

# Vaccine Innovation: Products with Limited Commercial Market?

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# Objective

- **In the context of the overall US vaccine system, outline types of challenges to vaccine development in the US**
- **Characterize infectious disease vaccines by market**
- **Discuss the role of government in vaccine development, specifically for products of limited commercial markets**

## Question to NVAC



- Given a technically feasible vaccine can be developed, should NVAC explore ways to foster innovation for products with little commercial market in the US?

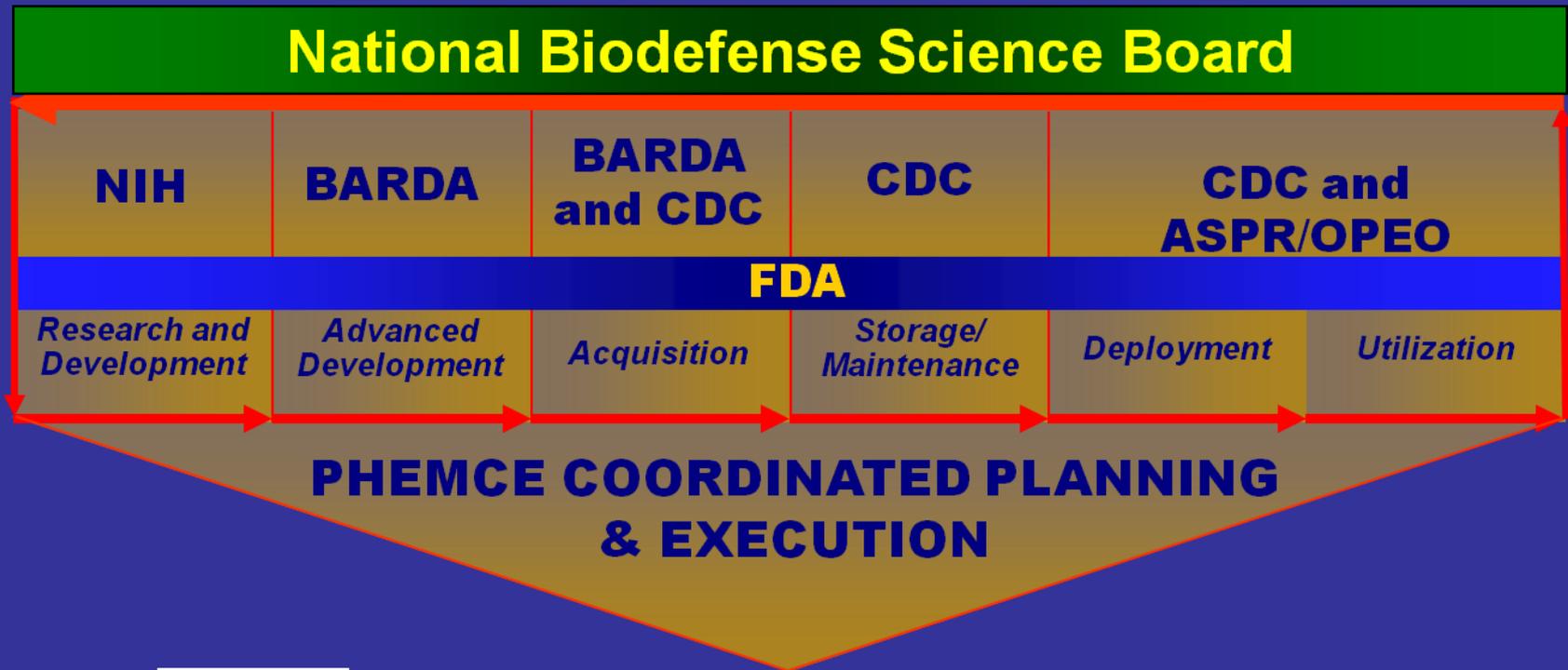
# What non-technical factors impede progress?

Factors related to the cost of development where



development costs exceed  $>$  potential market return

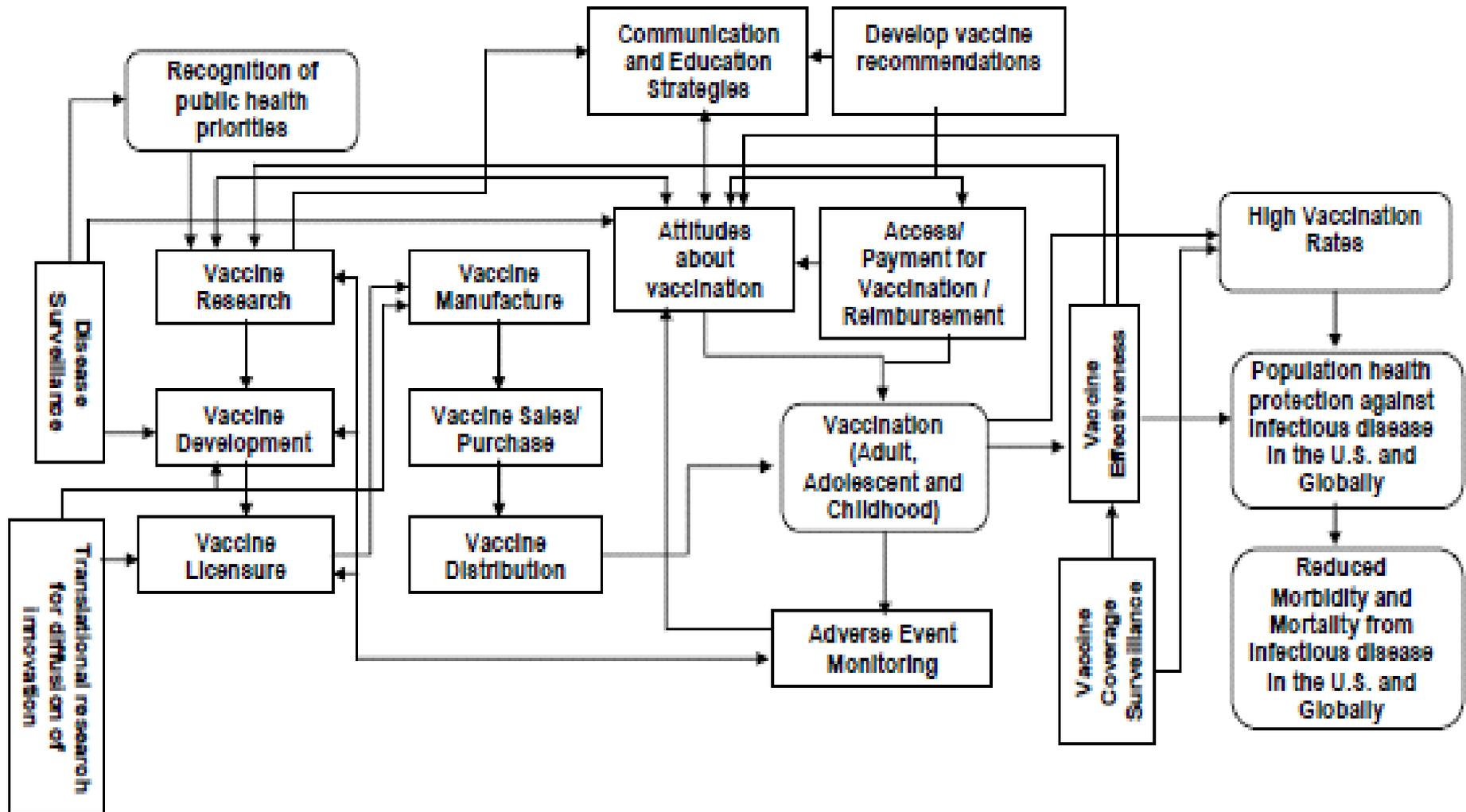
# Federal Public Health Emergency Medical Countermeasures Enterprise



Ex Officio Members:



# Many factors influence development decisions



# Some factors

- Research funding, development activities (e.g. reagent sharing, assay development), epidemiology/surveillance, liability protection
- Continuous and robust supply, vaccine financing, adequate reimbursement to providers and patients
- Role federal advisory committees (VRBPAC, ACIP, NVAC, NBSB)

# How do companies choose projects?

- **Why launch a projects?**
  - **Market, public health interest, technical feasibility, intellectual property, fit with other vaccines**

Stanley Plotkin, IOM Meeting; Dec 1, 2008; Irvine, CA



# How is a market determined?

- Demand from consumers developing countries (e.g. Lyme Diseases, aPertussis)
- Demand from authorities in developed countries (e.g. Mening C)
- Epidemiologic data (e.g. Pneumococcal conjugate)
- Expert opinion (e.g. Mumps)
- Guesses, buttressed by precise but inaccurate data (e.g. Hep B)

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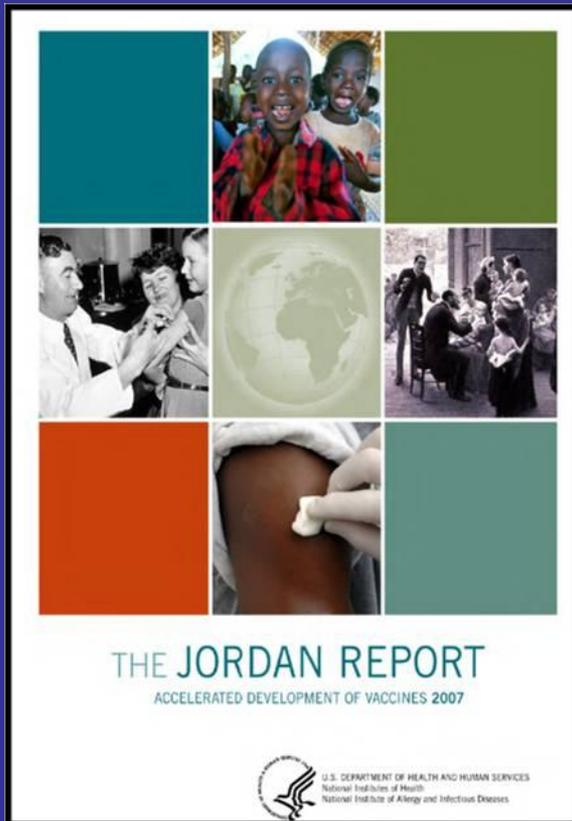


# Types of commercial markets – US Perspective

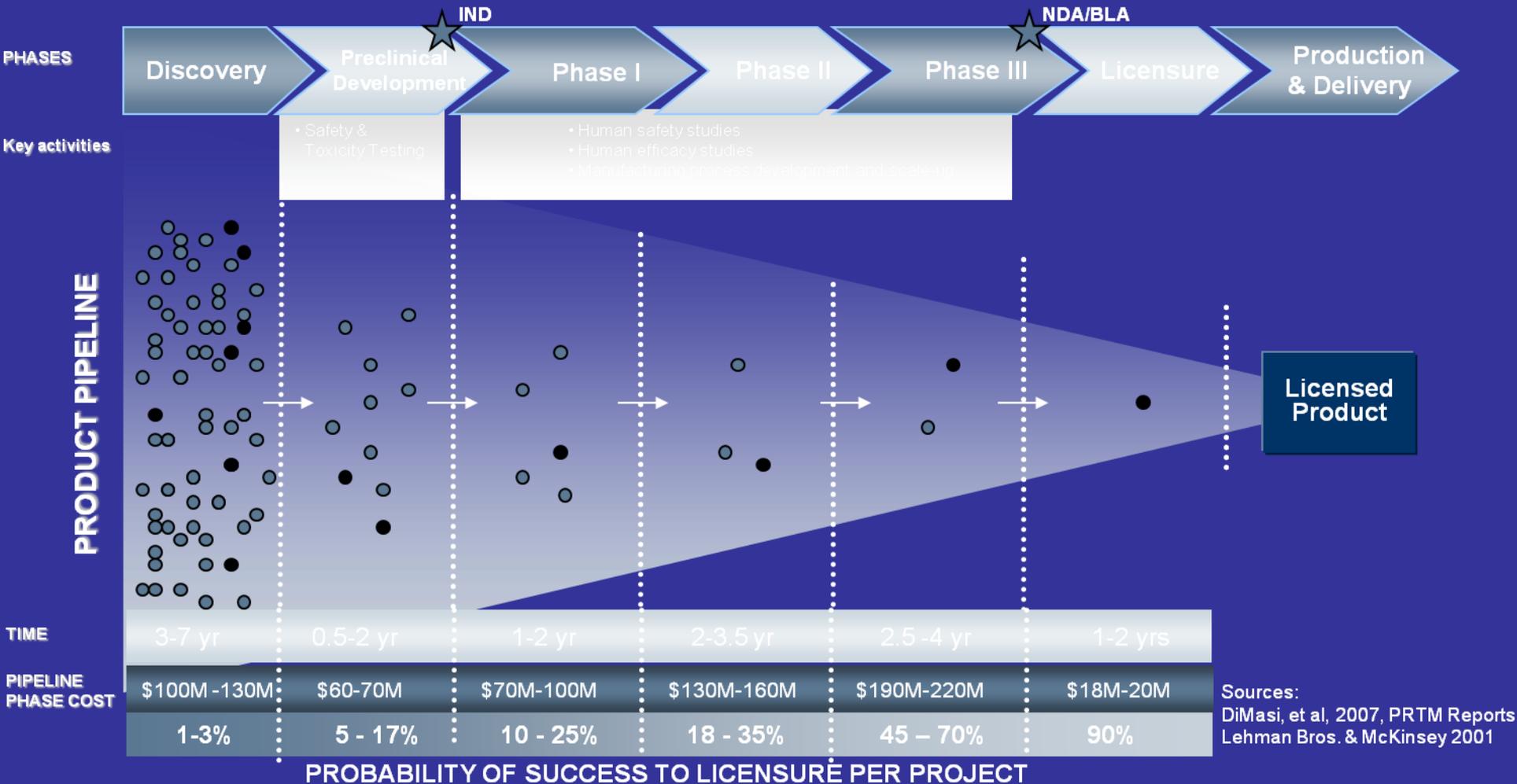
- **Routinely recommended**  
(childhood, adolescent, adult)
- **Orphan**  
(development  $\$ >$  market)
- **Travelers**
- **Developing World**
- **Bio-defense**
- **Emerging diseases (ED) and those ED that become endemic**
- **Large**
- **Limited**
- **Small**
- **Small/Large**
- **None**
- **Unclear**

# Upstream Research

- Much promising technology, advances in science, potential candidates
- NIH supports wide spectrum of basic science research
- Not all basic science translates into a vaccine – an innovation



# How “Big Pharma” Operates



# Summary

- **Many challenges above technical**
- **BARDA is an example of interplay of factors to address challenges; tough choices made on which products to support**
- **Vaccine innovation challenges due complexity of immunization enterprise**
- **National Vaccine Plan to address some these issues**

## Question to NVAC



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