Testimony of
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Thank you, Senator Alexander and distinguished members of the Africa subcommittee. I am the Operations Manager of Botswana's National Antiretroviral Program. I applaud the President's Initiative to commit major US funding to address HIV/AIDS in the parts of the world with the highest infection rates. I am also appreciate that notice has been taken of Botswana's National ARV Program and the Merck/Gates/Botswana Partnership, known as the "African Comprehensive HIV/AIDS Partnerships" (ACHAP), and our pioneering work in developing public-private partnerships to address this epidemic. As the longest running and largest public sector treatment program in Africa, I feel there is much to be learned from Botswana and it is my pleasure to share our experiences with you.

I am an American citizen who has spent most of his formative years and professional career in economically underdeveloped countries. To date I have worked on major HIV related public health projects in Botswana, South Africa and China. I have also supported numerous other initiatives in an advisory capacity across other developing countries. I did my MD and MPH at Harvard and subsequently and MBA at Oxford as a Fulbright Scholar. I then worked for the New York office of McKinsey & Company as a management consultant prior to my current position in Botswana. I am one of the Founding Partners of BroadReach Healthcare, a company that assists developing countries, funders and institutions strengthen health systems and implement appropriate, scaleable HIV/AIDS treatment models using public-private partnerships.

Through BroadReach, I am hired by the Merck/Gates/Botswana Partnership (ACHAP) and then seconded into the Ministry of Health as the Operations Manager of Botswana's National ARV Treatment Program. ACHAP is a tri-partite partnership between the Bill & Melinda Gates Foundation, The Merck Company Foundation//Merck & Co., Inc. and the Government of Botswana. The Merck and Gates Foundations have contributed a total of US $100 million to Botswana, spread over 5 years, to assist the country to combat HIV/AIDS. In addition, Merck donates its antiretroviral medicines to the ARV treatment program

In addition to a broad array of prevention, care and support programs, ACHAP was instrumental in launching, and currently supports, Botswana's ARV treatment initiative, called Masa, which is a Setswana word meaning "New Dawn".

Botswana, with a relatively small population of 1.7 million, was in the unenviable situation of having the highest prevalence of HIV in the world in 2001 with a staggering 38.5% of 15-49 year olds infected. Under the courageous and inspirational leadership of President Festus Mogae, Botswana decided that treatment with anti-retroviral drugs (ARV therapy) in the public health system should be introduced as a matter of policy to address this emergency.

The Government of Botswana approached ACHAP for assistance in establishing a National ARV treatment program. The first step was to conduct a detailed demand and

supply analysis and to develop an implementation strategy. The services of McKinsey & Company were commissioned to assist a joint team consisting of Ministry of Health personnel, ACHAP staff and McKinsey consultants, who conducted a 2.5 month detailed assessment of:

1. How many people would require ARV therapy (demand)
2. Based on that number, how well was the country prepared to service this demand (supply)
3. The resources that would be required to fill gaps in the healthcare delivery system
4. The optimal implementation model and approach based on organizational, political and contextual realities on the ground

The assessment revealed that there were approximately 300,000 HIV infected people in the country, of whom approximately 110,000 would require ARV therapy based on eligibility criteria of either CD4 count of <200, presence of an AIDS defining illness (regardless of CD4) or being an HIV positive child. The assessment also revealed significant deficits in capacity to meet such a demand.

The feasibility study culminated in a strategy document which explored and detailed a roadmap for how the Ministry of Health could build the requisite capacity and scale up of treatment. The national ARV Project team then developed a detailed implementation plan addressing the main areas requiring capacity/capability buildup which included:

- Policy, planning and project management (central and facility level)
- Information, Education and Communication (IEC) and community mobilization
- Training of health professionals (in ARV therapy, IT, laboratory, counseling, project management, monitoring & evaluation, operational research)
- Staff recruitment and retention
- Drug logistics (procurement, storage, distribution)
- Laboratory and testing logistics
- Information technology for nation-wide tracking and monitoring of patients, laboratory samples and medication utilization
- Procurement and upgrading of space
- Monitoring, evaluation and operational research

The national treatment program began in January 2002 and in 27 months has enrolled over 20,000 patients in 12 operating sites, of whom over 12,000 are on ARV therapy. The handout provides a detailed breakdown of patients by site. An additional 6000-plus patients are on ARV therapy in the private sector, making a total of over 18,000 people on ARV therapy in Botswana. This represents approximately 16.4% of all eligible patients on ARV therapy and makes Botswana the leading country in terms of proportion of HIV infected individuals on ARV therapy in Africa.

Overall, the program and the patients are doing remarkably well. Follow-up rates are above 90%, adherence rates above 85%, 85-90% of viral loads are suppressed by 6 months, CD4 levels are increasing and patients with wasting regain weight and people are able to return to work. Overall mortality after initiation is only 9% despite the average CD4 count of the patient population still being very low (about 81). In the largest treatment center in Gaborone, doctors reported a 50% decrease in hospital ward occupancy when the site reached the 3,000 patient level (that site currently has almost 5,000 on ARV therapy). This decrease was likely due to the fact that the initial cohort of very ill patients accounted for a disproportionately high number of hospital readmissions. Perhaps most heartening is the fact that there is a palpable elevation in the level and amount of dialogue about HIV in the general population and facilities are reporting an increase in the number of people who are coming forward and willing to get tested *prior* to becoming critically ill.

The program is currently operating in 12 sites across the country and our plan is to scale up to all remaining district and primary hospitals (each with 2-4 associated satellite clinics) this financial year. When fully rolled out, there will be 32 operating ARV sites in the country.

Current cost per patient for drugs and diagnostics ranges between US $580 to $1,580 per patient per year depending on the specific drug regimen prescribed. To date, the Merck/Gates/Botswana Partnership has spent about US $12 million on the ARV program. Over 90% of the overall program costs are supported by the Government of Botswana. Areas of support include:

Category	**Merck/Gates/Botswana Partnership (ACHAP) Support**
Needs assessments and establishing systems, policies and guidelines	ACHAP funded development of the initial ARV therapy feasibility study with McKinsey & Company.
Management support	ACHAP has provided the Operations Manager, seconded to Ministry of Health
Drug logistics	Merck donating Stocrin (Efavirenz) and Crixivan (Indinavir)
Recruitment of staff	ACHAP has committed a total of 66 health workers and IT positions
Training	ACHAP funding the National ARV training through KITSO and Preceptorship Programs
Information, Education & Communication (IEC) and Community Mobilisation	ACHAP has provided IEC consultant and IEC Officer and funded development of all IEC materials

IT system	ACHAP has seconded an IT specialist and funded the rollout of an interim IT solution, and provided computers to sites and project office
Laboratory and testing	ACHAP has funded CD4 and VL testing equipment in the National Reference Laboratories
Space Procurement and upgrading	ACHAP has constructed 4 treatment centers and funded the expansion of space at 16 satellite clinics

Despite the significant gains made in initially launching a national treatment program, we realize that we can not yet begin to congratulate ourselves because some significant challenges still remain, namely:

- The burden of disease is unprecedented and large (with a need to reach close to 40% of adults with treatment) and the geographic distribution of the population is wide
- Most people in country (including patients) still do not know their HIV status and only present for care at a very late stage (with advanced disease)
- There is still a large initial burden of very sick patients with extremely high "resource intensity". These patients take up a disproportionately large amount of health worker time leading to queues, which in turn can lead to a situation of perpetually insatiable demand
- There are significant staff shortages, and patient mobility makes it difficult to train staff across the country in a timely rate
- Civil society, NGO and CBOs lack adequate capacity to absorb the role of providing necessary supportive psychosocial and social welfare programs for patients, meaning that most of the burden falls on government
- Maintaining high adherence levels as the patient population gets larger (and less critically ill) will be a challenge
- Ensuring drug supply security is always a priority, and will become more challenging with additional end-point distribution sites
- Management and communications across a broad array of internal and external stakeholders

The program has now been running for a little over two years and one of the key success factors has been the ability to learn lessons and quickly readapt strategies as necessary. The key lessons we have learned to date include the following:

1. Capacity/capability build-up following a sigmoid rather than linear curve. Exponential growth (scale-up) in patient enrollment only after initial capacity is

developed (like a compound interest curve). This is largely due to the fact that, as the program begins:

- There are few trained staff (providers, assistants, administrators, etc);
- Those staff who have been trained are still "green";
- Newly trained staff see fewer patients per unit of time than an experienced and tenured staff member; and
- The initial cohort of patients who come forward is very sick and more complex (CD4 <80) - these patients require 5-10x the amount of time and effort compared to that for patients with a CD4 closer to 200.

Treatment volume expectations must therefore be tempered and managed carefully.

2. A phased rollout, if too slow, can result in the initial sites being overwhelmed. This excessive demand can lead to "perverse" resource buildup at a few sites at the expense of rolling out to new sites closer to where people live. In addition, the fewer the sites, the longer the distance patients have to travel for routine visits and this increases the risks of non-adherence.

3. Each new site experiences the same "teething problems", as such, there is little to be gained by slowly scaling up. The best strategy is to spread as widely and quickly as possible after the initial "pilot" sites.

4. Training is one of the most critical rate limiting steps to scaling up. Despite receiving classroom-based training, most sites could still not commence service provision. The most rapid and efficient mechanism of activating new sites is to provide onsite HIV specialist preceptors (doctors and adherence nurses), usually from the US or Europe (where there has been a long experience using the drugs) to provide hands on training and management support for a period of 3-6 months while the site gets on its feet. The Debswana Mining Company, the largest employer in Botswana, began their treatment program (private sector) prior to the National program and addressed their training needs through telemedicine where decisions of health workers on the ground were consulted, ratified and supported by an expert clinician panel based in South Africa. This innovative model has proved successful and helps to overcome a rate-limiting lack of clinician trainers by providing the ability to leverage one HIV/AIDS expert clinician over a large number of on-the-ground providers through technology.

5. The pre-ARV opt-in testing mindset, procedures and protocols were creating a functional bottleneck to people receiving timely access to life saving services. The only way to rationally manage demand for treatment and implement effective prevention programs is to ensure that as many people as possible have been tested and know their status. In Botswana testing rates are still low with less than 10% of the population knowing their HIV status. This is largely due to the fact that until recently, ARV therapy was not available and, as such, people had little incentive to test and know their status. This scenario is a key driver of patients presenting

only after they fall critically ill. Other drivers are fear, stigma and the natural tendency for people to wait until they feel unwell before seeking health services. Testing is therefore the most critical entry point for ARV therapy and associated care and prevention services. The point of testing provides direct access to positive and negative individuals and allows targeted interventions to be administered. Botswana has therefore become the first African country to implement routine opt-out testing on a national level, starting with health facilities. Routine opt-out testing will supplement the opt-in VCT efforts in an attempt to reach as many people as possible before they are critically ill. This will enable the provision of supportive services and therapy and avert the current situation where the majority of patients have completely lost their livelihood even if they eventually end up successfully on therapy.

6. The sickest patients (and those previously on treatment in the private sector) come forward first, and even at relatively small numbers, overwhelm the system. Almost 2 years into the program, the average CD4 count of patients at entry into the program is about 80 (during the first year it was between 50-60). The time and resource intensiveness associated with addressing the needs of such critically ill patients is estimated to be 5-10 times that of patients who are not yet critically ill and are initiated closer to a CD4 count of 200 (eligibility criteria). Over 90 percent of our patients do well despite being initiated at such a late stage of the disease. However, the result is that an unacceptably long queue begins to grow. The situation is further exacerbated by the natural triage that occurs at facility level. Health workers triage the sickest of the sick to the front of the line on any given day, creating a *de facto* lower CD4 eligibility criteria for *actually* accessing therapy. If these dynamics are allowed to persist, ARV therapy becomes "emergency" therapy resulting in an effort-intensive race to save the patient, and resulting in a higher potential for adverse outcomes and increased mortality. The ideal scenario is for all HIV positive people to have CD4 tests and be monitored until the time it is appropriate to start them on therapy, at which point they would have received all the necessary counseling and would be in much less danger of "succumbing to the queue". So, in addition to routine opt–out testing, the solution has been to split the queue, with specific days and/or times reserved for those with higher CD4 counts (identified from the database) and other days open to the normal first-come, first served patients (where patients with very low CD4 counts and/or critically ill can still access care). In this way, more patients can be enrolled per unit of time and can be prevented from ever having to first become critically ill inpatients in the hospitals (at which point most have lost their livelihood).

7. The bulk of work associated with implementing an ARV program is not the initiation of patients on ARV therapy, but rather the high levels of adherence and compliance required. Since patients will spend the majority of their time in the community, it is dangerous to over-emphasize the creation of brick and mortar healthcare infrastructure at the expense of building systems that track and monitor patients as they move between the health facility and their community and across

different geographies. For any new program that is about to start, the highest priority and bulk of initial effort should go towards establishing a robust and reliable patient tracking and Monitoring and Evaluation (M&E) system. With this in place, it allows a country many degrees of freedom in experimenting with different models of service provision (community outreach worker models, traditional wheel and spoke "network" referral models, observed therapy models etc) with the reassurance that any negative deviations will be quickly identified and remedied. The most fundamental tenet of ARV therapy is that the health professional knows who their patient is and can monitor what is happening with them.

8. Public private partnerships can help accelerate implementation by acting as key "catalysts" for action, and by providing money which is "faster and more flexible" than that spent by governments. The Merck/Gates/Botswana Partnership's "secondment" model - through which key technical expertise has been introduced to supplement the Ministry of Health's management capacity - has proved particularly effective. Not only does this model allow for an unprecedented level of co-responsibility, mutual monitoring and early problem identification, it allows for real skills transfer to occur between the seconded experts and local staff.

9. There are no easy solutions to the human resource shortages. Botswana does not have a medical school and, as such for doctors and certain other key cadres of staff, the country is dependent on expatriate labor. Most expatriates do not speak the language meaning that a large proportion of nurse time is spend doing interpretation. The global market rates for staff and lucrative opportunities presented by development partners in the local market make it difficult to attract top talent at current public sector rates.

10. Although critical and fundamental for success, money is but one of a series of numerous bottlenecks of increasing complexity that must be overcome if ARV therapy is to be offered successfully. Other equal, if not more important issues to be addressed, are to do with availability of leadership, management, political will (especially important is the streamlining of bureaucracy), information for policy and planning, accountability, and ultimately local capability and capacity (human resources, skills, equipment, infrastructure and systems). All these elements are essential for the ARV supply chain to function and deliver a consistent reliable service

With the broader global epidemic in mind, it is clear that governments cannot fight this battle alone. All sectors and individuals must play an active role. The natural tendency for governments is to focus on developing, building and utilizing only public sector capacity. However, a holistic and non-judgmental assessment often reveals numerous potential sources of significant untapped capacity in the private sector (including private sector doctors, hospitals, laboratories, etc), NGOs, CBOs, civil society, the faith-based sector, and the community at large. The Merck-Gates Partnership (ACHAP) has clearly

demonstrated the "catalytic" value of tapping into non-traditional private sources of skills, expertise and money. It has also demonstrated a feasible and viable mechanism through which the tremendous skills and resource base of the private sector can be leveraged for public good in a results-oriented fashion.

The burden of disease in most countries is such that no sector is likely to be able to address the complexities single-handedly. Looking continent wide, it is clear that traditional models and linear thinking will never overcome this epidemic. Patients must be empowered and equipped to participate maximally in their own care. New mutually enriching partnerships and innovative models must rapidly be deployed and the appetite to take risks must be increased dramatically. This can be done safely if built on a foundation of sound management, monitoring, evaluation, accountability and true ownership by countries.

Availability of treatment has introduced hope in an environment that had adapted to death and despair. Not only does availability of treatment save lives, there is strong anecdotal evidence that it provides concrete incentives and entry points for meaningful prevention programs and behavior change. We have an opportunity to capitalize on this link. A combination of strict results orientation coupled with willingness to explore new approaches that stretch our comfort zone will give us a realistic chance of turning the tide against this devastating disease.

Thank you for your time and consideration.

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