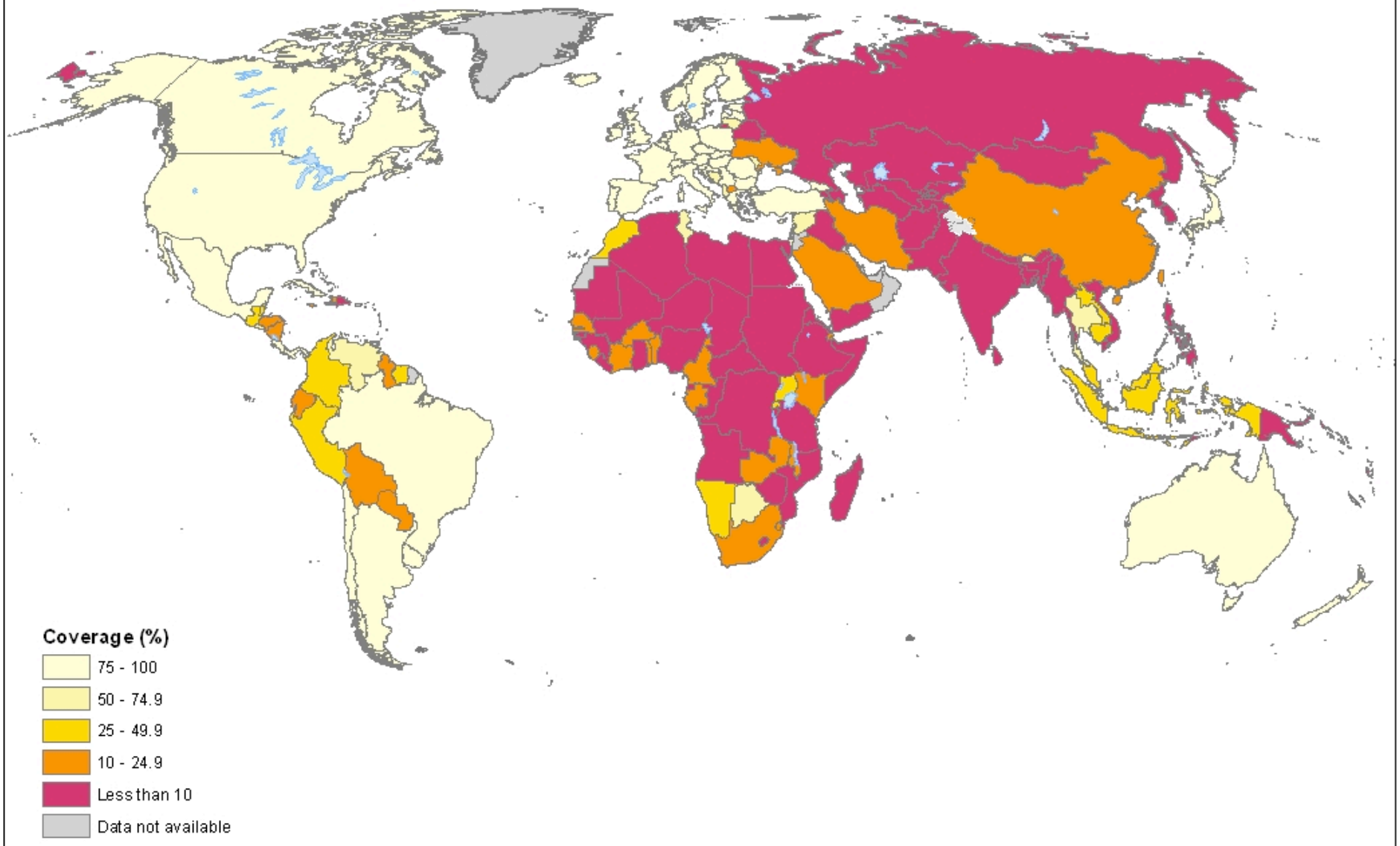
Policy Development in the Context of Market Projections

Pediatric Diagnosis and Monitoring Working Group Meeting
Denver, CO
February 9, 2006

Thomas N. Denny
New Jersey Medical School
Newark, NJ
dennytn@umdnj.edu

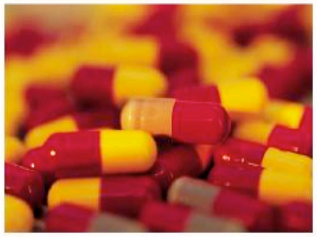
Estimated percentage of people on antiretroviral therapy among those in need, situation as of June 2005



“Push” and “Pull” Mechanisms

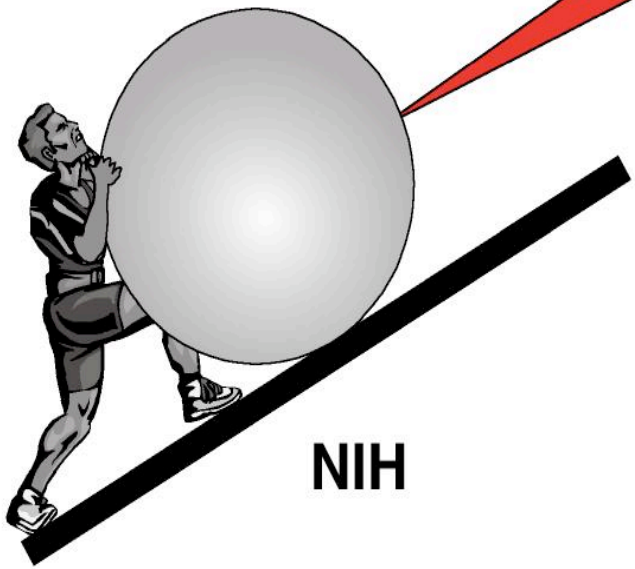
Supply = Push

Research provides new opportunities that lead to innovation.



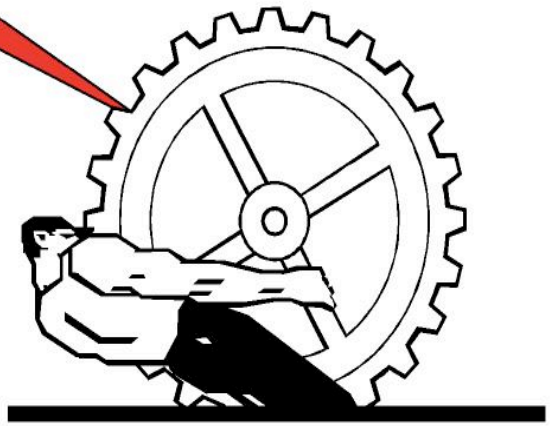
Demand = Pull

Respond to the needs of the marketplace. Need to be flexible, contractual, committable, not to be subject to political change.



NIH

$$

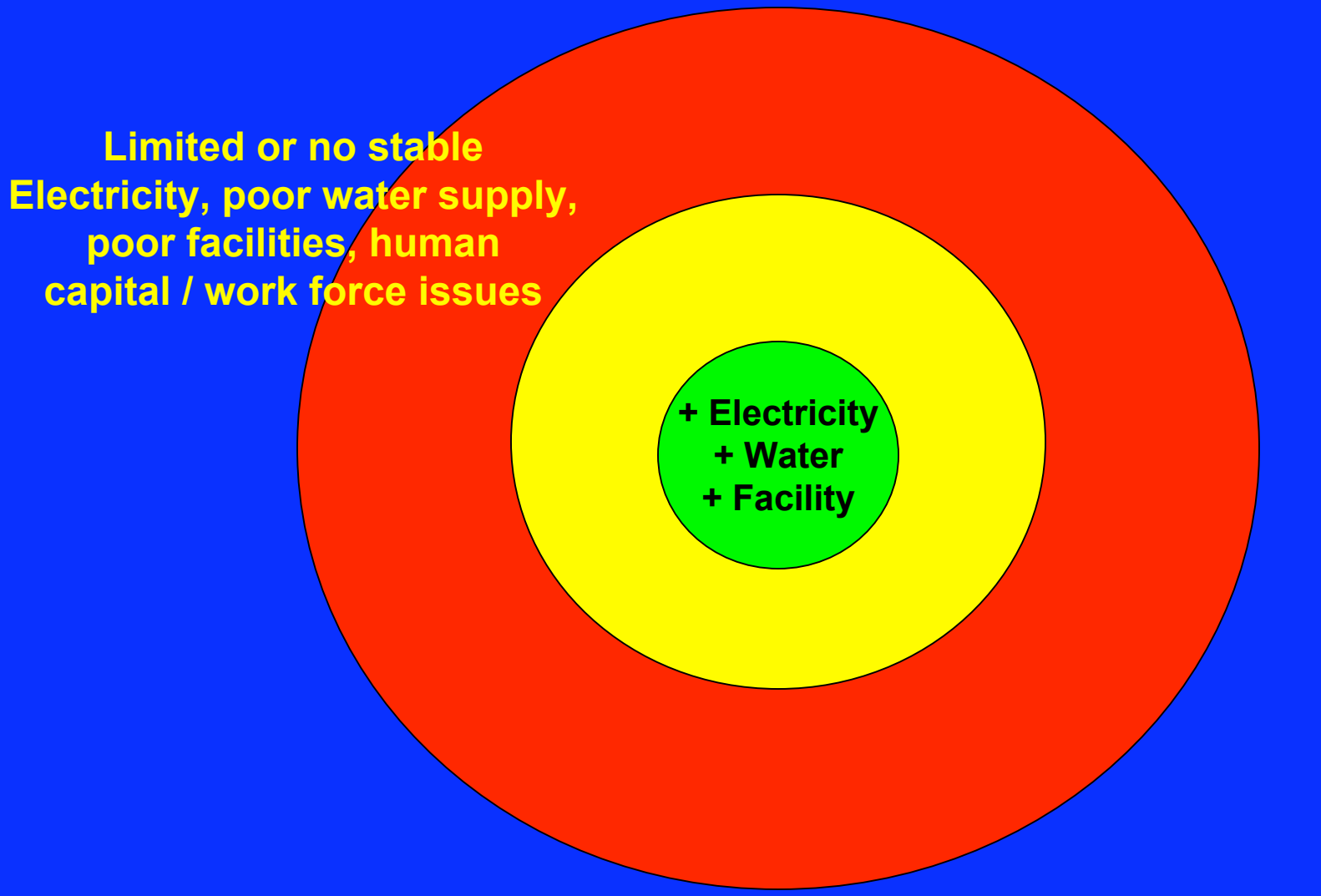


Bioshield

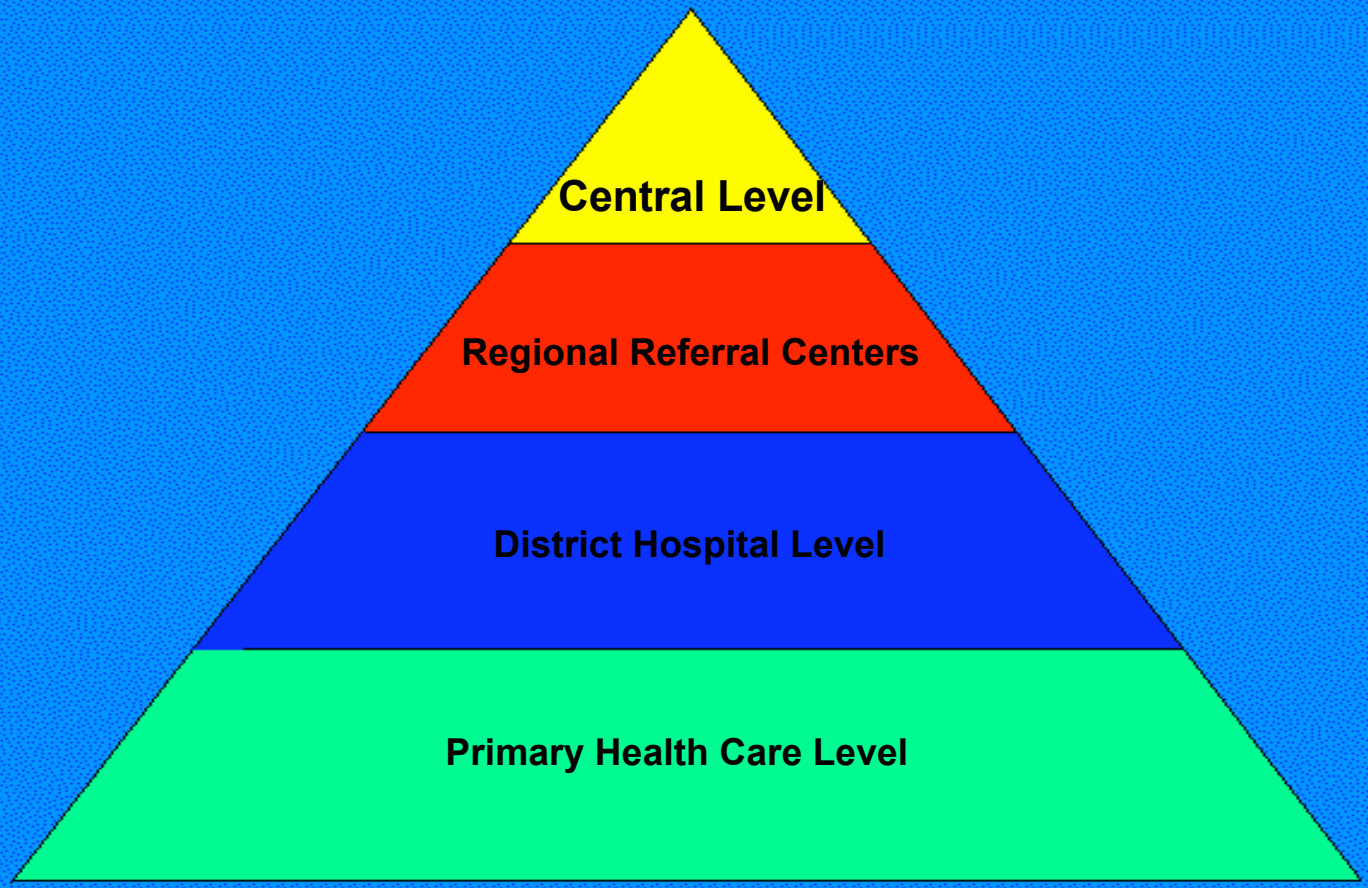
"Push" and "Pull" Mechanisms For Laboratory Diagnostics

- **Push**
  - **Gates**
  - **Duke Foundation**
  - **NIH (SBIRs)**
  - **Industry**
  - **HIV Forum**
- **Pull**
  - **Global Fund**
  - **World Bank**
  - **UNAIDS**
  - **PEPFAR**
  - **Clinton Foundation**
  - **NIH**

From 3 x 5 to Universal Access – Globally that means 10 million plus on ART by 2010



Levels of Clinical Care and Laboratory Services



Current Pediatric Therapy Needs (2005)

Current estimates of children in need of ART and PCP prophylaxis:

ART:

children = 660,000

infants = 270,000

PCP:

children = 4,000,000

infants = 2,100,000

Total = 7,030,000

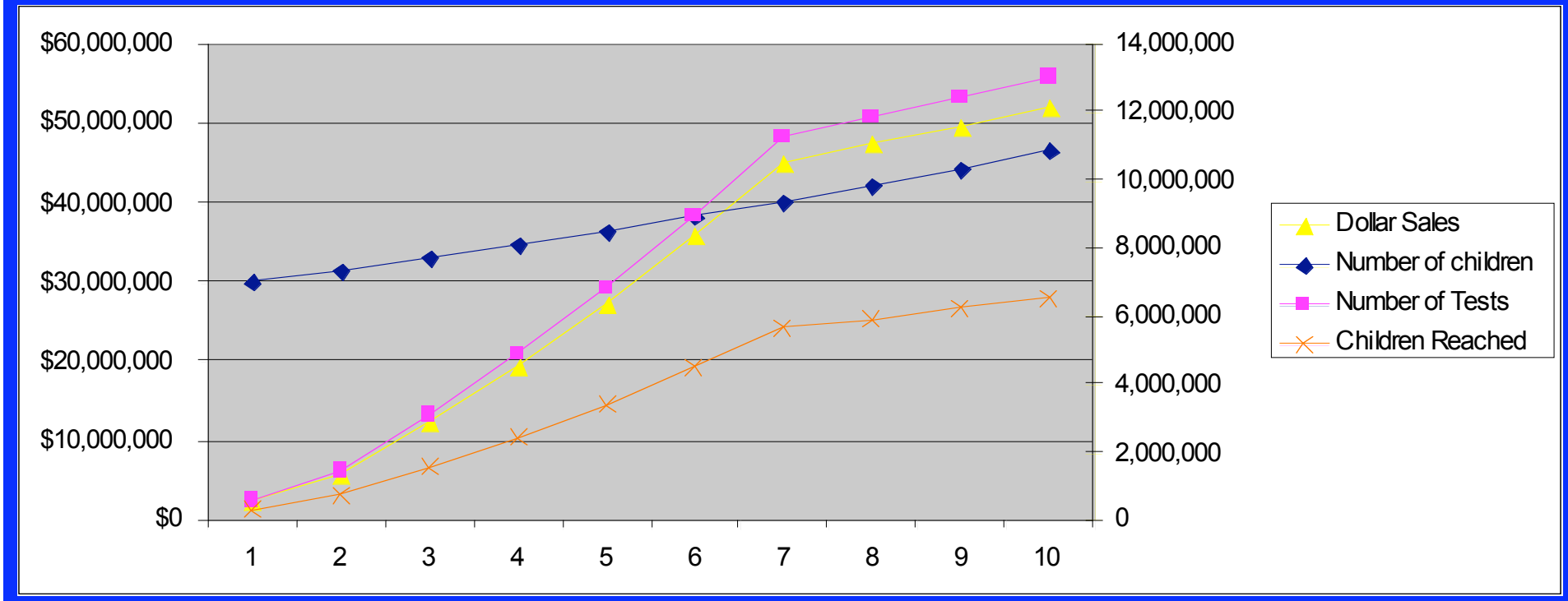
J. Ties Boerma et al. - Bulletin of the WHO, February 2006

Pediatric Lab Evaluation / Monitoring Schedule

- **CD4 Monitoring Frequency**:
  - At the time of diagnosis
  - Every 2 months during first 6 months of life
  - Every three months from 6-18 months of age
  - Every six months for children > 18 months of age

The Columbia Clinical Manual, Care and Treatment of HIV/AIDS In Resource-Limited Settings 2005 (M Rabkin, W El-Sadr and E. Abrams)

Pediatric Lab Testing Addressable Market



Net gain 5%/year (10% growth / 5% death rate
Children reached: 4% to 50% in five years – plateau @ 60%
Tests / year = 2
Ten year market: ~$297,000,000

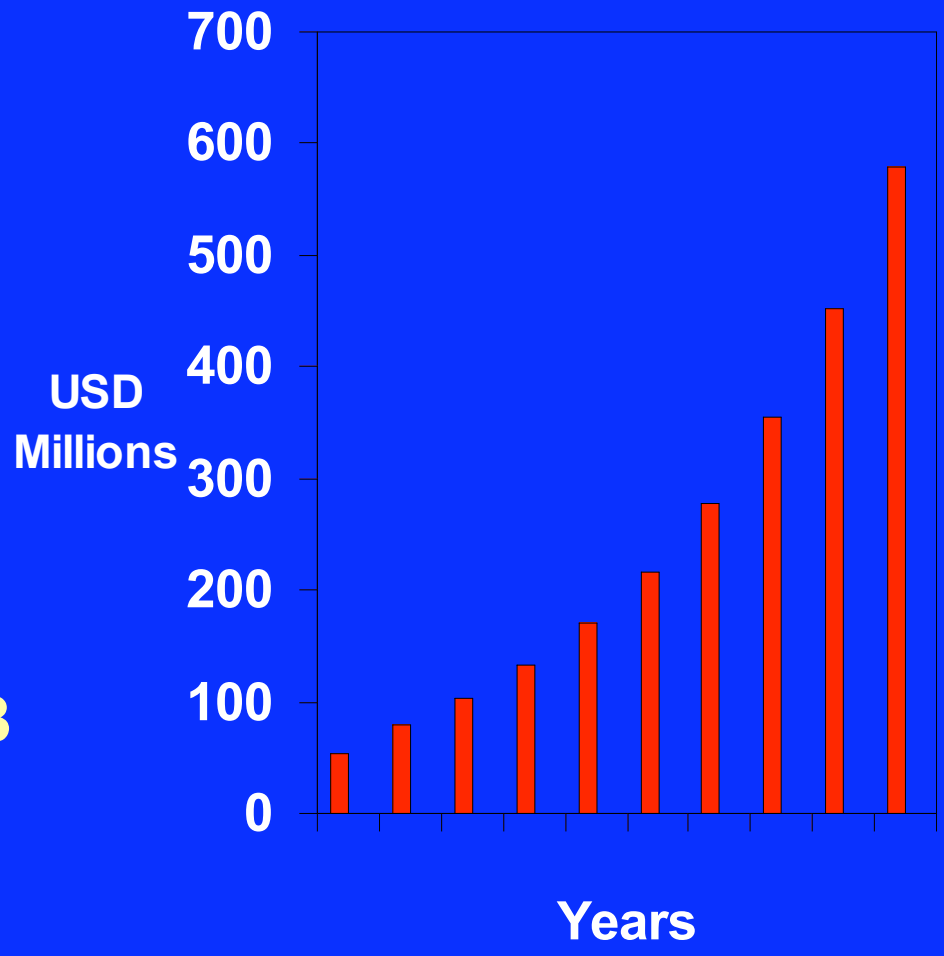
Global Health Council Update 2006

Table 2: Resource Needs for HIV/AIDS ($ Million)[i]

	2006	2007	2008
1. Prevention-Related Activities			
1.1 Vulnerable Populations[ii]	$ 1,897	$ 2,442	$ 2,895
1.2 Community[iii]	$ 2,952	$ 3,476	$ 4,014
1.3 Biomedical Prevention Strategies[iv]	$ 3,592	$ 4,053	$ 4,521
Prevention Total	**$ 8,441**	**$ 9,969**	**$11,430**
2. Treatment and Care Components			
2.1 Palliative Care	$ 308	$ 302	$ 295
2.2 Provider Initiated Testing	$ 66	$ 79	$ 109
2.3 OI Treatment	$ 686	$ 703	$ 707
2.4 OI Prophylaxis	$ 287	$ 403	$ 510
2.5 ART, Including nutritional support	$ 1,642	$ 2,482	$ 3,624
2.6 Laboratory Testing	$ 54	$ 79	$ 104
Treatment and Care Total	**$ 3,043**	**$ 4,048**	**$ 5,349**
3. Resource Needs for Support for OVC by Activity			
3.1 Education	$ 193	$ 287	$ 443
3.2 Health Care Support	$ 145	$ 174	$ 200
3.3 Family/Home Support	$ 971	$ 1,255	$ 1,604
3.4 Community Support	$ 14	$ 18	$ 25
3.5 Organization Costs	$ 246	$ 322	$ 422
Resource needs for support for OVC total	$ 1,569	$ 2,055	$ 2,694
4. Program Costs	$ 1,500	$ 1,400	$ 1,800
5. Human Resources	$ 400	$ 600	$ 900
TOTAL	**$14,900**	**$18,100**	**$22,100**

[i] UNAIDS. "Resource needs for an expanded response to AIDS in low and middle income countries" Seventeenth Programme Coordinating Board Meeting. 2005.
[ii] Includes activities targeted toward special populations, prevention programs for people living with HIV, programs focused on MSM, harm reduction programs for IDU, youth in school, youth out of school, programs focused on sex workers and their clients.
[iii] Community includes condom social marketing, public and commercial sector condom provision, prevention activities in the workplace, community mobilization, voluntary counseling and testing, and mass media efforts.
[iv] Includes improving management of STI, prevention of mother-to-child transmission, blood safety, post-exposure prophylaxis (health-care setting, rape, etc), safe medical injections, and universal precautions.

Global Health Council Data with Ten Year Projected Growth



Ten year = USD ~2.14B

"Push" and "Pull" Mechanisms For Pediatric HIV Laboratory Diagnostics

- **Push**
  - Gates
  - Duke Foundation
  - NIH (SBIRs)
  - Industry
  - HIV Forum

- **Pull**

~1 Billion USD Market

Essential Lab Package (Beyond 2005)

- **HIV Infection Status**
  - Serology (> 18 months of age)
  - PCR (< 18 months of age)

- **Immune Status**

- **Determine Viral Load**

- **Organ Function Testing**
  - Liver, Kidney


That's All, Folks!