Mr Sandy Holloway AO
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Dear Mr Holloway

I am submitting the following in my capacity as a development practitioner and as an Australia-based consultant to the International Partnership for Microbicides (IPM).[1] My comments relate to the sectoral focus of the aid program and the need to invest in health research to support more effective development responses.

The effectiveness of AusAID's response to global health priorities would be strengthened by support to strategic research priorities. A comprehensive health research agenda should include support to social, behavioural, epidemiological and biomedical research as well as operational research to inform effective approaches to disease prevention, treatment and care. As a component of such a strategy AusAID should support research and development (R&D) of HIV prevention technologies. Support to biomedical R&D would align AusAID with other leading OECD donors such as DFID and USAID, donors that prioritize biomedical research as an important pillar of development assistance. Opportunities for collaboration with other donors to fund strategic R&D priorities should be explored.

The importance of investing in health R&D to support improved health outcomes
Health research is one of the driving forces behind gains in human development and poverty reduction. In the twentieth century, vaccines against smallpox, polio and other childhood diseases greatly increased life expectancy. Donor agencies should have a clear focus on the potential contribution of new technologies to address the global health challenges of the twenty first century. Such a focus requires a long-term vision of the potential of new technologies to revolutionise health outcomes for the poor and vulnerable.

AusAID should fund research that contributes to the global pool of knowledge and technologies for development. AusAID requires a research strategy that guides investments, with the goal of promoting the production and uptake of technologies that will contribute to poverty reduction and the achievement of the MDGs. Implementation of such a strategy should include support to public-private partnerships that address the health priorities of developing countries. Not-for-profit research programs that develop new health technologies using resources of the public, private and philanthropic sectors offer an effective and highly efficient approach.

Health research should be supported through a coordinated, multi-partnered approach. The research capacity of developing countries, particularly clinical trial infrastructure, is a constraining factor. Efforts to strengthen health systems and scale-up the delivery of health services can support health R&D. Investments in R&D, such as clinical infrastructure and training, can also be supportive of broader health program objectives. Partnerships among product developers, donors and developing countries are needed if capacity constraints are to be overcome.

Current levels of investment in product development for the health needs of developing countries fall

[1] The International Partnership for Microbicides (IPM) is a non-profit foundation that supports the development and delivery of microbicides for HIV prevention. Please note that although I am a consultant to IPM, this submission has not been formally endorsed by IPM.

far short of the levels required to address disease priorities such as HIV, tuberculosis and malaria. While philanthropic funding from organizations such as the Bill and Melinda Gates Foundation plays a key role in driving global public health product innovation, increased support from governments is also needed to address funding gaps, support sustainability and ensure that product development is integrated into broader health and development strategies. Long-term commitments are necessary to build capacity in developing countries to participate in the R&D process.

A range of product development partnerships (such as IPM) have emerged over the past 10 years with the aim of developing health technologies to meet developing country needs. Product development partnerships are important vehicles to mobilize donors, public sector agencies, industry and developing countries in support of accelerated product development. Such partnerships can advocate for policies and intellectual property arrangements that support early access to affordable products by communities most in need.

Intersection of HIV prevention, gender and development

UNAIDS estimates that globally 33 million people are living with HIV. More than two million of those people were infected and 1.8 million people died from AIDS-related causes in 2009. Almost five million people are living with HIV in the Asia Pacific region. Populations most affected are often highly marginalized, including sex workers, injecting drug users and men who have sex with men.

The HIV pandemic has reversed many of the hard-won development gains achieved over decades. This has been the experience of much of sub-Saharan Africa where HIV is hyper-endemic. The Asia Pacific region is experiencing epidemics at lower levels that are concentrated among specific subpopulations. Significant HIV epidemics have emerged in Burma, Vietnam, Cambodia, and certain states of India, and the development impacts are beginning to affect Australia's near neighbours, particularly Papua New Guinea, and Papua Province of Indonesia where HIV prevalence exceeds 2% of the adult population. HIV affects people during their most productive years, reducing their capacity to work and care for themselves and their families. Treatment and other health-related costs are a drain on individual and household incomes, pushing many further into poverty. Health and social services are overburdened, and educational services are undermined. Socio-economic and gender-based disparities are exacerbated. Young women and girls are highly vulnerable.

HIV-preventative microbicides provide enormous potential in development settings. The impact of HIV is highly gendered, both in terms of transmission risk and the effect of HIV infection. Lack of power is the root cause of women's vulnerability, however, the development of reproductive rights, sexual autonomy and gender equality is a long-term goal requiring enormous effort over generations. An effective microbicide could contribute to this goal by increasing the capacity of many women to exercise control over their sexual health. Use of a male condom depends on the consent of a male partner; consent which is frequently lacking. Women need a method of HIV prevention they can control. In many contexts, women have limited or no opportunity to negotiate safe sex. Religious and cultural values defining women's roles, desire for children, fear of abandonment or domestic abuse, and sexual assault limit women's ability to protect themselves from HIV infection. Poverty and pressure from clients may also push some women into unsafe practices during commercial sex, including sex in exchange for food or other goods.

Microbicides

There is no vaccine against HIV, and no cure. HIV treatments can be highly effective in reducing morbidity and mortality but must be taken consistently for life, are costly, have serious side effects and require complex clinical management. Microbicides do not offer a 'magic bullet' solution, but have potential to offer an important new prevention option, particularly for women.

A microbicide is a substance that reduces the infectivity of the HIV virus. A range of microbicide products are currently being trialled that seek to prevent HIV transmission. Some products may also prevent transmission of other sexually transmitted infections (STIs). Microbicides are not yet available, but are undergoing clinical trials and with sufficient funding could become available to

HIV-affected communities before 2015. Microbicides have the potential to dramatically improve HIV prevention outcomes, particularly for women.

Microbicides may be produced in many forms, including gels, films, tablets or a vaginal ring that slowly releases active ingredients. Some microbicides are being designed only for women (vaginal products), while others (rectal products) will be able to be used by both men and women.

Microbicide development is a long and complex process. IPM identifies the most promising microbicide technologies and invests in their development including regulatory pathways for approval and planning for distribution of products to women in the developing world. This approach draws on lessons learned in responding to almost 30 years of the HIV pandemic, and is designed to facilitate optimal, ethical and high impact rollout of microbicide products as soon as possible.

The first microbicides studied did not prove effective in reducing risk of HIV infection. In 2010, microbicide research reached an historic turning point. Results from the groundbreaking CAPRISA[2] study provided 'proof of concept' that an antiretroviral (ARV) -based microbicide gel can prevent women being HIV infected through sex with an HIV-positive partner. The findings demonstrated that women who used the vaginal gel were 39 percent less likely to be infected with HIV than those using a placebo gel. Among women who used the gel consistently and correctly, HIV infection was reduced by more than 50 percent. The gel also more than halved a woman's risk of contracting herpes simplex virus type 2: a lifelong and incurable STI that can increase the risk of HIV infection.

A microbicide delivering less than 100% efficacy would need to be used in conjunction with other HIV prevention methods (such as condoms) to optimise prevention. IPM is undertaking market research and product acceptability studies on a number of different formulations and delivery methods to ensure microbicides will be both technically effective and applicable to people's individual situations. For example: social research is considering issues related to accessibility and ease of use, and cultural factors particularly those related to gendered roles and reproductive health; HIV program specialists and civil society are providing input into ways in which microbicides might optimally be rolled out in conjunction with current HIV prevention programs.

Recent trial results have triggered renewed international focus on microbicide development, with confirmatory trials planned for 2011. The first microbicide may be available in some communities as early as 2013. Other, more efficacious microbicides are required. These include microbicides for rectal use, likely to be particularly useful in targeting sex between men.

Since 2004, IPM has obtained several non-exclusive royalty-free licenses from pharmaceutical companies to develop, manufacture and distribute ARV compounds as microbicides in developing countries. These agreements serve as a model of public-private partnership in fostering global health solutions, as these licensing agreements give IPM the full rights to distribute microbicides at no or low cost in resource poor countries.

Supporting achievement of the Millennium Development Goals

Seven of the eight MDGs directly impact women, maternal and child health, all of which are profoundly influenced by the burden of HIV. Uptake of HIV-preventative microbicides has the potential to increase the likelihood of meeting the MDGs.

Goal 1: Eradicating extreme poverty and hunger	Rural women are responsible for producing half of the world's food and between 60 and 80 percent of food in most developing countries. Food production and other employment reduces or ceases when women fall ill from HIV-related complications or stop working to care for family members infected with HIV.

[2] Centre for the AIDS Programme of Research in South Africa (CAPRISA) is an AIDS research institute of the University of KwaZulu-Natal and Columbia University. The trial was conducted by CAPRISA in partnership with FHI and CONRAD with funding from USAID. Gilead Sciences donated the ingredients for the gel.

Goal 2: Achieving universal primary education	When a parent becomes ill or dies, the likelihood of children attending school is significantly reduced. Girls are more likely than boys to leave school to provide care or to take over family agricultural and income-support roles.
Goal 3: Promoting gender equality	Reproductive health and gender equality are central to a woman's ability to build on her capabilities and control her destiny.
Goal 4: Reducing child mortality	Globally, HIV is responsible for about three percent of child deaths. Protecting women against HIV infection will reduce the number of children born with HIV, and also decrease the number of orphaned children.
Goal 5: Improving maternal health	HIV is a leading cause of death and morbidity for mothers and pregnant women.
Goal 6: Combating HIV/AIDS, malaria and other diseases	Microbicides offer a new and highly efficacious method of HIV prevention, particularly as their use does not rely on men's participation.
Goal 8: Developing a global partnership for development:	Ensuring that new HIV prevention technologies such as microbicides are approved for use and distributed to those women most in need requires public-private partnerships and coordination from all levels of the international community.

Conclusion

AusAID's has demonstrated continuing leadership on HIV in Asia and the Pacific for more than a decade. Recently, Australia increased its support to the Global Fund to Fight AIDS, Tuberculosis and Malaria. These contributions are welcomed, but do not fund health R&D.

The joint efforts of the donor community, and particularly the leadership of OECD members including AusAID, are essential to ensure the HIV pandemic does not continue to expand.

Australian support to global public-private partnerships focused on developing new HIV prevention technologies has potential to contribute to dramatic reductions in HIV transmission, increase gender empowerment and improve maternal and child health. A number of leading international agencies and governments currently fund microbicide research, although UNAIDS has reported a significant funding gap to progress the next phase of research and development; a gap totalling tens of millions of dollars. Those funding the work of IPM include the Bill and Melinda Gates Foundation, the World Bank, UNFPA, the Rockefeller Foundation, and the governments of Belgium, Canada, Denmark, France, Germany, Ireland, the Netherlands, Norway, Spain, Sweden, UK and USA.

Support from the Australian Government to product development partnerships to address HIV, such as those led by IPM, could not only accelerate global efforts but would also facilitate greater opportunities for influencing early rollout of new products in countries of Asia and the Pacific region that are most heavily affected by HIV.

Yours faithfully

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