An Overview of Gilead’s Developing World Access Program

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Associate Director, International Access Operations
Gilead Sciences
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About Gilead Sciences

- **Worldwide presence**
  - 4,200 employees
  - 25 offices on four continents

- **14 marketed drugs; active R&D program**
  - Primary therapeutic areas: HIV/AIDS, liver disease, serious cardiovascular and respiratory conditions
  - Nine successful acquisitions, expanding company’s reach

- **Committed to ensuring global access**
  - Believe our responsibility to patients extends beyond the lab and developed-world markets
Perspectives on Medical Need

• **Scientific contract:**
  - We have seen major innovations in therapy for infectious diseases over the past 30 years
  - Access to capital to fund these innovations is supported by intellectual property protection

• **Social contract:**
  - Despite scientific progress, we face ongoing challenges in delivering treatment
  - Sustainable solutions are required across the spectrum of healthcare
The Global HIV/AIDS Pandemic

More than 34 million estimated to be living with HIV...

- North America: 1.5 million
- Caribbean: 240,000
- Latin America: 1.4 million
- Western & Central Europe: 820,000
- Middle East & North Africa: 460,000
- Sub-Saharan Africa: 22.5 million
- Eastern Europe & Central Asia: 1.4 million
- East Asia: 770,000
- South & South-East Asia: 4.1 million
- Oceania: 57,000

...nearly 95% in the developing world

Gilead Access Program

- Program initiated in April 2003

- **Objective:**
  
  To make our HIV medications accessible to all patients who need them, wherever they may live

- **Particular focus on countries hardest hit by the HIV/AIDS epidemic:**
  - All of Africa
  - Select countries in Asia / Pacific
  - South America
  - Caribbean
  - Eastern Europe
Gilead Access Program Model (2006-2011)

International Access Operations

Gilead Brand

• Access to Viread and Truvada
• 130 countries via distributors
• Tiered Pricing

Indian Generic Licenses

• Provide for adequate capacity in least developed countries
• Proven track record in delivering high volume/low margin quality products
• Achieve the lowest price
Regional Distributor Network

11 Distributors Reaching 130 Countries

*Manufacturing and Distribution for Africa, in Africa
Role of Regional Distributor Network (2006 -2011)

International Access Operations

- Stendhal (Latin America)
- IDS (Asia)
- Aspen (Africa)

IDS Thailand (Thailand)
Medical Access (Uganda)
Phillips (Kenya)

- 11 Gilead Regional Distributors
- 48 Gilead Country Sub - Distributors

Activities

- Submitting and maintaining product registrations
- Medical Education & Training initiatives
- NGO and MOH outreach
- Pharmacovigilance and safety reporting
- Enhance local treatment guidelines
- Demand Forecasting and Product Supply
Enabling Access

• Gilead has taken the approach of segmenting 130 Access countries into two groups
  - Low-Income (No-Profit pricing) in 106 countries
  - Low-Middle Income pricing in 24 countries

• **Low-Income Countries** – GNI per capita of $1,000 or less and / or an extremely high burden of HIV
  - Viread & Truvada Sold at Not for Profit

• **Lower Middle-Income Countries** – GNI per capita of $1,000 - $3,000
  - Viread & Truvada sold at small margin
Gilead’s Indian Generics Partnerships (2006-2011)

- Gilead has entered into licensing agreements with 13 Indian companies to manufacture API and finished tablets
  - Full technology transfer to enable faster production and ensure quality
  - Develop any tenofovir-based FDC or pediatric formulation
  - Free to sell API within India with no royalty payment to Gilead
  - Free to set own price for finished product, distribute in 95 least developed countries (India, South Africa, Thailand)
  - 5% royalty to Gilead on price of finished goods
  - Seek WHO or tentative FDA approval
### Impact of Gilead Access Program

#### Patients

<table>
<thead>
<tr>
<th>Year</th>
<th>Generic</th>
<th>Gilead</th>
<th>All ARVs</th>
</tr>
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<tbody>
<tr>
<td>2006</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>2007</td>
<td>4%</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>2008</td>
<td>10%</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>2009</td>
<td>21%</td>
<td>21%</td>
<td>21%</td>
</tr>
<tr>
<td>2010</td>
<td>27%</td>
<td>27%</td>
<td>27%</td>
</tr>
<tr>
<td>Q2 2011</td>
<td>27%</td>
<td>27%</td>
<td>27%</td>
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</table>

#### Generic Price

- **Viread/generic TDF**
  - Δ = 36%
  - Δ = 36%
  - Δ = 58%
  - Δ = 67%
  - Δ = 71%

Δ = Difference between partner and Gilead price (includes distributor markup)

#### Registrations

- **Viread HIV registrations**
  - 21
  - 19

- **Truvada HIV registrations**
  - 45
  - 38

- **Generic tentative FDA approvals/WHO prequalifications**
  - 1
  - 4

1. Assumed to be same as end of 2010
2. As of Sept 2011

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**Legend**

- Generics
- Gilead
- All ARVs
Generic licensing by Indian companies a proven model for global treatment access

To reach millions more people, Gilead significantly expanding licensing terms

- Offering first-ever future rights to pipeline products – goal is to reduce delays in high-quality, low-cost versions becoming available in developing countries

- Gilead first company to join Medicines Patent Pool; hope others will join as well
## Evolution of Generic Licensing

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<tr>
<td>TDF and TDF-containing regimens</td>
<td>Future rights to three pipeline products (pending approval): elvitegravir, cobicistat, Quad</td>
<td></td>
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<tr>
<td>- Goal is to ensure access soon after initial regulatory approval</td>
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<tr>
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<tbody>
<tr>
<td>95 developing countries</td>
<td>TDF: 112 countries</td>
<td></td>
</tr>
<tr>
<td>- Can also be sold for chronic hepatitis B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Cobicistat: 103 countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Elvitegravir/Quad: 100</td>
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<tbody>
<tr>
<td>5% royalty on sales of finished goods</td>
<td>TDF: 3%; pipeline: 5%</td>
<td></td>
</tr>
<tr>
<td>- Royalties waived for pediatric formulations</td>
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</tbody>
</table>
Key Roles of Regional Distributors

In addition to distributing branded product, regional distribution partners undertake key activities on behalf of the Access Program:

**Regional Distributors and Sub-Distributors**

- County-by-country product registration
- Supply and demand forecasting
- Pharmacovigilance and safety reporting
- Ongoing medical education and training
- Toolkits for paraprofessionals
- Key relationships (e.g., governments, U.N., NGOs, advocates)

**Access 2.0: Strengthening the Distributor Network**

- Allowed to pursue dual pricing via public (current price) and private markets in low-income countries
- Enabled to source generic product from licensees in low-income countries
- Increase support for distributors in their in-market activities from royalty revenues
Medicines Patent Pool

- Gilead announced a signed agreement with the Medicines Patent Pool on July 12, 2011

- Patent Pool granted similar terms as Gilead’s Indian partners, for purpose of sub-licensing to qualifying manufacturers in India:
  - TDF license in 112 countries; 3% royalty on finished products
  - Cobicistat license in 103 countries; 5% royalty
  - Elvitegravir / Quad license in 100 countries; 5% royalty
  - No royalty on pediatric formulations

- Sub-licensees have the option to pick and choose products to license

- Gilead will pay the Patent Pool 5% of collected royalties, up to $1 million annually, to help cover the Pool’s administrative expenses
There Is A Lot More To Do…

HIV

“Tip of the iceberg”
• ~1.8 Million patients on tenofovir

“Below the water”
• ~13 Million patients¹
  – ~ 4 Million on d4T and AZT
  – ~9 Million untreated

HBV

No significant treatment

“Below the water”
• ~350 Million² HBV Patients

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¹. With new WHO guidelines of treating with CD4 < 350
². Global prevalence of chronic HBV
Weak Healthcare Systems in Access Markets

Density of healthcare professionals per 1000 people:

<table>
<thead>
<tr>
<th>Region</th>
<th>Density</th>
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<tbody>
<tr>
<td>Africa</td>
<td>2.3</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>4.0</td>
</tr>
<tr>
<td>South East Asia</td>
<td>4.3</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>5.8</td>
</tr>
<tr>
<td>Europe</td>
<td>18.9</td>
</tr>
<tr>
<td>USA</td>
<td>24.8</td>
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Healthcare systems strengthening is critical to ensuring sustainable access to treatment.
Health Systems Strengthening (HSS) is key to improving patient lives

Creating sustainable measures in the war against diseases
“There is an urgent need for the developed nations to facilitate creation of sustainable measures in the war against killer diseases such malaria, tuberculosis and HIV/AIDS and that the appropriate and sustainable methods of tackling the leading killer diseases would be to create capacity for local drug manufacturers through technology transfer.”

President Mwai Kibaki of Kenya

"As long as people lack adequate education and health care, infrastructure, access to land, capital, finance and market institutions, they simply cannot take advantage of growth. They are trapped in a vicious cycle of poverty,"

President Jacob Zuma of South Africa

“[The greatest challenge was]...Significantly improving and strengthening our health system – building and expanding our health infrastructure, rapidly scaling up our health workforce and revamping our information systems. We want to achieve universal access to primary health services of an acceptable standard to all Ethiopians.”

Dr Tedros Adhanom Ghebreyesus, Health Minister, Ethiopia
PEPFAR Healthcare System Strengthening

- **PEPFAR**: Tracking and Counting 140,000 New Health Workers
  - PEPFAR will “…help partner countries to train and support retention of health care professionals and paraprofessional.”
Aligning Stakeholders with Resources

Health System Stakeholders
- Physicians
- Nurses
- Pharmacist
- Community Health Workers
- Patients
- Ministry of Health, Finance
- Procurement agents

Value-Added Resources
- High Technology Tools
  - Diagnostic/monitoring instruments
  - Text/mobile treatment support
- Measurement/Tracking Systems
  - Compliance/adherence monitoring
  - Adverse event reporting
  - Quality forecasting and planning support
  - Cost-benefit analysis model
- Skills Training
  - Patient education
  - Healthcare worker education and materials
  - High-value skills training (ARV therapy, etc.)
Gilead IAO Heath Systems Resources Tools

Distributor Portal

Patient & Healthcare Worker Education Materials

HiV-Link Mobile SMS

Demand & Supply Management

Point of Care: CD4 & Viral Load Testing

Cost Benefit Analysis Tool
Other Areas of Unmet Medical Need

• Chronic hepatitis B (HBV)
  - More than 350 million people worldwide living with chronic HBV infection
  - Chronic HBV can lead to liver disease and cancer – HBV second only to tobacco as a cancer-causing agent in humans
  - Viread approved in many countries for HBV; generic licensees can sell Viread for HBV in the same countries as for HIV

• Visceral Leishmaniasis (VL)
  - VL affects an estimated 12 million people worldwide, vast majority in developing countries
  - World’s second-deadliest parasitic disease (after malaria)
  - Working closely with WHO, MSF, others to expand access to low-cost AmBisome for VL treatment
Looking Ahead: Gilead’s Role

• Gilead strongly committed to Access Program
  – Proven model now reaching 1.8 million HIV patients
  – Program is financially self-sustaining and scalable
  – There are still lessons to be learned and we will remain flexible so the program can grow and evolve as needed

• Over coming years, Gilead’s goal is to reach millions more patients
  – Will look to distributor and generic partners to continue playing key roles, particularly on HIV pipeline products
  – Our focus will remain on developing innovative new medicines, and supporting collaborative research on the most effective ways to use them
  – Partnerships will continue to be critical to achieving these goals
Advancing Therapeutics. Improving Lives.

Thank you.