key appointments. The AIDS-in-Africa posting sat vacant until Mataka was appointed last month. Mataka still hasn't met Ban. A couple of weeks into her appointment, she spoke strongly about the need for the G8 leaders to stay committed to the goal of universal access to treatment, which the UN defines as 80 per cent. Three years from now, at least 11 million people will need AIDS treatment. These are numbers too big to ignore.

The people of Zambia and Botswana have a life expectancy of about 37 years, among the lowest in the world, and only slightly better than neighbouring Zimbabwe. Lewis, in *Race Against Time*, wrote of meeting a group of citizens in Zambia, and noticing that the only people around were grandparents, children and very young mothers.

"There it was, visually: The new face of large parts of Africa," he recalled. "Or perhaps one should say, the absent face of Africa."

From what I can tell from one phone interview, Mataka seems likely to be just as passionate and outspoken as Lewis. Yet they will be speaking, in the main, to different audiences. "We are two completely different people with two completely different backgrounds," she tells me.

Lewis has been influential in Canada because of his charisma and compassion. He continues to be the conscience of rich countries. Mataka isn't yet a household name in the rich world; she doesn't even have a Wikipedia page yet. But we don't really need another Stephen Lewis. Mataka can be, instead, the conscience of poor countries. She speaks in

practical terms about the need for women in Zambia to have economic and social power.

"Female condoms are expensive, they are not user-friendly, they are not readily available. So women need to address the power dynamics in their relationships."

And, I imagine, she can represent the needs of those countries to the men in suits in New York or Geneva or Davos or wherever. A single "my dear" from her would cow even the most severe international bureaucrat. She is eager to see science help women empower themselves, through the ongoing work on the development of a **microbicide**, for example.

AIDS is becoming a woman's disease in sub-Saharan Africa, where 4.6 per cent of young women are living with HIV (contrast that with 1.7 per cent of young men). But Mataka, on the ground, sees positive change that we faraway observers don't. "Women are actually talking about their situation," she notes. "That was unheard of a few years ago. This very morning, I was at a workshop where women were talking about the power dynamics in their own homes that make them vulnerable to the epidemic."

The job of special envoy is a really just a platform. Its influence depends on the energy of the person holding the position. Whether Mataka will be a successful advocate for the people of Africa depends largely on her ability to withstand the contrast between tragedy and indifference, day in and day out, and never despair.

"Dicing with death a game for 'playas'"

Date: 10 June 2007

Source: *Sunday Times*

Author(s): Claire Keeton

<http://www.sundaytimes.co.za/PrintEdition/News/Article.aspx?id=487559>

Risky sex is part of a recreational pattern. "Playas" who average six girlfriends in three months, people living with HIV and those with sexually transmitted infections who drink alcohol are among the groups being targeted to stop the spread of HIV.

The need for focused, effective HIV prevention programmes was high on the agenda at the third South African Aids Conference in Durban this week.

Dr Mickey Chopra from the Medical Research Council's Health Systems Research Unit, who presented survey results on men with high-risk sexual habits, said: "There is little information about these men. Prevention strategies have not had the impact they should have had and they have been very general. Now we need to focus on understanding the key sexual networks that are driving the epidemic."

For this research, Chopra's team recruited men from Khayelitsha who had more than one partner, and had at least one partner three years younger than them. Some 400 men joined the study last year; their number of partners over three months ranged from two to 39, with the average being six partners. When it comes to HIV risk, Chopra said these "playas" tended to be a hidden group; the sugar daddies with the Mercedes-Benz cars were a more visible problem, he said.

"These playas were a bit better off [than most residents], had a better education and were more likely to be employed," he said of the men surveyed. Their average age was 28 and most were unmarried.

The key findings were that:

- These men tended to have a "steady girlfriend" from Monday to Friday but on weekends had sex with casual girlfriends known as kwapheni or once-off girlfriends;
- The vast majority of their friends thought it was acceptable for them to have multiple partners and their status diminished if they did not;
- They used condoms only about a third of the time with their steady girlfriends, and about 51% of the men had inconsistent condom use with their casual partners;
- They had more than double the incidence of HIV, when compared with the general population (12% versus 5%); and
- They did not think they were at risk of HIV, even though they practised risky sex .

Chopra said: "We found these men had quite distinct rituals in the way they spent their recreational time. On Fridays they would often meet up with a small group of friends at somebody's house and always end up at a tavern or shebeen, where they would meet certain women. Sometimes they would drive somewhere to find 'fresh fields'."

Chopra said the Western Cape government was looking at what steps it could take to stop these patterns - like targeting recreational venues without alcohol. He said most shebeen owners were supportive of HIV prevention.

Meanwhile, another study showed that short-term counselling could dramatically decrease the rate of unsafe sex among participants. This was according to researcher Professor Seth Kalichman of the Human Sciences Research Council and the University of Connecticut.

One-hour counselling sessions were conducted among 143 participants (all drinkers) at a Cape Town clinic for sexually transmitted infections. The results included a 65% reduction in unsafe sex over a follow-up period of six months.

Kalichman said: "Unlike the International Aids Conference in Toronto last year, which was very depressing because it focused on what we wish we had (vaccines and **microbicides**), the South African conference is clearly asking for behavioural intervention, which does work and is available now. But the interventions must also be science based - not just education and condoms." He highlighted the importance of "positive prevention" directed at people living with HIV. This is one of the priorities of South Africa's New Strategic Plan on HIV/Aids.

"Combining prevention services for the most at-risk HIV- negative groups with universal access to HIV testing and positive prevention offers the best opportunity to control HIV/Aids in Africa," he said, quoting from the Journal of the American Medical Association.

"Women call for own HIV measures"

Date: 10 June 2007

Source: *Daily Monitor (Uganda)*

Author(s): Jan Ajwang, Grace Natabalo

<http://www.monitor.co.ug/sunday/news/news06102.php>

As efforts to curb HIV/Aids prevalence in Uganda continue, a minister has called for increasing female controlled preventive measures. Ms Rukia Nakadama, the Minister of State for Gender said that more women were getting infected by HIV than their male counterparts. She said this calls for methods that can safeguard women's health.

"New and long-term prevention methods are needed, particularly methods that are within the realm of women's control," Ms Nakadama said on Friday. She was addressing delegates at the opening of the Commonwealth Partners Forum conference on gender and new preventive technologies at Speke Resort Munyonyo in Kampala. The conference was premised on the theme: "Investing in Gender Equity: Ensuring the Development of and Access to New Prevention Technologies". The conference was a build up to the Eighth Women Affairs Ministers Meeting scheduled for June 11-14. Downplaying the use of the male condom, Ms Nakadama said the contraceptive does not empower women sexually because they do not have control over its usage. "They [women] have no control over the condom and instead have to depend on the man to protect themselves, making them more vulnerable to HIV/Aids," Ms Nakadama said.

She said this was a major cause of increasing HIV infections among married couples because the women cannot do anything to prevent it. She instead encouraged the use of New Preventive Technologies (NPTs) that favour women to protect themselves without having to depend on their male partners. Nakadama cited methods such as cervical barriers, **microbicides** and vaccines as those that can empower women. Dr Florence Mirembe, a gynaecologist from Makerere University's Medical School, told the delegates that **microbicides** are substances that can be applied topically before sexual intercourse to prevent HIV infection and other sexually transmitted infections. She said the **microbicides** include gels, creams, suppositories, foams, sponges and vaginal rings.

"**Microbicides** have potential to prevent HIV infection in both men and women by creating a mechanical barrier, prevention of multiplication, directly killing the virus and bringing about an immune reaction," Dr Mirembe said.

Microbicides are one of the new technologies towards HIV prevention but are still under research.

She said the **microbicides** are women controlled, easier to use than female condoms and do not always require cooperation of one's partner. Ms Nakadama said there is need to highlight NPTs as important health tools for women and girls as HIV is taking a disproportionate toll on them. The female condom was introduced a few years ago to control HIV infection but it has failed to become popular among women. "Some women said it looked like a sack and others said it was giving them difficulty during sexual intercourse. Maybe they need a different shape that is pleasing," Dr Kihumuro Apuuli, Director of the Uganda Aids Commission, said.

In a draft communiqué from the meeting expected to be fed into the Eighth Women Affairs Ministers Meeting agenda, the panel of doctors called for the government to channel more resources to finance the NPTs. Presenting the communiqué, Dr Grace Bantebya, the chairperson of the Uganda Women Network, said "the key message is that government must invest more in new technologies and increase funding in the already existing ones to have an effective strategy against HIV/Aids."

"South African AIDS delegates issue contraception call"

Date: 08 June 2007

Source: *Agence France Presse*

http://ca.news.yahoo.com/s/afp/070608/health/safrica_health_aids&printer=1

South Africa's national AIDS conference wrapped up on Friday with delegates issuing a call for contraception to be made more widely available and for more research into prevention methods.

Male circumcision and female condoms both needed to be more readily obtainable, delegates said in a draft declaration document which also outlined new suggestions over the topic of testing. "Circumcision should be conducted, preferably before males become sexually active," reads the document obtained by AFP.

During the four-day conference, scientists argued it was time to implement recommendations by the United Nations' World Health Organisation (WHO) for the use of male circumcision to prevent HIV infections, criticising the government for failing to move towards a widespread circumcision programme.

"Although the routine nationwide implementation of the WHO guidelines is not feasible at present, circumcision should ultimately be available and accessible to every man," delegates said.

The third national conference also focused on gender issues, lamenting on continued violence towards women who are the majority of South Africa's 5.5 million HIV sufferers.

Njongonkulu Ndungane, the Anglican archbishop of Cape Town, called for an end to macho attitudes that saw men treat women as second-class citizens. "So I dream that our eyes will be opened and our cultures will be transformed. Women will freely be able to negotiate safe sex and fathers will not blame mothers for their HIV infections," said the archbishop.

Female condoms which have been shown to prevent HIV and also put the onus of protection onto women were not as widely available as they should be, said the declaration. "We commit ourselves to increasing the supply of female condoms to meet the demands ... expanding the range of female condoms (and) advocating for a reduction in the cost of female condoms," it added.

Much research is currently under way in South Africa towards developing female **microbicides** and new HIV vaccines and delegates agreed they would like to see more investment on research. During the conference there was also a call to make AIDS drugs more accessible with one non-governmental organisation, the AIDS Law Project, threatening pharmaceutical giants MSD and Abbott with a law suit if they did not issue licences for generic versions of two drugs within three months.

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3. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Cell surface expression of CCR5 and other host factors influence the inhibition of HIV-1 infection of human lymphocytes by CCR5 ligands"

Author(s): Ketas TJ, Kuhmann SE, Palmer A, et al

Reference: N/A 364(2):281-90. E. pub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=17428518&ordinalpos=9&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Published Abstract: Several CCR5 ligands, including small molecules and monoclonal antibodies (MAbs), are being developed as therapies for infection with strains of human immunodeficiency virus type 1 (HIV-1) that use CCR5 for entry (R5 viruses). The efficacy of such therapies could be influenced by inter-individual differences in host factors, such as CCR5 expression levels. To study this, we used peripheral blood mononuclear cells (PBMCs) from humans and rhesus macaques. The half-maximal inhibitory concentrations (IC(50)) of the small-molecule CCR5 ligands CMPD167, UK427,857 and SCH-D, and of the PRO 140 MAb, differ by >2 logs in a donor-dependent manner. We studied this variation by using flow cytometry to measure CCR5 expression on PBMCs from six of the human donors: the IC(50) values of both SCH-D and PRO 140 correlated with CCR5 expression ($R(2)=0.64$ and 0.99 , respectively). We also determined the efficacy of the CCR5 ligands against HIV-1 infection of HeLa-derived cell lines that express CD4 at the same level but vary 2-fold in CCR5 expression (JC.48 and JC.53 cells). The moderately greater CCR5 expression on the JC.53 than the JC.48 cells was associated with proportionately higher median IC(50) values for all four CCR5 ligands but not for a soluble CD4-based inhibitor or a non-nucleoside reverse transcriptase inhibitor. We conclude that differences in CCR5 expression on human PBMCs, which can be affected by CCL3L1 gene dose, may influence the antiviral potency of CCR5 ligands in vitro, but other host factors are also likely to be involved. These host factors may affect the clinical activity of CCR5 inhibitors, including their use as topical **microbicides** to prevent HIV-1 transmission.

"Perceptions of Sexual Assertiveness among Adolescent Girls: Initiation, Refusal, and Use of Protective Behaviors"

Author(s): Auslander BA, Perfect MM, Succop PA, et al

Reference: N/A 20(3):157-62.

<http://www.mdlinx.com/pediatriclinx/news-article.cfm/1883320>

Published Abstract: STUDY OBJECTIVE: We describe adolescent girls' perceptions of sexual assertiveness and examine the relationship of these perceptions with developmental and interpersonal variables. DESIGN: Cross-sectional analysis. SETTING: Participants were recruited from a school-based health clinic and local colleges, and through snowballing to participate in a 6-month study examining **microbicide** acceptability. PARTICIPANTS: 106 sexually experienced girls (ages 14 through 21 years). METHODS: Girls described their demographics, sexual history, and romantic relationships and completed the Sexual Assertiveness Scale for Women (SAS-W), which assesses perceptions of sexual assertiveness: Initiation of Sex, Refusal of Unwanted Sex, and Pregnancy-STD Prevention. RESULTS: Girls perceived themselves as asserting themselves between 50% and 75% of the time with their current

or most recent partner. The Initiation subscale was not related to the other two subscales. In final models, girls with a prior pregnancy perceived themselves as initiating sex more than girls without a prior pregnancy. Having a greater number of lifetime partners was related to perceptions of less refusal, whereas greater number of partners, being sexually experienced longer, and engaging in more unprotected sex were related to perceptions of less implementation of preventive methods. None of the relationship variables were related to scores on any subscale. CONCLUSIONS: Most of these girls perceived themselves as sexually assertive. Given that sexual experience, not relationship factors, were related to perceptions of sexual assertiveness, the design of counseling messages should incorporate sexual experience. These messages should find effective ways to help girls both to communicate their sexual desires and to enhance their ability to protect themselves.

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4. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Extensively cross-reactive anti-HIV-1 neutralizing antibodies induced by gp140 immunization"

Author(s): Zhang P, Cham F, Dong M, et al

Reference: N/A 104(24):10193-98.

<http://www.pnas.org/cgi/content/abstract/104/24/10193?etoc>

Published Abstract: An immunization regimen was evaluated in rabbits consisting of the soluble, oligomeric form of envelope glycoprotein of HIV-1, strain R2 (gp140R2), or the surface component of the same envelope (Env), gp120R2, in the adjuvant AS02A. The gp140R2 was selected based on its unusual CD4-independent phenotype and the exceptionally broad neutralizing response in the infected donor. The gp140R2 immunogen induced antibodies that achieved 50% neutralization of 48/48, and 80% neutralization of 43/46 primary strains of diverse HIV-1 subtypes tested. The strains tested included members of standard panels of subtype B and C strains, and other diverse strains known to be neutralization resistant. The gp120R2 induced antibodies that neutralized 9/48 of the same strains. Neutralization was IgG-mediated and HIV-1-specific. These results demonstrate that induction of truly broad spectrum neutralizing antibodies is an achievable goal in HIV-1 vaccine development.

EDITOR'S NOTE: *The full text of this article is available for open access at*

<http://www.pnas.org/cgi/content/full/104/24/10193>

"The obligation to provide antiretroviral treatment in HIV prevention trials"

Author(s): Lo B, Padian N, Barnes M

Reference: N/A 21(10):1229-31. B, Padian N, Barnes M.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17545698&dopt=Abstract

Published Abstract: Providing antiretroviral therapy (ART) to participants who seroconvert during HIV prevention trials in developing countries is an ethical expectation. Promising treatment to the few seroconverters widens disparities within a resource-poor country and would be unjust. Such an assurance should be done in a way that also improves access to ART for others in the country. US funds for ART in poor countries from the PEPFAR should be available to all countries that host HIV prevention and clinical trials.

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5. EPIDEMIOLOGY

"Number of Indians with HIV far lower than previously believed, study finds"

Date: 08 June 2007

Source: *Associated Press*

Author(s): Sam Dolnick

http://hosted.ap.org/dynamic/stories/I/INDIA_AIDS?SITE=NVREN&SECTION=HOME

The number of Indians infected with HIV is far smaller than previously believed, according to new data that appears to vindicate critics who said earlier U.N. assessments of the country's epidemic were vastly overestimated. Experts say the still-unreleased survey is likely to show that India's number of HIV cases, which last year was said to be the highest in the world at 5.7 million, is actually well below that mark.

"The actual number we've come up with in aggregate is likely to be lower, and perhaps substantially lower," said Ashok Alexander, director of the Avahan, the Indian program of the Bill and Melinda Gates Foundation, which helped fund the study. Alexander declined to estimate what the new number would be, saying the data is still being analyzed and precise numbers would not be released for a few more weeks.

The new estimate comes from combining data collected from prenatal clinics; a survey of high-risk groups, such as sex workers; and from the government's National Family Health Survey - a method Alexander said was more reliable than the previous estimates, which relied largely on extrapolating from the prenatal clinic data.

The health survey - the third conducted since 1992-93 but the first to provide an HIV estimate - is considered the most comprehensive source and carries the most weight in determining the new figures. It covers about 200,000 people between the ages of 15 and 54, more than half of them women, and was conducted through face-to-face interviews all across India between December 2005 and August 2006.

A statement released Friday by the government's HIV control program, UNAIDS and the World Health Organization acknowledged that the new data provided "a more accurate picture of the epidemic because of availability of more information based on population surveys and improved data from high-risk groups."

But in an indication of how sensitive the new data is in India, where billions of dollars have been poured into prevention programs to stop the spread of HIV, the statement made no mention of the lower overall estimate. Instead, it only pointed out that HIV rates remain high about groups most at risk - sex workers and their clients, especially truckers; men who have sex with men; and intravenous drug users.

Daniel Halperin, an HIV and AIDS expert at the Harvard School of Public Health, said the new data put health officials in a bind. "On the one hand there's a real HIV epidemic in India and it needs to be addressed, but on the other, there's an understandable concern that people were worried that funding or attention could be diminished if the prevalence numbers come out lower," he said.

While health experts called the new data good news, they cautioned that HIV is still a major problem, particularly in southern Indian states where rates might be as high as 1 percent of the general population. "This is a bit like declaring victory before even fully fighting the battle," Alexander said. This is not the first time experts have questioned India's official HIV numbers.

Halperin and colleagues have published several studies in leading medical journals arguing that the number of AIDS victims in India and other parts of the world are actually far lower than the official numbers claim. In 2006, Indian doctors argued in a published report that the methodology gave a flawed picture because the amount of HIV-positive people reporting to prenatal clinics, sexually transmitted infection clinics and public hospitals was not representative of their true numbers in the population.

The lead investigator behind the report, Dr. Lalit Dandona of the Administrative Staff College of India in the southern city of Hyderabad, estimated the number of infected adults at between 3.2 million and 3.5 million. In a country with a population of more than 1.1 billion people, that's far fewer than 1 percent.

While Africa has long attracted most of the attention from international HIV experts, some Western AIDS organizations have argued in recent years that the Indian government was underestimating the scale of its HIV problem, Halperin said. He thought the new data could serve as vindication for Indian officials.

"It turns out that some people in the government years ago were correct in rejecting the notion that the epidemic was spiraling out of control," he said. Experts found the dramatic revision in line with an improved understanding of AIDS across the globe.

"There are corrections that happen in the data from time to time," said Paul Zeitz, executive director of the Global AIDS Alliance in Washington. "But if India still has millions of infections, there are still risks for increasing those numbers."

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6. OTHER PREVENTION APPROACHES

"Bringing back the sex into HIV/AIDS work in Africa"

Date: 13 June 2007

Source: *RH Reality Check*

Author(s): Masimba Biriwasha

<http://www.rhrealitycheck.org/blog/2007/06/12/bringing-back-the-sex-into-hiv-aids-work-in-africa>

It's not a revealing discovery that sexual engagement with multiple partners increases the likelihood of getting some kind of an infection, HIV included. But this is increasingly getting attention as HIV/AIDS workers and researchers grapple with a ballooning epidemic in sub-Saharan Africa, where just 12 percent of men and 10 percent of women know their HIV status. More than anything else, it shows the lack of integration of HIV/AIDS and sexual reproductive health that is characteristic of many programs in Africa.

For example, over the past few years the term "small house" has gained currency in Zimbabwe, a country with 18 percent HIV prevalence rate among the 15 to 49 age group. Small house simply refers to the extra-marital affairs that married men or women have in secret.

"Small houses are a form of concurrent relationship in which a person is having regular sexual relations with another person, while at the same time continuing to have sex with their current primary sexual partner," says Lois Chingandu, Executive Director of Southern Africa HIV and AIDS Information Dissemination Service (SAfAIDS) in an ongoing electronic forum discussion on accelerating-prevention measures in Zimbabwe.

Usually, such relationships often include a powerful element of sexual-economic exchange. Because of women's subordinate economic status, they often enter into the relationships for financial gain, making themselves vulnerable to HIV infection. Also, in many African countries, cultural and traditional practices encourage multiple partnerships for men. Like in many societies around the world, men's sense of masculinity is often associated with sexual prowess.

"Researchers increasingly attribute the resilience of HIV in Botswana - and in southern Africa generally - to the high incidence of multiple sexual relationships," reports The Washington Post. "Europeans and Americans often have more partners over their lives, studies show, but sub-Saharan Africans average more at the same time."

While it's clearly a fallacy to say such partnerships are unique to sub-Saharan Africa, they do indeed facilitate the transmission of HIV because of other reasons.

"The fact is that concurrent sex or small houses are a key driver of the epidemic for a number of reasons: people do not know their status when they engage in sex; condom use is zero in these relationships, despite high HIV awareness levels; mutual fidelity is very rare; small houses are themselves driven by other drivers like power dynamics and gender inequality, which make it difficult for women on both sides of the relationship to demand protection, even when they know they are at risk," says Chingandu.

The World Health Organization (WHO) estimates that sub-Saharan Africa alone accounts for 65 percent of all new HIV infections. The primary transmission of HIV is through heterosexual contact. The catch, however, is that most of the people who are infected, do not know that they are HIV-positive. Reducing the number of partners is key to HIV prevention, but must be promoted alongside the provision of other services - such as HIV testing, stigma reduction, access to treatment, and correct and consistent use of existing prevention methods. In many parts of sub-Sahara Africa, HIV/AIDS lives in the shadow of silence, fear and death, and many people prefer not to know their status.

The UN estimates that nearly 80 percent of the people with HIV in poor and developing countries do not know they have it. In Africa alone, nearly 20 million people with HIV are not aware they have the virus. The stigma associated with HIV/AIDS causes many people to shun HIV testing services. And when people enter into a sexual relationship, they trust each other after a period of time to forgo protective measures, putting themselves at risk. The rate of the spread of the disease increases in the event of multiple concurrent sexual relationships.

Unfortunately, the AIDS response in Africa has largely steered away from matters of sex and sexuality. While there's a large amount of printed material on HIV and AIDS, it often ignores the heart of the matter: sex. NGOs, government and AIDS funders have concentrated efforts on alleviating the social manifestations of the disease. There's every justification to provide services to the affected populations, but equally important is the need to tackle often-taboo subjects associated with sex in wide-scale campaigns.

"Africans are overwhelmed with information on AIDS but not nearly enough that is useful," said The Washington Post's Craig Timberg, in a recent online chat with his readers.

If heterosexual contact is the main cause of the spread of the epidemic, it is imperative for African societies to start exploring the cultural, traditional, social, economic and political dynamics that define sexual behaviour, especially between men and women. There's need to bring the sex back into HIV/AIDS work. Programs that promote safe sexual relations, even in multiple partnerships, need to be emphasized to harness the high rates of new infections.

"Condoms for Indian porn watchers"

Date: 11 June 2007

Source: *BBC News*

Author(s): Monica Chadha

http://news.bbc.co.uk/2/hi/south_asia/6740373.stm

A year after a programme was launched to sell condoms at theatres showing porn films in India, health officials say the response has been overwhelming. Officials in Surat, a city in western Gujarat state, say the idea is to spread awareness about HIV-Aids. They say research shows that people considered to be from high-risk groups frequent these cinemas.

Surat has a large number of migrant labourers who come to the city to work in its diamond and textile factories. Gujarat is not a high HIV/Aids prevalence state, but in its 2004 estimates, India's National Aids Control Organisation (Naco) said there had been a significant increase in the number of cases being reported in the state.

Encouraging

Snehlata Bhatia, project manager of the programme at Surat Municipal Corporation, said the state could be described as a "middle prevalence" state. Since they decided to target audiences at theatres showing pornographic films, the results had been more than encouraging, she said. "In our attempts to spread HIV/Aids awareness, we study where our target groups live, the places they visit," Mrs Bhatia told BBC News.

Condoms and sex are still taboo in India

"We are already working with the diamond industry and the builder's association and when we realised that a lot of migrant labourers were coming to these cinemas to watch porn films, we got in touch with these cinemas." The cinemas in question charge 20-30 rupees (less than \$1) a show - an amount most small-time migrant workers are able to spare.

According to Dinesh Prajapati, a member of the Sargam Manav Seva Charitable Trust, an NGO working on the project, many migrant workers who visit these theatres often pick up prostitutes hanging around the cinemas and take them inside the hall or to a cheap guest house afterwards. "Here, we are reaching out to two major high-risk groups and we don't only provide them with condoms to promote safe sex, but also give them information about HIV/Aids and other sexually-transmitted diseases," he said.

Messages

The condoms are either handed out by volunteers and NGO workers or sold at the ticket counter. In some theatres, messages regarding safe sex are printed on the back of the tickets and short films on the subject are screened before the shows. To make condoms easily available at any time of day, social workers have also roped in small shops selling tobacco products outside the cinemas. The move has paid off.

Mr Prajapati said: "People now don't hesitate to buy condoms from the ticket counter or the tobacco shop. Many times they come and talk to our social workers about sexually-transmitted diseases, seek advice on treatment and where to get it and now some of them even attend our group meetings."

India has more HIV/Aids cases than any other country, the UN says.

Another NGO involved in the project, the Shri Ramkrishna Charitable Trust, has taken it one step further and made condoms available at some barber shops as well. Campaigners see buying condoms freely as a great step forward in a society which still regards sex as a taboo subject to be dealt with behind closed doors only. In fact, two months ago, the neighbouring state of Maharashtra banned sex education in schools after some legislators protested it would corrupt young minds.

But as this experiment in Gujarat shows, with authorities trying out new ways and methods of spreading the message to the masses, more people seem to be listening.

According to UNAids, India has some 5.7 million people infected with the HIV virus, more than any other country in the world. But a new study disputes the figures, it says the number of infections in India could be as low as three million.

"Government attacked over expired female condoms"

Date: 10 June 2007

Source: *New Vision*

Author(s): Joyce Namutebi

<http://www.newvision.co.ug/D/8/13/569707>

"The condoms expired from the stores, while women were being infected (with HIV/AIDS) everyday. That is a criminal offence," Dr. Margaret Muganwa of the Global Campaign for **Microbicides**, said during a meeting for the Commonwealth experts at the Speke Resort Munyonyo in Kampala on Friday.

The attack comes at a time when research shows that there is an increase in the number of women infected with the HIV virus worldwide. By 2005, women made up almost 50% of HIV infected adults worldwide, with nearly 60% in Sub-Saharan Africa and almost 30% in Asia Pacific.

Muganwa, who admitted to having used the female condom, revealed that she found it appropriate and user-friendly. She was responding to concerns by participants over availability and accessibility of these condoms.

The meeting on gender equity and development of and access to new prevention technologies attracted HIV/AIDS and women's health experts and researchers and government officials of different Commonwealth countries.

The Director General of the Uganda AIDS Commission, Dr. Kihumuro Apuuli, noted that the Ministry of Health imported female condoms three years ago but they expired from the stores because women were unwilling to use them. Dr. Noah Kiwanuka of the Rakai Health Sciences Programme and Apuuli warned that although male circumcision reduces acquisition of HIV in men, circumcised people were not immune to HIV/AIDS.

"Africa urged to circumcise males to fight AIDS"

Date: 07 June 2007

Source: *Reuters*

Author(s): Paul Simao

<http://www.reuters.com/article/healthNews/idUSL0727245220070607>

South Africa and other African nations hard hit by AIDS should consider a mass campaign to circumcise males to help stem the spread of the epidemic, researchers at a major AIDS conference in South Africa said. The call to increase circumcisions in boys as well as some adults comes in the wake of growing evidence that the practice could offer men as well and their sexual partners more protection from HIV.

In a presentation on Thursday that cited studies from Uganda, Kenya and South Africa, Neil Martinson of South Africa's Perinatal HIV/AIDS research unit said circumcision could reduce the risk of HIV infection by up to 60 percent although it did not offer total protection from the virus.

"I think this is very conclusive evidence," Martinson told about 100 delegates at the Third South African AIDS Conference in Durban. At the moment, circumcision is less common in southern and eastern Africa than in northern African and most parts of western Africa. Describing the attitude of South Africa's government toward circumcision as "deafening silence", Martinson urged it and other African governments to try to build support for expanding the number of circumcisions done in hospitals and clinics.

The World Health Organization has already recommended male circumcision as one of the many ways developing nations, particularly in Africa, could use to tackle AIDS. Mozambique, Malawi and several other countries are heeding the call, but South Africa so far has remained silent. Some health officials in South Africa, where 12 percent of 47 million people are infected with HIV, have warned that males who are circumcised might engage in more risky sexual behavior. They also have argued that it is not an accepted practice in much of the country.

Uncircumcised males appear to be at a higher risk of HIV infection because the virus is effective at penetrating tiny cuts and fissures that develop in the foreskin. Removing it leaves behind a hardened layer of skin that is believed to be more resistant to HIV. Most circumcisions carried out in southern Africa usually occur as part of tribal rituals, often when men are in their early 20s, an age when many have already been exposed to HIV through their sexual behavior.

The relatively primitive nature of many of these "traditional" circumcisions also can lead to high rates of infection and other health problems.

"The complication rates are small when carried out in medical settings," Bertran Auvert, a French professor of public health who has conducted research on the relationship between HIV and circumcision rates in Africa, told a separate presentation at the conference. He said there was overwhelming evidence to support the WHO recommendation.

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7. POLITICS AND POLICY

"Potentially incompatible goals at F.D.A."

Date: 11 June 2007

Source: *The New York Times*

Author(s): Gardiner Harris

<http://www.nytimes.com/2007/06/11/washington/11fda.html?adxnnl=1&adxnnlx=1181590051-kS7i2clciOWEpGcceYq/SQ>

Safety and speed are the yin and yang of drug regulation. Patients want immediate access to breakthrough medicines but also want to believe the drugs are safe. These goals can be incompatible. Race a drug to market and much is likely to remain unknown when patients take it. Test a drug thoroughly to assess all possible risks and its release may be delayed by years.

A series of drug-safety scandals has led many on Capitol Hill to question whether the Food and Drug Administration has failed to strike the right balance between speed and safety. A clear sign of this imbalance, these critics say, is the increasing number of F.D.A. drug-safety officers who say they have been punished or ignored after uncovering dangers of popular medicines.

The latest to suffer this fate is Dr. Rosemary Johann-Liang, 42, who recommended more than a year ago that the diabetes drug Avandia carry the agency's strongest possible safety warning for its effects on the heart. Dr. Johann-Liang spent Friday sadly winding down her nearly seven-year career at the F.D.A. She turned in her BlackBerry,

laptop and office key, and she went to the agency library to make sure she had no overdue books. She wished her colleagues well.

A pediatrician and expert in infectious diseases, Dr. Johann-Liang joined the agency in December 2000 and rose through the ranks. For four years, she reviewed drug applications as a medical officer and then team leader. Two years ago she became a deputy division director in the agency's office of surveillance and epidemiology, the group that examines the safety of already-marketed drugs.

In February 2006, one of her safety reviewers, Lanh Green, went to her with a problem. The agency's Office of New Drugs had asked Ms. Green to determine whether eye problems that sometimes resulted from taking Avandia and a similar drug, Actos, were a serious issue. But Ms. Green noted that visual deficits were just one part of a drug-induced swelling problem that could lead to weight gain, ankle swelling and, if left untreated, heart failure.

Alerts about some of these problems were scattered throughout the two drugs' labels. Ms. Green suggested consolidating them and highlighting the heart risks with a boxed warning, the agency's most severe. After a weeklong review, Dr. Johann-Liang agreed.

"There's no doubt these problems are caused by these drugs, and there's no doubt that patients are continuing to suffer bad outcomes," Dr. Johann-Liang said. A week later, top officials from the new drug office walked by Dr. Johann-Liang's office and into the office of her boss, Dr. Mark Avigan, she said. Nearly an hour later, she said, the door opened, the officials left and Dr. Avigan called her in. "Mark told me that they were upset with our recommendation," Dr. Johann-Liang recalled. "They decided to act like the review never happened."

Dr. Avigan took over the supervision of the safety review of Avandia and Actos and told Dr. Johann-Liang that she could no longer approve strong safety recommendations without his say-so, she said. Over the next year, she was increasingly excluded from crucial safety reviews and meetings, which contributed to her decision to leave the agency on Friday, she said.

In an interview, Dr. Avigan said that he did not intend to punish Dr. Johann-Liang. "My view was simply that when there were conversations going on about important safety issues that were likely to garner a lot of attention, that I needed to be in the loop," he said.

On Wednesday, the F.D.A. commissioner, Andrew C. von Eschenbach, announced that the agency had asked for boxed warnings on Avandia and Actos, more than a year after Dr. Johann-Liang's recommendation. At least four other F.D.A. safety reviewers in recent years have been punished or discouraged after uncovering similar drug dangers, according to Congressional investigations. Among them:

In 2003, Dr. Andrew Mosholder discovered that antidepressants led some children to become suicidal. When his findings were leaked to a reporter, the agency began a criminal investigation. Dr. Mosholder was prevented from speaking to an advisory committee about his analysis, and the agency hired Columbia University researchers to reanalyze the data; they concluded a year later that Dr. Mosholder had been right.

In 2006, Dr. David Ross became increasingly concerned about reports of serious illness and death from patients taking the antibiotic Ketek. Dr. Ross met with top agency officials and pleaded with them to take action. Nothing happened, he said. A month later, Dr. Ross complained privately to Congressional investigators. After articles about

Ketek's safety problems appeared in *The Wall Street Journal* and *The New York Times*, the agency and Ketek's maker, Sanofi-Aventis, agreed to take actions.

After the articles were published, Dr. von Eschenbach held a meeting with Dr. Ross, Dr. Johann-Liang and other safety officials in which he urged them to keep their disagreements "inside the locker room," Drs. Ross and Johann-Liang said. Those who discussed issues with outsiders would be "traded from the team," Dr. Eschenbach said, according to Drs. Ross and Johann-Liang.

Dr. Ross left the agency in November for the Department of Veterans Affairs. Dr. von Eschenbach later told a Congressional panel that he had intended his remarks to Dr. Ross and others to encourage scientific debate. Senator Charles E. Grassley, Republican of Iowa, said Drs. Johann-Liang, Mosholder and Ross were part of a pattern demonstrating the need for reforms at the F.D.A.

Heidi Rebello, an F.D.A. spokeswoman, said that the "F.D.A. is not aware of any kind of retaliation," and that staff members "are committed to respecting all legal rights and protections of our employees." In interviews, safety reviewers said problems at the agency could be traced back to a deal struck in 1992.

In the 1980s, the F.D.A. took nearly three years to approve most drugs. The AIDS crisis demonstrated that such long delays could condemn to death patients who might have been helped by recent scientific breakthroughs. F.D.A. managers said they did not have enough people to assess reviews more quickly.

So in 1992, Congress helped the F.D.A. and the drug industry reach a deal. Companies agreed to pay millions of dollars in fees, and the F.D.A. guaranteed that drug reviews would be completed within a year or as little as six months for a life-saving medicine.

At the time, it seemed a good solution. But the deal's fine print soon came to haunt the agency. Drug makers refused to let their money pay for the routine monitoring of drugs' safety once they were on the market. As the agency began to depend more and more on industry fees, those parts of the agency slowly withered.

Perhaps even more important, the culture at the F.D.A. shifted toward valuing speed over safety. The 1992 deal required annual reports to Congress listing review times, but no such reports were demanded of the agency's assessments of the safety of drugs already on the market. Managers are now largely judged on how quickly their employees make a decision on new drug applications, safety officials say. Questions about the safety of already-marketed drugs are increasingly seen as sand in the gears, they say.

Drs. Johann-Liang, Ross and two other safety officials said Congress should require the F.D.A. to make regular public assessments of the safety of approved medicines, act on reports of drug problems within a month or two, and require regular reports on the agency's adherence to these goals. Such requirements would lead to the promotion of safety-conscious managers, not just speed-conscious ones, they said.

The Senate last month passed a bill to overhaul the F.D.A. that includes more money for drug-safety assessments and requires an advisory committee to meet twice yearly to consider safety issues. The House will hold hearings on the legislation this week. The safety officials say the bill does not go far enough, because it does not require clear timelines for a response to safety issues. It also does not require regular public disclosure of F.D.A. safety reviews.

"If managers were held accountable on safety issues, they'd pay more attention to them," said Dr. Victoria Hampshire, who was disciplined and investigated criminally in part because of her work to uncover the dangers of a heartworm medicine that killed at least 500 dogs. Dr. Hampshire, who still works at the F.D.A., said employees in Dr. Johann-Liang's former office were "very demoralized. There's a feeling of fear," she said.

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8. HIV/AIDS FUNDING

"G-8's \$60 billion AIDS and Africa pledge criticized"

Date: 08 June 2007

Source: *Reuters*

Author(s): Madeline Chambers, Gernot Heller

http://ca.today.reuters.com/news/newsArticle.aspx?type=topNews&storyID=2007-06-08T121447Z_01_L05287913_RTRIDST_0_NEWS-G8-SUMMIT-COL.XML

World powers on Friday pledged \$60 billion to fight AIDS and other killer diseases ravaging Africa but development campaigners complained the Group of Eight had pledged little fresh cash for the poor.

German Chancellor Angela Merkel, hosting G8 leaders and leaders of five African states, trumpeted the agreement as a showpiece outcome of the three-day summit, along with Thursday's deal to push for greenhouse gas emissions cuts. "We are conscious of our obligations and want to fulfill the promises we made. And we will do that," said Merkel.

Campaigners complain that rich nations have fallen behind on commitments made to double development aid at a summit in 2005 in Gleneagles, Scotland and were unimpressed with Friday's deal, which restated the pledges made two years ago. Leaders said they would provide at least \$60 billion to fight AIDS, malaria and tuberculosis, global diseases that have devastated African countries and their economies.

But the declaration set out no specific timetable, saying the money would flow "over the coming years." Neither did it break down individual countries' contributions or spell out how much of the sum had been previously promised.

"I am exasperated," Irish rock star and anti-poverty campaigner Bono told Reuters. "I think it is deliberately the language of obfuscation. It is deliberately misleading."

U.S. President George W. Bush last week announced plans to double Washington's financial commitment to the anti-AIDS fight to \$30 billion over five years, which was included in the G8's headline figure of \$60 billion. Bush missed some of the morning sessions at the summit because of a stomach ailment but rejoined the leaders later.

FALLING SHORT

British aid agency Oxfam said the G8 will fall far short of its Gleneagles pledges. "We must not be distracted by big numbers. What the \$60 billion headline means at best is just \$3 billion extra in aid by 2010," said an Oxfam policy adviser. "Before this summit, Oxfam showed the G8 were set to miss their 2010 target by a massive \$30 billion.

Today's announcement may only close that gap to \$27 billion," he added.

Steve Cockburn of the Stop Aids Campaign said the pledge fell short of U.N. targets obliging G8 nations to spend \$15 billion per year to combat AIDS alone through to 2010. In comparison, the deal looks like committing them to about \$12 billion per year for all three diseases. Leaders also reiterated an overall pledge made in 2005 to raise annual aid levels by \$50 billion by 2010, \$25 billion of which is for Africa.

"The important thing is that we have recommitted ourselves to all the commitments we made a couple of years ago," said British Prime Minister Tony Blair who hosted the 2005 meeting. Campaigners were not convinced.

"Despite last-minute face saving measures, the G8 has failed its credibility test on Africa," said Collins Magalasi, ActionAids's country director for South Africa.

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9. ANNOUNCEMENTS

International AIDS Society and Kaiser Family Foundation partner to provide comprehensive online coverage of 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention

<http://www.ias2007.org>

The International AIDS Society (IAS) and the Kaiser Family Foundation today announced a partnership to provide worldwide online access to the 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2007) in Sydney, Australia, 22-25 July 2007. Held every two years, the conference unites scientists, clinicians, public health experts and community leaders to examine the latest developments in HIV-related research, and to explore how scientific advances can inform the global response to HIV/AIDS.

Request for proposals: Mathilde Krim Fellowships in Basic Biomedical Research

<http://www.amfar.org/rfp>

Deadlines

Presubmission notice due July 16, 2007

Letter of intent due July 26, 2007

Background and Program Submission

amfAR, The Foundation for AIDS Research, is pleased to announce the availability of support for Mathilde Krim Fellows in Basic Biomedical Research.

The goal of amfAR's Mathilde Krim Fellows in Basic Biomedical Research program is to provide funding for exceptional researchers who are new to the HIV/AIDS field. Krim Fellowship funding will support the successful applicant's ongoing HIV research and facilitate the transition to a productive and long-term career in the HIV/AIDS biomedical research field. A Krim Fellowship provides support for two years of postdoctoral research with the possibility of one additional year of research support during the first year of a tenure-track position.

Proposed research projects should pertain to HIV prevention or treatment, including viral eradication.

Krim Fellowship applicants must have a research or clinical doctorate and no more than four years of postdoctoral training at the time of submitting a letter of intent, and should intend to secure a tenure-track position at or before the end of the initial two-year funding period. The Krim Fellowship applicant must be mentored by an experienced HIV/AIDS investigator who is affiliated with the same nonprofit institution and is at the associate professor level or higher.

Detailed discussion of qualifications, application instructions, and required forms are posted at <http://www.amfar.org/rfp>

Available Funding Direct costs: \$113,636; indirect: 10%; performance period: two years starting January 1, 2008.

Application Process

Proposals must be submitted by e-mail on amfAR forms, which are available at <http://www.amfar.org/rfp>

University of Washington wins \$12.23 million contract

The U.S. Department of Health and Human Services has awarded a \$12.23 million contract to University of Washington, Seattle, for topical **microbicide** safety and efficacy evaluation in nonhuman primates.

The contract was awarded by HHS' National Institutes of Health, National Institute of Allergy and Infectious Diseases, Bethesda, Md.

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