

# How Can Vaccine Shortages Be Prevented?

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**Stephen L. Cochi, MD, MPH**

**Acting Director**

**National Immunization Program  
Centers for Disease Control and Prevention  
Atlanta, Georgia**



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# **Severe Vaccine Shortages Termed 'Unprecedented'**

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*Washington Post*  
April 20, 2002

# **Parental Concerns Follow Shortage of Vaccines for Kids**

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*Wall Street Journal*  
February 14, 2002

# **Critical vaccines, medicine run low**

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**Tetanus shots rationed—  
Congress probes shortage**

*San Francisco Chronicle*  
February 10, 2002

# Vaccine Market

- **Approximately 226 million doses in 2002**
- **Approximately 2/3 used for children**
  - 11,000 infants born each day in the US
  - 2002 market included:
    - ~20 million doses of DTaP-containing vaccine;
    - ~19 million doses of polio vaccine;
    - ~12 million doses of MMR vaccine.
- **Majority of market for adults consists of influenza vaccine (~81 million doses in 2002)**

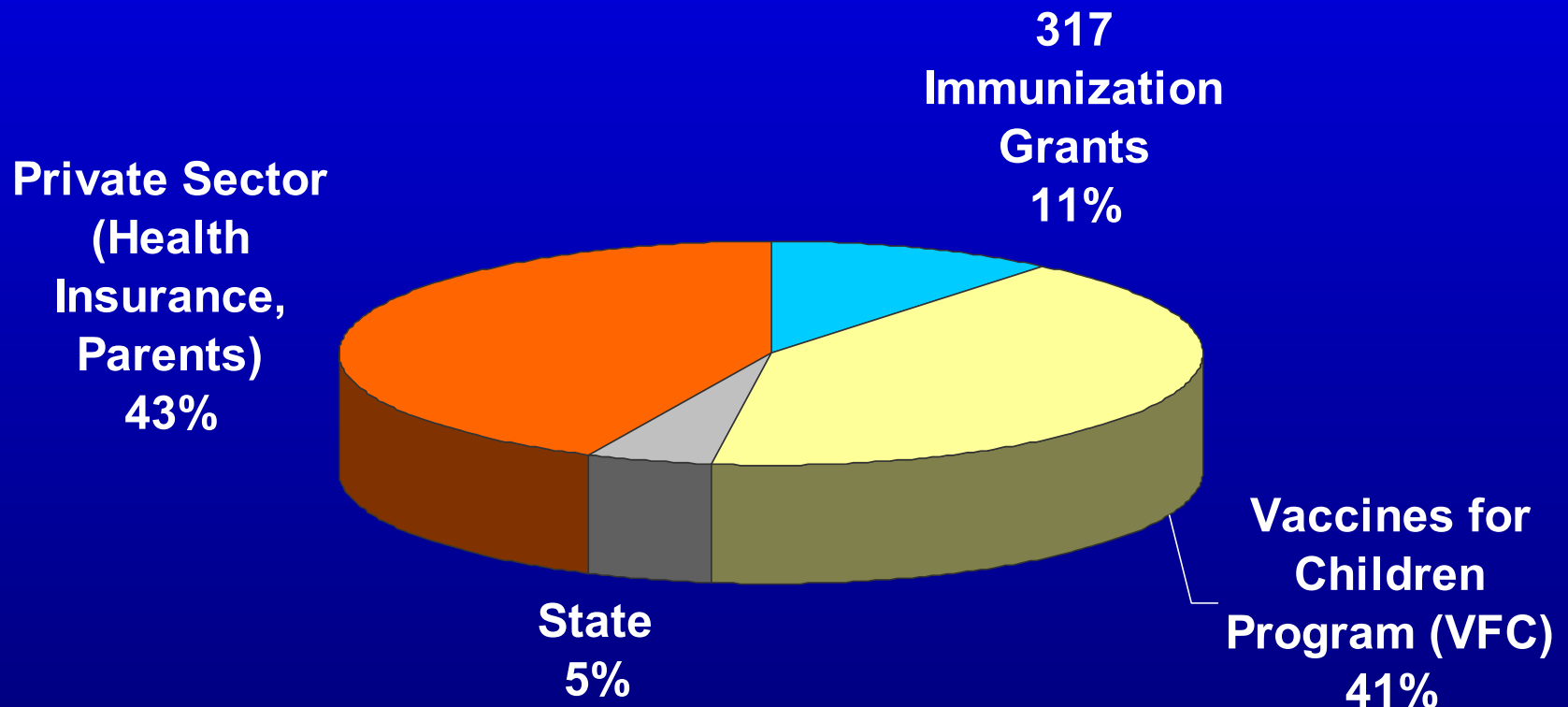
Source: 2002 Biologics Surveillance Data



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# Childhood Vaccine Doses Distributed by Funding Source Calendar Year 2002



Source: Biologics Surveillance Data 2002

# The Problem

- Began late 2000, with decreased availability of Td
- Expanded to include DTaP, PCV7, MMR and varicella vaccines
- Affected both public- and private-purchase vaccines, most providers, and many children



# Duration of Vaccine Shortages

<b>Vaccine</b>	<b>Approximate start of shortage</b>	<b>Resolution of shortage announced in MMWR</b>
<b>Td</b>	<b>November 2000</b>	<b>June 2002</b>
<b>DTaP</b>	<b>March 2001</b>	<b>July 2002</b>
<b>PCV7</b>	<b>September 2001*</b>	<b>May 2003</b>
<b>MMR</b>	<b>October 2001</b>	<b>July 2002</b>
<b>Varicella</b>	<b>October 2001</b>	<b>August 2002</b>
<b>PVC7</b>	<b>December 2003</b>	<b>ongoing</b>

\*CDC-reported shortages existed throughout most of 2001, but intensified in September 2001.

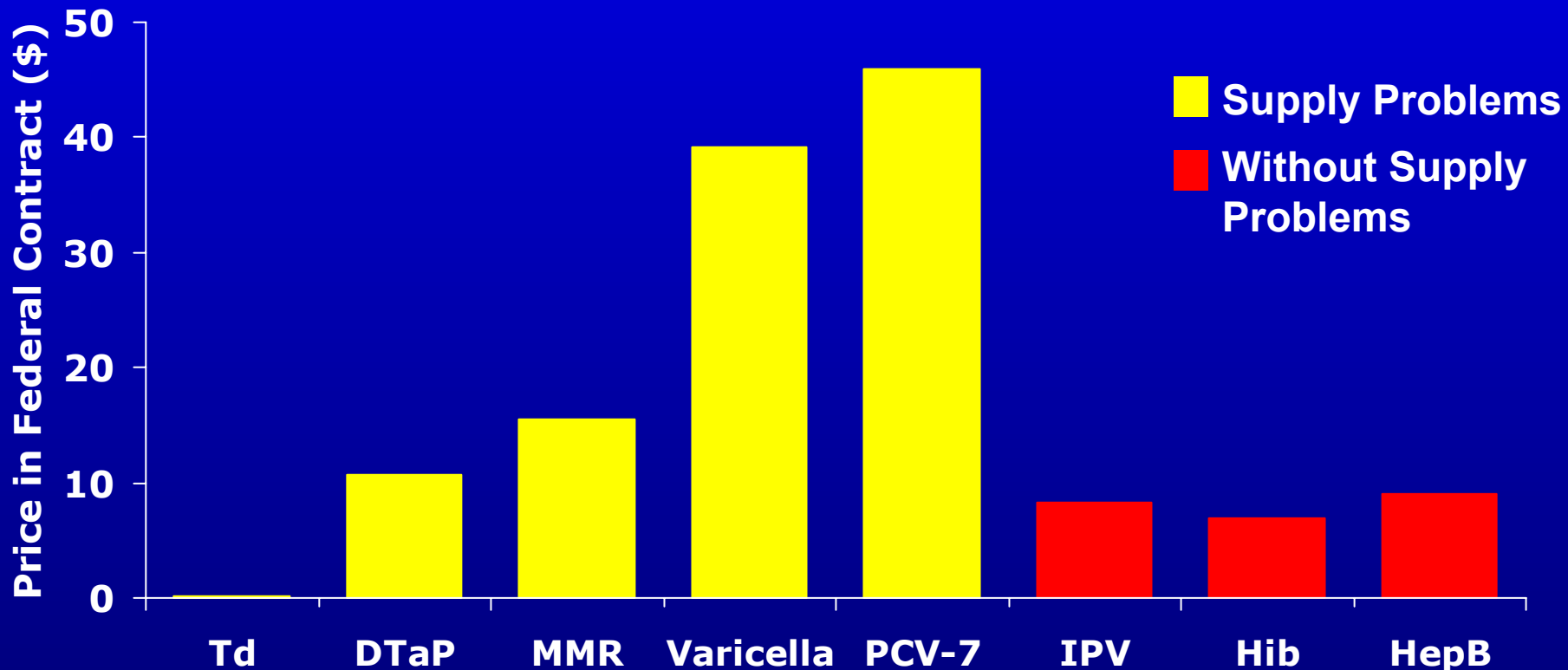
Adapted from GAO (2002) "Childhood vaccines: Ensuring an adequate supply poses continuing challenges."



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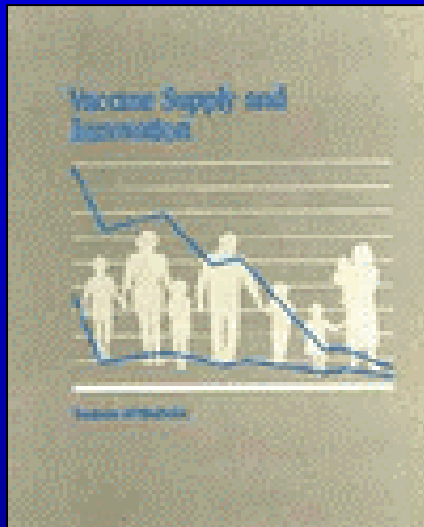
# Federal Contract Price for Vaccines With and Without Supply Problems



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# Vaccine Supply Concerns: A Recurring Theme



*“The history of previous ad hoc groups convened to address problems related to vaccine availability has been discouraging.”*

IOM: Vaccine Supply and Innovation (1985)

# Vaccines are Unique

## ■ Biological products

- Produced from living cells and organisms (increased risk for contamination)
- Requires growth (and the complex conditions that support it)
- *Each lot* must be tested for purity/potency
- Lengthy production time

## ■ Regulated differently than drugs

## ■ Safety paramount because recipients are healthy



# Causes for the Vaccine Supply Shortages

- Multifactorial
- Difficult to determine which are most important
- Vary by vaccine
- Two type of factors:
  - Immediate and specific
  - Contributing



# Immediate and Specific Factors

- Decision to cease DTaP/Td production
- Renovations of vaccine-filling suite for MMR and varicella vaccines
- Large initial demand for and unanticipated production/filling problems for PCV7
- Problems complying with cGMPs for some manufacturers
- Changes in vaccine recommendations regarding use of thimerosal



# Contributing Factors

- Low valuation of preventive measures
- High complexity/cost of vaccine development/approval/manufacturing process
- Decreased number of manufacturers
- Lack of investment in some manufacturing facilities
- Legal barriers to communication



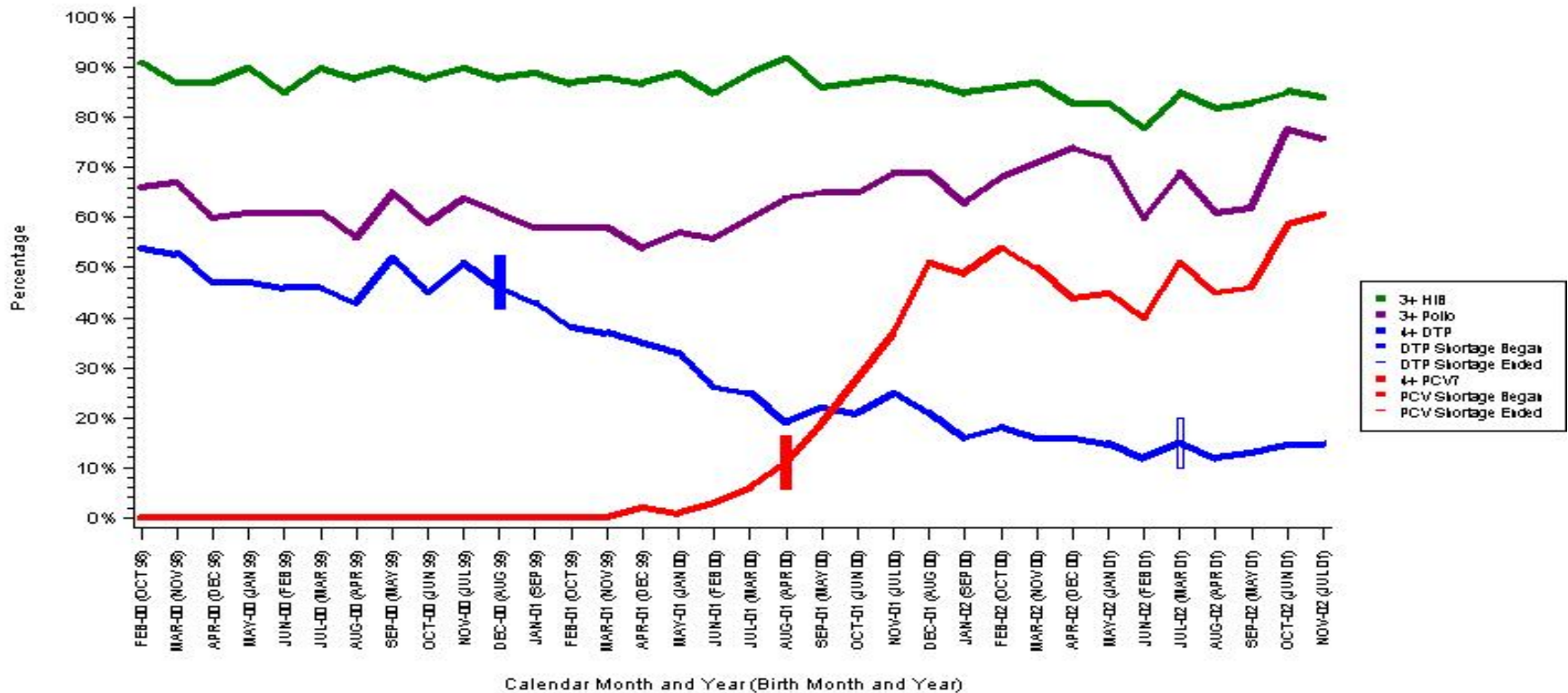
# **CDC Response to the Vaccine Supply Shortages**

- **Issued interim Advisory Committee on Immunization Practices (ACIP) recommendations**
- **Monitored orders, inventories and distribution**
- **Activated vaccine stockpile (MMR vaccine)**



# Impact on Immunization Coverage

Coverage Rates for 3+ Hib, 3+ Polio, 4+ DTP, and 4+ PCV7  
at age 18 months  
from FEB00 to NOV02 in Site F



(Bartlett, et al, unpublished data)

# US General Accounting Office (GAO) Investigation

- Requested by representatives from the House and Senate in 2001
- Report published in September 2002
- Recommendations for executive action:
  - CDC should develop a strategic plan for expansion of the national stockpile program
  - FDA should ensure widespread distribution of compliance guidelines to manufacturers and consider revising fast-track and priority review guidelines



# National Vaccine Stockpile Program

- Initiated in 1983 as a strategy to address short term supply disruptions
- Goal: Six month total national supply
- Dynamic inventory (storage/rotation)
- Utilized on at least 9 occasions since 1983. Most recently in 2003 to manage measles outbreak in the Marshall Islands
- Current status: CDC has purchased target quantities for E-IPV, MMR and Varicella vaccines. Partial target quantities of Hib, Hep B, Hep A, and PCV have been purchased. DTaP purchases are pending. Stockpile buildup with full vaccine delivery to be completed in 2007.



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# **National Vaccine Advisory Committee (NVAC)**

## **Recommendations I**

- **Strategies to be implemented in the immediate future**
  - **Increase CDC funding to expand national vaccine stockpile program**
  - **Increase support for FDA's CBER**
  - **Re-iterate role of NVAC/NVPO in prioritizing vaccine development and distribution**
  - **Require advance communication from manufacturers planning to cease manufacture of vaccines**
  - **Increase availability of vaccine supply status information**
  - **Initiate campaign to emphasize safety, efficacy and benefits of vaccination**



# National Vaccine Advisory Committee (NVAC) Recommendations II

- **Strategies that require additional study**
  - Evaluate appropriate incentives for manufacturers to sustain the vaccine supply and stimulate development of new vaccines
  - Streamline and strengthen the regulatory process and FDA activities, including
    - Supporting international harmonization of the regulatory process
    - Reviewing implementation of cGMPs to assure science-based decisions about vaccine safety and efficacy





# Notice to Readers: National Vaccine Advisory Committee Report on Strengthening the Vaccine Supply

The National Vaccine Advisory Committee has released a report entitled "Strengthening the Supply of Routinely Recommended Vaccines in the United States: A Report of the National Vaccine Advisory Committee." The report describes the immediate and contributing factors leading to the 2001--2002 vaccine supply shortages and outlines 12 recommendations to prevent future shortages. The report is available at <http://www.cdc.gov/od/nvpo/nvac-vsr.htm>.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

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# **CDC Efforts Underway to Address GAO/NVAC Recommendations**

- **Stockpile strategic plan completed**
- **Vaccine Management Business Improvement Project is developing operating procedures for stockpile management based on strategic plan**
- **Operating procedures will address all aspects of stockpile management – from target quantity adjustment to release procedures and notification**
- **FY 2004 budget allocation of \$200 million provides funding for continued stockpile development**
- **Budget includes \$40 million for the development of an influenza vaccine stockpile**
- **Stockpile purchases and vaccine deliveries for all routinely recommended childhood vaccines will be completed by 2007**



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# Summary

## How Can Vaccine Shortages Be Prevented?

- Expansion of vaccine stockpiles
- Increased support for regulatory agencies
- Maintenance/strengthening of liability protections
- National campaign to emphasize benefits/value of vaccines
- Financial incentives for manufacturers
- Streamline regulatory process





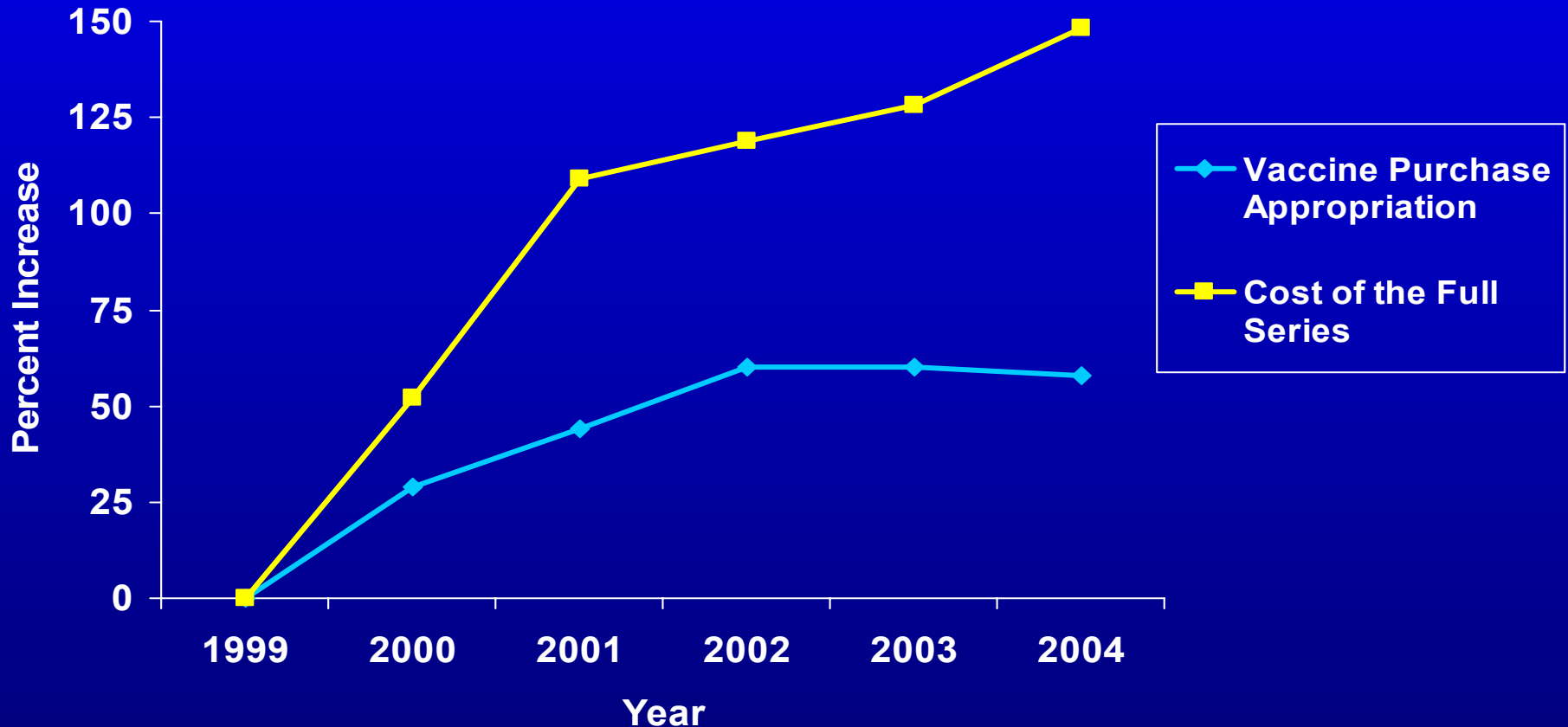
# EXTRA SLIDES



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# Percent Increase of the Cost of Full Series vs. Percent Increase of Appropriation



Percentage Calculations: % increases are cumulative using 1999 as the base year.



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# Public Sector Vaccine Cost to Fully Vaccinate a Child



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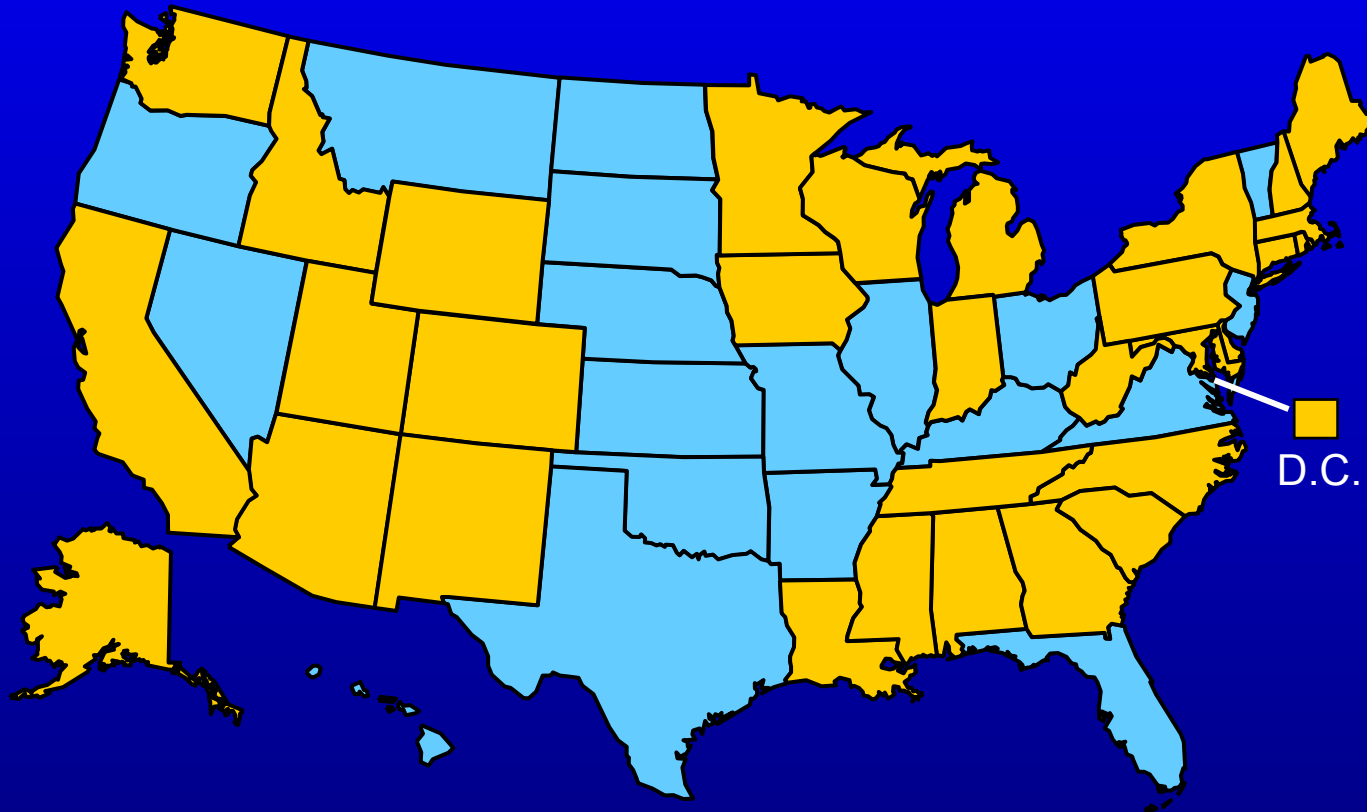
# Number of Children Who Could Potentially Receive Full Series with 317 funds



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# Pneumococcal Conjugate Vaccine (PCV) Two-Tier Policies, by State, United States\*



If all States implemented PCV and flu, the 2004 funding shortfall would be \$55 Million

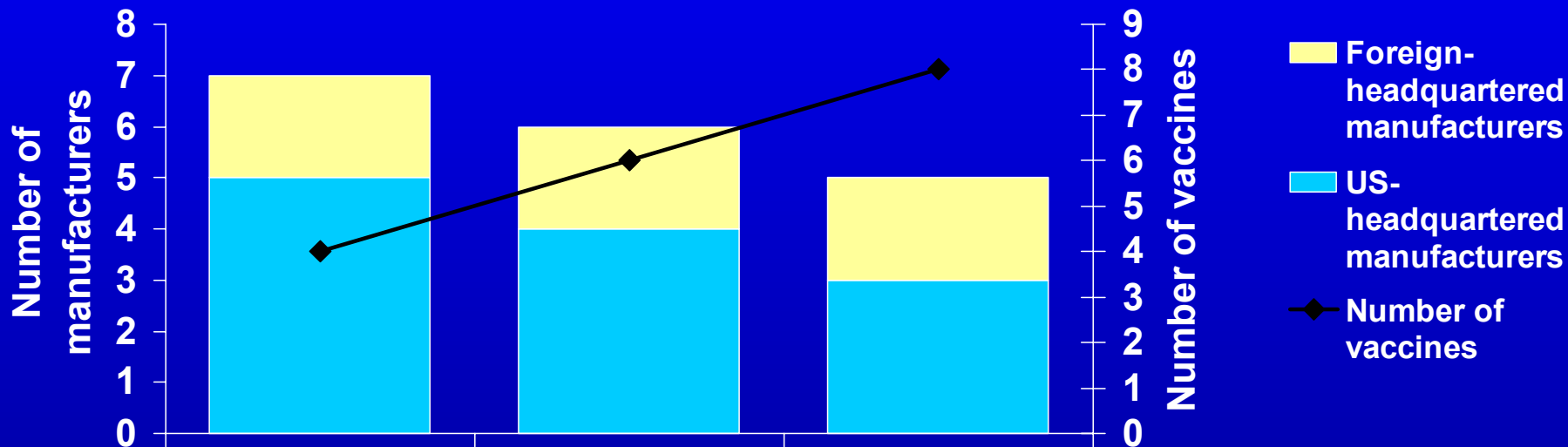
■ States with a two-tiered PCV policy  
(19 states are not implementing PCV with 317 funds)

■ States without a two-tiered PCV policy

\*As of February 2003



# Vaccine Manufacturers for Routinely Recommended Childhood Vaccines in the US, 1983-2003



1983

1993

2003

Manufacturer	Vaccines
Connaught Laboratories, Inc.*	Td/DT DTP MMR OPV
Lederle Laboratories	
Massachusetts Public Health Biologics Laboratory	
Merck Vaccine Division	
Michigan Department of Public Health	
Scalvo*	
Wyeth-Ayerst Laboratories	

Manufacturer	Vaccines
Lederle Laboratories	Td/DT DTP/DTaP MMR OPV Hib Hep B
Massachusetts Public Health Biologics Laboratory	
Merck Vaccine Division	
Michigan Department of Public Health	
Pasteur Merieux Connaught*	
SmithKline Beecham*	

Manufacturer	Vaccines
Aventis Pasteur*	Td/DT
Glaxo Smith Kline*	DTaP
Massachusetts Public Health Biologics Laboratory	MMR
Merck Vaccine Division	IPV
	Hib
Wyeth Vaccines	HepB
	Varicella
	PCV7

Td/DT = tetanus and diphtheria toxoids

DTP = pertussis vaccine/diphtheria and tetanus toxoids

MMR = measles/mumps/rubella vaccine

OPV = oral poliovirus vaccine

IPV = inactivated poliovirus vaccine

Hib = *Haemophilus influenzae* type b vaccine

Hep B = hepatitis B vaccine

Varicella = varicella vaccine

PCV7 = pneumococcal conjugate vaccine

\* Foreign-headquartered manufacturers



**Meeting**

**American Enterprise Institute for Public Policy Research**

**Title**

**“How Can Vaccine Shortages Be Prevented?”**

**Presenter**

**Stephen L. Cochi, MD, MPH**

**Date**

**April 2004**

**File**

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