
PDVI

Ensuring Vaccine Access

Richard T. Mahoney, PhD
Director, Vaccine Access
Pediatric Dengue Vaccine Initiative
International Vaccine Institute
Seoul, Korea



Why Access?

- The lessons of Hep B
 - Don't wait till licensure – start early!
 - Clearly enunciate the burden of disease
 - Involve endemic developing countries
 - Address a wide range of issues – many things to do
 - Build wide international consensus
 - Promote competitive supply
 - Improved public health is the measurement of success



Why Access?

- The evolution of PDPs* – Oxford Conference
 - Many PDPs, e.g. Aeras, IAVI, et al., have concluded that their mission must include helping to ensure access
 - The meaning of partnership: **not just a technology but jointly reinforcing outcomes**
 - Public sector: **improved public health**
 - Private sector: **a market**
 - A PDP becomes an invaluable global resource of expertise that is essential to **ensuring a public health impact**

*PDP = Product Development Partnership



Why Access?

- A part of a more mature concept of public sector involvement in health technology innovation*
 - Discovery
 - Development
 - Delivery
 - + Advocacy

* As enunciated by the Bill & Melinda Gates Foundation

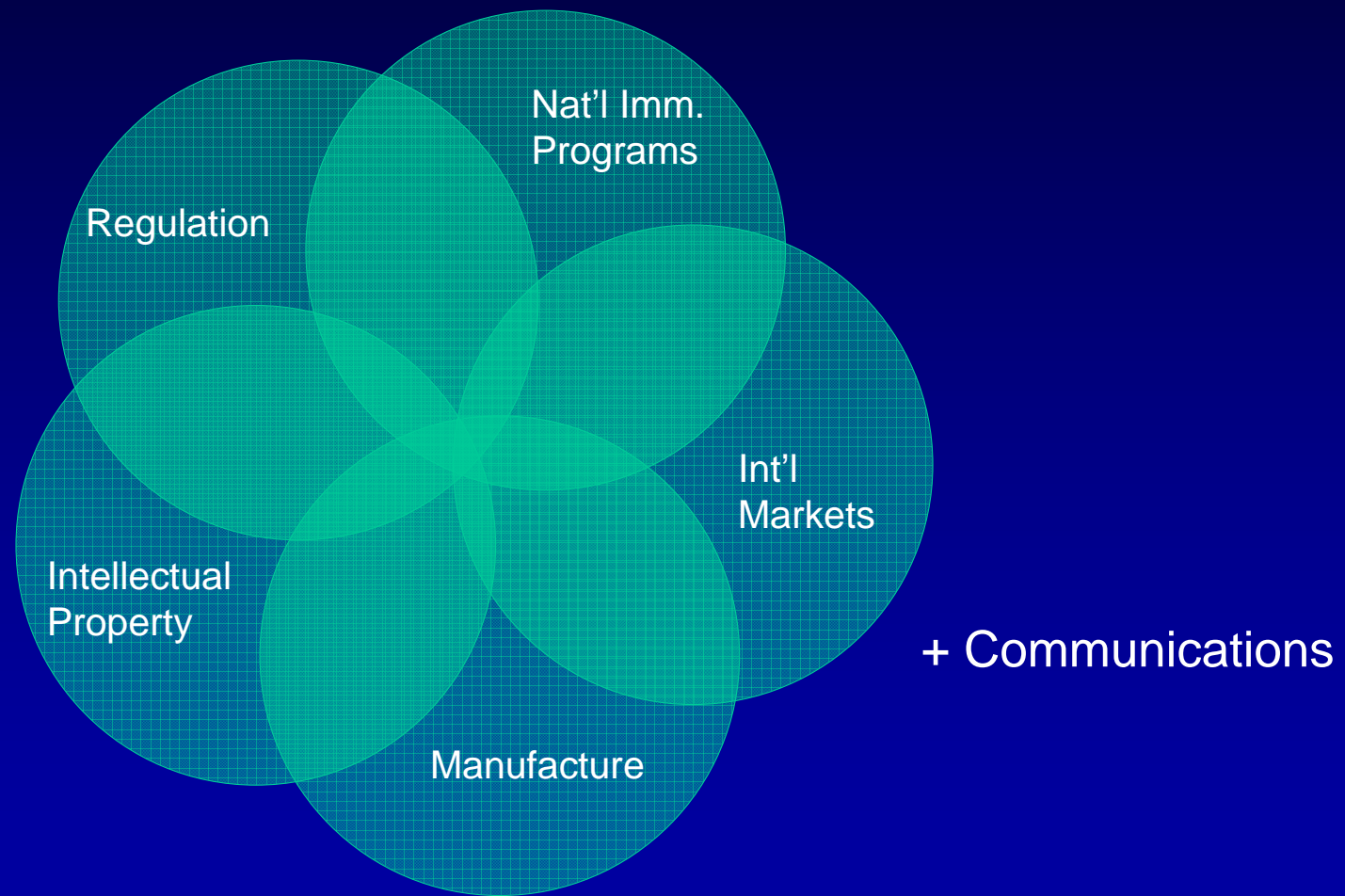


How Access?

- Unlike R&D, there is no widely accepted evidence-based intellectual framework for Access.
- R&D has preclinical, Phase 1-3, Post Phase 3, Adverse Events monitoring, etc.
- How do we do Access?



Linked Components of Vaccine Access



Core Cross-cutting Activities

- Dengue Prevention Boards
- Investment Case



Core Cross-cutting Activities

- **Dengue Prevention Boards:**
 - Asia Pacific Dengue Prevention Board (APDPB)
 - Americas Dengue Prevention Board (AmDPB)
 - Independent experts from endemic countries who review key issues in dengue prevention and issue authoritative reports to help advance the field



APDPB Membership

- Members
 - Agus Syahrurachman, Indonesia
 - Nihal Abeysinghe, Sri Lanka
 - Gregory Dever, Palau (US)
 - Jeffrey Hannah, Australia
 - Tom Kiedzynski, South Pacific
 - Ken Lam, Malaysia
 - Pratap Singhasivanon, Thailand
 - Thien Nguyen, Vietnam
 - Eng Eong Ooi, Singapore
 - Sirenda Vong, Cambodia
 - Yukiko Wagatsuma, Japan
- Observers
 - SEARO
 - WPRO



AmDPB Membership

- Members
 - Anabel Alfaro Abando, Costa Rica
 - Juan Jose Amador, Nicaragua
 - Antonio Arbo, Paraguay
 - Jose Cordero, Puerto Rico
 - Eduardo Fernandez, Honduras
 - Maria Guzman, Cuba
 - Jorge Mendez, Mexico
 - Pedro Vasconcelos, Brazil
 - Iris Villalobos, Venezuela
- Observers
 - Jose Luis San Martin – PAHO
 - Wellington Sun – CDC
 - Steve Waterman – CDC



Dengue Prevention Boards

Crosscutting mechanism for Access

- APDPB
 - Surveillance, June 2007, Colombo
 - Diagnostics, December 2007, Bangkok
- AmDPB:
 - Surveillance, January, Mexico City
 - Diagnostics, Mid-year, Brazil
- Issue joint report on surveillance meetings
- Joint meeting: Investment Case I, Third quarter 2008
- Other topics
 - Case management and treatment
 - Burden of Disease
 - Vector control
 - Health Education
 - Vaccines



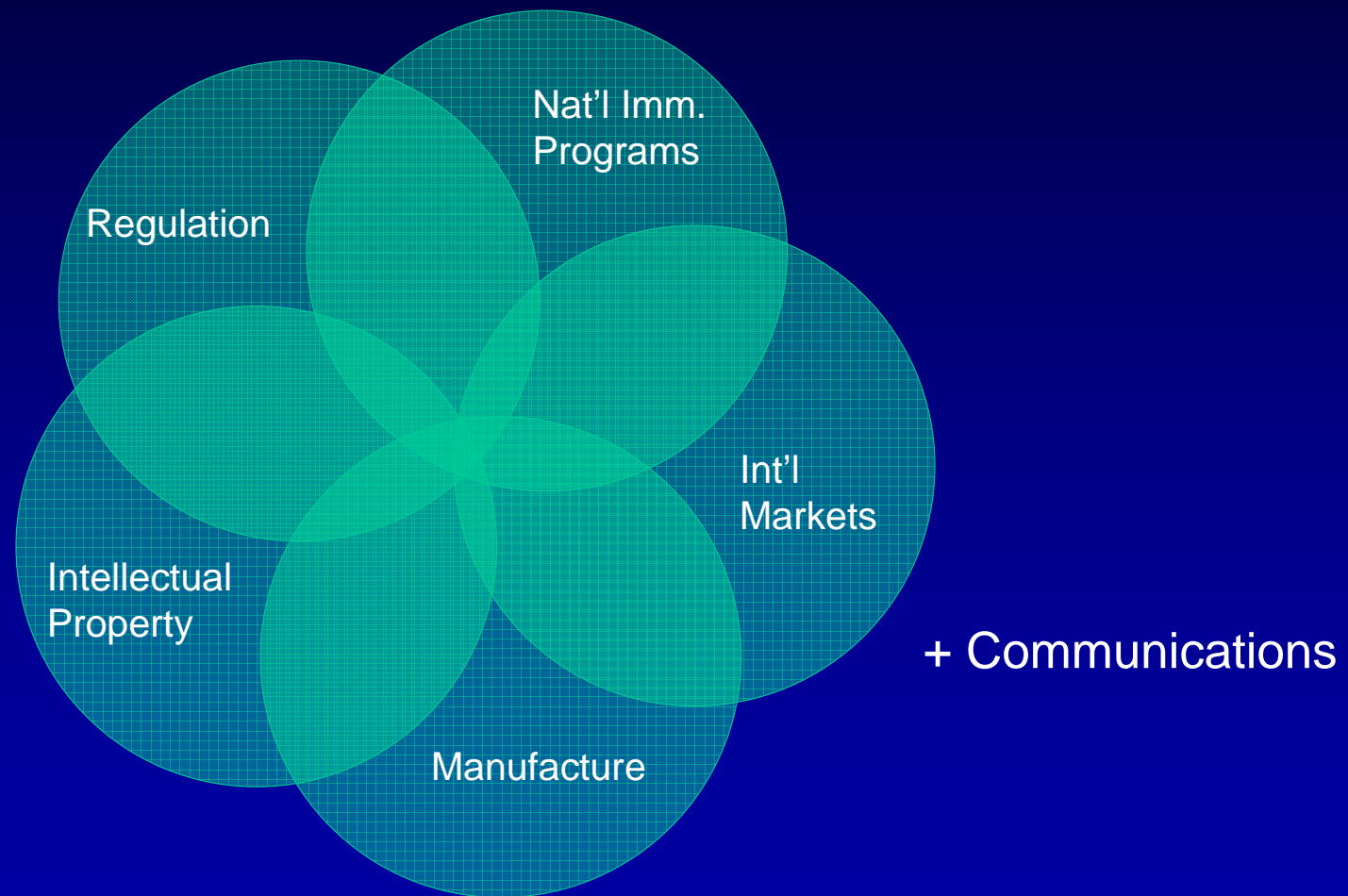
Investment Case

- A comprehensive document laying out the justification and need for funding and support of discovery, development and delivery of dengue vaccines and diagnostics.

*If it takes \$2-3 billion over the next 10 years to get from today to general availability of dengue vaccines, how do we do it **in detail**?*



Linked Components of Vaccine Access



The PDVI Vaccine Access Program

- National immunization programs/Domestic markets
- International markets/global procurement and supply
- Regulatory systems
- IP management systems
- Manufacture



Domestic markets/ National immunization programs

- Cost of illness – undervalued dengue?
 - Much priority setting is mortality based
 - Dengue causes great morbidity and financial burden to government, health providers, patients and their family
- Vaccine use projections in public and private sectors
- Modeling of national immunization plans
- Key input to Investment Case



The PDVI Vaccine Access Program

- Domestic markets/national immunization programs
- International trade/global procurement and supply
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International trade/ Global procurement and supply

- **Bottom up strategy:** Work with a group of endemic developing countries to launch vaccine procurement in advance of international commitment. Leads to pressure on international policy makers to act, *cf.* hepatitis B
- **Innovative procurement strategies**
 - Advance Market Commitments (AMCs)
 - Can donors accelerate the innovation of dengue vaccines by guaranteeing a market?
 - Combined procurement by several countries, e.g. PAHO Revolving Fund
 - Long-term procurement agreements (IFFIm)



The PDVI Vaccine Access Program

- Domestic markets/national immunization programs
- International trade/global procurement and supply
- **Regulatory systems**
- IP management systems
- Manufacture



Regulatory Issues

- Working with WHO
 - Developing Countries' Vaccine Regulators Network
 - DCVRN “Statement” on dengue vaccines
 - In-depth training course
 - Joint review of clinical trial applications
 - Update guidelines for manufacture of dengue vaccines (pre-qualification)



Regulatory Systems

- Member countries of DCVRN
 - Brazil
 - China
 - Cuba
 - India
 - Indonesia
 - Russia
 - South Africa
 - South Korea
 - Thailand
- Additional countries as observers recommended by PDVI
 - Cambodia
 - Colombia
 - EMEA
 - Mexico
 - Nicaragua
 - Philippines
 - United States
 - Vietnam
 - Other?



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Access IP Map

- Shows how IP could help determine manufacturers' market strategy and potential role of second comers.
- Patents are specific to country in which issued
- Key patents for dengue issued in US, Europe, Japan, etc. but not developing countries
- Patent applications on new technologies are being submitted in developing countries
- But know-how is very important particularly for a vaccine like dengue that will be tetravalent



The PDVI Vaccine Access Program

- Domestic markets/national immunization programs
- International trade/global procurement and supply
- Regulatory systems
- IP management systems
- **Manufacture**



Manufacture

- Role of manufacturers in developing countries –
 - PDVI accords high priority to working with developing country manufacturers
 - Preliminary case study has shown that developing country manufacture has the potential to be less costly
 - PDVI partnerships with Butantan, Biological E InViragen/Shantha and Panacea will include assessment of advantages/disadvantages of these producers

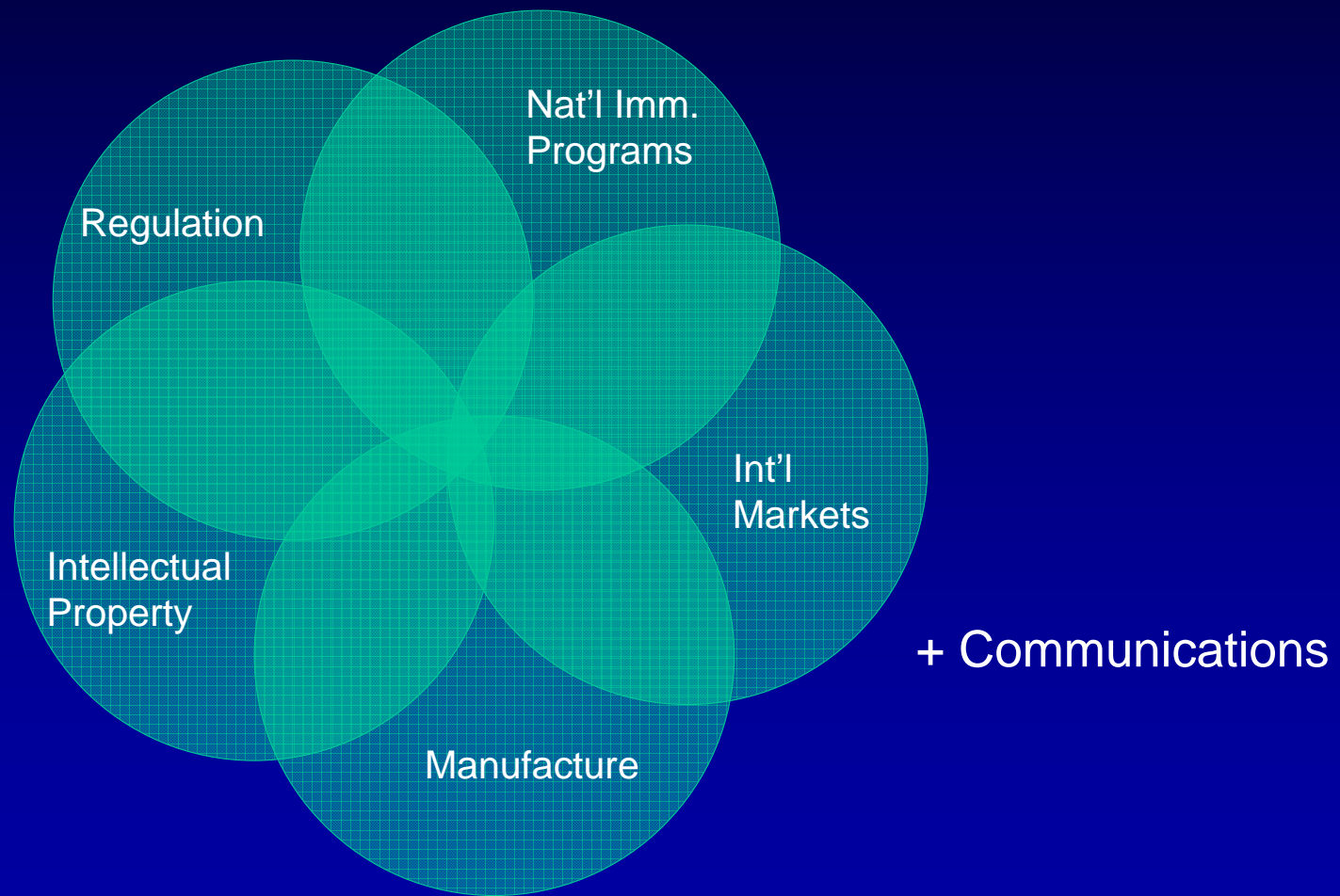


Summary

- The world of public sector involvement in health technology is changing
 - Not enough just to have a technology
 - Work through public-private partnerships
 - Want to have an impact on public health
 - No established methodology for access
- PDVI's methodology addresses five dynamically linked components of access to improve public health with vaccines



Components of Access



Thank you

