



# ALLIANCE FOR MICROBICIDE DEVELOPMENT

**10 August 2007, Volume 8, Number 31**

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](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. ALLIANCE UPDATES AND COMMUNITY NEWS

### Dr. Sharon Hillier to receive lifetime achievement award

On August 10th, Dr. Sharon Hillier will receive the Lifetime Achievement Award from the Infectious Disease Society for Obstetrics and Gynecology. The award will be presented at the annual meeting of the American College of Obstetrics and Gynecology in Boston, Massachusetts.

The Alliance extends warm congratulations and appreciation to Dr. Hillier for her contributions to reproductive health in general and **microbicides** in particular.

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## 2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

### "Griffithsin, a potent HIV entry inhibitor, is an excellent candidate for anti-HIV microbicide"

**Author(s):** Emau P, Tian B, O'keefe BR, et al

**Reference:** N/A 36(4-5):244-53.

<http://www.blackwell-synergy.com/doi/abs/10.1111/j.1600-0684.2007.00242.x>

**Published Abstract:** *Background* The predominant mode of HIV-1 transmission is by heterosexual contact. The cervical/vaginal mucosa is the main port of HIV entry in women. A safe and effective topical **microbicide** against HIV is urgently needed to prevent sexual transmission. Hence, we evaluated griffithsin (GRFT), a 12.7 kDa carbohydrate-binding protein, both native and recombinant GRFT, potently inhibited both CXCR4- and CCR5-tropic HIV infection and transmission in vitro. *Methods* The antiviral efficacy of native and recombinant GRFT against CXCR4- and CCR5-tropic HIV and SHIV strains and SIVmac251 was evaluated by in vitro assays. We also evaluated the time course of antiviral activity and stability of GRFT in cervical/vaginal lavage as a function of pH 4-8. *Results* Griffithsin blocked CXCR4- and CCR5-tropic viruses at less than 1 nM concentrations and exhibited a high potency. GRFT was stable in cervical/vaginal lavage fluid and maintained a similar potency of anti-HIV activity. GRFT is not only a highly potent HIV entry inhibitor, but also prevents cell fusion and cell-to-cell transmission of HIV. *Conclusions* The in vitro efficacy of GRFT revealed low cytotoxicity, high potency, rapid onset of antiviral activity and long-term stability in cervical/vaginal lavage. GRFT is an excellent candidate for anti-HIV **microbicide** development.

### "Overcoming recruitment challenges: lessons learned from a safety and feasibility study of a diaphragm/microbicide combination in South Africa"

**Source:** *J Acquir Immune Defic Syndr.* 2007 Aug 01;45(4):481-82. Letter to the Editor.

**Author(s):** Greg Guest, Lawrence Severy, Claire von Mollendorf, et al

Recruiting for HIV prevention trials has been, and continues to be, a challenge. This is particularly true as more HIV prevention products, such as vaginal **microbicides**, move into phase 3 effectiveness trials, where large sample sizes are needed. In the past, cohort and feasibility studies have examined motivations 1-3 and willingness to participate<sup>4,5</sup> in HIV prevention studies. Another approach has been to document demographic and other predictors of study participation.<sup>6</sup> Most of these studies have been in the context of vaccine trials and have not dealt with other types of HIV prevention trials. Additionally, few studies have looked at why individuals do not enroll in HIV prevention trials when approached by study recruiters (ie, those participants who never make it to the formal screening process).

Documenting why individuals do not enroll in clinical studies is important for more effectively targeting willing and eligible populations from which to recruit. In this report, we present recruiting data from a randomized, placebo-controlled, safety and feasibility study of ACIDFORM gel (SRI International, Inc., Menlo Park, CA) with a diaphragm in South Africa. The study had a target enrollment of 120 women, which was successfully attained after 12 months of recruiting. Eligibility criteria included, among other things, women who were between the ages of 18 and 48 years, not pregnant or planning on getting pregnant, in a sexually active and mutually monogamous relationship, not currently breast-feeding, and HIV-negative. Trial participation required that participants use a cervical diaphragm and vaginal **microbicide** every time they had intercourse for the 6-month duration of the study.

Recruiting for the study took place in community centers, public parks, and public health clinics within Johannesburg. All potential study participants were given a brief initial description of the study and eligibility criteria. Women who showed no interest at this point were asked the reason for not wanting to join, and the reason was noted. Women who expressed interest were invited to the study clinic for screening, and their contact information was obtained. Those women who went to the study clinic were given additional study information. During this time, if a woman refused screening or was ineligible for the study, her reason was noted. All failed recruiting efforts were documented with a recruitment log, which noted the date and time and reason for not screening. All reasons noted are based on participants' responses and were documented at face value (ie, not probed for further information). No names or identifying information was recorded in this log, nor was any demographic information recorded. None of the women in our sample underwent formal screening.

Altogether, field staff approached 1144 women who did not screen for the study. In 2 cases, reasons were not properly documented and so were removed from the data set. The reasons were coded into 15 substantive categories. Reasons that did not comprise at least 0.5% of the total were placed into an "other" category. As illustrated in Table 1, the most common reasons for not screening were related to eligibility criteria, such as breast-feeding (20%), not sexually active (14.1%), and pregnant or planning on becoming pregnant (13.2%). Other commonly cited reasons were lack of interest (13.1%) and fear of HIV testing and/or receiving test results (10.6%). Only 3.5% of the reasons cited related to the study product, and to the diaphragm exclusively.

Most of the reasons for not screening for the trial had to do with factors beyond the control of potential participants and were not related to the study product. Findings point to the importance of focusing recruitment efforts more precisely. Study recruiting materials, such as advertisements, could be more explicit in describing eligibility criteria. Formative research could also be useful by identifying areas where eligible participants are likely to be found in concentrated numbers. Sampling strategies that rely on participants' social networks, such as respondent-driven sampling,<sup>7</sup> are designed to recruit individuals with similar characteristics and could be helpful in streamlining the recruitment process. Researchers might also consider, when possible, loosening or waiving eligibility criteria not

essential to participant safety or the study design so as to accommodate a wider range of participants. This, however, was not an option for the study described; as a safety study, it was important to adhere strictly to the eligibility criteria so as to avoid unnecessary complications or confounding factors influencing the data.

Recruitment efforts may also need to be adapted during the enrollment period. In the study described, the recruitment strategy changed over the course of the trial, as staff identified areas that did not yield good numbers. Recruitment catchment areas were geographically expanded into other communities. Initially, recruitment focused on communities directly surrounding the study clinic (eg, Yeoville Clinic [ie, Hillbrow, Berea, Yeoville, Bez Valley]). Efforts were then expanded to the Alexandra Township in hopes of finding women at lower risk for HIV so as to render a more favorable HIVpositive - to - HIV negative ratio. Recruitment efforts were also shifted from public health clinics to HIV testing and counseling clinics to try and reduce the number of women who might decline based on concerns about HIV testing (eg, they had already tested HIV-negative).

Additionally, community involvement proved to be invaluable in improving recruitment efforts throughout the study. Study staff attended community meetings, gave presentations to community organizations, and consulted the inner city community advisory group. The study also set up a referral system with a number of community organizations for ineligible participants, and a number of organizations referred potential participants to the study clinic. Additionally, the study involved experienced individuals from other projects to analyze the level of community engagement and advise community health workers with regard to their messaging about the gel and diaphragm. Experience from this trial (and others) has shown that planned and concerted efforts toward building rapport and trust between researchers and communities are well worth the time and effort.

#### *Acknowledgments*

This research was funded by the United States Agency for International Development. Greg Guest, PhD and Lawrence Severy, PhD: Family Health International; Durham, NC. Claire von Mollendorf, MD: University of Witwatersrand; Johannesburg, South Africa. Lut Van Damme, PhD: CONRAD; Arlington, VA

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**EDITOR'S NOTE:** This article is published in the Digest with the permission of author Lut Van Damme.

**"Pregnancy prevention practices among women with multiple partners in an HIV prevention trial"**

**Author(s):** Macqueen KM, Johnson L, Alleman P, et al

**Reference:** N/A Epub ahead of print.

[http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list\\_uids=17667340&dopt=AbstractPlus](http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17667340&dopt=AbstractPlus)

**Published Abstract:** Women enrolled in **microbicide** and pre-exposure prophylaxis (PrEP) HIV prevention trials are not allowed to continue use of study products when pregnant because of fetal safety concerns. High pregnancy rates among women in trials can undermine statistical measures of safety and effectiveness. **METHODS::** Women enrolled in a PrEP trial in Ghana, Nigeria, and Cameroon had an overall pregnancy rate of 52 per 100 person-years of observation. In-depth interviews were conducted with 67 women who were asked to describe any changes made in their pregnancy prevention practices after enrolling in the trial. **RESULTS::** Most women (n = 44, 65%) reported changing pregnancy prevention practices after enrolling in the trial. Twice as many reported using condoms for pregnancy prevention after enrollment (n = 56, 84%) than before (n = 27, 40%). Cluster analysis identified site-specific patterns. Nigerian women tended to report using condoms for dual protection before and after trial enrollment. Cameroonian women tended to rely on natural methods before and after trial enrollment. Ghanaian women tended to switch from hormonal methods to condoms. **CONCLUSIONS::** The role of condoms in HIV prevention trials must not be diminished. Their use-effectiveness for contraception is likely too low for **microbicide** and PrEP trial needs, however. HIV prevention trials with women should be appropriately staffed to provide effective contraceptive counseling and, if needed, direct provision of contraceptives. This must be done without undermining women's reproductive rights.

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

**"Condom use and vaginal Y-chromosome detection: the specificity of a potential biomarker"**

**Author(s):** Ghanem KG, Melendez JH, McNeil-Solis C, et al

**Reference:** N/A 34(8):620-23.

<http://www.stdjournals.com/pt/re/std/abstract.00007435-200708000-00018.htm;jsessionid=G36DII8PpT08WYq6FKGtyTTkGDWscJHMT50jQLH3ZdLrC6gQQKDG!2112021004!181195629!8091!-1>

**Published Abstract:** *Objective:* Detection of vaginal Y-chromosome sequences (YCS) may be a useful biomarker to validate sexual behavior reporting in women. We describe the effects of condom use on the detection of vaginal YCS. *Methods:* Fifty-six women were asked to abstain from sexual intercourse for 14 days. On day 15, participants

were asked to engage in sexual intercourse with their male partners using condoms. Self-collected vaginal swabs were obtained on days 14, 16, and 17. YCS were detected using the Roche LightCycler with the use of positive controls. *Results:* Forty-four of 56 women completed the study. Five women (11.4%) had detectable YCS. The overall specificity of the YCS assay with condom use was 92% (95% CI: 80%-98%). Although women who reported receptive oral sex and digital penetration within 48 hours of swab collection had a higher detection rate of YCS [RR 2.3 (95% CI: 1.1-4.6) and 3.6 (95%CI: 1.6-8.5), respectively], the mean concentration of YCS was much less than that associated with unprotected vaginal intercourse ( $P < 0.001$ ) *Conclusions:* Condom use during intercourse appears to prevent vaginal YCS detection; this may be a useful biomarker to validate self-reported condom use.

### "Effect of visual screening on cervical cancer incidence and mortality in Tamil Nadu, India: a cluster-randomised trial"

**Author(s):** Sankaranarayanan R, Okkuru Esmey P, Rajkumar R, et al

**Reference:** N/A 370(9585):398-406.

[http://www.sciencedirect.com/science?\\_ob=ArticleURL&\\_udi=B6T1B-4PB8KWD-11&\\_user=10&\\_coverDate=08%2F10%2F2007&\\_rdoc=1&\\_fmt=summary&\\_orig=browse&\\_cdi=4886&\\_sort=d&\\_docanchor=&view=c&\\_ct=1&\\_acct=C000050221&\\_version=1&\\_urlVersion=0&\\_userid=10&md5=7b9ee0a884b8](http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T1B-4PB8KWD-11&_user=10&_coverDate=08%2F10%2F2007&_rdoc=1&_fmt=summary&_orig=browse&_cdi=4886&_sort=d&_docanchor=&view=c&_ct=1&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=7b9ee0a884b8)

**Published Abstract:** *Background* Cervical cancer is the most common cancer among women in developing countries. We assessed the effect of screening using visual inspection with 4% acetic acid (VIA) on cervical cancer incidence and mortality in a cluster randomised controlled trial in India. *Methods* Of the 114 study clusters in Dindigul district, India, 57 were randomised to one round of VIA by trained nurses, and 57 to a control group. Healthy women aged 30 to 59 years were eligible for the study. Screen-positive women had colposcopy, directed biopsies, and, where appropriate, cryotherapy by nurses during the screening visit. Those with larger precancerous lesions or invasive cancers were referred for appropriate investigations and treatment. Cervical cancer incidence and mortality in the study groups were analysed and compared using Cox regression taking the cluster design into account, and analysis was by intention to treat. The primary outcome measures were cervical cancer incidence and mortality. *Results* Of the 49 311 eligible women in the intervention group, 31 343 (63.6%) were screened during 2000-03; 30 958 control women received the standard care. Of the 3088 (9.9%) screened positive, 3052 had colposcopy, and 2539 directed biopsy. Of the 1874 women with precancerous lesions in the intervention group, 72% received treatment. In the intervention group, 274 430 person years, 167 cervical cancer cases, and 83 cervical cancer deaths were accrued compared with 178 781 person-years, 158 cases, and 92 deaths and in the control group during 2000-06 (incidence hazard ratio 0.75 [95% CI 0.55-0.95] and mortality hazard ratio 0.65 [0.47-0.89]). *Interpretation* VIA screening, in the presence of good training and sustained quality assurance, is an effective method to prevent cervical cancer in developing countries.

### "Effects of HIV protease inhibitors on the intestinal absorption of Tenofovir Disoproxil Fumarate in vitro"

**Author(s):** Tong L, Phan TK, Robinson KL, et al

**Reference:** N/A Epub ahead of print.

[http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list\\_uids=17664327&dopt=AbstractPlus](http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17664327&dopt=AbstractPlus)

**Published Abstract:** HIV protease inhibitors (PIs) modestly affect the plasma pharmacokinetics of tenofovir (TFV; -15% to +37% in exposure) following co-administration with its oral prodrug TFV disoproxil fumarate (TDF) by a previously undefined mechanism. TDF permeation was found to be reduced by the combined action of ester cleavage and efflux transport in vitro. Saturable TDF efflux observed in Caco-2 cells suggests that, at pharmacologically relevant intestinal concentrations, transport only has a limited effect on TDF absorption, thus minimizing the magnitude of potential intestinal drug interactions. Most tested PIs increased TDF apical to basolateral permeability and decreased secretory transport in MDCKII cells over-expressing P-glycoprotein (Pgp; MDCKII-MDR1) and Caco-2 cells. PIs were found to cause a multi-factorial effect on the barriers to TDF absorption. All PIs showed similar inhibition of esterase-dependent degradation of TDF in an intestinal subcellular fraction except amprenavir that was found to be a weaker inhibitor. All PIs caused a dose dependent increase in the accumulation of a model Pgp substrate in MDCKII-MDR1 cells. Pgp inhibition constants ranged from 10.3 microM (lopinavir) to > 100 microM (amprenavir, indinavir and darunavir). Analogous to hepatic cytochrome P450-mediated drug interactions, we propose that the relative differences in perturbations in TFV plasma levels when TDF is co-administered with PIs is based in part on the net effect of inhibition and induction of intestinal Pgp by PIs. Combined with prior studies these findings indicate that intestinal absorption is the mechanism for changes in TFV plasma levels when TDF is co-administered with PIs.

### "High-mannose-specific deglycosylation of HIV-1 gp120 induced by resistance to cyanovirin-N and the impact on antibody neutralization"

**Author(s):** Hu Q, Mahmood N, Shattock RJ

**Reference:** N/A Epub ahead of print.

[http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list\\_uids=17658575&dopt=AbstractPlus](http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17658575&dopt=AbstractPlus)

**Published Abstract:** HIV-1 uses glycans on gp120 to occlude its highly immunogenic epitopes. To better elucidate escape mechanisms of HIV-1 from carbohydrate-binding agents (CBA) and to understand the impact of CBA-escape on viral immune evasion, we generated and examined the biological properties of HIV-1 resistant to cyanovirin-N (CV-N) or cross-resistant to additional CBAs. Genotypic and phenotypic characterization of resistant env clones indicated that 3-5 high-mannose residues from 289 to 448 in the C2-C4 region of gp120 were mutated and correlated with the resistance levels. The specificity and minimal requirements of deglycosylation for CV-N resistance were further assessed by mutagenesis study. The sensitivity of resistant variants to a range of CBAs, immunoglobulins, sera and monoclonal antibodies (MAb) were investigated. For the first time, our data have collectively defined the high-mannose residues on gp120 affecting CV-N activity, and demonstrated that CBA-escape HIV-1 has increased sensitivity to immunoglobulins and sera from HIV patients, and particularly to V3 loop-directed MAbs. Our study

provides a proof-of-concept that targeting HIV-1 glycan shields may represent a novel antiviral strategy.

### "HIV-1 fusion peptide decreases bending energy, promotes curved fusion intermediates"

**Author(s):** Tristram-Nagle S, Nagle JF

**Reference:** N/A Epub ahead of print.

<http://www.biophysj.org/cgi/content/abstract/biophysj.107.109181v1?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=HIV+fusion+peptide&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>

**Published Abstract:** A crucial step in HIV infection is fusion between the viral envelope and the T-cell membrane, which must involve intermediate membrane states with high curvature. Our main result from diffuse x-ray scattering is that the bending modulus  $K_C$  is greatly reduced upon addition of the HIV fusion peptide FP-23 to lipid bilayers. A smaller bending modulus reduces the free energy barriers required to achieve and pass through the highly curved intermediate states and thereby facilitates fusion and HIV infection. The reduction in  $K_C$  is by a factor of 13 for the thicker, stiffer diC22:1PC bilayers, and by a factor of 3 for DOPC bilayers. The reduction in  $K_C$  decays exponentially with concentration of FP-23 and the  $1/e$  concentration is less than 1 mole % peptide to lipid, which is well within the physiological range for a fusion site. A secondary result is, when FP-23 is added to the samples which consist of stacks of membranes, that the distance between membranes increases and eventually becomes infinite at full hydration (unbinding); we attribute this both to electrostatic repulsion of the positively charged arginine in the FP-23 and to an increase in the repulsive fluctuation interaction brought about by the smaller  $K_C$ . While this latter interaction works against membrane fusion, our results show that the energy that it requires of the fusion protein machinery to bring the HIV envelope membrane and the target T-cell membrane into close contact is negligible.

### "Older persons' exclusion from sexually transmitted disease risk-reduction clinical trials"

**Author(s):** Levy BR, Ding L, Lakra D, et al

**Reference:** N/A 34(8):541-44.

<http://www.stdjournal.com/pt/re/std/abstract.00007435-200708000-00004.htm;jsessionid=G3pdt6pqnN2vSrLcWY3y2p5QzkjZHzz1QwM1dnj2nYMvbZy8F0X0!-170133123!181195628!8091!-1>

**Published Abstract:** *Background:* The incidence of HIV and AIDS is growing faster among individuals 50 and older compared to those under 40. Although the majority of clinical trials aimed at treating diseases have been found to exclude older individuals, it is not yet known whether this bias extends to sexually transmitted disease (STD) risk-reduction clinical trials published in a wide range of journals. *Methods:* We conducted a systematic review of STD risk-reduction clinical trials that were published in the English-language journals included in MEDLINE between January 1, 1994, and January 1, 2005. *Results:* Over two-thirds (73%) of these clinical trials excluded persons over the age of 50 and 89% excluded persons over the age of 65. The level of inclusion of these older individuals showed no improvement during the 10 years of the systematic review. *Conclusions:* The pattern of excluding individuals above

the age of 50 from STD risk-reduction clinical trials has persisted even though AIDS is increasing most rapidly in this age group. Therefore, a need exists to increase older individuals' representation in these clinical trials.

### "Self-reported mechanical problems during condom use and semen exposure: comparison of two randomized trials in the United States of America and Brazil"

**Author(s):** Chen MP, Macaluso M, Blackwell R, et al

**Reference:** N/A 34(8):557-62.

<http://www.stdjournal.com/pt/re/std/abstract.00007435-200708000-00007.htm;jsessionid=G34f10QQCL7ZffByMSXvqJtL1q4QtBGS2JRQ7vwp2QnhxfS2VZhG!2112021004!181195629!8091!-1>

**Published Abstract:** *Objectives/Goal:* To compare self-reported condom use problems and objectively determined semen exposure in 2 populations. *Study Design:* Two randomized crossover trials in the United States and Brazil compared the failure rates of the female condom (FC) and male condom (MC). Participants used both condom types, completed condom-specific questionnaires to report problems, and collected precoital and postcoital samples of vaginal fluid. Prostate-specific antigen (PSA) was detected by immunoassay. *Results:* Problems with condom use were reported less frequently in the Brazilian study (rate difference: FC = 24%, P(less than)0.0001, MC = 5%, P = 0.003). By contrast, the PSA detection rates were similar for both the FC and the MC (rate difference: FC = 2%, MC = 1%, not significant). These results suggest that the PSA detection rate was similar in the 2 study groups and that self-reported problems may be a less reliable measure of condom failure. *Conclusions:* Use of biomarkers of condom failure like PSA may help to strengthen the validity of studies promoting behavior change for the prevention of sexually transmitted diseases.

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## 4. EPIDEMIOLOGY

### "South African health minister says HIV epidemic easing"

**Date:** 02 August 2007

**Source:** *Associated Press*

<http://www.kpic.com/news/health/8876967.html?fromrss=1>

The HIV infection rate is dropping among young, pregnant women in South Africa but it is on the rise for the country's older women, according to a government study released Thursday. The 2006 survey showed the rate of infection for the virus that causes AIDS fell among pregnant women under 20 from 15.9 percent in 2005 to 13.7 percent last year, and from 30.6 percent to 28 percent in women aged 20-24.

In the hardest hit 25-29 year-old group, it fell from 39.5 percent to 38.7 percent. However, the prevalence among women older than 40 increased from 19.8 percent to 21.3 percent in the same time period. And the overall infection rate among pregnant women in the worst-hit province of KwaZulu-Natal was unchanged, at 39.1 percent.

South African Health Minister Manto Tshabalala-Msimang, who has long been criticized for voicing doubts about the safety and effectiveness of AIDS drugs, said the results showed "a statistically significant decrease" in the overall prevalence of HIV-infected pregnant women from 30.2 percent in 2005 to 29.1 percent last year.

"In the last three years, we have been noticing a stabilizing of HIV prevalence in the country. This year we have seen a turning point," she told reporters. "We are quite excited to see this downward trend."

About 33,000 pregnant women took part in the survey - more than double the previous year.

Independent health experts welcomed the drop, but said the statistics may show nothing more than that the epidemic was holding steady, as has been the case for years. South Africa has an estimated 5.4 million people living with HIV, the second highest after India, which has a much bigger population. Last year, an estimated 950 South Africans died each day from AIDS-related diseases and a further 1,400 were infected each day, according to the Medical Research Council.

David Bourne, epidemiologist at the University of Cape Town, agreed with the minister that the decline was "good news" and that the epidemic was "turning." However, he said the decline in the overall rate of infection to 29.1 percent was not statistically significant, as it fell within the margin of error of the study. Bourne said the minister was still "in denial" that antiretroviral drugs were working. "She is using the statistics not scientifically but in a way which suits her agenda. It is not prevention which has caused the change but treatment," he said.

Regardless, the health minister was upbeat. "It may be a small percentage, but that for us is significant enough because it means those messages (of prevention) around which we have been working for many years are beginning to sink in," she said. "We are beginning to see behavioral changes and that's why we see this decrease." Tshabalala-Msimang has been the target of international criticism for espousing the use of beetroot, garlic, lemon and the African potato in the fight against AIDS, earning her the nickname "Dr. Beetroot."

Deputy President Phumzile Mlambo-Ngcuka was appointed last year to lead efforts in revamping South Africa's AIDS strategy, effectively sidelining Tshabalala-Msimang, who had been ill but recently resumed her duties.

Bourne said - ironically - the success of the rollout of AIDS drugs made it more difficult to interpret the prevalence statistics. As less people died, prevalence figures may not decline as rapidly as expected and might even rise, he said. "The older prevalence figures that have been used for the last 15 years are no longer an appropriate way of measuring the epidemic. What we want to know is the new cases," he added. The government survey gave no information on the number of new infections.

Tshabalala-Msimang said rates had plateaued in recent years and the government, intent on seeing AIDS cases drop, had intensified prevention programs among young people. She said more than 288,000 people were currently on antiretroviral treatment provided by the government.

Aids activist welcomed the decline but questioned whether the government's anti-AIDS campaign was a success. "The thing that is critical is a decline in the incidence rate of new infections," said Nathan Geffen of the Treatment

Action Campaign, which has repeatedly criticized the government for lack of political leadership on AIDS.

The South African government has made reducing the number of new HIV infections one of its main targets, and aims to extend treatment to 80 percent of those with AIDS by 2011.

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## 5. HIV/AIDS VACCINES

### "Nanoparticle tech to develop oral HIV vaccine"

**Date:** 08 August 2007

**Source:** *US-PharmaTechnologist.com*

**Author(s):** Katrina Megget

<http://us-pharmatechnologist.com/news/ng.asp?id=78887>

Emerging specialty pharmaceutical company Nanotherapeutics will be using its nanoparticle drug delivery technology to develop an HIV oral peptide vaccine after entering into a two year agreement with the National Cancer Institute (NCI). The Florida-based company will use its proprietary NanoDRY drug delivery technology to develop the peptide vaccine candidate into an oral form which will have targeted delivery to the lower gastrointestinal (GI) tract. The HIV peptide vaccine candidate, which will target mainly homosexual men, is currently undisclosed but has been developed by the vaccine branch of the NCI to be delivered via the rectum.

Speaking to US-PharmaTechnologist.com, Nanotherapeutics president and co-founder Dr James Talton said the vaccine in its current form was not providing as high an immune response as expected in mouse models and the NCI wanted the vaccine to be developed in an oral form. Nanotherapeutics will formulate the vaccine so that the protein candidate is encapsulated into nanoparticles, which are encapsulated within a pH sensitive particle to target the lower GI tract, which is then incorporated inside the capsule. The nanoparticles will be made up of poly(lactic-co-glycolic acid) (PLGA), a biodegradable and biocompatible synthetic copolymer, which has been shown in studies to be effectively taken up by the immune cells of GI tract known as goblet cells; the area that is targeted by the vaccine.

"These types of particles show they can target specific areas of the GI tract depending on how they are packaged," Talton said. The GI tract is targeted for this vaccine because of the specific immune response that can be generated. The oral formulation to be tested will be the peptide candidate plus one of two immune modulators, which are similar to an adjuvant, but target particular cells to illicit an immune response. The formulation would use the NanoDRY technology which produces dry powders for the delivery of large and small molecules. It uses a low-shear method of rapidly forming particles of controlled size and shape.

Talton said the oral vaccine, which will be trailed in mice models later this year, had many advantages including the targeted delivery technique, a high uptake rate of the vaccine in the targeted immune cells, was noninvasive and easy to manufacture. The action of the oral vaccine also promised to make the vaccine potentially more effective than other HIV vaccines. "This has a real good shot," Talton said.

The Cooperative Research and Development Agreement between Nanotherapeutics and the NCI marked a significant milestone for both the company and the development of novel HIV vaccines, Talton said. "We have been interested in working with the NCI. It's not easy to get in their doors. We're very flattered they came to us and wanted to partner. This really helps to get publicity in the area of oral nanoparticles and I really hope this [drug] works."

Besides NanoDRY, Nanotherapeutics has two other drug delivery technologies: NanoCOAT, which is a solventless-encapsulation system for coating micron and sub-micron size powders to control the rate of drug release; and NanoQUAD, which cryo-mills 50 plus kg/hr of unprocessed powders creating particles that are suitable for a variety of purposes. In 2005, the company received funding from the National Institute on Drug Abuse to develop an oral nanoparticle medication to treat opiate addiction.

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## 6. OTHER PREVENTION APPROACHES

### "HIV education through theatre"

**Date:** 09 August 2007

**Source:** *The Swazi Observer*

**Author(s):** Zinhle Matsebula

<http://www.observer.org.sz/main.php?id=37068&section=entertain>

The Swaziland National Youth Council has co-ordinated a 'Community Theatre for HIV Prevention among Children and Youth' concept. The main focus of the project is to reduce HIV infection among children and the youth using theatre as an educational tool. The project will be implemented by theatre groups namely Swaziland Theatre for Children and Young People (SWATCYP), Siphila Nje Drama Society, People's Education Theatre (PET), Communication Arts Network (Pom Pom) and Siphocosini Youth Association.

The theme of the concept is 'Be Seen, Be Heard, Be HIV-free'. Young people and children will be expected to come up with productions bordering around promoting abstinence, raising awareness on entry points of HIV infection - Intergenerational relationships as well as child abuse and exploitation, these being the objectives of the project. Competitions would be held at all the 55 constituencies in the country and the winners will compete at regional level and from there at national level. The project is funded by United Nations Population Fund (UNFPA), United Nations Children Fund (UNICEF) and NERCHA, who have agreed to resourcefully support the implementing partners since it has been noted that theatre is by far the most innovative and effective method of reaching out to children as well as young people with knowledge and life skills on HIV and AIDS.

NERCHA's Sibusiso Mngadi gave an overview of the project, noting that they fully supported it. "Theatre has an element of education and we are hoping to use the tool to educate children and the youth about the dangers of HIV and AIDS. We are in full support of the project and would like to congratulate the youth council for launching such a concept," Mngadi said. NERCHA Deputy Director reiterated Mngadi's statement emphasising that they were fully behind the project.

"It is a pleasure to note that we are moving a step further where we are changing the concept of doing things. We strongly need to commit ourselves to issues pertaining the youth," Mabuza's said. He noted that it was vital that the focus be on prevention as it was evident that intergenerational relationships tended to contribute more in the escalation of HIV infection. "Older men tend to sleep with young girls. This project is aimed at educating whilst entertaining the youth," he said. Mabuza further thanked all stakeholders and said they were looking forward to the start of the project.

UNICEF's Nonhlanhla Hleta-Nkambule said the organisation was pleased and excited about the project. "The beneficiaries of the project are the children and young people and this is an avenue for them to express themselves. We hope to cover all the 55 constituencies and look forward to a fruitful partnership with SNYC," she said. UNFPA's Marjorie Mavuso noted that children below the age of 18 years tended not to think about consequences of their behaviour thus the project would make them talk about such. She said they were hoping for tangible results and positive behaviour change from such a project. Mavuso also thanked NERCHA and UNICEF for partnering with the organisation.

Ministry of Regional Development and Youth Affairs PS representative Sipiwe Sibandze said the ministry supported the initiative and were also excited about the project as it would maximise HIV education through theatre and at the end change the mindset of the youth who are most vulnerable. SNYC Chairperson Honourable Mphiwa Dlamini said the organisation was grateful to the funding partners as well as the theatre groups, noting that it was encouraging that the project would start at grass-roots level - the constituencies. He promised that they would make sure the project was properly co-ordinated.

### **"Niger's religious leaders unite to fight AIDS"**

**Date:** 06 August 2007

**Source:** *Reuters*

**Author(s):** Abdoulaye Massalatchi

<http://www.alertnet.org/thenews/newsdesk/L06627292.htm>

Muslim, Catholic and Protestant leaders in Niger have joined together to try to teach the impoverished country's young people how to protect themselves against HIV/AIDS. The religious leaders formed an alliance meant to lend weight to government efforts to combat the spread of the disease, including promoting the need for people to take AIDS tests and helping better integrate those already infected.

"Because of their impact on communities and households, and the way they are organised and present on the ground, religious organisations are ideally placed to influence people's values and behaviour," Religious Affairs Minister Labo Issaka said.

Almost half the population of the former French colony is aged under 15 and its birth rate was the highest in the world in 2006. Landlocked on the southern edge of the Sahara, it ranked bottom of the latest U.N. human development index. Just over 1 percent of people aged between 15 and 49 are infected with HIV in Niger, according to U.N. statistics, one of the lower prevalence rates in sub-Saharan Africa. But with rapid population growth authorities have vowed not to be complacent. They set up around 40 medical centres in Niamey where people could have voluntary,

free tests in late June and early July but only 9,000 youths turned up, well below the anticipated 22,000.

Niger is 95 percent Muslim and, as in the rest of Muslim West Africa, Islamic preachers have huge influence over the daily lives of much of the population. When the government of Senegal, another predominantly Muslim West African state, started trying to fight HIV/AIDS in the late 1980s by sending doctors into villages to teach people about condoms, they were given a hostile reception. Religious teachers initially thought promoting contraception risked creating a generation of promiscuous infidels. But they gradually agreed to preach abstinence and fidelity while not criticising condom use. In a marked contrast to Nigeria, where some Muslim clerics say AIDS is part of a Western conspiracy to wage war on Islam, the strategy paid off. Senegal had the second lowest prevalence rate in sub-Saharan Africa in 2003.

Less than half of children in Niger go to school and eight in 10 adults are illiterate, making fighting AIDS by conventional educational methods difficult. "Our aim is to establish a screening culture for HIV/AIDS in this country," said Abdoulaye Bagnou, head of a government anti-AIDS body.

### **"The passions behind the pill: helping women in poverty is what drove the development of the oral contraceptive"**

**Date:** 05 August 2007

**Source:** *U.S. News and World Report*

**Author(s):** Katherine Leitzell

<http://www.usnews.com/usnews/news/articles/070805/13pill.htm>

When the birth control pill was first approved by the Food and Drug Administration in 1957, it was only as a treatment for menstrual disorders. But backers of the pill, and doctors who prescribed it, were keenly aware that it was, first and foremost, a contraceptive. And they well understood all the political, moral, and social baggage that came with it.

The pill didn't emerge from a grass-roots movement or any widespread discontent with available birth control. Instead, it resulted from the passions of four quirky individuals who were committed to the idea of a safe, reliable, and - most important - female-controlled type of contraception. "It's not like women were clamoring for a new form of birth control," says historian Elizabeth Watkins. "They were making do with available methods."

But at least one woman was clamoring. Activist Margaret Sanger, the founder of Planned Parenthood, had made headlines in the early 1900s with her efforts to educate women about contraceptives like condoms and diaphragms and to make them available to women in poverty. Because her own mother had conceived 11 children and died penniless, Sanger felt a calling "to help poor women have fewer children to be brought up." In the early years of her struggle, Sanger was considered a radical and a socialist, and she took part in several labor strikes.

Charged with obscenity for mailing pamphlets on birth control, Sanger left the country to avoid a jail sentence. But she continued her campaign from Britain, eventually returning to open a clinic in a Brooklyn storefront, where she, her sister Ethel, and a team of nurses handed out information and fitted women for diaphragms. Sanger and her sister were rewarded with 30 days in jail for violating the Comstock Law, which prevented dissemination of information about birth control.

*Financial backing.* By the 1950s, Sanger had retreated from her socialist connections and brought her fight to the middle class. In 1953, Katharine McCormick, the millionaire widow of the heir to the International Harvester fortune, approached Sanger and offered her financial support. McCormick was active in philanthropy and women's rights and had a strong interest in science, being one of the few women to have graduated from the Massachusetts Institute of Technology.

The two approached Gregory Pincus, a struggling laboratory scientist who was considered a world expert on human reproduction. They offered to fund his laboratory in exchange for his developing an oral form of birth control, a simple pill that could be popped like an aspirin tablet. Pincus, despite initial reservations, quickly came up with a simple method. He found that injecting rabbits with a daily dose of the hormone progesterone was enough to thicken their cervical mucus and stop them from ovulating, thereby preventing pregnancy. The fact that the pill also regulated a women's monthly cycle was a happy accident.

To get the drug through human trials, the group needed a medical doctor. They shrewdly settled on John Rock, a highly respected fertility expert who was also Roman Catholic. Sanger, who was fervently anti-Catholic, initially bristled at the idea, but she soon realized that Rock would be useful politically. "Being a good R.C. and as handsome as a god," she wrote, "he can just get away with anything." Indeed, Rock helped bring the pill into the mainstream, and for a while his insistence that the pill was a "natural" method of birth control even seemed to ensure that the church would sanction it for married couples. It wasn't until 1968 that the pope formally denounced the pill as an artificial interference with procreation.

The FDA's 1957 decision forever changed the lives of American women. By the time the pill was approved for contraceptive use in 1960, 500,000 women were already using it. By 1990, 80 percent of all American women born since 1945 had tried it.

Because the pill's popularity coincided with the beginnings of the feminist movement, it became a symbol of the sexual revolution. Watkins says that the pill alone didn't cause the sexual revolution, but, she says, it did cause a contraception revolution. Says Anita Nelson, professor of clinical Obstetrics and Gynecology at the University of California-Los Angeles: "The pill gave a woman the ability to control her own fertility."

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## 7. POLITICS AND POLICY

### "South Africa's Mbeki sacks minister who questioned AIDS policy"

**Date:** 09 August 2007

**Source:** *Agence France Presse*

<http://news.brisbanetimes.com.au/south-africas-mbeki-sacks-minister-who-questioned-aids-policy/20074409-sh6.html>

South African President Thabo Mbeki has axed his deputy health minister who questioned the national AIDS policy, a move experts Thursday warned could have a "deadly" impact in the HIV-blighted nation. Mbeki, who attracted flak

some years ago for questioning the link between HIV and AIDS and who is seen to be sensitive to criticism that the government is not doing enough to combat the pandemic, sacked Nozizwe Madlala-Routledge on Wednesday.

"It is true that Nozizwe Madlala-Routledge was sacked ... by the president," Mbeki's spokesman Mukoni Ratshitanga told AFP on Thursday. Although no official reason was given for her sacking, observers said it could be linked to her open criticism that the government's policies on HIV and AIDS policies were not far-reaching enough.

Madlala-Routledge is no stranger to controversy and is believed to be in Mbeki's bad books after she advocated a review of health policy and clashed with her boss, Health Minister Manto Tshabalala-Msimang. Tshabalala-Msimang has been a major target of criticism both at home and abroad over her approach to AIDS, earning the name of Dr Beetroot for touting the use of vegetables to help combat the disease. But the feisty minister, who has turned a deaf ear to calls for her resignation by AIDS activists and some opposition members, is viewed by many to have Mbeki's full support. Experts and politicians Thursday roundly slammed the decision.

South Africa's main AIDS lobby group, the "Treatment Action Campaign" (TAC) which forced the government to provide free antiretroviral treatment to sufferers, said Mbeki had made a huge mistake. "This is a dreadful error of judgement that will harm public healthcare and especially the response to the HIV epidemic," the TAC said in a statement. "It indicates that the president still remains opposed to the science of HIV and to appropriately responding to the epidemic," it said.

South Africa's main labour coalition COSATU, in its strongly-worded statement said that Mbeki's decision to sack the minister had put all the progress achieved under her "in jeopardy" and raised "fears that the National Strategic Plan (against HIV/AIDS) will come to nothing." "This dismissal also raises the danger that it is part of a broader drive to purge all political opponents from their positions. It will deepen a culture of sycophancy..." the Congress of South African Trade Unions (COSATU), said.

Feisty opposition figure Patricia De Lille, who heads the Independent Democrats party, said: "Coming just hours before the dawn of our 13th Women's Day since Freedom (in 1994), this is an insult to every single South African woman who has the courage to stand up for the truth. She said the president "has fired the wrong person and this will have direct and deadly impact on the lives of our millions of poor."

The sacked deputy minister had recently exposed abysmal health facilities at a government hospital in relatively underdeveloped Eastern Cape province. "Instead of reacting defensively, she acknowledged the crisis and spoke of the national emergency of our high child mortality rate," the TAC said.

South Africa recently launched an AIDS plan with the aim of halving new infections by 2011, focusing on the youth among whom most new infections occur. South Africa's overall HIV prevalence was 18.4 percent last year, with some 5.41 million people living with the disease, 257,000 of which are children under the age of 14. The United Nations pinned South Africa's prevalence rate at 18.8 percent in 2005.

South African media reports however suggested that Madlala-Routledge had been fired because of a recent unauthorised trip she took to an AIDS conference in Spain. The reports said that Madlala-Routledge "defied" Mbeki's orders and attended the conference which cost 16,000 rand (2,285 US dollars/1,656 euros). She had also taken her son and an aide.

## "Strait-laced Chechens admit AIDS is a problem"

**Date:** 01 August 2007

**Source:** *Reuters*

<http://www.reuters.com/article/healthNews/idUSL0182151720070801?feedType=RSS&rpc=22&sp=true>

In Chechnya, a society built on traditional values that has been fighting a separatist war for a decade, even talking about AIDS has been taboo. But faced with a growing HIV/AIDS problem, the leadership of the Russian republic is being forced to confront the problem.

At a public ceremony on Wednesday, senior Chechen officials inaugurated an AIDS centre in the capital Grozny. "Of course, the mentality of the Chechen people does not allow us to speak about problems such as AIDS and drug addiction because Chechens never faced such problems," said Kheda Aidamarova, chief doctor of the clinic. "The traditions of the Chechens did not allow people to lead a dissipated lifestyle. "But today, as a result of the war, there is chaos in society which has led to problems like AIDS and drugs and people exhibiting low moral standards."

The Caucasus nation is based on close-knit clan ties, Muslim faith and rigid norms of morality combined with a centuries-old tradition of blood feud. Official data show Chechnya has 719 people infected with HIV but the actual number may be much larger. The number of HIV-infected Russians exceeds 400,000 although specialists estimate the actual figure may be as high as 1.3 million.

"We must... not turn away from people who have problems like AIDS," Aidamarova said. "Our aim is that people should not keep their problems to themselves but that they should feel support."

Chechnya's president, Ramzan Kadyrov, was the first to break the taboo and to discuss the AIDS issue openly. Street billboards for the AIDS centre advertise a healthy lifestyle and urge people to help those infected with HIV. Not everyone is eager to have an HIV test, however, and only a few of the infected dare to confess to their relatives and loved ones they are ill because the stigma on their clan could stick forever.

"None of my relatives knows I am infected," said a Grozny resident who requested anonymity. "And why should they? All the same, I am incurable and I must not spoil their life with my problems. Let them believe I am ill with some other disease."

## "Europe's clinical trials partnership programme in peril"

**Source:** *Lancet*. 2007 Aug 04;370(9585):362.

**Author(s):** Editorial

<http://www.thelancet.com/journals/lancet/article/PIIS0140673607611684/fulltext>

On July 17, the findings of an independent expert group on the troubled European and Developing Countries Clinical Trials Partnership (EDCTP) programme were released. The review was commissioned by the European

Commissioner for Research Janez Potocnik following a very critical European Court of Auditors report in 2005 and ahead of a possible new funding round.

Despite an attempt by EDCTP to gloss over the core message in a highly spun press release, the report makes depressing reading. EDCTP needs to improve substantially if new funding is to be provided, with drastically improved governance and tangible outputs by the end of 2008. Many areas are highlighted as problematic including its complicated co-funding rules, which make it impossible for projects to be initiated by researchers from developing countries and which lead to wasteful duplication in the review process.

Since its initiation in 2003 as a global public-private partnership, EDCTP has had four different executive directors, has only spent a fraction of the possible €600 million, has not developed a clear vision and convincing strategy, and lacks political and public accountability. How realistic, then, is what essentially amounts to going back to the drawing board?

Allyson Pollock, director of the Centre for International Public Health Policy at the University of Edinburgh and a member of the review panel, disagrees with the recommendations of the other members and explains in a separate dissenting chapter, and in speaking to *The Lancet*, why she thinks that EDCTP is unlikely to meet the objectives laid out. Pollock believes that the serious concerns about political control and accountability cannot be overcome in the present structure and that the best way forward would be to fold EDCTP into European Commission (EC) control. She goes further, though, in her recommendations and urges the EC to work with governments in Africa to provide a coherent and comprehensive north-south partnership research strategy grounded in public-health needs.

These are sensible and welcome suggestions. Only then, will Europe get a step closer to the goal it stated for EDCTP: "To reduce poverty in developing countries by improving the health of the populations".

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## 8. HIV/AIDS FUNDING

### "WB grants Afghan govt \$10m to control AIDS prevalence"

**Date:** 01 August 2007

**Source:** *Pajhwok Afghan News*

<http://www.pajhwak.com/viewstory.asp?lng=eng&id=40330>

The World Bank has okayed a \$10 million grant to support the Afghan government's efforts to maintain a low prevalence rate of HIV/AIDS for both the general population and groups at high risk. The HIV epidemic was at an early stage in Afghanistan, concentrated among high-risk groups, mainly injecting drugs users (IDUs) and their partners, the World Bank said on Tuesday. A 2006 study found that three percent of the IDUs in the city of Kabul were HIV-positive. To date, it said, the officially reported number of HIV cases was 71 most of them men. But UNAIDS and WHO estimate a prevalence of between 1,000 to 2,000 HIV positive cases.

In a statement, the bank said the Afghanistan HIV/AIDS Prevention Project was designed to strengthen national capacity to respond to the epidemic by scaling up prevention programs targeting people engaged in high-risk behaviours, including injecting drug use and unsafe sex. The vulnerable groups at high risk included IDUs, sex workers and their clients, truckers and prisoners, the press release added. Objectives of the project are to improve the knowledge of HIV prevention, strengthen surveillance of HIV prevalence and high-risk behaviours, map and estimate the sizes of groups engaged in high-risk behaviour and use communications and advocacy to reduce the stigma related to the deadly disease.

"Although the HIV prevalence is low, it has a high potential for rapid spread due to the current increase in injecting drug use, said Mariam Claeson, World Bank's HIV/AIDS Coordinator for South Asia Region. To date, HIV and AIDS prevention programmes have been fragmented on a small scale. There are a few local and international NGOs and development partners that provide prevention services to high-risk and vulnerable populations. This project will be critical in helping fill this gap."

In Kabul, the Ministry of Public Health has developed the Afghanistan National HIV and AIDS Strategic Framework (2006-2010) to deal with the challenge. This framework aims to maintain a low prevalence of HIV-positive cases and reduce mortality and morbidity associated with the epidemic. The four priority areas of the framework include strengthening communications and advocacy, boosting surveillance, providing interventions for people at highest risk and building programme-management capacity.

### **"Australia extends US\$86 million to fight against HIV/AIDS in Indonesia"**

**Source:** *Associated Press*

<http://www.thejakartapost.com/detailgeneral.asp?fileid=20070803144055&irec=21>

Australia under the scheme of the Australia - Indonesia Partnership for Fighting HIV donated a cash worth to some A\$100 million (US\$85,682,000) to strengthen the prevention and handling of the HIV virus spread in Indonesia. A press statement from the Australian Embassy said on Friday the partnership aimed to support the activities that could prevent and limit the spreading of HIV virus, increase the quality of life of those infected with the deadly virus, and reduce the economic and social impacts of the disease in Indonesia.

Australian Ambassador for Indonesia Bill Farmer said Australia has become Indonesia's main partner in the fight against HIV for more than a decade. The partnership is built upon the ongoing Australia donation and the success of the program being achieved to date, he added. The donation has given important contribution toward the fight against HIV in Indonesia, including the implementation of the Methadone-based treatment in jails which has been developed in 95 jails across the country.

The partnership scheme will also support Indonesia in preventing the spread of HIV and to treat and support those infected with HIV/AIDS, the statement said. The partnership, it said, will also support the leaders to overcome the stigma relating with AIDS. Australia will cooperate with the Indonesian government institutions, including the Papua and West Papua provincial administration, to manage and fund the responses towards HIV.

The A\$100 million-worth program is part of the Australian total commitment worth A\$1 billion (Rp8 trillion) to fight against HIV/AIDS in the Asia Pacific region up to 2010 as announced by Australian Foreign Minister Alexander Downer last week in a regional ministerial level meeting in Sydney.

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## 9. PHARMACEUTICAL INDUSTRY

### "FDA approves new AIDS drug"

**Date:** 06 August 2007

**Source:** *Associated Press*

[http://www.usatoday.com/news/health/2007-08-06-fda-aids-drug\\_N.htm](http://www.usatoday.com/news/health/2007-08-06-fda-aids-drug_N.htm)

The government approved a novel drug Monday to help patients with the AIDS virus who are running out of options, while acknowledging lingering questions about the pills' long-term effects. Pfizer Inc.'s Selzentry is the first anti-AIDS drug that works by blocking a crucial doorway, called the CCR5 receptor, that the HIV virus often uses to enter white blood cells. New York-based Pfizer said the pill, known chemically as maraviroc, would be available next month, but did not return phone calls seeking the planned price.

It marks the first in a new class of HIV medicines since 2003, when the FDA approved an injectible "fusion inhibitor" that blocks a slightly later stage of infection. Researchers have long known that people who naturally lack a working version of the CCR5 doorway are somewhat resistant to HIV infection, and slow to develop AIDS if they do become infected. But the race to develop CCR5 receptor blockers slowed with concerns that this family of drugs might cause serious side effects, including liver or heart damage, and an increased risk of other infections or cancer.

The Food and Drug Administration approved Selzentry after concluding that certain hard-to-treat patients need the new option - but is requiring Pfizer to conduct further research to assess long-term side effects, said Dr. Debra Birnkrant, the agency's HIV drugs chief. For that select group, Selzentry's "benefits clearly outweigh the risks," Birnkrant said. "That doesn't mean there aren't any risks."

The drug is not for the newly diagnosed, but only for patients whose virus is fast becoming resistant to today's HIV drugs, she stressed. Those patients also must get a blood test to ensure the HIV strain they have uses the CCR5 pathway. Doctors would send a frozen blood sample to a San Francisco testing company, Monogram Biosciences. Patients determined to have so-called "R5 virus" would take the twice-a-day pill in addition to their usual HIV drugs.

In a six-month study where patients added either Selzentry or a dummy pill to their regular medicine, Selzentry users were twice as likely to have their virus levels become almost unmeasurable, she said. Topping the side-effect list is a stern warning that the drug may damage the liver, with symptoms that may at first mimic an allergic reaction. People who develop signs of hepatitis or an allergic reaction should see a doctor immediately. Pfizer also warned that studies counted more cardiovascular problems, including heart attacks, in Selzentry users. Other side effects include dizziness, upper respiratory infections and fever.

Pfizer said it planned to use the brand name Celsentri outside the U.S. The FDA forced a spelling change for fear of mixups with similar-sounding drugs here, Birnkrant said.

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## 10. ANNOUNCEMENTS

### **AIDS Vaccine 2007**

<http://www.hivvaccineenterprise.org/conference/index.html>

AIDS Vaccine 07 will be held in Seattle, Washington, USA on August 20-23. The primary goal of the AIDS Vaccine 2007 Conference is to maximize opportunities for collaboration and information exchange and assemble some of the most experienced scientists involved in the field of HIV vaccine and HIV biology from developed and developing countries. For more information, please visit the above conference website.

### **Hormonal Contraception and HIV**

[www.fhi.org/en/RH/Pubs/Network/v24\\_1/index.htm](http://www.fhi.org/en/RH/Pubs/Network/v24_1/index.htm)

The latest *Network* publication from Family Health International (FHI) is devoted to issues related to hormonal contraception and HIV. The following articles may be of particular interest, and all articles can be found at the above website.

- Hormonal Contraception and HIV
- Hormonal Contraception and HIV Acquisition
- Hormonal Contraception and STI Acquisition Explored
- Hormonal Contraception used by HIV-infected Women
- How Does HIV Therapy Affect Hormonal Contraception?

### **International HIV/AIDS Alliance-The Loop**

<http://www.aidsalliance.org/sw1280.asp>

Established in 1993, the International HIV/AIDS Alliance is a global partnership of nationally-based organisations working to support community action on AIDS. These national partners help local community groups and other non-governmental organisations (NGOs) to take action on AIDS, and are supported by technical expertise, policy work and fundraising carried out at the UK-based international secretariat and across the Alliance. In addition to community and country-based programmes, the Alliance also has extensive regional programmes and works on a range of

international activities such as support for South-South cooperation, operations research, training and good practice development, as well policy analysis and advocacy.

The Loop provides a monthly overview of the latest news from the International HIV/AIDS Alliance, and is available for free upon registering at [www.aidsalliance.org/contacts](http://www.aidsalliance.org/contacts). Back issues of The Loop are available at <http://www.aidsalliance.org/sw21338.asp>.

### **Job opening at CHAMP - Online Organizer**

[www.champnetwork.org](http://www.champnetwork.org)

The Community HIV/AIDS Mobilization Project (CHAMP) is building a powerful, national community-based movement that bridges HIV/AIDS, human rights, and struggles for social, economic and racial justice.

CHAMP mobilizes people living with HIV, community activists, researchers, academics and policy advocates throughout the United States and links them with allies around the world in the fight for HIV prevention justice. We're arming a new generation of leaders with tools and resources to challenge and change HIV/AIDS prevention policies; to attack the root causes of the epidemic such as poverty, homophobia and racism; and to join allied campaigns for sentencing reform, health care access, gender equity and other issues....

If you think that sounds hot, then check out this job.

CHAMP's Online Organizer will bring our already strong Internet presence firmly into Web 2.0. As a member of our small, sharp, diverse and intergenerational organizing team, you'll be our staff strategist for integrating online tactics into our campaigns; build our web presence by crafting and maintaining a new website and blog; ensure that we make the most of our DemocracyInAction CMS for organizing, fundraising and other communication challenges; help our staff learn best practices for online work; and win real victories in shared struggles against HIV/AIDS, racism, homophobia and gender discrimination.

To view the job posting, please visit <http://www.champnetwork.org/media/CHAMP-Online-Organizer-Post.doc>

### **New report on donor funding for health in low- & middle-income countries**

<http://www.kff.org/hivaids/7679.cfm>

Donor governments, including the United States and European nations, provide the bulk of international funding for health in low- and middle- income countries each year. Despite significant increases in such funding, however, it still falls short of need as estimated by the World Health Organization's Commission on Macroeconomics and Health. A new report prepared by the Kaiser Family Foundation and the Center for Strategic and International Studies (CSIS), "Donor Funding for Health in Low- and Middle- Income Countries, 2001-2005," provides an analysis of donor commitments for health and includes detailed tables and charts.

Highlighted findings include:

- Between 2001 and 2005, Official Development Assistance (ODA) for health rose from \$7.2 billion to \$15.7 billion, but health did not rise as fast as some other sectors and some areas of health, including basic infrastructure and training, received little funding.
- The United States is the single largest donor to health, accounting for almost a quarter (23%) of commitments in 2005. European nations, collectively, account for an even larger share (29%), and the European Commission which represents the European Union and its 27 member nations, adds another 9%.
- Donors channel the greatest share of their health funding to Sub-Saharan Africa (33%), followed by South and Central Asia (18%).

The full report is available at <http://www.kff.org/hiv/AIDS/7679.cfm> . For more information, please contact Rob Graham at [rgraham@kff.org](mailto:rgraham@kff.org) or (650) 854-9400.

### **Upcoming APHA Annual Meeting and Expo Deadline**

[www.apha.org/meetings](http://www.apha.org/meetings)

Early-Bird Registration Discount Deadline Is Aug. 23. Register now for the APHA Annual Meeting and Expo in Washington, D.C., and save! An early-bird discount of \$115 is offered for registrations received by Aug. 23. Full registration fees become effective between Aug. 24 and Oct. 1. After Oct. 1, attendees must register on site. Washington, D.C., hotels are filling up fast, so register for the meeting and make hotel reservations today!

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