IPM’s mission is to prevent HIV transmission by accelerating the development and accessibility of safe and effective microbicides for use by women in developing countries.

Microbicides are vaginal products being developed to reduce the transmission of HIV during sexual intercourse. Microbicides could take the form of a gel, cream, film, suppository or sponge, or be contained in a vaginal ring that releases the active ingredient gradually. A microbicide could also be in a new formulation and use a delivery method yet to be invented.
AIDS is the world’s most deadly infectious disease and claims more than three million lives annually. Over 40 million people are now living with HIV — more than ever before. In many parts of the world, AIDS has become an escalating social and economic disaster, undermining education, health and other sectors and setting back development goals by decades.

On a global level, HIV transmission occurs predominantly through heterosexual sex. Marriage and pledges of fidelity do not protect women from HIV infection. Worldwide, many women newly infected with HIV are practising monogamy within a marriage or a long-term relationship.
Twenty-five years after the disease we now call AIDS was first recognised, the epidemic continues to outpace global efforts to bring HIV infection rates under control. Every day, nearly 14,000 people are newly infected with HIV — an increasing share of them women and girls. The burden of HIV is truly staggering among young women: Globally, 75 percent of young people infected with HIV are female.

It is increasingly clear that halting the spread of HIV/AIDS will require a long-term and global effort. HIV/AIDS must be tackled on many fronts, including expanded delivery of existing prevention and treatment options and the development of new prevention technologies — including microbicides — that can easily be used by women and girls.

In 2005, global leaders demonstrated increasing support for research and development (R&D) of new HIV-prevention methods. At the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) meeting in June and at the Group of Eight (G8) Summit in Scotland in July, government leaders agreed that microbicide and vaccine research are an essential part of a comprehensive and integrated response to the AIDS epidemic. G8 leaders acknowledged the important role of product development partnerships — such as the International Partnership for Microbicides (IPM) — in accelerating drug R&D. Also in 2005, UNAIDS issued a detailed policy paper calling for greatly expanded HIV-prevention efforts, including the development of new prevention technologies.

We must sustain this momentum in 2006 and beyond, and hold global leaders to their commitments to advance microbicide efforts. Policy makers, health officials and the public — north and south — need to understand the importance of increasing global investment in microbicides in order to realise their potential for significantly reducing global HIV incidence.

There are many significant challenges ahead in microbicide research. Although several candidate products are now in large-scale efficacy trials, new candidates are urgently needed in the pipeline. Particular attention must be paid to developing the most promising, low-cost and easy-to-use products. We also must promote community engagement at clinical trial sites to ensure local and national ownership of — and sustained support for — microbicides.

New HIV-prevention technologies are essential if the world is to end AIDS and realise economic and other development targets over the coming decades. At IPM, we look forward to another year of progress toward the goal of developing safe and effective microbicides for use by women throughout the world.

Chair of the Board
Els Borst-Eilers, M.D., Ph.D.

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Over the past year, IPM has grown tremendously as we have pursued our goals of expanding the pipeline of candidate microbicides, launching safety studies and planning efficacy trials — all of which lay the groundwork for rapid global access to future microbicides.

We are happy to report advances in all three of these areas. To expand the microbicide pipeline, IPM entered into new agreements with Merck & Co., Inc. and Bristol-Myers Squibb in October. These agreements provide IPM with royalty-free licences to develop, manufacture and distribute the companies’ compounds for use as microbicides in resource-limited countries. IPM is currently conducting safety studies of dapivirine (TMC120 gel), a drug licensed in 2004 under an agreement with Tibotec Pharmaceuticals, Ltd., and is planning to test the product in a large-scale efficacy trial as soon as capacity and funding are secured.

IPM is also working to establish new clinical trials capacity, particularly in sites throughout Africa. Site development activities are implemented in close collaboration with local communities, advocacy groups and national governments and are informed by the experiences of other researchers testing new HIV-prevention interventions.

In order to ensure that our clinical trials meet the highest ethical standards and are capable of maintaining community support, IPM has developed comprehensive guidelines for the conduct of its clinical trials. The guidelines detail our commitment to provide study volunteers with support and services during and after the trial.

Preparing for rapid global access to microbicides among women and girls in resource-limited countries drives all aspects of our work. For example, access considerations help determine which compounds we pursue for development. And IPM’s licensing agreements with research partners address intellectual property, manufacturing and other issues that will affect global access when a microbicide is licensed for use.

I would like to thank the many donors who have committed their support for microbicide research over the last year. In 2005, IPM raised more than US$40 million from new and existing donors, bringing the total to nearly US$155 million. We have been working with donors and microbicide developers as part of the Microbicide Development Strategy to map gaps in R&D, identify and prioritise steps toward filling those gaps and quantify the resources needed to do so.

Moving forward, I am hopeful that all the work to develop a new prevention technology for women will continue to fall into place. We at IPM are fortunate to be part of a cutting-edge global movement to not only halt the spread of HIV, but ultimately to reverse it and eradicate HIV/AIDS.
HIV IN AFRICA

Increasing HIV prevalence among women, especially women in resource-poor nations, reveals how critical it is that the epidemic be halted. The Joint United Nations Programme on HIV/AIDS (UNAIDS) depicted the growing impact on women in Africa in its annual report on the epidemic in December 2005 (see chart below).

HIV prevalence among 15-24 year-old men and women, selected countries in sub-Saharan Africa, 2001-2005

Overview

IPM is a non-profit product development partnership dedicated to accelerating the development of and accessibility to microbicides in order to greatly reduce HIV infection among women in resource-limited nations. Capitalising on the expertise and resources in both the public and private sectors, IPM pursues microbicide development through state-of-the-art scientific efforts and advocacy to promote awareness, funding and supportive policies for the development and delivery of microbicides.

IPM is working to increase the efficiency of microbicide product development and testing. IPM-supported researchers screen compounds, design new product formulations, establish the manufacturing capacity necessary for product testing, develop clinical trial sites and conduct safety trials. The organisation is now engaged in expanding its clinical trial capacity and planning for a large-scale microbicide efficacy trial.

IPM advocates for increased funding for microbicide R&D and future access to microbicides and other new prevention technologies. Through its collaboration with local communities and civil society groups, IPM is helping address the needs and concerns of women who may participate in microbicide clinical trials or become users of a microbicide in the future.

A safe and effective microbicide would be a powerful tool to advance HIV-prevention efforts. When they become available, microbicides will need to be delivered as part of a package of HIV-prevention options, including treatment for sexually transmitted infections, distribution of male and female condoms and behaviour-change programs, along with other new prevention technologies now under development, including AIDS vaccines.

“The women of Africa need new prevention options. They are at tremendous risk for HIV, so they should be empowered with an option to reverse the pandemic. Microbicides will put HIV prevention into their hands.”

Graça Machel, President, Foundation for Community Development
WORKING WITH THE PRIVATE SECTOR

As a product development partnership, IPM seeks to marshal expertise and resources in the private sector to advance microbicide research. IPM establishes partnership agreements with private companies that allow it to develop industry products for use as microbicides in less-developed countries. Three leading pharmaceutical companies have now entered development partnerships with IPM.

In October 2005, IPM finalised agreements with Merck & Co., Inc. and Bristol-Myers Squibb (BMS) to develop new antiretroviral compounds as potential microbicides. Under these two separate agreements, Merck and BMS each granted IPM royalty-free licences to develop, manufacture and distribute their compounds for use as microbicides in resource-limited countries. As part of the agreement, IPM will receive a share of the profit to forward its mission if the products are developed for commercial use in the developed world by Merck, BMS or another for-profit company.

The new compounds are part of a class of antiretrovirals known as entry inhibitors that block entry of HIV into human cells and, hopefully, prevent HIV infection. Some of the compounds bind directly to HIV; others bind to the CCR5 receptor on human cells.

IPM is also conducting safety trials with dapivirine, a candidate microbicide gel created by the Johnson & Johnson subsidiary Tibotec Pharmaceuticals, Ltd.
Accelerating Microbicide R&D

While all of the words in IPM’s mission statement are important, one of the words most emphasised is “accelerate.” With more than 6,000 women newly infected every day, the world needs a microbicide immediately. To ensure that a successful product will be available, IPM must be unrelenting in its efforts to identify promising new products and test them in clinical trials when warranted.

IPM aggressively seeks opportunities to expand the microbicide pipeline by developing products with varied mechanisms of action, with the knowledge that a greater diversity of approaches will improve the probability of success. In 2005, IPM successfully negotiated agreements with two major pharmaceutical companies — Merck & Co., Inc. and Bristol-Myers Squibb — to develop new antiretroviral compounds as potential microbicides.

In addition, researchers around the world can submit drugs to IPM for evaluation and, if they are deemed of sufficient potential, receive financial support from IPM for their development. Researchers submit proposals for the development of microbicide candidates through a simple application process on the IPM website.

An important part of drug development involves animal models to measure potential efficacy in humans. During 2005, IPM’s pre-clinical team began developing an animal model for testing microbicides that include non-nucleoside reverse transcriptase inhibitors (NNRTIs). No appropriate animal model currently exists for testing this class of drugs, complicating evaluation of the safety of these products before they enter human trials. In addition, IPM provided financial support for the pre-clinical development of several candidate microbicides, including Cyanovirin-N, UC 781 and PMPA (see chart page 6).

Development of formulations and delivery systems for microbicides remains a top priority for IPM. IPM is now working to optimise a gel formulation for a microbicide containing an NNRTI. Last year, IPM also signed agreements with several groups to develop new microbicide delivery vehicles, including vaginal rings, controlled-release technologies and solid dosage forms.

IPM has made rapid progress in the development of dapivirine (TMC120 gel), readying the product for safety trials in 2005. In March 2005, IPM initiated manufacturing operations at its new Good Manufacturing Practices (GMP)-certified facility. The new facility is capable of manufacturing drug products for safety and expanded safety trials and will expedite the process of getting drugs to trial. The plant can fill applicators — the standard method of microbicide delivery — and package products for use in trials. The facility has produced several batches of placebo and dapivirine for use at IPM’s clinical trial sites in Rwanda, South Africa and Tanzania.
### IPM CLINICAL TRIALS

<table>
<thead>
<tr>
<th>STUDY</th>
<th>STUDY NAME AND LOCATION</th>
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<td></td>
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<td></td>
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<tr>
<td>IPM005B</td>
<td>Dapivirine gel expanded safety trial</td>
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<td>IPM007</td>
<td>Seroconverter protocol</td>
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<tr>
<td>IPM008</td>
<td>Dapivirine vaginal ring trial</td>
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<td>IPM009</td>
<td>Dapivirine gel efficacy trial</td>
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<td></td>
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<td></td>
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<tr>
<td>IPM010</td>
<td>Dapivirine gel male tolerance trial</td>
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<tr>
<td></td>
<td>Belgium</td>
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* Estimated number of volunteers in study

### IPM INCIDENCE STUDIES

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<tr>
<th>STUDY</th>
<th>STUDY NAME AND LOCATION</th>
<th>STATUS</th>
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<tbody>
<tr>
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<td>Completed</td>
</tr>
<tr>
<td></td>
<td>Kenya (Mombasa)</td>
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<tr>
<td>IPM002A</td>
<td>Cross-sectional study</td>
<td>Ongoing</td>
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<tr>
<td></td>
<td>Nigeria (Benue, Nasarawa)</td>
<td></td>
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<tr>
<td>IPM002A</td>
<td>Cross-sectional study</td>
<td>Planned</td>
</tr>
<tr>
<td></td>
<td>Kenya (Meru, Naivasha, Nandi Hills, Thika)</td>
<td></td>
</tr>
<tr>
<td>IPM002A</td>
<td>Cross-sectional study</td>
<td>Planned</td>
</tr>
<tr>
<td></td>
<td>Rwanda (Kigali)</td>
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<tr>
<td>IPM002B</td>
<td>Cohort study</td>
<td>Planned</td>
</tr>
<tr>
<td></td>
<td>Kenya (Mombasa)</td>
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<tr>
<td>IPM002B</td>
<td>Cohort study</td>
<td>Ongoing</td>
</tr>
<tr>
<td></td>
<td>Tanzania (Moshi)</td>
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</table>
Initiating Clinical Trials

Extensive preparation is needed to ensure clinical trials of microbicides meet all regulatory and ethical requirements and produce meaningful results. In 2005, IPM’s site development and clinical work focused on the operational aspects of launching its initial safety trials and developing additional trial sites for future large-scale efficacy trials.

IPM also developed guidelines for the conduct of its clinical trials. These guidelines have been reviewed by a number of experts, including ethicists. In addition, IPM developed trial site capacity and readiness through training sessions and a series of meetings for investigators and staff. For example, an investigators meeting in July brought together for the first time site staff working in Rwanda, South Africa and Tanzania to review and discuss the trial protocol.

At the end of the year, staff at these sites began screening participants for a safety trial of dapivirine, which started in October 2005. An expanded safety trial of dapivirine was also started in Belgium.

IPM has initiated several epidemiological studies in preparation for its large-scale efficacy trial of dapivirine. These studies are gathering information on HIV incidence rates in participating communities and will help researchers assess whether sites are suitable for large-scale trials. The epidemiological studies are being conducted in Kenya, Nigeria and Rwanda and involve collaborators from Belgium, the Netherlands, Nigeria, Rwanda, South Africa and the United States. IPM’s goal is to identify between 10 to 20 new sites for safety and efficacy trials of dapivirine and other microbicides.

IPM also continues to research the use of TMC120 in a vaginal ring delivery system in addition to a gel. In 2005, results from a vaginal ring study demonstrated that the rings are a viable method of microbicide delivery. IPM and Tibotec Pharmaceuticals, Ltd. also conducted a second vaginal ring study among 13 women in Belgium to evaluate the feasibility and safety of using a different kind of ring.
OPENING REGULATORY PATHWAYS

IPM works with regulatory agency staff in many countries to facilitate the review of clinical trial protocols and, eventually, licensing applications for the use of microbicides.

Sponsors of drug trials typically work with regulatory agencies to design studies so that they meet all regulatory requirements. The types of studies required will vary from product to product, but regulatory requirements are generally well established for many drug products.

When a whole new drug class – such as microbicides – is introduced, regulatory agencies must create new guidelines. These guidelines will be based on several criteria, including a risk/benefit analysis for the population in which the product is being considered for distribution. Regulatory guidelines on microbicides will likely change as research continues to provide new information.

In 2005, IPM met with staff of national regulatory agencies in Africa, Europe and North America to discuss regulatory considerations and prepare for microbicide clinical trials. IPM also collaborated with the World Health Organization (WHO) to build regulatory capacity in resource-limited countries. In January 2005, IPM participated in a regulators’ meeting in Ethiopia organised by the African office of WHO (AFRO). Several African regulatory agencies were represented at the meeting and similarities and differences between regulatory issues concerning HIV vaccines and microbicides were discussed.

IPM and WHO also co-hosted a meeting of regulators from the Southern African Development Community in Muldersdrift, South Africa, in 2005. Regulators from 14 southern African nations gathered to learn more about microbicide development as well as pre-clinical, quality and risk-benefit considerations. Representatives from the South African Ministry of Health and the Medicines Control Council of South Africa attended and addressed the group.
Securing Global Access

IPM’s commitment to global microbicide access informs all of its work. IPM is laying the foundation for access in several ways, including establishing innovative intellectual property agreements that enable delivery of microbicides in resource-limited settings; selecting for development products that are mindful of the realities of women’s lives; and designing policies and delivery strategies to promote successful product distribution. The ultimate goal is to maximise the HIV-prevention impact of microbicides by making them widely accessible to women at risk of HIV infection in resource-limited countries throughout the world.

In 2005, IPM established the Global Public Policy department to lead policy research, analysis and advocacy to support microbicide development and ensure future access to microbicides.

IPM works closely with local partners to evaluate country preparedness for microbicide distribution. The organisation has also sponsored studies and consultations in South Africa and Zambia to identify challenges to the successful delivery of microbicides. Similar research, funded by the European Commission, is planned in India and several additional countries in sub-Saharan African during 2006.

Understanding the product preferences of the women who will use microbicides is crucial if these products are to be adopted and widely utilised. In 2005, IPM finalised plans for a market survey exploring women’s preferences on microbicide use. It compares three different gel formulations. Results from this survey, expected in 2006, will directly inform product design and development.

“New prevention technologies such as vaccines and microbicides are essential in order to turn the tide against HIV in Mozambique. More than 1.3 million people in Mozambique are already living with HIV. We are working closely with the international community to help inform people about microbicides and encourage new ways to prevent the spread of HIV.”

Dr. Paulo Ivo Garrido, Minister of Health, Mozambique
IPM is working to establish an enabling environment for microbicide development and global access. By educating policy makers and opinion leaders worldwide, IPM is building a powerful case for investment in microbicides and policies that promote global availability of these products, when licensed.

In 2005, IPM joined forces with the Global Campaign for Microbicides and the Alliance for Microbicide Development to advocate for microbicides in advance of the 2005 G8 Summit in Gleneagles, Scotland. In their official Summit Communiqué on Africa, G8 leaders for the first time recognised the role of microbicides as part of a comprehensive response to HIV/AIDS. G8 leaders also endorsed the public-private partnership model as an important strategy for accelerating research on neglected diseases.

Following the summit, the United Kingdom made a significant financial commitment to microbicide development.

“We believe a microbicide will provide a powerful new option for African women to protect themselves. We encourage the G8 to also support efforts today towards preparing for future access to effective microbicides.”

Manju Chatani
Coordinator of the African Microbicides Advocacy Group
Raising Awareness & Support

IPM is a global advocate for microbicide development and delivery. The organisation mobilises resources for microbicides and seeks the engagement and support of policy makers, advocates, people living with HIV/AIDS and others. IPM collaborates with other organisations to position microbicide development as an essential component of a comprehensive and integrated response to HIV/AIDS.

In 2005, IPM joined with a variety of international groups, including the UNAIDS’ Global Coalition on Women and AIDS, to raise global awareness about microbicides. IPM worked with microbicide champions such as Graça Machel, President of the Foundation for Community Development in Mozambique, and Stephen Lewis, UN Special Envoy on HIV/AIDS in Africa, to highlight the importance of new prevention technologies, including microbicides and vaccines. Last year, IPM took its message to a special meeting on the HIV/AIDS epidemic at the United Nations and to audiences from Maputo, Mozambique, to Brussels, Belgium. The microbicides briefing in Maputo, opened by Dr. Paulo Ivo Garrido, Mozambique’s Minister of Health, brought together southern African activists, NGO representatives, government officials and researchers.

IPM also enriched its working relationships with AIDS activists and policy makers in 2005. IPM has started to engage a dialogue between a working group of scientists and women living with HIV, to discuss a variety of issues concerning HIV-positive women and their role in microbicide research and clinical testing. IPM met with AIDS activists at meetings in Boston, Rio de Janeiro and Tucson, Arizona, to initiate ongoing and open dialogues. IPM also sponsored briefings with national and international policy makers in Brussels, New York and Washington, DC.

Projections developed in 2005 by IPM, the Global Campaign for Microbicides and the Alliance for Microbicide Development show that the microbicide field requires an annual investment of US$280 million to ensure timely development of safe and effective microbicides. New funding commitments for IPM announced in 2005, along with ongoing support from Canada, the Netherlands, the Rockefeller Foundation, the Bill & Melinda Gates Foundation and the European Commission, will advance IPM’s work. On World AIDS Day, December 1, 2005, Denmark, Ireland, Sweden and the United Kingdom announced nearly US$30 million in renewed commitments to IPM. These commitments were in addition to funding received against pledges made in 2004 from Norway, the United States and the World Bank.
Financials

Statement of Financial Position Year Ending December 31, 2005

ASSETS

Current Assets
- Cash $10,758,546
- Short term investments 45,806,839
- Pledges receivable 1,190,760
- Pre-paid expenses 112,359
- Total Current Assets 57,868,504

Furniture, Equipment and Leasehold Improvements
- Less accumulated depreciation of $382,549
- Pre-paid Rent and Maintenance 595,007
- Security Deposit 59,963
- TOTAL ASSETS 59,971,739

LIABILITIES AND NET ASSETS

Current Liabilities
- Accounts payable $1,822,380
- Accrued expenses 281,876
- Payroll withholdings 21,244
- Total Current Liabilities 2,125,500

Deferred Rent 28,359
- Total Liabilities 2,153,859

Net Assets
- Unrestricted 56,296,454
- Temporarily restricted 1,521,426
- Total Net Assets 57,817,880
- TOTAL LIABILITIES AND NET ASSETS 59,971,739

REVENUE

Contributions $38,787,700
- Interest and other revenue 943,428
- Unrealised gain on investments 51,951
- Unrealised loss on currency translation (341,969)
- Realised loss on currency translation (60,586)
- TOTAL REVENUE 39,380,524

EXPENSES

Program Services
- Access $141,693
- Clinical/regulatory affairs 5,643,373
- External affairs/policy 1,996,783
- Research and development 8,512,182
- Total Program Services 16,294,031

Supporting Services
- General and administrative 2,121,965
- Fundraising 359,838
- Total Supporting Services 2,481,803
- TOTAL EXPENSES 18,775,834

CHANGE IN NET ASSETS $20,604,690
- NET ASSETS AT THE BEGINNING OF YEAR 37,213,190
- NET ASSETS AT THE END OF YEAR 57,817,880

IPM’s net assets are the result of accumulated contributions toward future microbicide product development, which will require significant additional financial support. The complete audited statements are available upon request to the Chief Financial Officer.
A YEAR OF GROWTH AT IPM

IPM’s staff continued to expand throughout the year. By the end of 2005, there were 34 employees. The organisation is headquartered in Silver Spring, Maryland, USA, and now also has staff in Kenya, South Africa and Rwanda to provide support to clinical trial sites throughout Africa.

### EXECUTIVE MANAGEMENT

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
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</thead>
<tbody>
<tr>
<td>Chief Executive Officer</td>
<td>Zeda F. Rosenberg, Sc.D.</td>
</tr>
<tr>
<td>Chief Financial Officer</td>
<td>Alex K. Brown*</td>
</tr>
<tr>
<td>Chief Medical Officer</td>
<td>Annaléne Nel, M.D., Ph.D.*</td>
</tr>
<tr>
<td>Chief of External Relations</td>
<td>Pamela Norick</td>
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### DEPARTMENTS

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</thead>
<tbody>
<tr>
<td>Clinical Affairs</td>
<td>Annaléne Nel, M.D., Ph.D., Chief Medical Officer</td>
</tr>
<tr>
<td>External Relations</td>
<td>Pamela Norick, Chief of External Relations</td>
</tr>
<tr>
<td>Resource Development &amp; Communications</td>
<td>Martin Mehta, Executive Director</td>
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<tr>
<td>Global Public Policy**</td>
<td>Saul Walker, Executive Director</td>
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<tr>
<td>Finance &amp; Administration</td>
<td>Alex K. Brown, Chief Financial Officer</td>
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<td>Project Management</td>
<td>Karen Douville, Executive Director</td>
</tr>
<tr>
<td>Research &amp; Development</td>
<td>Joseph Romano, Ph.D., Executive Director</td>
</tr>
</tbody>
</table>

* Alex K. Brown and Annaléne Nel joined IPM in 2006.
** Global Public Policy is managed from IPM Belgium.
Board, Donors & Advisors

BOARD OF DIRECTORS 2005

DR. QUARRAISHA ABDool KARIM
Director - Columbia Southern African Fogarty International HIV/AIDS Training and Research Programme, SOUTH AFRICA

DR. ELS BORST-EILERS (CHAIR)
Former Minister of Health, Welfare and Sport and Deputy Prime Minister, THE NETHERLANDS

DR. ALEX COUTINHO (VICE-CHAIR)
Executive Director - The AIDS Support Organisation, UGANDA

DR. MAHMOUD FATHALLA
Professor of Obstetrics and Gynaecology - Assiut University, EGYPT

DR. HENRY GABELNICK (SECRETARY)
Executive Director - CONRAD, USA

MR. RAJAT GUPTA
Senior Partner Worldwide - McKinsey & Company, USA

DR. SETH HARRISON (TREASURER)
Managing General Partner - Apple Tree Partners, USA

DR. A. N. (JERRY) KARABELAS
Partner - Care Capital, USA

DR. DAVID KESSLER
Dean - University of California, San Francisco School of Medicine, USA

MS. ANJALI NAYYAR
Vice-President of Country and Regional Programmes - International AIDS Vaccine Initiative, USA

DR. ZEDA ROSENBERG
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