



ALLIANCE FOR MICROBICIDE DEVELOPMENT

27 April 2007, Volume 8, Number 16

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

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

Its purpose is to:

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

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

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1. ALLIANCE UPDATES AND COMMUNITY NEWS

New data: Federal spending on microbicides

<http://www.microbicide.org/microbicideinfo/reference/FedMicrobicideSpendingTableFY2008.pdf>

The Alliance for Microbicide Development is pleased to report the latest figures on spending by the United States government on microbicide research and development, as provided by the US National Institutes of Health/Office of AIDS Research, US Agency for International Development, and Centers for Disease Control and Prevention. A table summarizing these figures is posted on the Alliance website at <http://www.microbicide.org/microbicideinfo/reference/FedMicrobicideSpendingTableFY2008.pdf> The reporting period covers Fiscal Years 1997 through 2008; figures for FY1997 through 2006 are actual expenditures, figures for FY2007 and 2008 are estimated. Although we know that more investment will be needed to arrive at a safe, effective, and affordable microbicide to help prevent HIV/AIDS, we hope that you are gratified by the increase over this period and the hard work by many different advocacy groups and supporters that made it possible.

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2. MEDIA COVERAGE OF MICROBICIDES

"House committee praises Bush Administration for efforts to fight HIV/AIDS pandemic, cites further challenges"

Date: 25 April 2007

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44476

The House Committee on Foreign Affairs during a hearing on Tuesday applauded the progress of the President's Emergency Plan for AIDS Relief in its fight against HIV/AIDS worldwide but raised questions about the program's long-term strategy for tackling challenges associated with the pandemic, *CQ HealthBeat* reports. According to *CQ HealthBeat*, the hearing "provided a preview" of the issues that might arise when Congress reviews PEPFAR for reauthorization next year. Ambassador Mark Dybul, who serves as the U.S. global AIDS coordinator and administers PEPFAR, said the program is on track to reach its goals. As of September 2006, about 822,000 people were receiving access to antiretroviral drugs with PEPFAR support, Dybul said. He added that 61.5 million people had been reached by HIV/AIDS prevention campaigns. Some committee members asked how PEPFAR can help strengthen health systems and infrastructure in focus countries, as well as address shortages of health care workers, *CQ HealthBeat* reports. Other members asked how PEPFAR programs could partner with other programs to prevent HIV-positive people from contracting other diseases, including tuberculosis and malaria. According to Dybul, some PEPFAR-funded laboratories are used to diagnose TB. In addition, some committee members raised concerns about recommendations in a recent Institute of Medicine report that Congress eliminate all budget allocations in PEPFAR, including spending requirements for prevention efforts and abstinence and fidelity programs. Dybul said such funding allocations have been useful in addressing HIV/AIDS prevention issues, adding that PEPFAR allows each focus country to develop its own HIV/AIDS prevention strategy. Dybul said it would be years before the use of new technologies, such as an HIV/AIDS vaccine and **microbicides**, could be put into place. He also said that PEPFAR is examining circumcision programs following recent studies that found male circumcision can significantly reduce HIV transmission through heterosexual sex. Dybul said, "We're still in an emergency," adding, "The trick is how you respond to an emergency and at the same time build a sustainable response." Committee Chair Tom Lantos (D-Calif.) said, "The battle against HIV/AIDS is a marathon, it is not a sprint" (Blinkhorn, *CQ HealthBeat*, 4/24).

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3. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Anti-HIV microbicides: don't forget basic immunology"

Author(s): Silverstein G

Reference: N/A 369(9571):1429. Free registration required.

<http://www.thelancet.com/journals/lancet/article/PIIS0140673607606655/fulltext>

Published Abstract: Jan Balzarini and Lut Van Damme (March 3, p 787)[1] provide an excellent Review of candidate **microbicide** agents to prevent or minimise HIV infection in the vaginal canal. In panel 1 of their article, they list the properties of an ideal anti-HIV **microbicide**. However, the list does not include what might be the most important caveat: the agent should not attract inflammatory cells to the vaginal canal. Basic immunology details that the human body responds to the presence of non-self molecules by mobilising inflammatory cells, including antigen-presenting cells and T cells. Both of these cell types are subject to HIV infection. Accordingly, should large numbers of inflammatory cells be present after administration of candidate **microbicides**, and should the latter **microbicides** fail to neutralise or kill 100% of infectious HIV particles, the stage would be set for higher HIV infection rates. Evidence to support this hypothesis is provided in reports of a terminated phase III clinical trial of the **microbicide** cellulose sulfate, in which more new HIV infections were noted in women who were using the **microbicide** than in women who used a placebo gel.[2]

This is not the first time in HIV/AIDS research that basic immunological concepts have failed to get the attention they deserve. After the isolation of HIV-1 in 1983-84, the scientific community pursued an intensive, but ultimately fruitless, programme to develop a vaccine. In using HIV-1 proteins extracted from virus grown in tissue culture or produced through genetic engineering, researchers failed to take account of the high rate of mutation of HIV and how HIV strains evolve over time *in vivo*.

These early failures in HIV vaccine development could have been anticipated, as could the possibility of failure of a candidate **microbicide**. Accordingly, the first property to be assessed with any candidate **microbicide** is how strong an immune response it elicits when chronically applied in the vaginal canal.

References

1. Balzarini J, Van Damme L. **Microbicide** drug candidates to prevent HIV infection. *Lancet* 2007; 369: 787-797.
2. Altman LK. Tests of drug to block HIV infection are halted over safety. *New York Times* Feb 1 2007;.

"Community perspectives on care options for HIV prevention trial participants"

Author(s): Macqueen KM, Namey E, Chilongozi DA, et al

Reference: N/A 19(4):554-60.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=17453597&query_hl=2&itool=pubmed_docsum

Published Abstract: There is on-going global debate and policy-setting concerning researchers' obligations to meet the health needs of people participating in HIV prevention trials in resource-poor settings. The perspectives of local community stakeholders on this issue are poorly understood as most of what is presented on behalf of communities where research takes place is anecdotal commentary. Using qualitative methods (130 in-depth interviews and 20 focus groups) we assessed perceived fairness of different strategies to meet the health needs of women who become HIV-infected during a hypothetical vaginal **microbicide** trial. Respondents included HIV prevention research participants, community stakeholders and health-care service providers in ten sites in seven countries (South Africa, Malawi, Tanzania, Zimbabwe, Zambia, India, US). Many respondents perceived referrals to

be a potentially fair way to address care and treatment needs but concerns were also voiced about the adequacy of local health-care options and the ability of trial participants to access options. Most respondents viewed the provision of antiretroviral treatment by researchers to HIV-infected trial participants as unfair if treatment was not sustained beyond the end of the trial. The results underscore the importance of effectively linking trial participants to sustainable, community-based treatment and care.

"Willingness to use microbicides is affected by the importance of product characteristics, use parameters, and protective properties"

Author(s): Morrow KM, Fava JL, Rosen RK, et al

Reference: N/A 45(1):93-101.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=17325607&query_hl=5&itool=pubmed_docsum

Published Abstract: BACKGROUND: Along with efficacy, a **microbicide's** acceptability will be integral to its impact on the pandemic. Understanding Product Characteristics that users find most acceptable and determining who will use which type of product are key to optimizing use effectiveness. OBJECTIVES: To evaluate psychometrically the **Important Microbicide Characteristics (IMC) instrument** and examine its relationship to willingness to use **microbicides**. RESULTS: Exploratory and confirmatory factor analyses revealed 2 IMC subscales (Cronbach's coefficient alpha: Product Characteristics subscale (alpha = 0.84) and Protective Properties subscale (alpha = 0.89)). Significant differences on Product Characteristics subscale scores were found for history of douching (P = 0.002) and employment status (P = 0.001). Whether a woman used a method to prevent pregnancy or sexually transmitted disease (STD) in the last 3 months (P < 0.001) and whether she used a condom during the last vaginal sex episode (P < 0.001) were significantly related to her rating of the importance of **microbicides** being contraceptive. Product Characteristics (r = 0.21) and Protective Properties (r = 0.27) subscale scores and whether a **microbicide** had contraceptive properties (r = 0.24) were all significantly associated (P < 0.001) with willingness to use **microbicides**. CONCLUSIONS: Formulation and use characteristics and product function(s) affect willingness to use **microbicides** and should continue to be addressed in product development. The IMC instrument serves as a template for future studies of candidate **microbicides**.

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4. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Do tests devised to detect recent HIV-1 infection provide reliable estimates of incidence in Africa?"

Author(s): Sakarovitch C, Rouet F, Murphy G, et al

Reference: N/A 45(1):115-22.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=17460475&query_hl=8&itool=pubmed_docsum

Published Abstract: The objective of this study was to assess the performance of 4 biologic tests designed to detect recent HIV-1 infections in estimating incidence in West Africa (BED, Vironostika, Avidity, and IDE-V3). These tests were assessed on a panel of 135 samples from 79 HIV-1-positive regular blood donors from Abidjan, Cote d'Ivoire, whose date of seroconversion was known (Agence Nationale de Recherches sur le SIDA et les Hepatites Virales 1220 cohort). The 135 samples included 26 from recently infected patients (less than or equal to 180 days), 94 from AIDS-free subjects with long-standing infection (greater than 180 days), and 15 from patients with clinical AIDS. The performance of each assay in estimating HIV incidence was assessed through simulations. The modified commercial assays gave the best results for sensitivity (100% for both), and the IDE-V3 technique gave the best result for specificity (96.3%). In a context like Abidjan, with a 10% HIV-1 prevalence associated with a 1% annual incidence, the estimated test-specific annual incidence rates would be 1.2% (IDE-V3), 5.5% (Vironostika), 6.2% (BED), and 11.2% (Avidity). Most of the specimens falsely classified as incident cases were from patients infected for >180 days but <1 year. The authors conclude that none of the 4 methods could currently be used to estimate HIV-1 incidence routinely in Cote d'Ivoire but that further adaptations might enhance their accuracy.

"Narrative review: antiretroviral therapy to prevent the sexual transmission of HIV-1"

Author(s): Cohen MS, Gay C, Kashuba AD, et al

Reference: N/A 146(8):591-601.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=17438318&query_hl=8&itool=pubmed_docsum

Published Abstract: Antiretroviral therapy (ART) has prolonged and improved the lives of persons infected with HIV. Theoretically, it can also be used to prevent the transmission of HIV. The pharmacology of ART in the male and female genital tract can be expected to affect the success of the intervention, and ART agents differ considerably in their ability to concentrate in genital tract secretions. Emergency ART is considered to be the standard of care after occupational exposures to fluids or tissues infected with HIV. More recently, ART for prophylaxis after nonoccupational HIV exposures has been widely used and most countries have developed specific guidelines for its implementation. However, developing clinical trials to prove the efficacy of ART postexposure prophylaxis has not been possible. Experiments with rhesus macaques suggest that therapy must be offered as soon as possible after exposure (within 72 hours) and must be continued for 28 days. Additional nonhuman primate experiments have demonstrated protection from HIV infection with ART preexposure prophylaxis, and several clinical trials are under way to evaluate the safety and efficacy of this approach. The degree to which ART offered to infected persons reduces infectiousness is of considerable public health importance, but the question has not been sufficiently answered. This article provides a review of the data on the use of ART to prevent the sexual transmission of HIV and identify challenges to improving and clarifying this approach.

5. EPIDEMIOLOGY

"60 pc HIV-infected living in rural India: WHO"

Date: 26 April 2007

Source: *Press Trust of India*

<http://www.expressindia.com/fullstory.php?newsid=85505>

Sixty per cent of the estimated 5.2 million HIV-infected adults in India are living in rural areas, according to a WHO report.

Though commercial sex is the major reason behind the prevalence of the pandemic in most parts of the country, injecting drug use (IDUs), especially in north-eastern states, Delhi, Mumbai and Chennai, is fast emerging as a major source of transmission. "Analysis of surveillance data by place of residence indicates that HIV has been spreading to the rural areas," the report said. "Of the estimated 5.2 million HIV-infected adults in India, 3.05 million or nearly 60 per cent were residing in rural areas. Of the reported AIDS cases, sexual transmission accounts for 86 per cent in India," the report said.

Apart from several states recording a higher HIV prevalence among rural sentinel surveillance sites than urban sites, the dreaded disease has now started penetrating the low-risk general population, the report pointed out. "The HIV epidemic of Manipur that was once a concentrated epidemic among IDUs, is now considered a generalised epidemic," the report said. In 2005, seven of the 10 ante-natal clinic sentinel surveillance sites in Manipur recorded an HIV prevalence of one per cent or above indicating the spread of infection from high-risk to low-risk populations, report said.

The report said HIV among IDUs increased markedly from seven per cent in 2002 to 23 per cent in 2005. Increasingly, HIV infection rates are being observed among IDUs in not only in northeastern states, but other urban areas like Delhi, Mumbai and Chennai, it said.

The WHO report said that in five of the 35 states and union territories, the median adult prevalence rate is 1 per cent. These states are Andhra Pradesh, Karnataka, Maharashtra, Manipur and Nagaland. Mumbai continues to remain the city where HIV prevalence among sex workers remained consistently high. The city continues to see 40 to 50 per cent prevalence among the this high-risk group for the past five years.

Though, HIV prevalence rates has begun to decrease in some of the southern states, it is increasing in the north-eastern states. "In Maharashtra, where HIV prevalence among sex workers has remained as high as up to 50 per cent for several years, 18 of 30 districts and 16 of 25 districts in Karnataka have HIV prevalence of one per cent or above among ante-natal clinic attendees at government health centres," it said.

Highlighting the need for collecting data on HIV transmission among homosexuals, the report said there was "high HIV transmission among homosexuals". "In India, HIV prevalence among this population ranged from one per cent to 40 per cent across the 18 targeted intervention sites," the report said.

The report said the early IDU epidemics in India were in the north-eastern states where up to 70 per cent of the IDUs were injected.

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6. POLITICS AND POLICY

"World Bank board delays decision on updating health strategy after European members object to changes in family planning policy"

Date: 25 April 2007

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44481

The World Bank Board of Directors on Tuesday deferred a decision on updating the bank's health strategy after several European members objected to a U.S.-backed proposal that would require family planning services, including abortions, to be provided only to people of a certain age, bank officials said, the *Wall Street Journal* reports (Hitt, *Wall Street Journal*, 4/25). Directors from Belgium, France, Germany and Norway in a letter dated April 19 demanded that the bank endorse family planning programs, *AFP/Yahoo! News* reports (*AFP/Yahoo! News*, 4/25). According to bank sources, Whitney Debevoise, the U.S. representative on the board, proposed changing the phrase "reproductive health services" to "age appropriate access to sexual and reproductive health care" into the bank's Strategy for Health, Nutrition and Population Results, *Reuters* reports. Representatives from France, Germany, Italy and Norway during the meeting on Tuesday objected to the proposal, sources said (*Reuters*, 4/24). According to the *New York Times*, some bank officials said that the dispute was resolved by the end of the day and that the word "services" stayed in the report (Weisman, *New York Times*, 4/25). World Bank President Paul Wolfowitz earlier this month said there has not been any change to bank policy on family planning, adding, "We have a new health strategy going to the board, which I think makes it very clear, and I want to make it clear, personally: I think reproductive health is absolutely crucial to what I have said over and over again is a major part of the development agenda, which is making sure that women can contribute equally with men" (*Kaiser Daily Women's Health Policy Report*, 4/16). According to *Reuters*, the World Bank has loaned more than \$3 billion for more than 30 years for population and reproductive health programs, which include preventing HIV/AIDS, unintended pregnancies, sexually transmitted infections, and pregnancy-related illnesses and deaths (*Reuters*, 4/24).

"U.K. backs program that aims to improve drug access, including to antiretrovirals, in developing countries"

Date: 23 April 2007

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/rep_hiv_recent_rep.cfm?dr_cat=1&show=yes&dr_DateTime=23-Apr-07#44410

United Kingdom International Development Secretary Hilary Benn on Wednesday announced that the country will support the Medicines Transparency Alliance -- an initiative that aims to improve access to quality medical care, including HIV/AIDS treatment, in developing countries -- the *Financial Times* reports. MeTA aims to improve access to quality medicine by providing information about HIV/AIDS, malaria and tuberculosis drugs to governments, not-for-profit organizations and pharmaceutical companies, the *Times* reports. The initiative also aims to increase efficiency, bolster drug procurement and fight corruption by making information about drug costs public. MeTA -- which is funded by a 25 million pounds , or about \$50 million, five-year grant from the Department for International Development -- will draw on DFID's experience with its existing Extractive Industries Transparency Initiative, which aims to improve the quality of public procurement for medicines. In addition, MeTA hopes to increase awareness about drug procurement processes and other logistical issues, according to the *Times*. "We want better information on the price of drugs, their availability and quality," Benn said, adding, "We know that there are big mark-ups on drugs, drugs are not always available, distribution is not working and the quality is often not effective." The Bill & Melinda Gates Foundation and other donors are considering lending support to MeTA. Pilot projects are scheduled to be launched this summer in nine countries -- including Ghana, Jordan, Kyrgyzstan, Peru and the Philippines -- the *Times* reports. MeTA aims to draw on the experiences in the pilot countries and launch the initiative worldwide by the end of next year (Jack, *Financial Times*, 4/19).

Related News

In related news, U.K. International Development Minister Gareth Thomas on Thursday announced that the country supports the "right of developing countries to use the flexibilities" of international patent regulations, such as issuing compulsory licenses, when they face a "big public health issue," Reuters reports. According to Reuters, controversy over access to medicine in developing countries has "flared" since Thailand issued a compulsory license for Abbott Laboratories' antiretroviral Kaletra. Although Thomas did not comment specifically on the situation in Thailand, he said that he hopes there will be "more action in terms of lowering prices on second-line" antiretrovirals. According to Thomas, many antiretrovirals still are "simply unaffordable for countries with over-stretched health budgets." He added, "There is also a debate to be had about whether we can see more companies within the industry moving to the low-cost, high-volume way of doing things. We want to explore whether there are the right incentives for that" (Hirschler, Reuters, 4/19).

"World health fund has new director, new challenges"

Date: 22 April 2007

Source: *The Boston Globe*

Author(s): John Donnelly

http://www.boston.com/news/nation/washington/articles/2007/04/22/world_health_fund_has_new_director_new_challenges/

The fight to save tens of millions of lives from AIDS and other infectious diseases has reached a critical crossroads, and Michel Kazatchkine stands in the middle of it.

Kazatchkine, the former French HIV/AIDS ambassador who did his postdoctoral work at Harvard Medical School, tomorrow will take over the Global Fund to Fight AIDS, Tuberculosis, and Malaria -- a critical start-up humanitarian

group that most Americans have never heard of. "You all set?" Anthony Fauci, director of the US National Institute of Allergy and Infectious Diseases, asked him earlier this month in a visit in Fauci's office. "Anxiety is growing," Kazatchkine said, laughing slightly.

Kazatchkine will lead a financing organization that in its first five years has committed \$7.1 billion to 136 countries, including \$1.9 billion from the United States, its largest benefactor. But the Global Fund, along with the US government's own ambitious AIDS program, is trying to address the difficult question of how to sustain the work for decades to come. "We're still in an emergency response, and yet we have to start building [each] country's ownership of the programs," Kazatchkine said during one of two below-the-radar trips to Washington in the last month, part of what he called his "listening tour."

That adjustment, he believes, could be most difficult for the US government program -- known as PEPFAR, for the President's Emergency Plan for AIDS Relief -- which he praised as "starting faster and more efficient" than the Global Fund, but lagging behind the Fund in letting developing countries take the lead.

Under the Global Fund model, countries submit proposals, the Fund reviews them, and approved programs begin. The Geneva-based organization was designed to have a small staff, now at 300 people, so it wouldn't become another United Nations-like bureaucracy. PEPFAR, by contrast, acted more like a general directing an army, setting targets, selecting programs, sending scores of US experts into countries, and looking for local partners along the way.

While the Fund has become indispensable in many countries, its model hasn't worked well in several areas. In a few high-profile cases, government officials have either stolen millions, can't account for the money, or have allowed it to sit in bank accounts. And nongovernmental groups, especially faith-based organizations, have had little influence and little funding in many countries.

Some critics and supporters of the Fund have said that Kazatchkine also must forge a different path from his predecessor, Sir Richard G. A. Feachem. Feachem has been praised as an articulate voice in the fight against the killer diseases but he also faced criticism for his spending. An internal inspector general report, first reported by the *Globe* earlier this year, detailed office parties that cost thousands of dollars and limousines that cost as much as \$900 a day.

Taking a \$1.85 Metro ride recently -- from Fauci's office in Bethesda, Md., to a meeting in downtown Washington -- Kazatchkine insisted that he wasn't taking public transportation for the benefit of the reporter who accompanied him. "I am a public servant," he said. "I'm sure people will look at how I behave." He added, "I don't have the reputation of being a flashy Hollywood person. I don't have the reputation of being vindictive. I am a professional person."

Kazatchkine, 61, was born in Courbevoie, France, outside Paris. Russian was spoken in the house. His father was a Russian native who had resisted the Nazis and was imprisoned in a concentration camp, where he contracted tuberculosis. Kazatchkine remembers his father only as sickly; he died when Kazatchkine was 20. His mother, working as a dressmaker at home, supported the family. He attended medical school in Paris, studied immunology at the Pasteur Institute, and completed his postdoctoral work at Harvard and St. Mary's Hospital in London.

From 1977 to 1980 at Harvard, he worked in the laboratory of a giant in the immunology field, K. Frank Austen. "He already had some excellent training," said Austen, who is now 79 and still at Harvard. "He settled in and played a major role."

Austen and his students were exploring how specific proteins first warn the body of microscopic threats. At the time, little was known about these proteins, which acted as a kind of a fire alarm for a person's immune system.

Kazatchkine was the lead author in three studies published in leading scientific journals. But he wasn't always in the lab. One of his best memories involved the culinary experience at Fenway Park. "I don't think that hot dogs are particularly tasteful, but they were tasteful in context," he said. "And they serve beer in those plastic glasses, and when the glasses are half empty, they are easy to spill, no?"

Soon after leaving Harvard, in 1983, Kazatchkine, then a clinical immunologist, treated a French couple just back from Africa with high fever and severe immune deficiency. It was his introduction to HIV, the virus that causes AIDS. In 1985, he started a Paris clinic specializing in AIDS. That eventually propelled him to senior positions in France, including director of the French National Agency for AIDS Research from 1998 to 2005. But he always saw AIDS patients -- until now. He left his practice to take on his new duties. "I wrote 220 letters to 220 patients to apologize," he said. "That has been one of the most difficult decisions of my life. But it's too much to continue seeing them. I also have to show the Global Fund that I'm becoming fully committed."

His early goals include quadrupling donations to \$8 billion annually by 2010; developing stronger ties with other organizations fighting the three diseases; and committing to "full accountability and transparency" of Fund operations.

Fauci told him the Fund needed to better define its mission. "There's a sort of vagueness about it," Fauci said.

When the meeting ended, Kazatchkine showed a small group with him how to exit the National Institutes of Health campus. He had been here many times before and had known Fauci for years, but he had come this time with new responsibility, and that weighed on his mind. "It's very important that we start with a strong and trusting relationship," he said, entering the Metro.

"Medicines without doctors: why the Global Fund must fund salaries of health workers to expand AIDS treatment"

Author(s): Ooms G, Van Damme W, Temmerman M

Reference: N/A 4(4):e128.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0040128>

Published Abstract:

EDITORS' NOTE: *Because this essay has no published abstract, we have included the introductory text below. The full text of the essay is available at* <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0040128>.

The Global Fund to Fight AIDS, Tuberculosis and Malaria ("the Global Fund") was created to fight three of the world's most devastating diseases. Since its creation in 2002, it has struggled with the difficult task of focusing on three diseases, and at the same time supporting the fragile public health systems that are supposed to implement this fight on the ground.

Recent internal comments from the Global Fund suggest an intention to focus more on the three diseases, and to leave the strengthening of health systems and support for the health workforce to others. This could create a "Medicines without Doctors" situation in which the medicines to fight AIDS, tuberculosis, and malaria are available, but not the doctors or the nurses to prescribe those medicines adequately.

We believe that this would be a strategic mistake, as the Global Fund has an advantage that makes it a key actor in the field of supporting health workforces. Most other donors are forced to aim for sustainability in the conventional sense (implying that beneficiary countries should gradually replace international funding with domestic resources); the Global Fund has been promised sustained funding by the international community, allowing it to make sustained commitments to beneficiary countries. This is what some of the countries most affected by AIDS, tuberculosis, and malaria need to increase their health workforce. Their health workforce challenges are too big to consider a gradual replacement of international funding with domestic resources.

We also believe that the debate about this intention should be public, and we hope to launch the public debate with this article.

We use the examples of two countries - Mozambique and Malawi - trying to fight against a full-blown AIDS epidemic with a fragile health system, to underline the crucial role of Global Fund support to the health workforce.

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7. PHARMACEUTICAL INDUSTRY

"Nurturing baby steps in drug development"

Date: 23 April 2007

Source: *Drug Researcher.com*

Author(s): Mike Nagle

<http://drugresearcher.com/news/ng.asp?id=75974>

Nurturing slow and steady progress is the key to successful drug development, rather than relying on breakthroughs, according to a report from the Association of the British Pharmaceutical Industry (ABPI).

Although there are a record number of potential drugs in the combined pipelines of nearly 50 pharma companies operating in the UK, it "must be nurtured" to achieve success. The ABPI's "A-Z of Medicines research" report has revealed that over the last four years, the number of potential drugs in clinical development has nearly doubled from 561 to 950 compounds, with patients offered new hope in nearly 50 disease areas.

However, as research and development costs soar - the same report show a 700 per cent increase over the last two decades to £3.31bn (€4.88bn), the productivity of the pharma industry as a whole is declining and the ABPI acknowledges that many of these compounds will not make it through the stringent, 12-year development period, and most that do make it, will not be medical 'breakthroughs'. "Research must be nurtured," said Dr Richard Barker, head of the ABPI. "It would be incorrect and unrealistic to assume that, by some miraculous process, we jump

the various stages of development and create the 'perfect' medicine for a disease."

"The 'first of kind' medicine is rarely the 'best of kind' that offers patients the best treatment," he added.

The majority of the compounds are in early to mid stage clinical development - with 362 in Phase I trials and 349 in Phase II. 240 potential drugs are undergoing late stage, Phase III development, where large numbers of patients are treated with the investigational compound. "One of the key facts about medicines research is that advance is not usually made through sudden leaps in knowledge but through small but vital steps in the advance of our understanding of a condition and how to treat it," said Dr Barker. "If we relied solely on breakthroughs, our overall achievements would be less - each of those 950 compounds in development has the potential to lead to a small but significant improvement to the treatment of disease - and, over time, we shall be able to look back and see how far we have come."

Of the diseases being targeted by pharma companies, the one with the largest number of potential new drugs is cancer, with 170 possible drugs being investigated. This is followed by cardiovascular disease drugs (109), mental disorders (62), diseases of the endocrine system (59), respiratory diseases (53) and dementia (20).

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8. ANNOUNCEMENTS

EDCTP announces new Executive Director

<http://www.edctp.org/No-02-Vol-2.250.0.html>

EDCTP is very pleased to announce the appointment of Prof. Charles Mgone as the new EDCTP Executive Director. Professor Mgone was formerly Head of the EDCTP Africa Office in Cape Town, a post which he took up on 2 January 2006.

Born in Tanzania, Charles Mgone has considerable experience in research and research administration. He initially trained as a clinician in Tanzania and the United Kingdom, practising and teaching Paediatrics as well as conducting research. While in the UK he took a PhD in Medical and Molecular Genetics a discipline which he continued to pursue in studying various aspects of infectious diseases including measles, malaria, HIV/AIDS, chlamydia and other sexually transmitted infections. During this period he worked as the Deputy Director and later as the Acting Director of the Papua New Guinea Institute of Medical Research. Prof. Mgone has served as advisor at international and national levels on various matters, especially on malaria and HIV/AIDS but also on child and public health issues. He has written many papers in peer-reviewed journals and has served as the chief editor of the Papua New Guinea Medical Journal. He is the current Chief Editor of the Tanzania Paediatric Journal.

Before joining EDCTP, Prof. Mgone was Network Director of the African Malaria Network Trust (AMANET) where he was responsible for coordinating the African response to the malaria burden through accelerating the development of malaria vaccines and other interventions. In this role, he was responsible for developing and overseeing capacity development of African institutions and scientists conducting clinical trials. This included networking of the African

scientific community; creation of an enabling environment through training; enhancing of ethics review and regulatory framework and the provision and management of grants.

Charles Mgone has an unwavering commitment to accelerating clinical trials and enabling strong African input to genuine partnerships with European researchers working on the poverty related diseases of HIV/AIDS, malaria and tuberculosis. Together with his powerful vision of capacity building and networking of research centres and clinical trial sites across sub-Saharan Africa, this accords exactly with the mission and objectives of EDCTP and we are extremely fortunate to now have him in the position to take the lead in this important endeavour.

Charles Mgone is appealing to European research institutions and all Africans working in this field to join hands in the EDCTP effort to alleviate the burden of these diseases and the poverty and suffering they cause in sub-Saharan Africa.

"African researchers have become increasingly aware of the important role they must have in tackling the diseases that so blight the African continent and its people. At the same time, many European member states have shown, through their participation in EDCTP, a genuine interest in working together through joint programmes and in partnership with their African counterparts. I call on scientists, industry, research funders and national governments in Africa and Europe to grasp this opportunity and press forward with the development of genuine ongoing partnerships which result in solid African ownership and leadership of sustainable initiatives to tackle HIV/AIDS, Malaria and TB and other poverty related diseases."

Upcoming Meeting: Is Male Circumcision the Key to Stopping the AIDS Epidemic?

On Monday, May 7th, the Council on Foreign Relations (New York) will host a meeting on Male Circumcision and HIV Prevention "Is Male Circumcision the Key to Stopping the AIDS Epidemic?" Laurie Garrett will chair the discussion with Mark Dybul, U.S. Global AIDS Coordinator, U.S. Department of State and Thomas R. Frieden, Commissioner, New York City Department of Health and Mental Hygiene, on the policy implications of recent studies that have found that circumcision lowers a man's risk of acquiring HIV infection by 60%.

This is an on-the-record, open meeting, media welcome. RSVPs are required. For this event, please RSVP to: kschneider@cfr.org. Further details are below:

Date: Monday, May 7, 2007

Time: 5:30 - 7:00 p.m. (5:30 - 6:00 p.m. reception; 6:00 - 7:00 p.m. meeting)

Where: Harold Pratt House, 58 East 68th Street, New York

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