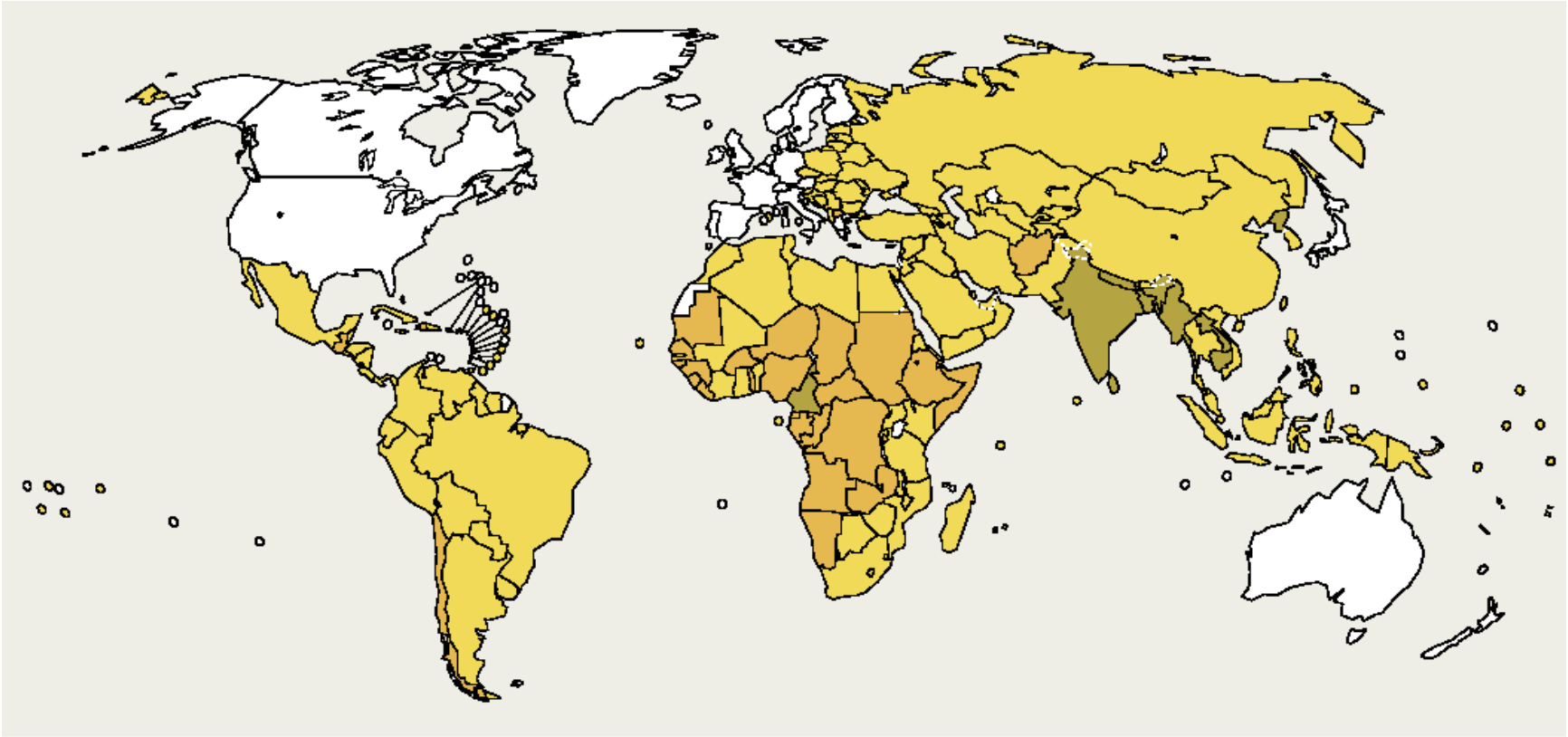
HEP B AS A CASE STUDY

Use of hepatitis B in national immunization schemes



122 countries or 74% hepatitis B vaccine given to infants

12 countries or 7% use hepatitis B vaccine in part of the country or among adolescents

31 countries or 19% do not use hepatitis B vaccine

Source: WHO/UNICEF Joint Reporting Form, 2004. Data collected from 192 WHO Member States, as at 20 September 2004.

Project aim & lessons from Hep B

- Aim: to shorten the lag between vaccines being proven safe and effective for use in the industrial world, and their introduction in to developing countries

- 15 years elapsed between development of vaccine and [near-] universal vaccination programmes
  - Required intervention of Task Force
    - Conducted demonstration programs to build global and national consensus for use of vaccine
  - Concentrated efforts of members to demonstrate the need for and feasibility of universal hepatitis B vaccination
  - Could not wait for WHO, EPI and UNICEF procedures. Supported by PATH

- Use was limited due to
  - Lack of awareness of disease burden
  - High price

Hep B Task Force Success

- Stimulated competition among manufacturers to reduce price
- Sealed bid and tender system to establish pricing procedure in Indonesia 1987
  - Seen as formality, expected few companies to compete
  - Lowest bid among many was a surprise. Cheil expected (PATH had negotiated transfer agreements). $0.95 from Korean Green Cross Company and willing to commit to provide vaccine to other public sector agencies
- Indonesian government adopted National Immunization program 1991
- Task Force defended scientific legitimacy of new Asian 'cheap' vaccines *and* convinced Western manufacturers to accept lower profits

Hep B Key Lessons 1

- Necessary to have a national ‘champion’,
  - Minister of Health in Indonesia 1984
- Culture not used to this type of entrepreneurship
  - Faced problems when addressing the possibility of local production, such as a belief that PATH was a private money-making organization
  - Involved a direct relationship with competitors
- Need to resolve conflict of interest with pharmaceuticals, and those representing both the Government and PATH (undermine local credibility)
- Careful choices required to transfer vaccine technology
  - Failed in Thailand, although success in adoption in to National Immunization program

Hep B Key Lessons 2

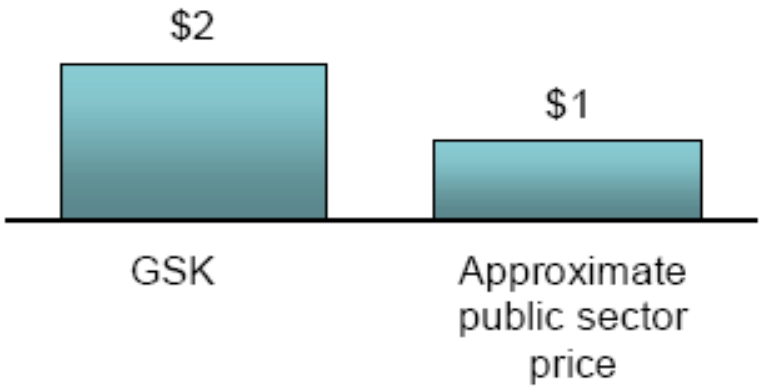
- Need to be aware of national politics and hierarchy
  - Role of PKK (woman's movement) in Indonesia
  - Chinese movement towards private healthcare early 1990s restricted 'effective market' (Now China is cited by GAVI as 'Success Story' with accelerated immunization between 1999-2002)
- Need to be aware of national culture
  - Education materials poorly managed in Indonesia
  - Wasted money on booklets
  - Television more effective for raising awareness
  - Sri Lanka Ministry of Health placed amulet on poster

HEP B current situation

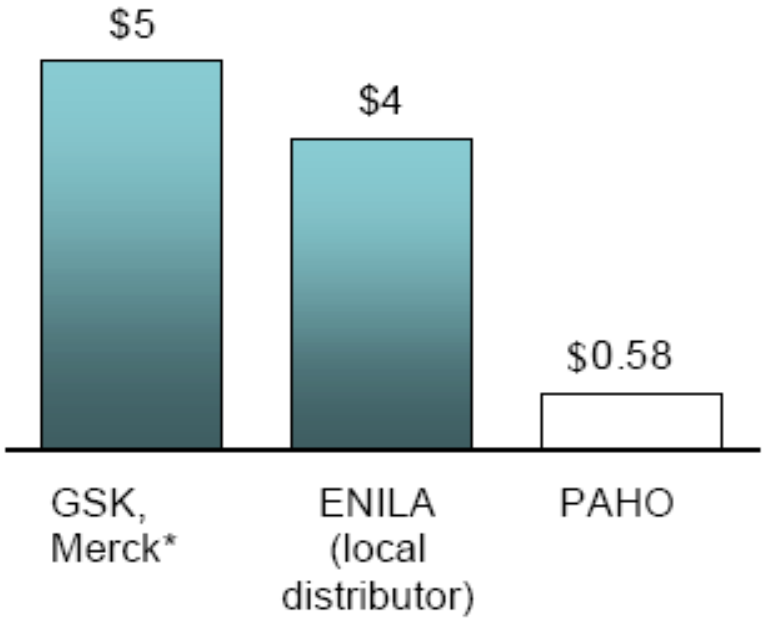
- Recombinant DNA vaccine now
- WHO recommends all infants receive hepatitis B vaccination
- Combination vaccine proven efficacious
  - but in Costa Rica, fewer than half of children returned for second dosage in trial
- Problems
  - GAVI Bridge Financing Proposals Phase I. Prices increased, lack of consensus on institutional responsibilities, lines of accountability, inaccurate demand forecasts
  - UNICEF lack of supplies of DTP3

LDC market tier pricing Hep B

India, 2001
Hep B vaccine price
$/dose



Brazil, 2000
Hep B vaccine price
$/dose

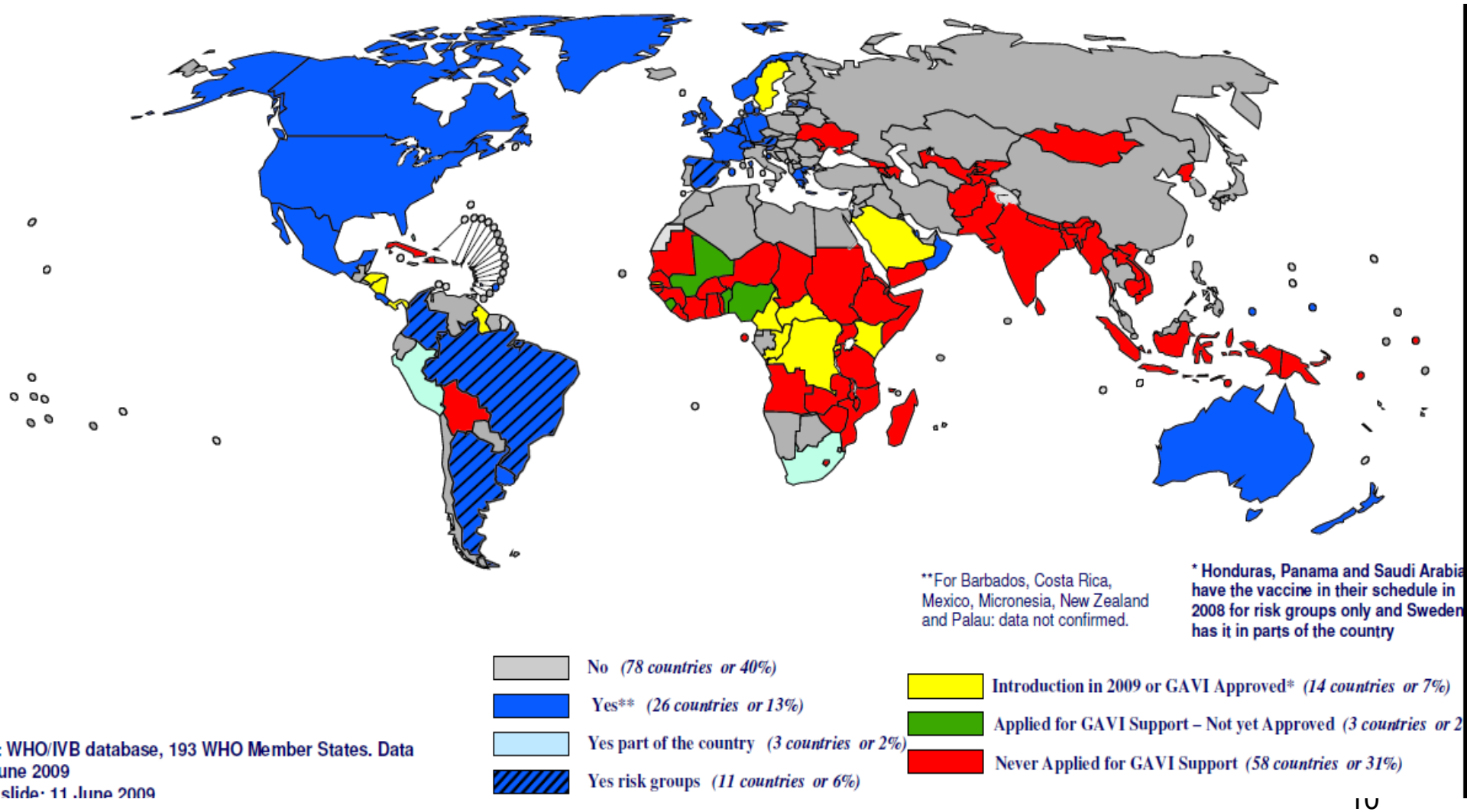


* Price of GSK and Merck; private clinics may then mark up the price further.

Source: McKinsey India; McKinsey Brazil

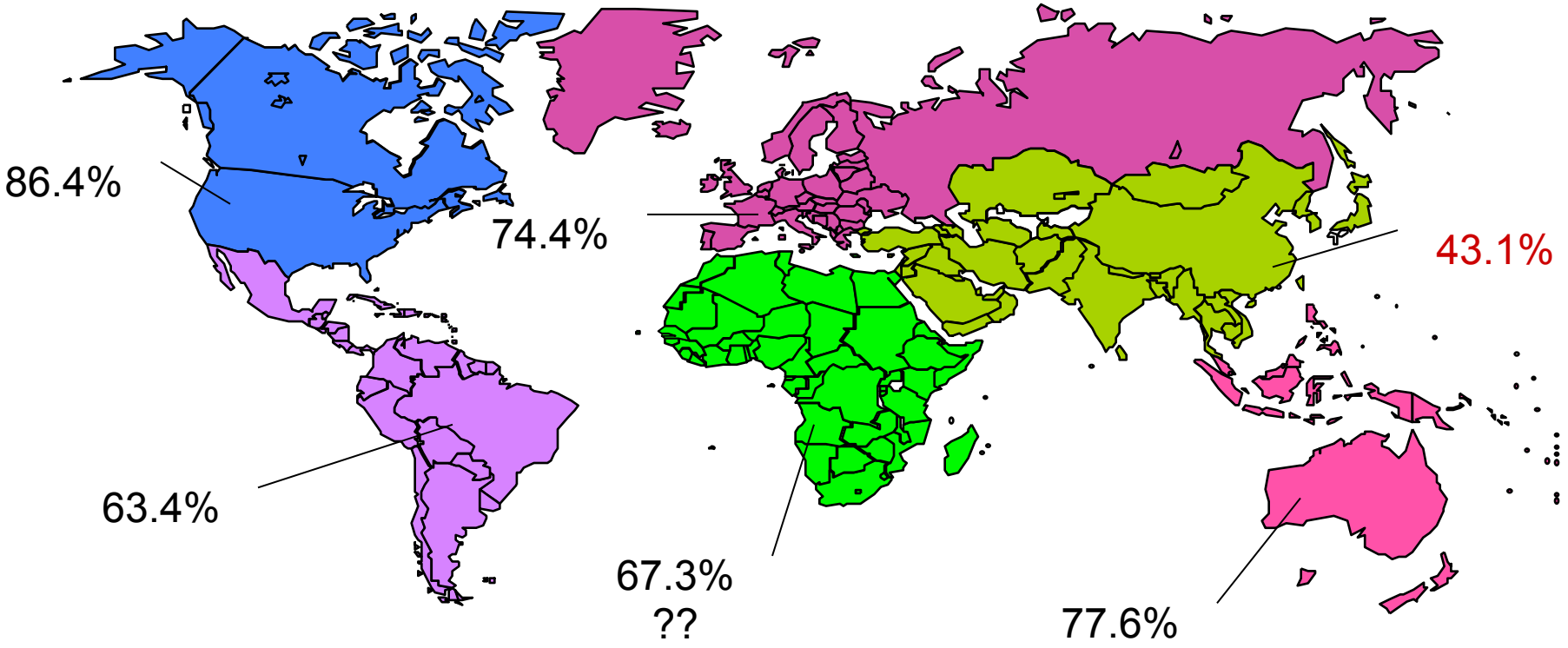
PNEUMOCOCCAL CASE STUDY

Pneumococcal Conjugate Vaccine 2008



Source: WHO/IVB database, 193 WHO member States, Data as of June 2009

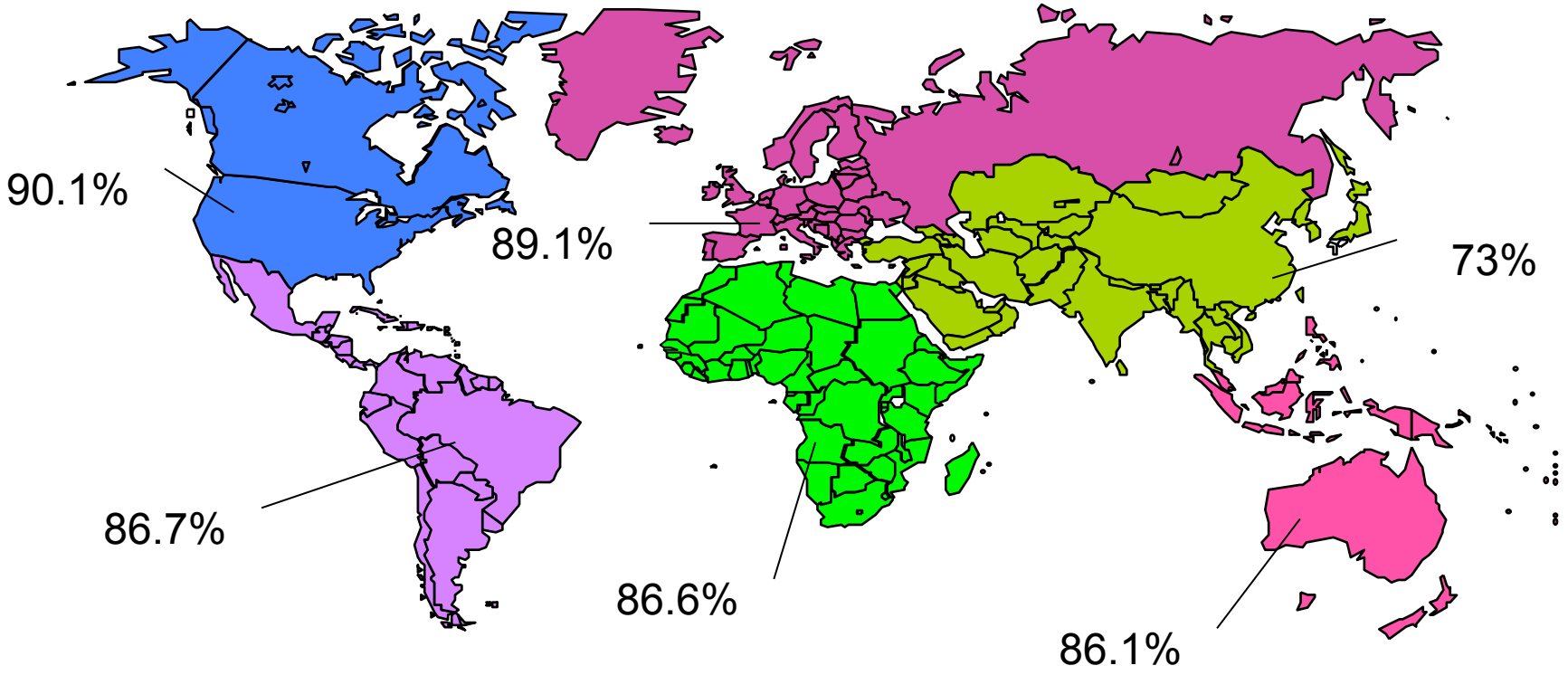
Coverage of 7 valent Pneumococcal Conjugate Vaccine



All regions except Asia >60% coverage; Asia 43%

Source: Hausdorff W. Clin Infect Dis 2001

Coverage of 11 valent Pneumococcal Conjugate Vaccine



All regions except Asia >85% coverage; Asia >70%

Source: Hausdorff W. Clin Infect Dis 2001

Pneumonia: Leading child killer

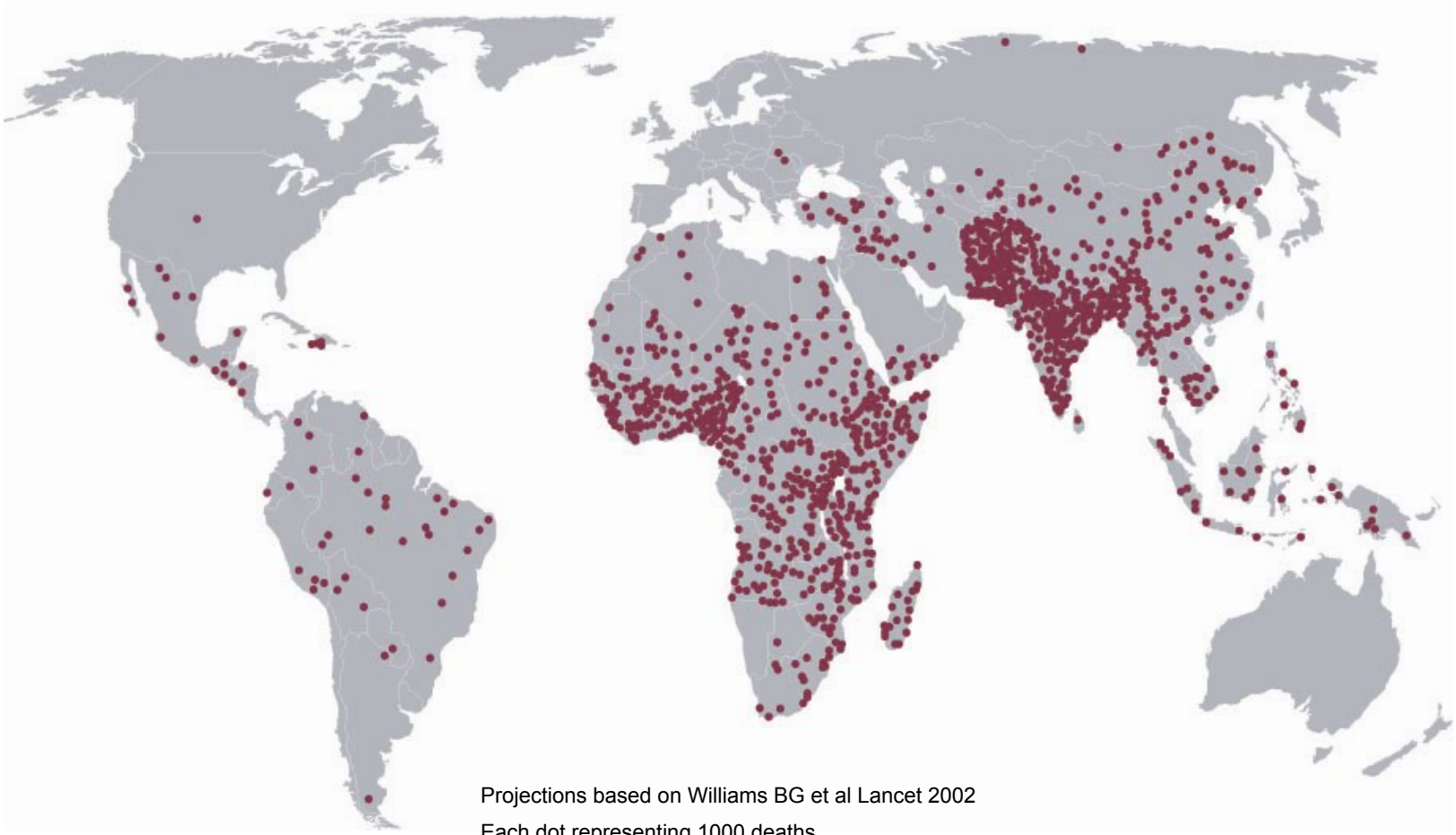
Pneumonia

- Mortality: ~25% of the 10M child deaths / yr
- Morbidity: ~151 million cases each year
  - –13-20 million are severe enough to require hospitalization

Pneumococcal disease

- Pneumococcus is the leading cause of child pneumonia deaths (~40%)
- About 1 in 10 child deaths due to pneumococcal disease

Nearly 70% of child pneumonia deaths occur in Africa & So. Asia



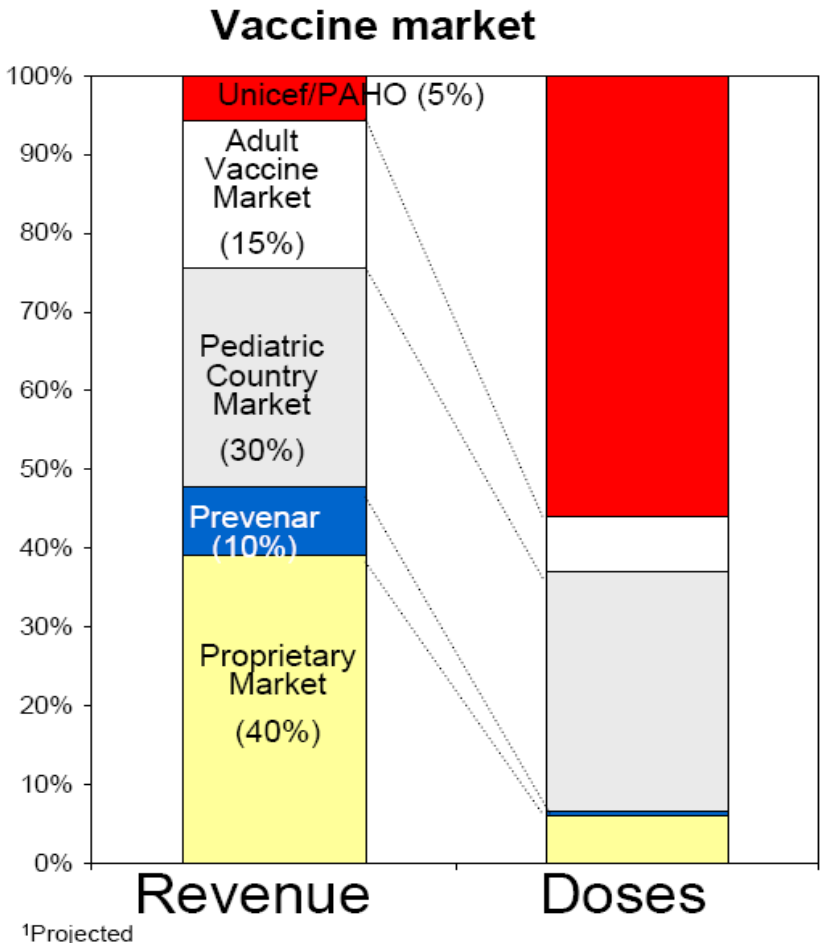
Projections based on Williams BG et al Lancet 2002

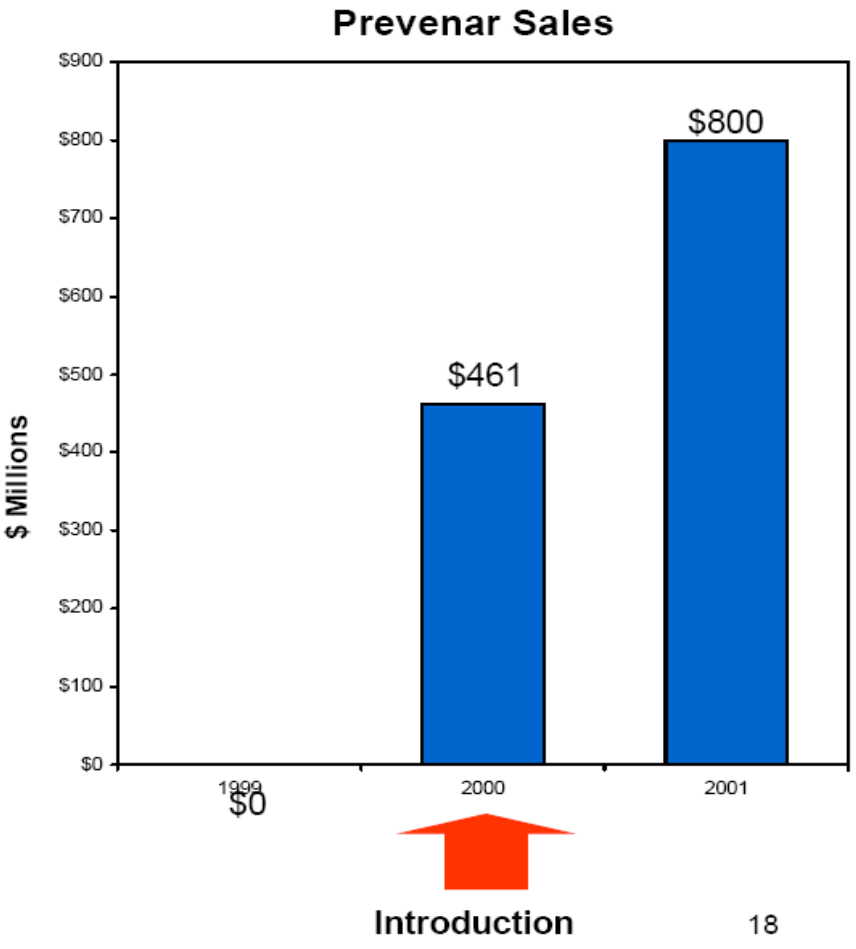
Each dot representing 1000 deaths

Prevention of pneumococcal disease is important

- HIV increases risk 20-40 times
- Antibiotic resistance complicates treatment
- Pneumococcal pneumonia follows pandemic influenza
  - –Additional ~4.5M pneumococcal pneumonia cases and 450,000 deaths in children in GAVI countries

Prevenar: An interesting case study





Prevenar: The first ‘blockbuster’ vaccine?

- Specifics about pneumo 90 serotypes, vary in impact around the world
- Capacity and IO issues
- Return to these issues below, since they mean that apparently simple policy solutions need to be much more subtle
- Others following this pattern
- MORE ON PNEUMOCOCCAL BELOW WHEN WE DISCUSS ROLE OF GAVI

Prevenar a big US success

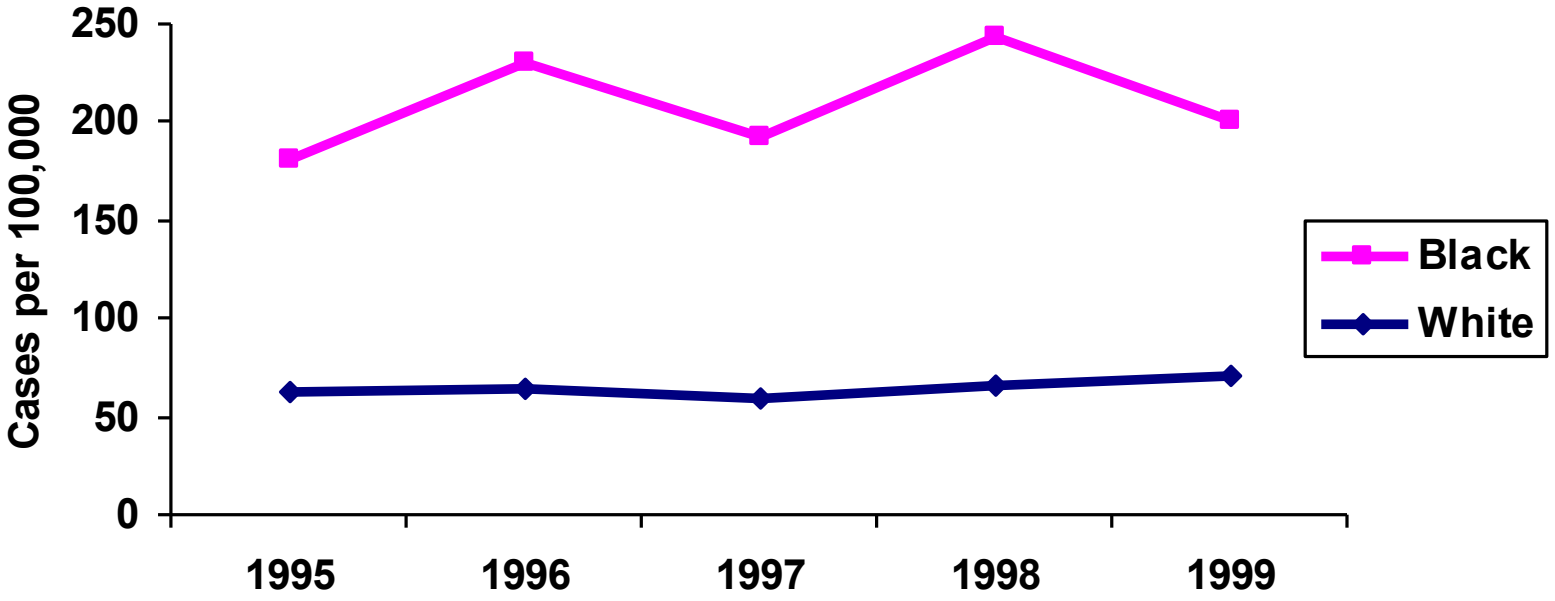
"The vaccine is having a greater effect than anyone had imagined"

- Dr. Brendan Flannery, US CDC

Large herd immunity effect benefits the elderly

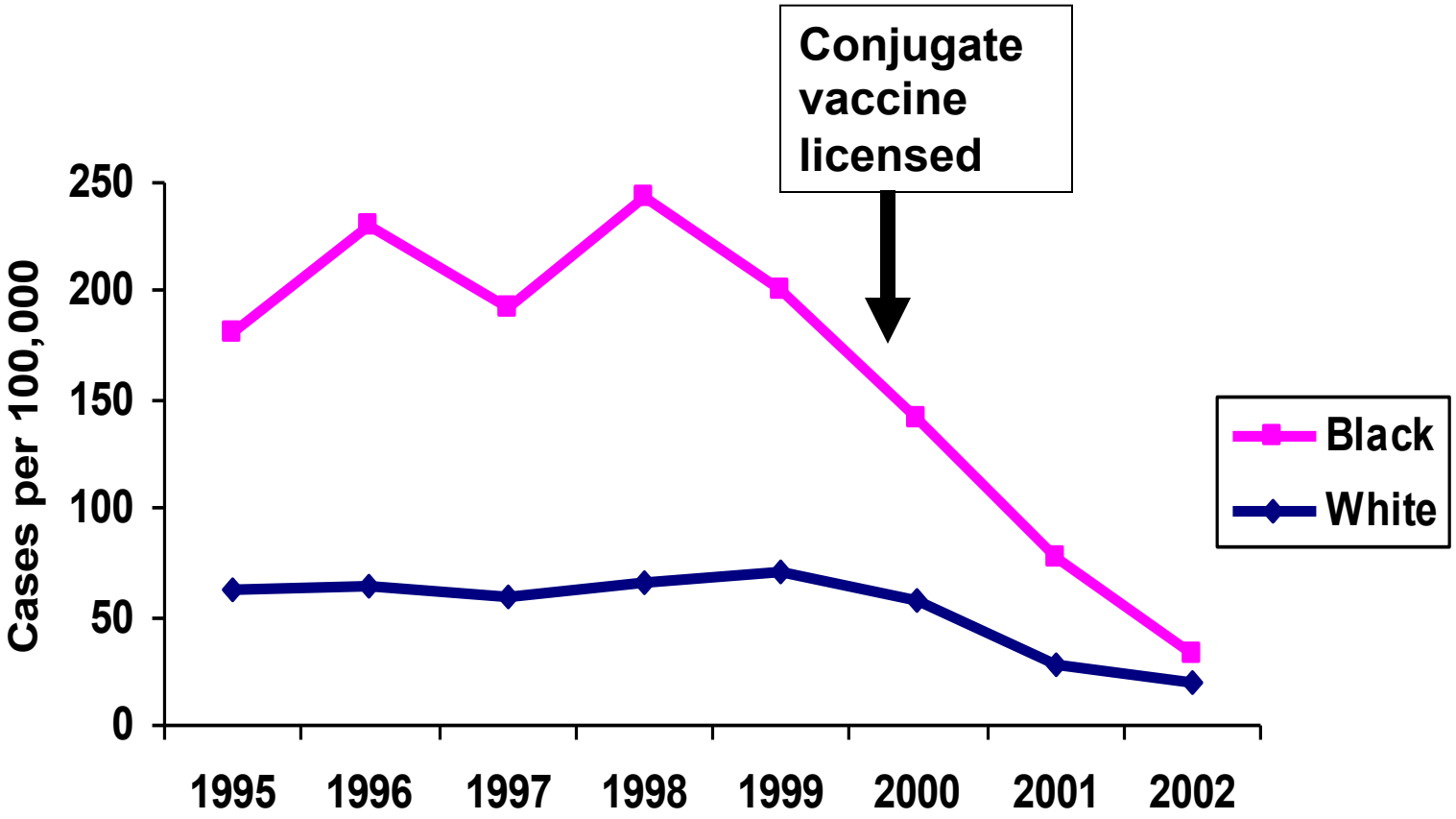
Routine vaccination in the United States is eliminating racial gap in pneumococcal disease…

Invasive Pneumococcal Disease in the USA, By Race, Children <5 years old, 1995 – 2002



Ref: Flannery B et al. JAMA 2004

Invasive Pneumococcal Disease in the USA, By Race, Children <5 years old, 1995 – 2002



Ref: Flannery B et al. JAMA 2004