Introductory Remarks: Innovation and Access in Medicines

Dr. Harvey E. Bale

Director General, IFPMA

Berlin November 2004

New & Re-Emerging Diseases

- HIV/AIDS
- SARS
- Various Influenzas
- Dengue
- Lyme Disease
- Hantavirus
- Ebola Virus
- TB, Malaria, Dengue

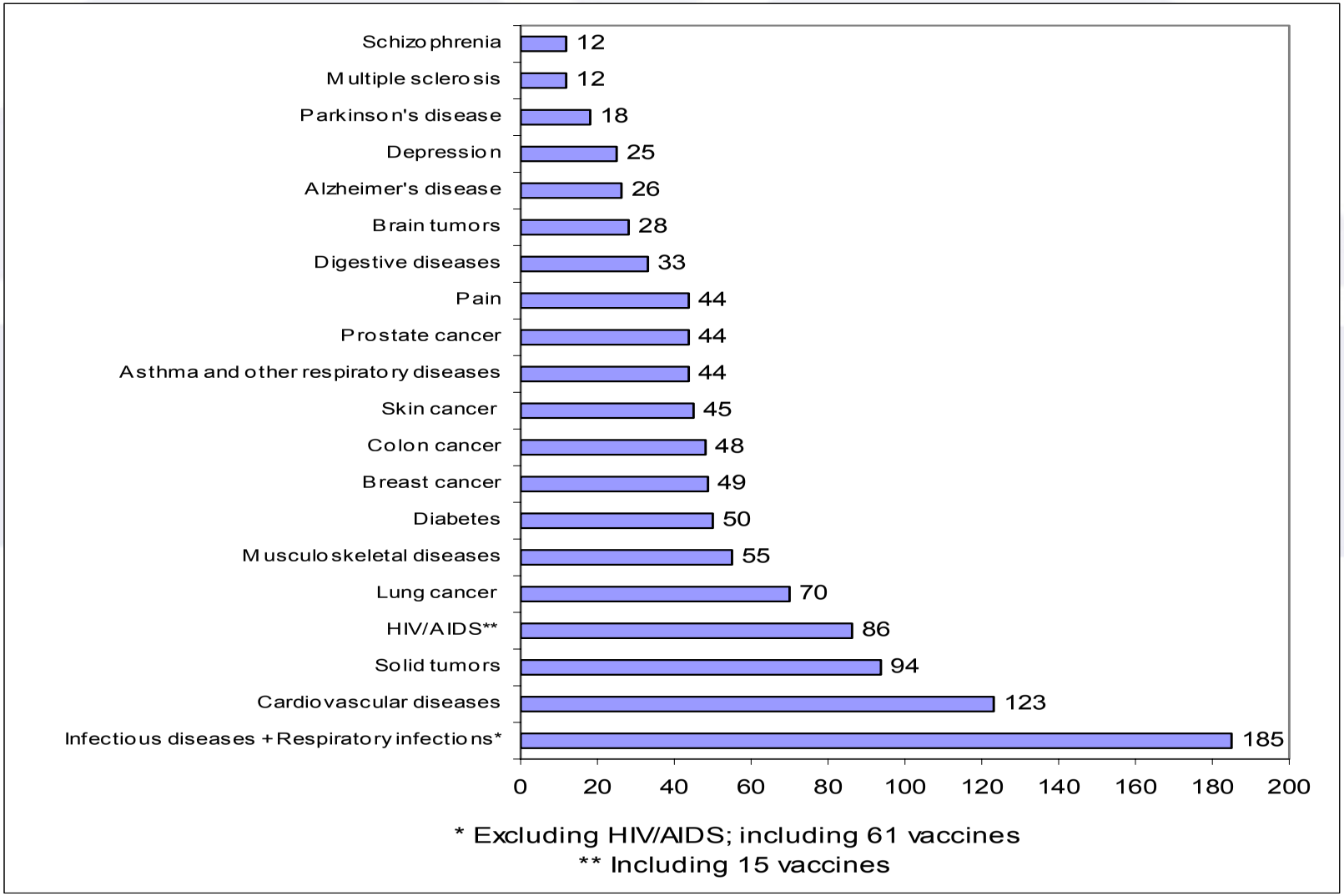
HIV/AIDS

- 65 million have been infected: 25 million deaths and more than 40 million are currently infected
- HIV/AIDS and the status of other diseases (e.g., malaria, TB) point to disparities in health outcomes between developed and developing countries
- No cures, no vaccines – yet -- though 20 ARV's have prolonged life and made AIDS a manageable chronic disease – (*for those who can access these ARV's)*

Industry Innovation

- Over 20 ARV's have been developed
- 80 HIV/AIDS medicines in clinical trials, including more than a dozen vaccines
- Recent developments: fusion inhibitors (Fuzeon) and integrase inhibitors
- Key partnerships between the public and private sector in drug development

Drug and Vaccines in Clinical Development for Selected Diseases



Key Role of Drug Resistance

- Emerging as important issue in HIV/AIDS as well as being serious problem in fight against TB, malaria and other infectious diseases (e.g., streptococcal pneumonia)

- ***Points to the need for continuous innovation even for HIV/AIDS and other diseases having current therapies***

Process of Pharmaceutical R&D

R&D Stage	Research & Discovery	Preclinical development	Phase I	Phase II	Phase III	Registration	Phase IV
Main Activities	Drawing on basic exploratory research to identify targets, initial research on new compounds is carried out in the laboratory (high throughput screening, lead identification and optimization) to select the	Selected compounds are studied in animals under Good Laboratory Practice for toxicity and safety; in parallel, specific analytical methods are developed for	Successful compounds are then tested in humans in 3 phases of clinical trials: ▪ Phase I – safety and tolerability in healthy volunteers ▪ Phase II – safety, efficacy and bioequivalence studies in small groups of patients ▪ Phase III – large trials with different populations to demonstrate proof of			If the results of clinical trials are satisfactory in terms of quality, efficacy and safety, a regulatory dossier is presented to the regulatory authorities for	Post-marketing studies involving thousands of patients are initiated after the launch of the medicine, to identify any previously unforeseen side effects.
Success Rate*	Less than 1 %		70 %	50 %	50 %	90 %	
Time	4-6 years	1 year	1-1.5 Years	1-2 years	2-3 years	1-2 years	Several years

Patents and Access

'We need to combine incentive for research with access to medication for the poor. Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people.'

Kofi Annan, UN/UNAIDS/WHO press release
April 5, 2001

Four Pillars of Innovation

- **Successful Healthcare Systems**

  Enable swift dissemination of innovation and appropriate application of new medicines

- **Efficient Markets**

  Help perceive innovation as investment and lead to efficient allocation of scarce public health resources

- **Effective Intellectual Property Protection**

  Build a solid base for knowledge based economy and provide for an incentive to innovate

- **Adequate and Predictable Regulatory Requirements**

  Create stable but evolving regulatory environment to streamline innovation process

Improving Access to Therapy

- Unequivocal and ongoing political commitment by national governments;
- Strengthened national capacity;
- Engagement of all sectors of national society and the global community;
- Continued investment in research and development by the pharmaceutical industry
- Efficient, reliable and secure distribution systems; no parallel trade
- Significant additional funding from new national and international sources