

Vaccine Supply

Advisory Committee on Immunization Practices

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Outline of Presentation

- I. Influenza Vaccine Production and Distribution
- II. Update on Varicella-Based Vaccine Supply
- III. Update on HepA Vaccine Supply
- IV. Update on Hib Vaccine Supply



Influenza Update

- Update on Current Influenza Vaccine Season
- History of Influenza Vaccine Production and Distribution



Influenza Vaccine Manufacturers

2007-08 Influenza Season

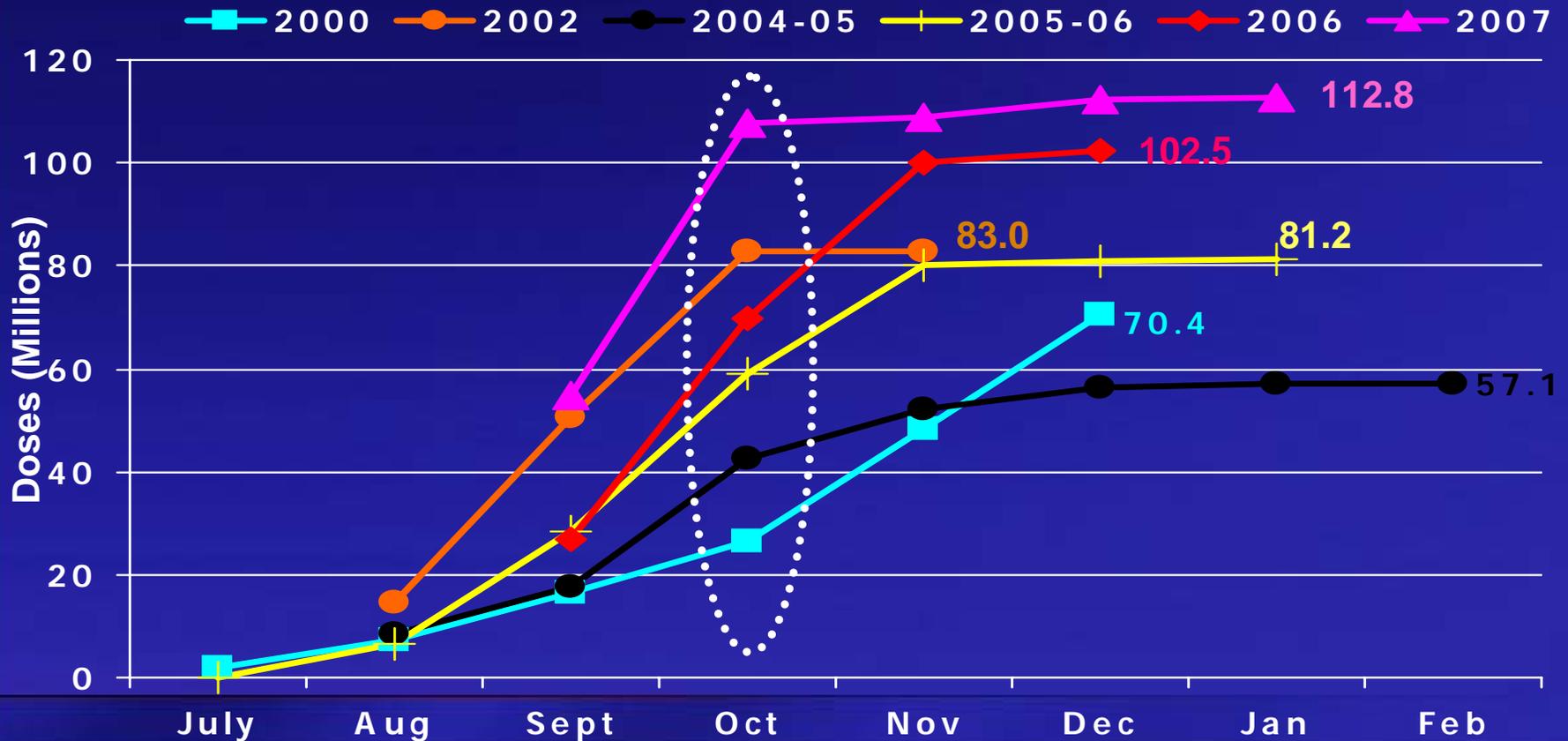
Manufacturer	Vaccine	Formulation	Preservative	Age indication
Sanofi pasteur, Inc.	Fluzone [®] , Inactivated TIV	Multi-dose vial	Yes	≥6 months
		Single-dose prefilled 0.25mL syringe	None	6--35 months
		Single-dose prefilled 0.5mL syringe or vial	None	≥ 36 months
Novartis Vaccine (formerly Chiron Corporation)	Fluvirin [™] Inactivated TIV	Multi-dose vial	Yes	≥ 4 years
		Single-dose prefilled 0.5 mL syringe	Trace	≥ 4 years
MedImmune Vaccines, Inc	FluMist [™] LAIV	Single-dose sprayer	None	2--49 years*
CSL Biotherapies	Afluria [®] Inactivated TIV	Single-dose prefilled 0.5 mL syringe	None	≥ 18 years
		Multi-dose vial	Yes	≥ 18 years
GlaxoSmithKline Biologicals (subsidiary of GlaxoSmithKline PLC)	Fluarix [®] Inactivated TIV	Single-dose prefilled 0.5 mL syringe	Trace	≥ 18 years
ID Biomedical Corporation (subsidiary of GlaxoSmithKline PLC)	FluLaval [™] Inactivated TIV	Multi-dose vial	Yes	≥ 18 years

* Certain risk groups excluded

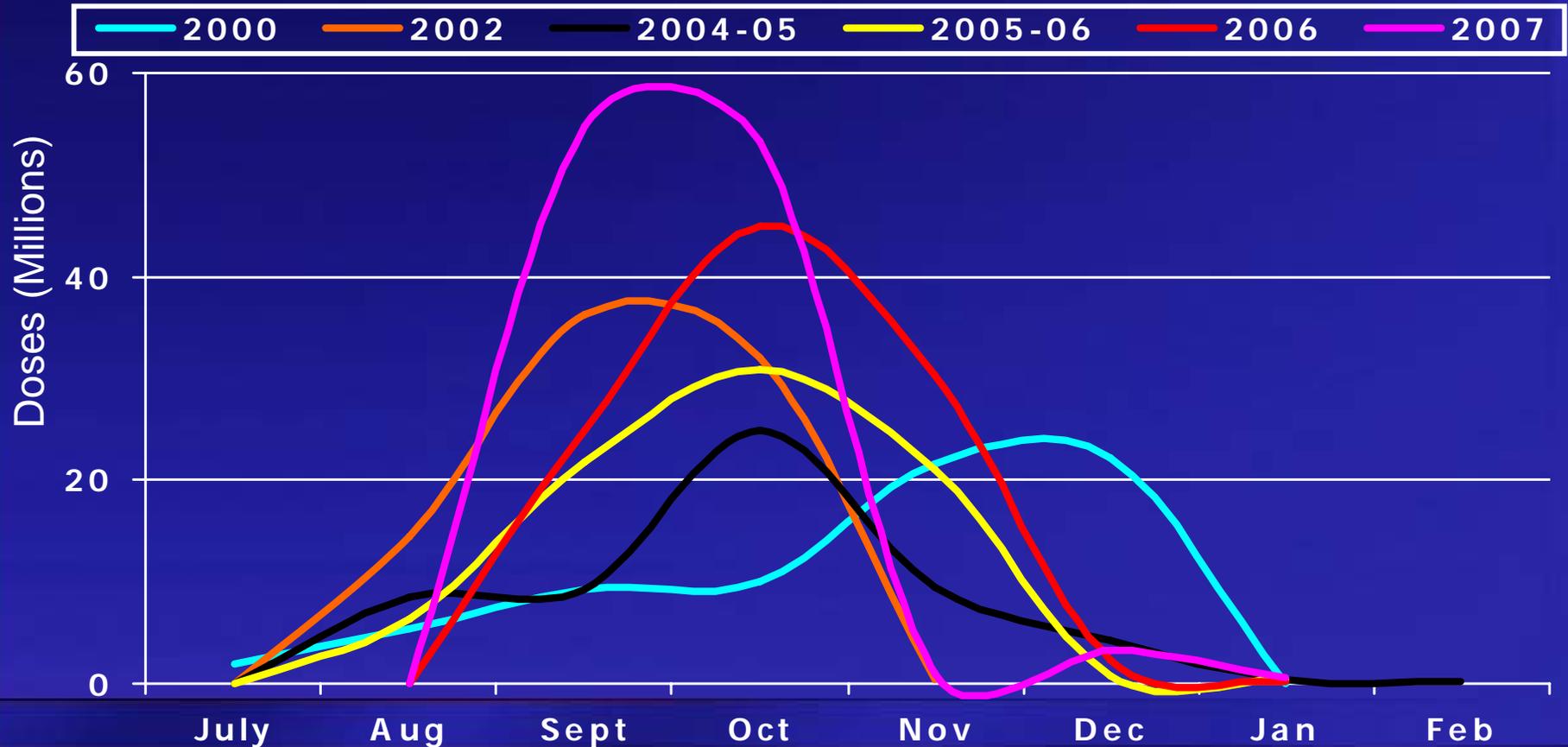


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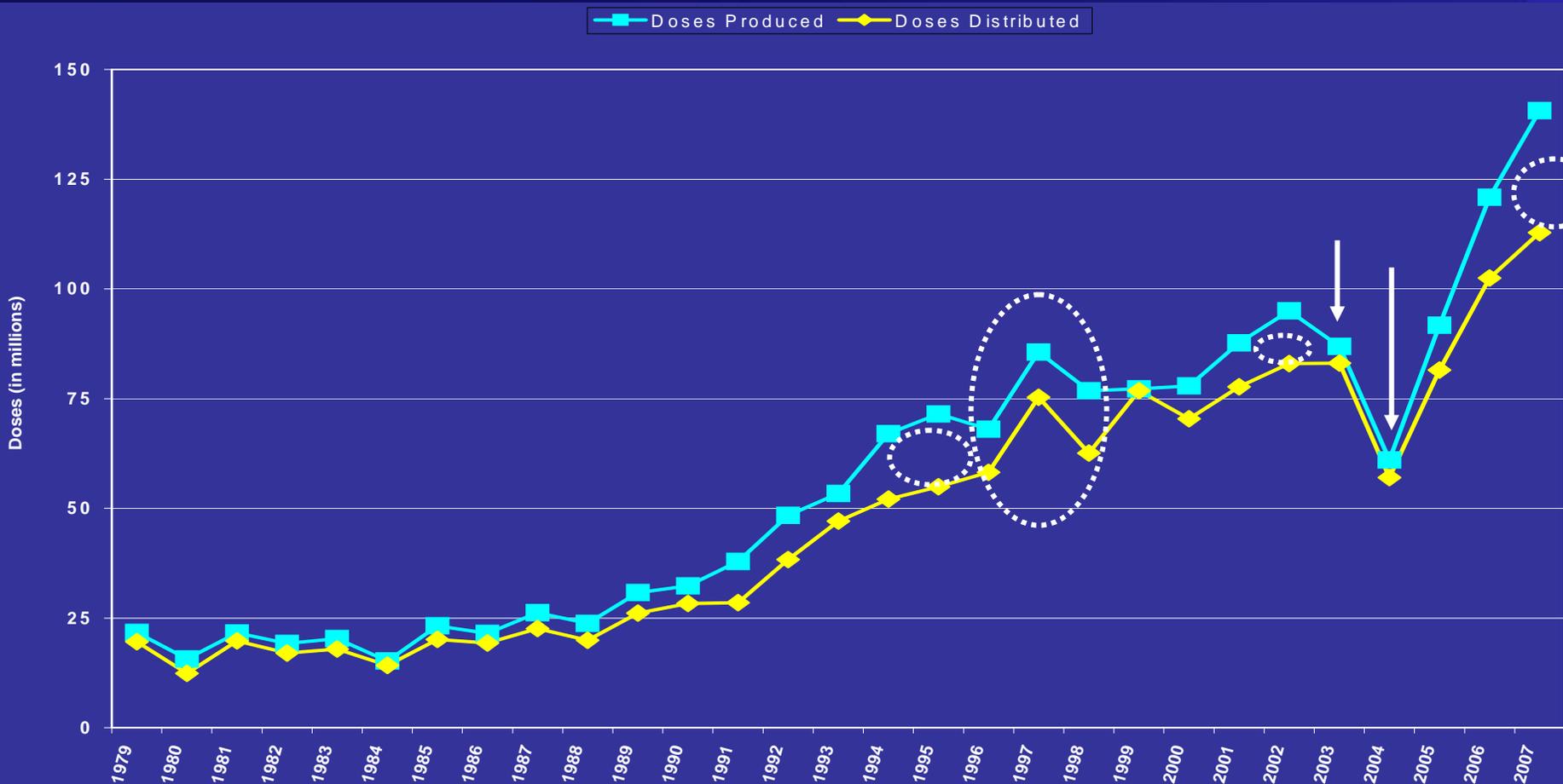
Cumulative Monthly Influenza Vaccine Distribution



Monthly Influenza Vaccine Distribution



Projecting Demand in a Changing World (Influenza)



Influenza Vaccine Production and Distribution

Historical Perspective

<u>Years</u>	<u>Doses Produced</u>	<u>Avg Distributed</u>	<u>Diff (range)</u>
1979-88	20.8 M	18.3 M	1.0-3.9M
1989-98	30.8 to 85.6M	26.1 to 75.3M	4.0-16.6M
1999-2007	Growth to 140.6M	Growth to >112.8M	0.5-27.8M



Historical Perspective (1999-2007)

Season	Doses Distributed	Doses Not Distributed	Outcome
1999-2000	76.8	0.5 (0.6%)	On Time
2000-01	70.4	7.5 (9.6%)	Marked Delay
2001-02	77.7	10.0 (11.4%)	Delay
2002-03	83.0	12.0 (12.7%)	On Time
2003-04	83.1	3.8 (4.4)	Late Season Demand
2004-05	57	4.0 (6.6 %)	Shortage
2005-06	81.5	7.0 (7.7%)	'Relative Delay'
2006-07	102.5*	18.4 (15.2%)	'Relative Delay'
2007-08	112.8*	27.8 (19.8%)	---

* New Tracking System to the level of major distributors



Influenza Summary

- Challenges in the past several years
- Increased Production and Distribution Capacity
- ??Administration Capacity??
- Where will demand/market go from here



Update on Varicella-Based Vaccine Supply

- **Varicella Zoster Virus (VZV) Bulk is used to Manufacture**
 - **Varicella Vaccine**
 - **MMR-V Vaccine**
 - **Zoster Vaccine**



VZV Bulk Process

- Lower than Expected Yields
- Temporary Suspension of Production
- Adequate Bulk available to produce varicella and zoster vaccine
- No Changes in Current Vaccine Policy Recommendations



MMWR Notice to Readers

- **Feb 23, 2007**
 - Prioritize production of Varicella vaccine and Zoster Vaccine
 - Expect depletion of MMR-V by end of 2007
- **May 11, 2007**
 - Expect depletion of MMR-V by end of July, 2007



Current MMR-V Supply

- ProQuad[®] orders suspended in June
- Remediation process in progress
- Current VZV Bulk adequate to produce varicella and zoster vaccine
- Earlier Varivax[®] shipping delays resolved



VZV Summary

- No Change in recommendation for vaccination to protect against varicella disease
- Varicella vaccine (Varivax) and Zoster vaccine supply adequate to meet needs
- Remediation process for resuming MMR-V in progress



Hepatitis A Vaccine (July 2007)

- CDC informed of vaccine supply issue by Merck
- Backorders of Pediatric and Adult VAQTA[®]
- Supply in after September not known
- Adequate supply available from GSK
- No Change in ACIP recommendation



Hepatitis A Vaccine (Current Status)

- VAQTA[®] orders suspended for Adult & Pediatric Vial Formulation
- Estimated return to market late 3rd to 4th Qtr '08
- Adequate supply available from GSK
- No Change in ACIP recommendation



Hib Vaccine Supply – November

- Nov 1 –PedVaxHib unavailable for shipment
- CDC Vaccine Supply Stakeholder Work Group activated
- Stockpile doses released to meet November demand in Public & Private Sector
- Sanofi contacted to project ability to meet increased need
- CDC/IHS collaboration on AI/AN needs
- CDC evaluation of Public/Private demand, projected supply, stockpile availability, and potential for alternative sources



Hib Vaccine Supply December

- Dec 13 – Voluntary recall of certain lots of PedVaxHib and Comvax
- Urgent Vaccine Supply Stakeholder Work Group Meetings
- Dec 19 – MMWR Dispatch on supply and interim recommendations
- Allocations, stockpile releases adjusted due to recall and updated supply



Hib Interim Recs

- Defer routine Hib vaccine booster dose administered at age 12-15 months except for specific high-risk groups
- High-risk groups should continue to receive 12-15 month booster dose (e.g. asplenia, sickle cell disease, HIV infection, immunodeficiency syndromes, malignancies)
- Providers who use PRP-OMP Hib (PedVaxHib & Comvax) to serve AI/AN children in AI/AN communities continue to use PRP-OMP including administration of the 12-15 month booster dose



Hib Supply Summary

- Remaining Merck PedVaxHib/Comvax in Stockpile reserved for AI/AN communities
- Working with Sanofi to ensure availability of ActHib to meet interim recs need
- Current Merck estimate to return 4th Qtr '08

