



# ALLIANCE FOR MICROBICIDE DEVELOPMENT

**12 October 2007, Volume 8, Number 40**

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

#### Spotlight on HIV/AIDS Prevention

<http://www.globalhealth.org/news/article/9208>

The Global Health Council sponsored a briefing on HIV prevention issues featuring Khun Mechai Viravaidya - the founder of the Population and Community Development Association (PDA), which received the 2007 Gates Award for Global Health. Khun Mechai, a former Cabinet minister in the Thai government, has devoted his work over the last two decades to combating the spread of HIV in Thailand. PDA's work primarily focuses on a condom campaign in Thailand. The briefing will also focus on prevention strategies implemented by PEPFAR, the President's Emergency Plan for AIDS Relief, and the Alliance for **Microbicide** Development's latest work on this alternative prevention method. We hope you can join us for this very important briefing on HIV prevention.

Featured Speakers:

- Polly Harrison, Alliance for **Microbicide** Development: (Available presentation/documents): U.S. Fed. Gov. funding FY 1997 - 2008, **Microbicide** clinical trial candidates: Planned and Funded as of Sept. 2007, Ongoing as of Oct. 2007, Pre-clinical as of Sept. 2007.
- Caroline Ryan, Office of the Global AIDS Coordinator
- Khun Mechai Viravaidya, Population and Community Development Association (PDA), Thailand

**EDITOR'S NOTE: Presentations are available at the above website.**

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## 2. MEDIA COVERAGE OF MICROBICIDES

### "Scholar makes strides in anti-AIDS battle"

**Date:** 12 October 2007

**Source:** *The Nation*

**Author(s):** Gatonye Gathura, Arthur Okwemba

<http://allafrica.com/stories/200710111086.html>

A Kenyan researcher has developed a product that kills the Aids causing virus, prevents pregnancy and acts as a lubricant - firmly putting the country on a crowded international search for an effective but so far elusive **microbicide**.

Ongoing research in baboons, at the country's main biomedical research facility, the Institute of Primate Research (IPR), has demonstrated the gel's ability to immobilise sperms thus preventing conception, while laboratory studies have shown its ability to kill HIV by making the vaginal environment too acidic for the virus survival.

Dr Peter Gichuhi Mwethera, a senior research scientist and head of Department of Reproductive Health and Reproductive Biology at the IPR - a quasi government institution and a World Health Organisation collaborating centre - in an exclusive interview with the Nation, said he is partnering with a local pharmaceutical company - Universal Corporation Limited, to put the product in the market. The product, UniPron has been patented by the Kenya Industrial Property Institute.

According to the patent, Number 218, Dr Mwethera is credited with the development of a vaginal spermicide and **microbicide** to prevent pregnancy and the transmission of HIV.

"I have also applied for patent rights in India, Rwanda, China, Sudan, Tanzania and Uganda, which either have big populations, or with high HIV prevalence rates, making them attractive commercial outlets," says the researcher. With this success, Dr Mwethera and his team of local researchers have submitted a paper on their findings to two publications: Journal of Contraception and Journal In Vivo. Plans to get the product into the market are at advanced stage, with the first batch expected in the market in December or January, 2008. But Dr Mwethera says they will roll it out as lubricants first.

"The gel will only trade in the market as a **microbicide** and contraceptive once we have accomplished human clinical trials," says Dr Mwethera.

Universal Corporations Limited, the pharmaceutical company, which is going to manufacture the gel, says everything is set for production of the lubricant.

"The gel is stable and we are working on the final touches on packaging," says Dr George Muriithi, the company's head of quality assurance. With a shelf life of between 18 to 24 months, a tube of 50g of the gel is going to cost about Sh60, a price that is a fourth of what the cheapest lubricant selling in the market.

"This product is going to be a success in terms of availability and affordability," says Palu Dhanani, the director of Universal Corporation Limited. Last year, Universal Corporation Ltd. an investee company of Finfund, started producing saquinavir, an HIV medicine through a technology transfer programme extended by pharmaceutical giant Roche.

"It is the first time the company is working directly with a scientist to produce a lubricant and we are thrilled about it." According to Palu, the company has the capacity to produce two tones of the gel everyday and can go beyond this in response to levels of demand.

UniPron, according to the researcher, works by lowering the pH in the vagina to levels that will kill both sperms and microbes, including HIV, without interfering with the naturally occurring and beneficial bacteria in the vagina.

#### *The basic component*

Dr Mwethera's innovation revolves around what is called pH, and this is how it works: The human body is approximately 80 per cent water, the basic component that allow nutrients and various chemicals to be transported from one place to another. These water-based media can have either acid or alkaline properties which are measured by what is called pH. When the acid and alkaline properties are of equal strength, the pH is balanced, any imbalance could lead to profound effects on the body.

Known as UniPron, this **microbicide** gel is made of lemon juice and other ingredients, which, the researcher says, remain a trade and academic secret. With a pH level of 3.4, the gel works by lowering and stabilising the vaginal environment at PH levels of between 3.5 and 4.5.

#### *Kill the sperm*

At such levels, the environment is too acidic for the virus to survive. The same acidic pH will also kill the sperm, hence its capability as a contraceptive. A normal woman's pH level is within this range. But the mixing of the man's semen with vaginal mucus results in the levels rising to neutral or alkaline points (7.0 to 7.2), which allows for conception, but also unfortunately, is conducive for the for HIV survival. This gel, however, ensures this does not happen for at least three hours, the time frame within which the product is effective. Women who will be using it as a **microbicide** are going to apply different dosages depending on the size of their vagina.

They are further going to apply it a few minutes before or during sexual intercourse. After three hours from the time of application, the **microbicide** will lose its efficacy. The challenge is going to be among commercial sex workers who engage in many sexual encounters in a single day. This is because if the **microbicide** is used several times in a day, it is going to leave the vaginal environment constantly acidic.

Such acidity is capable of killing the beneficial vaginal bacterium, leaving the woman vulnerable to infections like fungal. Lemon juice has been used for contraception and vaginal hygiene purposes for centuries.

### *Can cause damage*

Studies in Nigeria and elsewhere show that some women also believe that lemon and lime juice might help protect them from HIV infection. New research findings, however, demonstrate that rather than helping, these juices can cause damage that could make it easier for HIV to enter the body.

"We have been privy to this information and in discussions with prostitutes along Koinange Street, we discovered that they use lemon juice frequently for vaginal douching," said Dr Mwethera. "However, this is not done for control of viruses, but for the temporally tightening of the vagina to impress their clients." This, he says, results in vaginal dryness, which is dangerous as sexual intercourse could lead to the development of lesions along the vaginal walls, making it riskier for HIV and other infections.

To control the acidity generated by lemon juice, the team, he says, worked with different chemical combinations to reach an acceptable and working mix which is being manufactured by Universal Corporation. In his animal studies consisting of 10 baboons, Dr Mwethera says he tested whether the product caused irritation on the genitals and reached at a convenient dose and mix that is safe and does not affect the epithelium - cells in the vaginal lining.

As evidence that the UniPron Gel does not affect the integrity of the vaginal tissue, thus causing lesions or abrasions, Dr Mwethera presents a pathology report. The pathology, conducted by Dr I. O Farah, the current director general of the National Museums of Kenya, was done on the 10 baboons.

### *Lead to irritation*

The pathologist in his report made available to Nation, concludes that, "there was no detectable histological changes in any of the 10 biopsies examined," - meaning the gel does not lead to irritation or eroding of the vaginal wall cells - epithelium.

Now Mwethera joins a crowded field of global search for a **microbicide** which kills the HIV. According to data from the Alliance for **Microbicide** Development, about 29 studies are on various stages of progression across the world. The research, he says, has benefited from a Sh15 million grant from the Government of Kenya, his personal input and that of the partnering company - Universal Corporation Limited.

According to a Memorandum of Understanding between Dr Mwethera and Universal Corporation, accruing benefits will be shared between him, the company, a third legal entity and other contributing entities. IPR director Dr Thomas Karanja notes that the institute is looking at this product with great interest as there is no proven **microbicide** on the market.

Dr Gichuhi Mwethera, who firmly puts Kenya on the international map on biomedical research, has published extensively in international journals including, Biochemical Journal, Journal Reproductive Fertility, In-Vitro, Contraception and J. Med Primatol, but says Kenyan scientists have produced too many research papers and it was time to put products on the market. Born 42 years ago, and married to Mary, a high school teacher, and father to Lilian, Barbara, Nancy and Terry, he studied at Kenyatta University, University of Bristol in the UK, did a postdoctoral in reproductive and molecular biology at the University of North Carolina in the US and has been a visiting research scholar at Katholiek University, Leuven, Belgium in In-vitro fertilisation (test-tube babies technology). For the last six years, he has been a board member of Pumwani Maternity Hospital, chairs a constituency Aids control committee and

currently he is a senior research scientist and head of department of Reproductive Health and Reproductive Biology at the Institute of Primate Research. The Institute of Primate Research (IPR) was established by Louis Leaky in 1960 with monkeys as models to understand human evolution and as a facility for collection and studies of East African primates. Since then, IPR has expanded and is now focused on the breeding and use of non-human primate for the study of human diseases. The Institute has outdoor and indoor housing facilities for breeding colonies of about 270 primates.

IPR is an institution of the National Museums of Kenya NMK and is currently located in 400 acres of Ololua natural tropical forest near Karen, approximately 20kms from Nairobi. The institute is a World Health Organisation (WHO) collaborating centre in human reproduction and tropical disease research, and also described as a member of the European Union-supported Primate Vaccine Evaluation Network.

### "U.'s peptide discovery spurs hope of HIV prevention and treatment"

**Date:** 11 October 2007

**Source:** *Deseret Morning News (Salt Lake City)*

**Author(s):** Lois M Collins

<http://deseretnews.com/article/content/mobile/0,5223,695217674,00.html>

University of Utah School of Medicine researchers have discovered a potent peptide that may prevent HIV from entering human cells, sparking hope of both prevention and new treatment options. The "D-peptide" is 40,000 times more potent at preventing HIV from entering human cells than other known agents of the same class of inhibitors, says Dr. Michael S. Kay, assistant professor of biochemistry and lead author of research published this week in the Proceedings of the National Academy of Sciences online.

At the heart of their findings are HIV's "pocket" and peptides, which are natural and artificial compounds including hormones and antibiotics that tackle various biological jobs. The researchers screened "billions" of peptides before they found a class called D-peptides, says Brett Welch, a U. graduate student and the study's first author.

The D-peptides bind tightly to HIV's "pocket," which acts as an entryway through which the virus enters human cells. When the D-peptide binds to it, it fills the pocket and prevents HIV from getting in. The pocket was discovered in the late 1990s, and researchers ever since have been looking for ways to inhibit it. This, says Kay, is the first time researchers have succeeded.

Kay started working on the project as a post-doctoral researcher at MIT eight years ago. He continued the work when he came to the U. six years ago. They are not at the "end of the lab stage. We've done everything we can do there." The next step will be preclinical testing using animal models and studies to examine issues such as toxicity. In a couple of years, Kay predicts, human clinical trials can begin.

There are a couple of ways the D-peptides might fight HIV infection. The most exciting, Kay says, is its potential as a **microbicide** that could be applied as a topical prophylactic, primarily for women.

Because of the peptide's structure, it's also possible it could one day be developed into an ingestible prevention or treatment. Peptides normally degrade rapidly in the body, so if you swallow them, the stomach consumes them pretty quickly. But the D-peptides, which are artificial, not natural, are a mirror image of what the body's used to, and it doesn't know how to break them down, offering the possibility they could be an effective tool in an ingestible form. The expectation, Kay says, is that they would survive the body's normal degradation process for "dramatically longer."

The ultimate, scientists agree, would be an HIV vaccine, but there isn't one yet and "there's no clear path" to creating one, Kay says. "Rather than wait for the ultimate solution, you do what you can to protect people."

He's enthusiastic but cautious. "We don't want to overstate it. There's a lot of work to do. But we are excited. It's now ready to be tested more thoroughly."

He said the researchers are looking for industrial partners to develop the D-peptides as a treatment for people who already have HIV infection, as well.

In a U. release on the discovery, researchers noted the study includes high-resolution structural analysis, using X-ray crystallography to reveal the atomic details of how D-peptides bind to the HIV pocket. This will guide the development of further improved inhibitors. The structures were obtained by collaborators Christopher P. Hill, Ph.D., U. professor of biochemistry; Andrew VanDemark, Ph.D., formerly at Utah and now an assistant professor at the University of Pittsburgh; and Anne Heroux, Ph.D., at the National Synchrotron Light Source at Brookhaven National Lab.

The research was funded by the National Institutes of Health, the U. Research Foundation and the American Cancer Society.

### **"Still losing the AIDS fight"**

**Date:** 09 October 2007

**Source:** *The Washington Post*

**Author(s):** Richard Holbrooke

<http://www.washingtonpost.com/wp-dyn/content/article/2007/10/08/AR2007100801342.html>

On the day you read this column, an estimated 12,000 people worldwide will contract HIV. Ninety percent of them, about 10,800 people, will not learn they are infected until full-blown AIDS hits them -- in 2015. Until then, those people will unintentionally spread the virus that lies silently within each of them.

But on Dec. 1, the 19th annual World AIDS Day, political leaders and international health officials will, once again, tell the world that although the fight is far from over, progress is being made. The fight is indeed far from over -- but don't believe the second half of such statements.

It is heartening that more than 2 million HIV-positive people are on lifesaving antiretroviral drugs (ARVs), thanks to generous programs from the United States, the European Union, the Global Fund, the Gates and Clinton foundations, and others. Americans should take pride in the fact that, with official aid of over \$13 billion since 2003, the United States has led the world in a manner that evokes generous programs of the past such as the Marshall Plan.

But real progress must be measured by the only criterion that ultimately matters: Is the number of people who are HIV-positive declining? The answer is a resounding no. The number of people infected each day still far outpaces the number of people going on treatment each day. Anthony Fauci, the famed director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, has stated the case in dramatic terms. Speaking in July at an international conference, Fauci said: "For every one person that you put in therapy, six new people get infected. So we're losing that game." He went on to say, "Clearly, prevention must be addressed in a very forceful way."

As a strategy to defeat HIV-AIDS, focusing primarily on treatment will never succeed; it can only keep (some of the) people already infected alive, and then only as long as they take ARVs every day for the rest of their lives. (If they stop taking ARVs, even for a few days, their infection will probably become drug-resistant.)

The only way to reverse the spread of the human immunodeficiency virus is to focus on prevention. If ever an ounce of prevention was worth a pound of cure, this is the case, since HIV lives undetected in people for about eight years before it explodes into full-blown AIDS. Here's the problem: More than 90 percent of the world's HIV-positive people do not know their status and unintentionally spread the virus for those eight years -- to their wives, lovers, people with whom they share dirty hypodermic needles, almost anyone.

With a vaccine apparently a decade or more away (another major clinical trial failure was announced last month) and a safe **microbicide** for women still eluding researchers, prevention needs immediate emphasis and far, far more resources. But most of those fighting HIV-AIDS -- dedicated, hardworking people -- are still reluctant to admit that current prevention strategies are failing. A viable prevention strategy would encompass education and counseling, free condoms, female empowerment, more male circumcision, and abstinence.

But none of this will work without widespread testing -- highly confidential but highly encouraged (which can now be done with simple, cheap 15-minute tests). I have been criticized in the past by some in the international health community for advocating testing, on the grounds that it would violate people's privacy. This is, of course, not my intent: Confidentiality must be respected.

And attention must be paid when Dr. Fauci speaks. Along with former president Bill Clinton, he is one of the few who have publicly advocated vastly increased testing as part of a strategy to stop the spread of HIV. (Even in the United States, according to the Centers for Disease Control and Prevention, at least one in four Americans with HIV do not know they are infected.) In no other medical epidemic in modern history has detection been such a low priority. But because HIV is sexually transmitted, it still carries stigmas in much of the world, including, until fairly recently, the United States. Those with AIDS lose jobs, are thrown out of their families, are denied medical help and are left to die alone. These appalling but widespread reactions lie behind long-standing international guidelines that testing should be completely voluntary.

Here is my challenge to the international health community: This year, tell the truth on World AIDS Day. Admit that we are still losing. Advocate strategies that emphasize prevention and detection, based on the successful "opt-out" testing systems being tried in Botswana, Lesotho and Malawi. If current policies are not changed, we will face uncontrollable growth in the costs of treatment of the victims of a disease that should be, as Bill Clinton has said, completely preventable.

*Richard Holbrooke, president of the Global Business Coalition on HIV/AIDS, Tuberculosis, and Malaria, writes a monthly column for The Post.*

## "When a microbicide trial goes wrong - Part 1"

**Date:** 09 October 2007

**Source:** *PlusNews*

<http://www.plusnews.org/Report.aspx?ReportId=74717>

This is the fourth article in a six-part series on the challenges of HIV-prevention research in South Africa. On Wednesday 10 October IRIN/PlusNews will look at the impact of a failed trial on the participants, followed by the challenges of designing an HIV-prevention trial on Thursday 11 October.

A telephone call on a Friday afternoon. That's how South African researcher Dr Roshini Govinden found out about a major setback in the field of **microbicide** research this year. The clinical trial she was head of in the country's east-coast KwaZulu-Natal Province would have to be stopped after results showed that the risk of HIV infection could increase.

When conducting clinical trials of a product that could potentially protect women from HIV infection, the ideal scenario would be getting it right the first time, without harm, and as quickly as possible, given that far greater numbers of women are at risk from HIV infection than men. But the reality is much more complex. The road to finding an effective **microbicide** - applied via a range of products like gels, films and sponges - that could help prevent the transmission of HIV and other sexually transmitted infections, has been long and not very successful.

In 2000, a large full-scale trial showed that the over-the-counter spermicide, nonoxynol-9, considered a potential **microbicide**, was unsafe after women in the study developed a higher risk of HIV infection. Seven years later, **microbicide** research was dealt another blow when the US-based reproductive health research organisation, CONRAD, announced the premature end of trials of a cellulose sulphate-based **microbicide** after the data safety and monitoring committee found a higher number of infections in the active group compared to the placebo group. This was a huge and unexpected disappointment, as preclinical testing of the **microbicide** had given no indication of a potential for harm, had caused minimal side effects when used in the vagina, and appeared acceptable to women.

CONRAD was conducting the trial in Benin (West Africa), India, South Africa and Uganda. In Nigeria, a cellulose sulphate trial by US-based Family Health International, was also stopped after the CONRAD findings.

Govinden, the principal investigator of the South African study, and Dr Gita Ramjee, director of the HIV Prevention Unit at the Medical Research Council (MRC), which conducted the trials, were catapulted into a storm of controversy when media reports suggested that trial participants had been used as "human guinea pigs", and that researchers had encouraged them to seek out sexual partners at local taverns and have unprotected sex. Almost 10 months after the trial stopped, Govinden is still a bit bruised from the negative publicity, which alluded that the trials had not been conducted in an ethical manner. "It was very stressful for me ... it was very difficult."

*What went wrong?*

In July 2007, Dr Lut Van Damme, lead investigator of the CONRAD trials, told delegates attending the fourth

International AIDS Society conference on HIV Pathogenesis and Treatment, in Sydney, Australia, that the reasons for the larger number of new HIV infections in the cellulose sulphate arm of the trial were not clear.

According to Dr Van Damme, inflammatory reactions, or disruption of the normal vaginal flora with frequent cellulose sulphate use, could be contributing factors. CONRAD is conducting more tests to find an adequate scientific explanation for the higher number of seroconversions (HIV infection) in the cellulose sulphate group. One of the biggest challenges in **microbicide** research is that the only way to check whether the product is working, is to measure new HIV infections as an outcome.

The efficacy of a treatment is often assessed by using surrogate markers like viral load (the level of HI-virus in the bloodstream) and CD4 cell count (measuring the strength of the immune system), which are used to predict whether the treatment is preventing disease progression. By using these surrogate markers, the trial investigator doesn't have to wait for opportunistic infections or deaths to occur.

HIV prevention trials, on the other hand, must enrol large numbers of women living in resource-limited settings, who are also at risk of HIV infection. Researchers place some of them in a placebo-control arm and wait for an event that no one wants - for some of them to become HIV-infected. In all prevention trials, some participants are likely to become infected - irrespective of the intervention - but getting the public to understand this was difficult, Govinden said.

"You are not trying to make people become HIV positive, or increase their risk; we make sure that all participants are counselled, have an adequate supply of condoms, and receive other prevention measures," she told IRIN/PlusNews.

### *Problems and pitfalls*

A week after the CONRAD announcement, public outrage erupted following sensational media coverage and health minister Manto Tshabalala-Msimang ordered a probe into the trials involving just over 600 women in KwaZulu-Natal Province.

"To make matters worse, people interviewed [in the article] weren't in our trial - not one of the trials that we as the unit had implemented ... it was just mischief making, and bad reporting," Govinden commented. She said it was unfortunate that the health department and the national ethics committee "actually chose to believe" the media, despite the "blatant inconsistencies" in the reports; the health department had received regular updates on the progress of the trials, and had been informed of the closure before the news broke.

"As the principal investigator of the Durban site, you may think I'm biased, but the trial was conducted in the best way possible," Govinden said.

Nevertheless, there is always room for improvement. In their report looking at South Africa's experience of the closure of the trials, Govinden and Ramjee suggested that quarterly meetings between the department of health, other governing bodies and researchers be held more often, as the current frequency of meetings was "clearly not sufficient".

The ethical review of clinical trials also needed to be strengthened, so that there would be "no doubts created about the trial conduct when there are unexpected trial outcomes". According to the report, regulatory bodies approve clinical trials, but do not conduct site reviews often enough, mainly because of a lack of human capacity.

Ntokozo Madlala, an advocacy officer at the Gender AIDS Forum, a non-governmental organisation monitoring **microbicide** trials in South Africa, acknowledged that "they [the MRC] were very efficient in getting us the results and tracing the participants," but had underestimated the power of the media, and had not worked closely enough with community advocates.

Many South Africans found the media accusations plausible because they appeared to confirm long-held suspicions of Western medicine; despite attempts to ensure that the correct facts were published, the public was more attracted to the sensational articles.

"I think the most important lesson that we learned from the cellulose sulphate trial is that when embarking on such major research, communities, the media, researchers and the population involved have to be prepared for any outcome that can occur," said Dr Khatijah Ahmed, a principal investigator of a South African trial of the **microbicide** gel, Carraguard, run by the Population Council, an international non-profit organisation.

#### *Picking up the pieces*

After the damage caused by the negative publicity of the trial closure, organisations working to mobilise communities to participate in **microbicide** trials now have their work cut out for them.

"It's so important that there's education, especially of the media ... the news was disappointing, but the greater disappointment was the way in which the media handled the news," said Ahmed, whose trial results are expected to be released at the end of the year. She admitted that efforts to motivate the community would be "so much more difficult" next time around.

According to Govinden, many people in the communities they were currently working in were under the incorrect impression that the minister had called for all **microbicide** trials to be stopped, and also believed that the gel inserted had contained HIV.

Nomusa (last name withheld), 33, a participant in the cellulose sulphate trial, finished her year-long course of the **microbicide** gel in November 2006. A peer educator who had recruited many women to enrol in the trial, Nomusa was often being stopped in the street and asked to account for why she had made people use "the gel with HIV".

The mother of four told IRIN/PlusNews that she would not encourage any more women to participate in other **microbicide** trials because it would be too difficult to get them to join. "People are always asking me how I am; they think I have HIV ... they don't believe me, they still believe the papers."

### 3. OTHER PREVENTION APPROACHES

#### "Sustaining awareness, a step at a time"

**Date:** 07 October 2007

**Source:** *The Washington Post*

**Author(s):** Michelle Boorstein

<http://www.washingtonpost.com/wp-dyn/content/article/2007/10/06/AR2007100601266.html>

AIDS Walk Washington drew its largest turnout in years yesterday, encouraging organizers who have been challenged to keep people focused on AIDS in the United States as awareness of it overseas has grown.

About 7,000 people took part in the event, nearly twice as many as last year. They raised \$800,000 as of yesterday -- more than the event, now in its 21st year, has collected since 1999.

At least one of every 20 District residents is HIV positive -- the worst infection rate per capita of any U.S. city, said Chip Lewis, spokesman for the event. The AIDS walk raises money for the Whitman-Walker Clinic in Washington, the area's largest provider of health services for people with HIV and AIDS.

Rhonda Anderson, 36, went with her 1-year-old son and several friends from the local chapter of Zeta Phi Beta, a historically black sorority. No one in the group knows anyone with HIV, but Anderson said they are worried about the high number of black women who get infected.

"People are getting married later, so they're not monogamous. And people think, 'Oh, yeah, you can take a drug and get over it,' " she said as dance music boomed.

JaVon Townsend and her brother Marcus knew someone with HIV -- their uncle, who died last year two weeks before the walk.

"I know it's real; it can kill people," said Marcus, 12. The siblings, of Waldorf, said their family did not speak openly about their uncle's disease.

Among those heading up Pennsylvania Avenue were clusters of corporate entrants in matching T-shirts, groups from houses of worship, drag queens and a squad of teenagers wearing shirts promoting abstinence. That group, Washington AIDS International Teens (WAIT), danced on stage and sang: "I need someone to wait for me, I need someone to be worthy of me, I want a happy fam-i-ly, so please, baby, wait for me."

To a trio of friends moving toward the Capitol, AIDS is more than a song; it's their life. Infected with HIV in the early '90s, the women have suffered seizures and strokes. But since going to the Whitman-Walker's Austin Center clinic in the early 2000s, they said they are much better.

"In 2001, they gave me six months to live," said Freda Lockhart, 44, who contracted HIV from her daughter's father, who died.

"They told me three to six" months, said Linda Ashby, 50, a recovered cocaine addict.

"If it wasn't for the center, I wouldn't be here," said Vera Colvin, 56.

As waves of walkers and joggers passed, Colvin said she isn't sure how much progress has been made in educating the public about how HIV is transmitted.

"They still think people can touch you and get it -- in 2007!" she said. "People are still ignorant."

### **"A groundbreaking television series tackles HIV/AIDS"**

**Date:** 04 October 2007

**Source:** *Inter Press Service News Agency*

**Author(s):** Cecile Walschaerts

<http://www.ipsnews.net/news.asp?idnews=39535>

It's a first for the Democratic Republic of Congo (DRC): a Congolese filmmaker directing a television series in Lingala - the most widely spoken language in the country -- about HIV/AIDS.

"The idea for this television series came to me by chance while I was looking at a programme on Congolese television," says Djo Tunda Wa Munga, who trained at INSAS, a film school in the Belgian capital, Brussels. "I was very surprised to see AIDS patients come openly and with uncovered faces to speak of the illness on television. I thus wanted to go and see more."

At the end of 2006 he tracked down the people from this programme and was inspired by the accounts of their lives to write a fictional television series called 'My Story'.

Financial assistance for the first episode, titled 'Papy', came from several organisations, including the International Organisation of the Francophonie and the King Baudouin Foundation -- created on the 25th anniversary of the reign of the late Belgian monarch. Wa Munga also received Belgian and German governmental aid, and he has the support of Peter Piot, director of the Joint United Nations Programme on HIV/AIDS (UNAIDS).

"During the screenings organised in Congo, the first episode seemed to have grabbed the public's attention -- what I hope above all that people will embrace the series," Wa Munga says.

The pilot, which the director filmed in record time in Kinshasa, was inspired by the story of Papy Ilunga, a policeman rejected by his family after the announcement that he was HIV positive.

The episode is acted by professional actors, but in certain instances the line between fiction and reality is blurred, as Wa Munga has also filmed the daily life of the Congolese capital and its residents.

"The foundation of reality is very important to my approach. From this, I try to establish story lines. Papy was very happy during the screening in Kinshasa, even if -- I believe -- certain moments of the film were painful for him," says the director.

Frank, moving and sometimes funny, the film charts Papy's efforts to cope with HIV/AIDS in the midst of rejection by his wife and others close to him.

"My story started when I was very ill; I felt death approach, but I could not accept it taking me away," says Romain Ndomba, the actor who plays Papy, in the film.

The message of the episode: the rejection of people ill with AIDS related diseases can hasten their death; without the support of their families, they do not have the will to fight.

'Papy' is scheduled to be shown on Congolese stations this month, then on TV5 Monde, an international channel. The production will also start showing soon at film festivals; on Friday, it will screen at the Fortnight of Francophone Cinema at the Wallonie-Brussels Centre in Paris.

"In supporting the film, we had two goals. They had to do with helping a Congolese cinematic project, but also an ambitious project to fight HIV/AIDS," explained Gerrit Rauws, health affairs director at the King Baudouin Foundation, during the presentation of the pilot in Brussels last month.

Noted Wa Munga: "There are no cinemas in Congo, there is no film industry either."

Rauws's observations were echoed by Sabine Ruppel, a technical councilor for Belgian governmental aid. "This film is a strong signal. Each Congolese can recognise themselves in it, and that's proof of success."

The two organisations provided about 71,000 dollars for 'Papy'.

The preview of the production can be seen on YouTube at <http://www.youtube.com/watch?v=khSuQqK0YWI>

UNAIDS puts at one million the number of people living with HIV/AIDS in the DRC, including 100,000 children younger than 14 -- this according to 2005 figures.

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#### **4. POLITICS AND POLICY**

##### **"GSK seeks WHO backing for cervical cancer vaccine"**

**Date:** 05 October 2007

**Source:** *in-Pharma Technologist.com*

<http://drugresearcher.com/news/ng.asp?id=80348>

GlaxoSmithKline is seeking prequalification status from the World Health Organisation for its new cervical cancer vaccine, Cervarix, in a bid to speed up its availability to developing countries.

Cervarix, which is already available in Australia and Sweden, was given the green light in Europe last month and the company has wasted no time in getting it out to potential users - with a launch yesterday in its home market, the UK, where it is priced at the same level as rival Merck and Co/Sanofi Pasteur MSD's Gardasil.

Cervarix was filed in the key US market in March but is not likely to be made available there until 2008 at the earliest.

A GSK spokesman told in-PharmaTechnologist.com that prequalification status can only be applied for three times a year - in January, May and September - which is why it has taken this step so quickly after being given the go-ahead in Europe; prequalification can only be sought once a product has been granted approval by a recognised drug regulator.

"It is the most effective way to access GSK's tiered pricing system," he added, pointing out that it means that rather than individual countries in the developing world having to review the data, this stage is conducted by the WHO over a year-long process, following which it may endorse the product for procurement by UN agencies and the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunisation), as well as for mass vaccination programmes across the developing world.

Under tiered pricing, GSK offers low-cost vaccines to major purchasers like UNICEF and the GAVI Alliance, as well as individual countries, based on their national income, the volume of doses ordered and the length of the contract.

Added Jean Stephenne, President and General Manager of GSK Biologicals: "By submitting Cervarix for prequalification as early as possible, we are working to eliminate the historical 15-20 year delay for new vaccines to become available in developing countries."

The prequalification programme was created by the WHO in 2001 to increase access to priority medicinal products that meet unified standards of acceptable quality, safety and efficacy, with a particular focus on those used for HIV/AIDS, malaria, tuberculosis and for reproductive health. Acceptance to this list also confirms a manufacturer's ability to fulfil large-scale UN tenders.

The spokesperson told in-PharmaTechnologist.com that no trials of Cervarix have yet been conducted in Africa, but that the submitted dataset contains the results from studies in a broad patient population of 30,000 females - one third of which were in Asia - showing 100 per cent protection against precancerous lesions caused by human papillomavirus types 16 and 18, which are responsible for 70 per cent of all cervical cancer cases worldwide.

There are more than 270,000 deaths each year from cervical cancer and 85 per cent of these occur in the developing world. Cervical cancer is the second leading cause of cancer in women.

Meanwhile, rival Sanofi Pasteur MSD said yesterday that it is seeking expanded labelling for Gardasil to combat vulvar and vaginal cancers caused by the human papillomavirus types 16 and 18.

The company sought prequalification from the WHO for Gardasil in May.

## **"PM wants sex education for children in HIV/AIDS fight"**

**Date:** 05 October 2007

**Source:** *The Jamaica Observer*

[http://www.jamaicaobserver.com/news/html/20071004T210000-0500\\_128023\\_OBS\\_PM\\_WANTS\\_SEX\\_EDUCATION\\_FOR\\_CHILDREN\\_IN\\_HIV\\_AIDS\\_FIGHT.asp](http://www.jamaicaobserver.com/news/html/20071004T210000-0500_128023_OBS_PM_WANTS_SEX_EDUCATION_FOR_CHILDREN_IN_HIV_AIDS_FIGHT.asp)

Prime Minister Bruce Golding on Wednesday called for a more robust programme on sex education for children if Jamaica is to be effective in the fight against HIV/AIDS. Golding made it clear that while the \$3-billion worth of international funding Jamaica has since received to fight HIV/AIDS was very important, it was even more critical that Jamaicans learn to exercise personal choice in a responsible way.

"We are going to have to desist with this foolish notion that sexual awareness is something we should hide from our children and that they must become adults before we introduce them to topics having to do with sexuality," Golding said.

The prime minister, who was addressing Wednesday's Sixth Annual United States Chiefs of Mission Conference on HIV/AIDS at the Terra Nova Hotel in Kingston, said adults will have to start talking to children about sex at an early age. He suggested that there be a strong partnership between the home and the school, as well as the church and community, in helping to educate children about sex and HIV/AIDS. The prime minister's call was supported by Dr Peter Figueroa, chief of epidemiology and AIDS in the Ministry of Health, who told the conference that throughout the Caribbean the percentage of children sexually active under age 15 had increased.

"Many of them are not using a condom or contraceptive when they are having sex and this is a serious problem," he said.

According to Figueroa, there was a need to get family life and health education into the schools, to include sex education and condom skills.

"While we emphasise abstinence we still have to prepare them with condom skills," he added.

In the meantime, the prime minister said that through a Pan Caribbean partnership, Jamaica has been able to synergise its efforts, ideas and policy approaches with those of other countries in the region. But he said it must be remembered that HIV/AIDS is a migratory disease which can travel the world and, therefore, the collaboration of partners will be a critical part of the effort to get on top of the challenges faced by regional states.

United States ambassador to Jamaica, Brenda LaGrange Johnson, said while there has been extensive migration, cultural exchanges and other interactions that enrich the region's cultures it also provided opportunities for the transmission of HIV/AIDS. She told the conference that US President George W Bush had reaffirmed his commitment to the fight against HIV/AIDS by announcing his intention to work with Congress to commit US\$30 billion over five years, doubling the initial commitment.

### **"Getting real with trials"**

**Date:** 31 August 2007

**Source:** *Drug Discovery News*

**Author(s):** Jeffrey Bouley

<http://www.drugdiscoverynews.com/index.php?newsarticle=1651>

You don't send a pilot out to fly and land his or her first plane with only book knowledge. According to INC Research and TheraSim, you shouldn't send researchers into a clinical trial without some hands-on experience with the issues they will face in that trial, either.

To help make sure clinical researchers do go into trials better prepared for success, therapeutically focused contract research organization INC Research has partnered with TheraSim, which has a strong position in clinical performance management (CPM) technology. Together, they are putting together a CPM system that will provide an interactive patient simulation environment designed to both assess and improve the skills and behaviors of clinicians. CPM itself is a relatively new field and the technology is aimed mostly at clinicians in patient care settings rather than clinical trials. But executives at both companies believe there is a pressing need to bring CPM to trial sites.

"We've had great success with CPM on the clinical side and it was always our intention to move into the trials management space," says David Hadden, CEO of TheraSim. "We're pioneering that effort with INC. The training of doctors hasn't changed much from the time of Hippocrates. So much of it is still about reading and listening to lectures. We're trying to train clinicians the same way we train pilots. If you give a newly schooled pilot a flight manual and a month to study it, he will still crash the plane. But if he spends a couple days in a simulator, he can probably fly and land it."

The system under development is designed to rapidly assess site competence; correct deficiencies in Good Clinical Practice and Good Laboratory Practice and protocol adherence through targeted training; and help clinicians develop new skills to continuously improve their competency at a site level. INC Research initially plans on implementing the TheraSim CPM system for investigator site training, which the company says is critical to the clinical trial process - particularly with the current lack of a global standards for training and development.

As Hadden notes, there are perhaps a dozen correct things clinicians can do to patients in a clinical trial, but there are thousands of ways to make mistakes. Using CPM system, he says, should help those clinicians make all the possible mistakes before they touch an actual study participant.

In addition, the system not only provides training but also collects data that can help predict and head off errors before they occur in a trial, notes Jean Chitwood, vice president of corporate administration at INC Research.

"It also helps with turnover," she adds, "because people who are originally trained in a study's protocol may leave and other people come on, so it gives us a platform on which to code the methodology so that we can make sure new staff are brought up to speed most efficiently."

"Our software does not create the methodology and protocols but it does a great job of ensuring that the behavior of clinical trial investigators and study coordinators conforms to the process," Hadden says. "TheraSim CPM measures and reduces the variability introduced by the human element in the process."

This can also help build confidence in global sites in which a company may need to operate clinical trials, Chitwood

says. With the need to conduct trials outside the United States increasing, this is a particular concern for U.S.-based companies that want to ensure consistent, repeatable standards worldwide and minimal trial variability.

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## 5. HIV/AIDS FUNDING

### "Gates charity bolsters approach"

**Date:** 09 October 2007

**Source:** *The Wall Street Journal*

**Author(s):** Marilyn Chase

[http://online.wsj.com/article/SB119189444472753026.html?mod=dist\\_smartbrief](http://online.wsj.com/article/SB119189444472753026.html?mod=dist_smartbrief)

The Bill and Melinda Gates Foundation today will start a \$100 million fund to nurture unorthodox approaches to global health, inviting scientists to bid for small, quickly awarded grants. While other philanthropies and government entities have dabbled in backing offbeat medical experiments, the Gates initiative is among the richest and most ambitious donor-backed programs of this kind.

The initiative follows two disappointments in large trials whose results were reported recently. The trials showed that the cervical diaphragm and a vaccine developed by Merck and Co. failed to prevent infection with the AIDS virus. If the new tack by the world's biggest private charity bears fruit, it could pave the way for similar moves by other grant providers.

The Grand Challenges Explorations program, to be announced in Cape Town, South Africa, will reach out to scientists in Africa and Asia, where disease is widespread and money is scarce, though it will be open to all comers. "Talent is grouped in great institutions, but not all of it," Mr. Gates said in an interview. "There's a real logic to being where a disease exists."

Typical multimillion-dollar Gates Foundation grants require lengthy applications supported by data, financial oversight and peer review often taking six months to a year or more -- which can overwhelm scientists in underdeveloped countries. "As grants get big, the risk element can get squeezed out," Mr. Gates said, adding "if you're giving away \$5 million at a whack," it requires accounting oversight and a mature development plan at odds with novelty.

The new streamlined program will use a shorter application form, and the review will take a few months. Grantees whose concepts prove promising can later apply for additional funding. Given the current atmosphere of fiscal constraint at the National Institutes of Health, where grants tend to favor traditional science, "the Gates program is a welcome move toward trying to fund new and high-risk ideas," said Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases at the NIH. He added that the NIH itself has been trying to address the need to support novelty through its Pioneer Awards.

As a secondary goal, Mr. Gates said he hopes his foundation's new grants will encourage scientists in developing countries to stay at home rather than emigrating.

The family philanthropy of the Microsoft Corp. co-founder and his wife boasts an endowment of \$34.6 billion. So far, it has committed \$13.7 billion in grants, with \$7.95 billion going to global health programs addressing AIDS, tuberculosis, malaria and childhood vaccines. Investor Warren Buffett's 2006 pledge of \$31 billion of his Berkshire Hathaway Inc. fortune to the Gates Foundation will eventually double the pace of annual grant giving to \$3 billion by 2009. Now, having funded many biomedical projects, Gates officials are looking to refill the pipeline with novel ideas.

"New ideas shouldn't have to battle for oxygen as hard as they do," said Tadataka "Tachi" Yamada, the foundation's executive director of global health. He points out that one "ludicrous" challenge to conventional wisdom -- the idea that bacteria and not stomach acid caused ulcers -- eventually won a Nobel Prize and changed the standard of medical care.

One example Mr. Gates cited was the foundation's sponsorship of a program that uses radiation to zap malaria parasites in their invasive stage, known as sporozoites. "Most people look at that and say, 'Whoa, this is pretty wild,' " Mr. Gates said.

Previous Gates grants have gone to more-mature research projects in malaria, AIDS and TB prevention. Refilling the epidemic-prevention pipeline has become more urgent after the failures of the HIV-diaphragm study and Merck's vaccine. A detailed call for proposals in the new endeavor is expected in the first quarter of 2008.

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## 6. PHARMACEUTICAL INDUSTRY

### "China luring preclinical players"

**Date:** 10 October 2007

**Source:** *in-Pharma Technologist.com*

**Author(s):** Kirsty Barnes

<http://in-pharmatechnologist.com/news/ng.asp?id=80470>

China is one of the best destinations to outsource preclinical work, delegates heard at this year's CPhI trade show in Milan.

"The preclinical challenge is having the right research models regarding the safety and protection of animals, but no matter how much care is taken by western labs, they are plagued by protest groups," DA Prasanna, vice chairman and managing director of Manipal Acunova told Outsourcing-Pharma.com.

"The Chinese scientific community has identified this as a niche area and the government has been working to provide an environment where these studies can be conducted to the satisfaction of global sponsors and regulatory

bodies so that the country can become a leader in the field."

Toxicology studies are not easy to perform and so China's heavy focus in this area has meant that they have developed good experience in this field and do a good job, he added. The speed of studies conducted in China has also contributed to the country's appeal.

In addition, the low cost base the country is able to offer is also a major draw card for those partaking in the high risk world of drug discovery. According to a recent report published by the UK Trade and Investment (UKTI) department, the local Chinese industry estimates that Phase I trials can be conducted in China for around 15 per cent of the equivalent cost in a Western country, while Phase II studies cost 20 per cent of the price in the west.

Indeed, the country's emergence as a favourite destination for outsourcing drug development has been reflected in a flurry of activity in this field of late.

In August China's Hutchison MediPharma, Chi-Med's R and D subsidiary, bagged a drug discovery and development agreement with drug heavy Eli Lilly.

Together, the two firms will focus on drug targets in oncology and inflammation at Hutchinson's facilities in Shanghai. China's attractive cost base was a factor in Lilly's decision to partner with the firm.

Although detailed financial terms were not disclosed, Hutchison will receive an upfront payment, annual R and D support fees, along with milestone payments of up to \$20m ((euro)14.2m) - \$29m per candidate at certain time-points and potential royalties on worldwide sales of any commercialised products. Hutchison will also have the option to take control of any candidates that Lilly rejects.

In July WuXi PharmaTech, the biggest Chinese contract research organisation (CRO) announced an initial public offering (IPO) on the New York Stock Exchange. Most of the firm's total net revenues over the last three years were generated from sales to customers located in the US.

The Shanghai-based CRO, which specialises in preclinical laboratory testing services, said it would use \$40m of the proceeds to build a preclinical drug safety evaluation centre in Suzhou, another \$40m to expand its Jinshan facility, and the balance for "general corporate purposes".

In March, preclinical bigwig Charles River Laboratories established a presence in China by signing a joint venture deal with Shanghai BioExplorer, a Chinese preclinical services provider.

The company said this is the first phase of an expansion programme in Asia, designed to support growing demand in this booming market.

"We expect demand for both research models and preclinical services in Asia to significantly increase over the next several years as pharmaceutical and biotechnology companies expand their research efforts in this market, and we intend to play a leading role in this emerging opportunity," said James Foster, chairman, president, and CEO of Charles River.

## "Factory to boost ARV rollout"

**Date:** 09 October 2007

**Source:** *PlusNews*

<http://www.plusnews.org/report.aspx?ReportID=74715>

A new Ugandan pharmaceutical factory has begun producing antiretroviral medication drugs locally, something the government says will significantly increase the number of HIV-positive people accessing the life-prolonging drugs across the country and the East African region.

The US\$38 million factory is the first in Africa to produce full triple-therapy generic ARVs, and is based in a suburb in the south of the capital, Kampala. In addition to ARVs, it will produce the anti-malaria medication, Lumartem, which contains Artemisinin and lumefantrine, but is significantly cheaper than the World Health Organization-recommended first-line brand of the same ingredients, Coartem.

"Government commits itself to its promise of purchasing the ARVs for AIDS patients and ACTs [Artemisinin-based combination therapies] for malaria from the factory for hospitals," Ugandan President Yoweri Museveni said during the inauguration ceremony on 8 October.

The plant was set up by local pharmaceutical company, Quality Chemicals Limited, with Indian pharmaceutical company Cipla Limited, one of the world's largest producers of generic drugs. It is expected to employ an estimated 500 people, including 200 scientists, and began trial runs after its inauguration; however, it will only be ready to produce for the local market in January 2008.

About 80,000 of the estimated 250,000 HIV-positive Ugandans who need ARVs have access to them at present. Health workers have, in the past, cited the high cost of imported drugs and the country's poor health infrastructure as the main reasons hampering ARV rollout.

"The project offers Uganda a regular and cheap supply of medication - our target is that everybody who requires ARVs will be getting them," Emmanuel Katongole, managing director of Quality Chemicals, said at the launch. "The ARV ingredients will be imported from India [and] the ARVs will be distributed in private hospitals, dispensaries and pharmacies; the cost of the drugs will be \$15 per month.

"Two million tablets will be manufactured per day per shift [and] 600 million tablets will be produced per annum. Future targets are 1.2 billion tablets if the plant is fully utilised," he added. "Some of the tablets will be exported to the East African Community countries [Burundi, Kenya, Rwanda and Tanzania], the Democratic Republic of Congo and Sudan."

The inauguration of the plant is seen as a further step in Uganda's fight against HIV/AIDS, for which the government has received accolades in the past. Museveni's aggressive stance against the pandemic in the 1980s and 1990s saw a decline in prevalence from a high of more than 20 percent to 6.4 percent now.

However, chinks remain in the country's anti-AIDS campaign; three health ministers lost their jobs in 2006 following allegations of misappropriation of grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria, and most recently, the government has been criticised for allowing ARVs worth almost \$1 million to expire in its national stores.

## *Improving the supply chain*

Analysts say the government must fill gaps in the supply chain if the new factory is to make any impact on ARV rollout across the country.

Health ministry officials say that for outlets to qualify to distribute ARVs, they must be accredited to administer the drugs and must meet other minimum requirements such as the presence of a laboratory, a trained doctor and a counsellor.

"These things take long to put up and the ARVs have a short shelf life of between 18 to 24 months, so by the time these are put in place, some of the drugs had lost some of their lifespan and some expired," explained Uganda National Medical Stores David Bagonza.

The director-general of health services, Sam Zaramba, said recently the government was working on harmonising the entry and exit of drugs into the stores, which would involve quantifying the country's needs at regular intervals. The government is also improving the standard of health centres across the country so more are able to handle ARV distribution.

Other African nations manufacturing ARVs are Egypt, Nigeria and South Africa; Mozambique also plans to start producing the life-prolonging medication.

### **"Eli Lilly: drug safety revolution 'within our grasp'"**

**Date:** 04 October 2007

**Source:** *Drug Researcher.com*

**Author(s):** Mike Nagle

<http://drugresearcher.com/news/ng.asp?id=80305>

The head of Eli Lilly has called for a reform of the US drug safety system, saying that an information revolution is 'within our grasp'.

Sidney Taurel, CEO of the pharma giant, used a speech at the Cleveland Clinic, US, this week to rebuke the health care industry, medical community and the US government, saying that not enough was being done to take advantage of advances in information technology (IT) and ensure drug safety.

"The use of prescription medicines always will be a matter of balancing benefits and risks," Taurel said. "Fortunately, systems are now within our grasp to more quickly identify both the true benefits and the full extent of risks associated with medicines in widespread use."

"The time is ripe for [US Food and Drug Administration] the FDA, the health care industry, and the medical community to collaborate on a reform of our nation's pharmacovigilance system," he added.

Although the US government is doing more to ensure pharma companies are obliged to conduct post-marketing (Phase IV) clinical trials, both to assess efficacy and safety, there are still plenty of examples of drugs being withdrawn from the market due to serious side effects.

One of the problems facing regulators is that Phase IV trials to gauge how safe a drug is have to be conducted on a large scale over a long time. The costs are high and this often makes pharma companies reluctant to conduct them.

Taurel outlined how a well-functioning health IT system could serve not only to frame hypothesis for Phase IV clinical research, but also become the practical equivalent of massive, real-world trials.

The data for such a system could be gathered from day-to-day medical practices, with an end result of a more accurate picture of a drug's efficacy and safety. Electronic Medical Records (EMR) already exist and are patient-specific repositories of clinical information on diagnoses, treatments and outcomes.

The system needs to be more widely implemented though, said Taurel, and the data needs to be properly blinded to protect patient privacy. If this data was combined with genetic information as well, it would become an extremely powerful tool for a personalised medicine approach to therapy.

Taurel said that as EMR systems are built up, they provide what amounts to a 'commons' in which organisations can collaborate to share health information.

Currently, Eli Lilly, Pfizer and Johnson and Johnson are collaborating with the not-for-profit group e-Health Initiative to test how safety signals can be located and understood using existing data. The Indiana Health Information Exchange and the Partners Healthcare System in Boston are also involved in the partnership.

"This sort of public-private experiment, along with national standards and regional expansion, will soon create a mass of basic infrastructure that could produce the sort of knowledge that will truly revolutionize patient care," concluded Taurel.

"We need to open our minds to the notion that electronic health care data represents a legitimate resource - to which access should in most cases be widespread and easy."

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## **7. ANNOUNCEMENTS**

### **Former Mexican Institutes of Health Director Joins Foundation**

<http://www.gatesfoundation.org/GlobalHealth/Announcements/Announce-071003.htm>

The Bill and Melinda Gates Foundation announced today that Dr. Jaime Sepulveda has joined the foundation's Global Health Program as director of Integrated Health Solutions Development. Dr. Sepulveda is former director of the National Institutes of Health of Mexico and also Mexico's former vice minister of health.

In his new position, Dr. Sepulveda will oversee the foundation's efforts to develop new tools and strategies for diseases and health conditions that claim millions of lives every year in the poorest countries. His specific areas of responsibility will include maternal, newborn, child, and reproductive health; vaccine-preventable diseases; and nutrition.

"Jaime is an accomplished health scientist, and throughout his distinguished career he has been a passionate advocate for health," said Dr. Tachi Yamada, president of the Gates Foundation's Global Health Program. "We're incredibly fortunate to have him leading our efforts to develop effective new tools to fight the world's greatest health problems."

Prior to joining the foundation, Dr. Sepulveda served for more than 20 years in a variety of senior health posts in the Mexican government. As director of the National Institutes of Health of Mexico from 2003 to 2006, Dr. Sepulveda oversaw Mexico's medical research institutes with a combined annual budget of more than \$1 billion. He also served as director-general of Mexico's National Institute of Public Health and dean of the National School of Public Health for almost a decade.

"I am excited and honored to join the Gates Foundation, and look forward to working with the foundation's grantees, partners, and staff," Dr. Sepulveda said. "This is an important time in global health research and development - we're closer than ever to new vaccines, drugs, and other tools that could greatly improve health in poor countries."

In addition to his research credentials, Dr. Sepulveda is an experienced implementer of effective health programs. As Mexico's director-general of epidemiology and later vice minister of health, Dr. Sepulveda designed Mexico's Universal Vaccination Program, which eliminated polio, measles, and diphtheria by more than doubling childhood immunization coverage in two years.

He also established a national health surveillance system that has trained hundreds of field epidemiologists and includes a network of state health laboratories. He is the founder of Mexico's National AIDS Council, and is credited with helping to implement early and aggressive HIV prevention campaigns.

Dr. Sepulveda holds a medical degree from National Autonomous University of Mexico and three advanced degrees from the Harvard School of Public Health. He is a member of the Board of Overseers of Harvard University and a member of the Institute of Medicine of the U.S. National Academy of Sciences.

The foundation's Integrated Health Solutions Development program is one of five teams in the recently reorganized Global Health Program. The others are Infectious Diseases Development, Global Health Discovery, Global Health Delivery, and Global Health Advocacy.

## **New HIV Prevention Technologies: The Agony and the Ecstasy of Microbicides**

<http://www.arhp.org/rh2007/2007presentations.cfm>

At the Reproductive Health 2007 Conference in Minneapolis, MN (26-29 September), Ward Cates, Sharon Hillier, and Anna Forbes presented information on **microbicides** in the plenary session "New HIV Prevention Technologies: The Agony and the Ecstasy of **Microbicides**." The titles of their sessions are provided below, and PDFs are available for download at the ARHP website.

- **Microbicides:** The Agony and the Ecstasy of HIV Prevention Research

- Challenges women may face regarding **microbicide** use
- **Microbicides**

## **New resources available on IRMWG.org**

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

Minutes from the October 2 , 2007 teleconference "Starpharma's VivaGel and it's relationship to the concept of rectal **microbicides**" with Dr. Jeremy Paull of Starpharma of Melbourne, Australia are available for download at [http://www.aidschicago.org/irmwg/docs/IRMWGcall\\_OCT\\_02\\_2007.pdf](http://www.aidschicago.org/irmwg/docs/IRMWGcall_OCT_02_2007.pdf)

"Future Sex 1: **Microbicides**" presented at "The Power of Prevention" in Chicago, October 11, by Dr. Peter Anton. Available for download at [http://www.aidschicago.org/irmwg/docs/Anton\\_FutureSex\\_Microbicides%2010-11-07.pdf](http://www.aidschicago.org/irmwg/docs/Anton_FutureSex_Microbicides%2010-11-07.pdf)

"Pre-Exposure Prophylaxis" presented at the same venue by Dr. Robert Grant. Available for dowload at [http://www.aidschicago.org/irmwg/docs/Grant\\_PREP\\_101107.pdf](http://www.aidschicago.org/irmwg/docs/Grant_PREP_101107.pdf)

## **Omololu Falobi Award for Excellence in HIV Prevention, Research, Community Advocacy**

<http://www.procaare.org/archive/procaare/200710/msg00010.php>

The African **Microbicides** Advocacy Group (AMAG) is proud to collaborate with partners to launch a new award to honour Omololu Falobi's memory and commitment to the field - "The Omololu Falobi Award for Excellence in HIV Prevention Research Community Advocacy" - to be awarded to a community advocate at the next **Microbicides** Conference in New Delhi, India in February 2008. He was a long-time HIV advocate and journalist; he founded the Journalists Against AIDS in Nigeria, was an instrumental pioneer member of the Nigerian Treatment Access Movement (TAM), and co-founded the Nigerian HIV Vaccine and **Microbicide** Advocacy Group. He was tragically killed last year in Lagos, Nigeria.

This award is being given in partnership and with the blessings of the Omololu Falobi Foundation, the Nigerian HIV Vaccine and **Microbicides** Advocacy Group (NHVMAG), Journalists Against AIDS in Nigeria (JAAIDS), and in collaboration with the Global Campaign for **Microbicides** (GCM) and the AIDS Vaccine Advocacy Coalition (AVAC).

Very shortly, there will be a nomination process to identify an outstanding community advocate in recognition of their contribution to the HIV prevention research field through community advocacy. The nominations will be reviewed by a committee of stakeholders in the field and the selected individual will then be recognized and awarded at the Closing Ceremony of the **Microbicides** 2008 Conference.

Every two years, the **Microbicides** Conference confers awards to young investigators and an award for life-time

achievement in the field. This new award for advocacy in Omololu's memory will be an important and ongoing recognition of the contribution of community advocates to the HIV prevention research field, and that their work can no longer go unrecognized.

For more information, please write to [amag\\_info@yahoo.com](mailto:amag_info@yahoo.com)

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