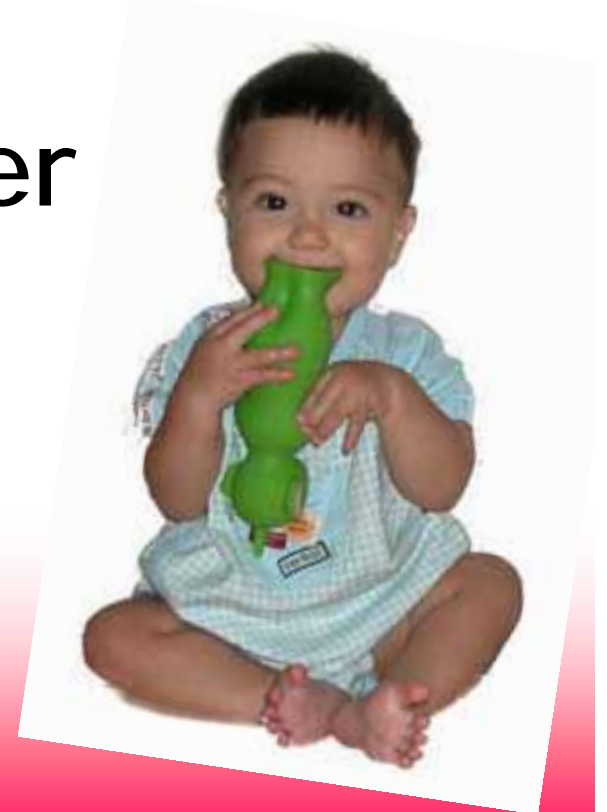


# DEHP: Concerns and Alternatives

Patrick Wooliever  
Tetra Tech EM Inc.



# Take Home Message

1. Increasing Medical Concerns -  
FDA Advisory: Minimize DEHP products in high-risk patient populations.
2. Tackle High-Risk Areas & Align Your Focus and Influence.
3. Alternatives Are Readily Available.
4. \$\$ - Additional Cost Is Relatively Low:  
~10-20% more, <\$20/patient/day

# The Larger Issue...PVC

- Most widely used plastic in medical products
  - Cost
  - Flexibility
  - Transparency
  - Resistance to breakage
- 27% of all plastic used in 1996
- The only common plastic that is chlorinated
- DEHP (di-ethylhexyl phthalate) often used as a plasticizer in medical devices



# DEHP

di (2-ethylhexyl) phthalate

- Migrates from PVC when in contact with fluids, air, or heat
- Lipophilic

Leaching increases with...

- Temperature
- Contact (storage time)
- Amount of fluid
- Agitation
- Lipid content



# Increasing Medical Concerns

- Reproductive & developmental toxicant
- Infertility, hypospadias spectrum, premature thelarche
- Targets Sertoli cells of the testes
- Liver and pulmonary effects
- ❖ **FDA and NTP issued warnings**



# Government Warnings

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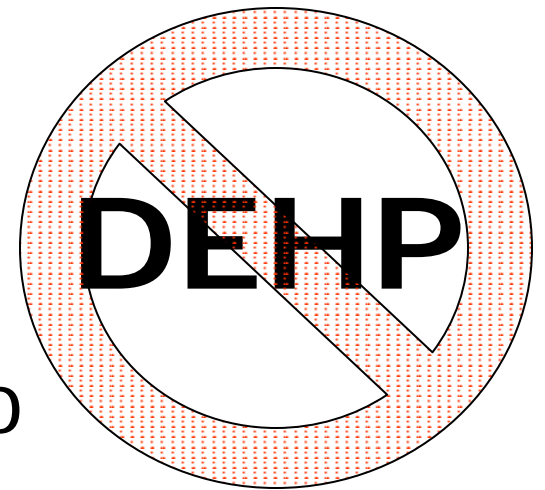
- **October, 2000:** US Department of Health, National Toxicology Program
- **March, 2001:** CA Medical Association Resolution: Eliminate DEHP in Neonatal Intensive Care Units
- **July, 2002:** FDA Public Health Notification



# FDA Public Health Notification

## Recommends:

- Using alternatives to DEHP-containing products for procedures with excessive exposures
- Reformulation of products to decrease/eliminate DEHP exposures
- Labeling of DEHP-containing products



# FDA Safety Assessment

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- FDA derived a “tolerable intake” (TI) for DEHP
  - Parenteral: 0.6 mg DEHP/kg/day
  - Oral: 0.04 mg DEHP/kg/day
- TI calculations based on NOAELs and LOAELs from numerous animal studies of testicular toxicity





# DEHP Exposures

mg/kg/day	Adult		Neonate	
	DEHP dose	TI/dose	DEHP dose	TI/dose
IV: crystalline	0.005	120	0.03	20
IV drugs w/vehicles	0.15	4	0.03	20
TPN (lipid)	0.13	5	2.5	0.2
Enteral nutrition		< 1.0	0.14	0.3
ECMO	3.0	0.2	14	0.04
Exchange Transfusion			22.6	0.02





Photo: Valerie Briscoe, JMMC

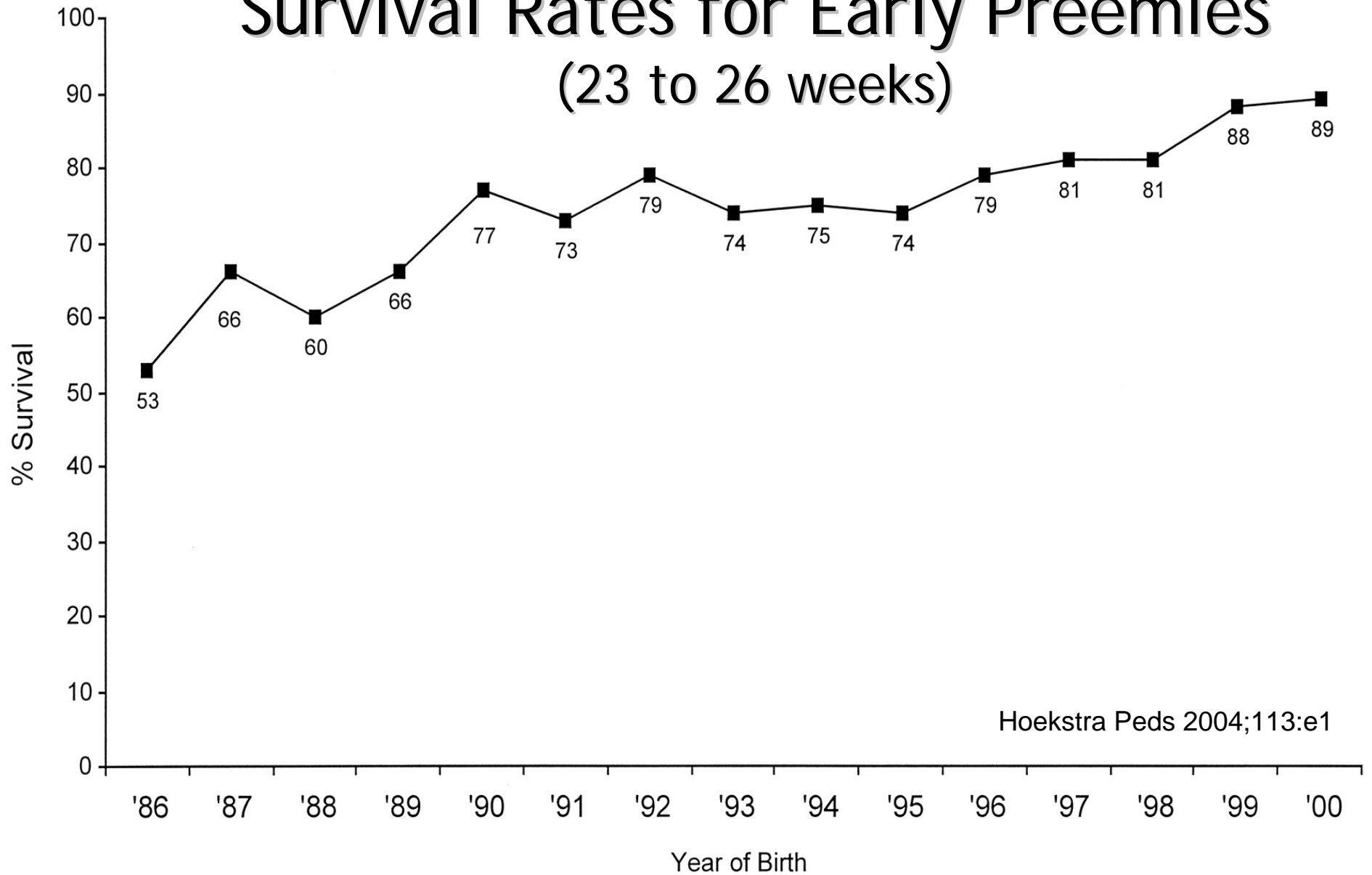
# Focus: High Risk Areas

## Early Preterm Infants

- Critically ill patient population
  - IV therapy
  - Parenteral and enteral feedings
  - Ventilation
  - Blood transfusion
- Long hospital stay
  - Prolonged therapies



# Survival Rates for Early Preemies (23 to 26 weeks)



Hoekstra Peds 2004;113:e1

# Most Sensitive System:

## Immature Male Reproductive Tract

- MEHP is the toxic metabolite
- Mechanism of Action
  - Decrease testosterone synthesis; interference with Leydig cell differentiation
- Target Tissues
  - Sertoli cells
  - Seminiferous tubules, sperm, epididymis, penis, prostate (fetal exposures)



# PVC/DEHP-Containing Products

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## Gloves

- ✓ Exam
- ✓ Surgery

## Bags

- ✓ IV
- ✓ Nutrition
- ✓ Blood

## Tubing



# Gloves

Low risk: not typically invasive or long-contact



1. Latex
2. Nitrile
3. PVC (usually marketed as latex-free)

❖ Parallel efforts to eliminate latex gloves because of allergies...

...but “latex-free” usually means PVC/DEHP



# Gloves - Alternatives

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- ✓ Use powder-free latex or nitrile
- ✓ Examine life cycle costs and performance of PVC gloves

## ...Tufts/1999 Kaiser Studies:

- Failure Rate:
  - PVC 30%
  - Nitrile/Latex 2%
- Staff use "double-gloving" for extra protection
- Nitrile/Latex gloves are cost competitive





# Tubing



High-risk: long contact, conveys air and fluids, some high volume

- PVC less prone to kinking
- Becomes more brittle with use as DEHP leaches



# Tubing - Alternatives

- ✓ Focus on tubing used to introduce fluids/gases into the patient
- ✓ Examine tubing upstream of equipment: e.g., wall to ventilator



Respiratory Therapy Ventilator



# IV Bags

High risk: long contact, some lipid fluids, some high volume

- PVC/DEHP-free alternatives available
- Driven by demand
- 3 Vendors: Baxter, Braun, Hospira (Abbot)



# IV Bags - Alternatives



- B Braun is the only current supplier of PVC/DEHP-free bags
- PVC bags:
  - Require an “overwrap” to preserve shelf life
  - Are thicker/heavier than alternatives

B Braun DEHP-free bags are cost competitive;  
10-20% more expensive



# Nutritional Bags - Alternatives

- Market demand exists:
  - Baxter: EVA (no-PVC)
  - Hospira (Abbot): PVC but w/o DEHP
  - Each has about 40% market share

PVC/DEHP-free alternatives are cost competitive



# Blood Bags

- Blood Bank Users:
  - Few PVC/DEHP-free bags available/used
  - DEHP used as a preservative



Tackle other areas first; raise awareness among blood banks/public



# JMMC DEHP Reduction Plan

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1. Establish DEHP reduction policy for NICU
2. Implement reduction plan
  - a. Get list of all supplies from Purchasing Dept.
  - b. Audit supply room and identify plastics used in “high-risk therapies.”
  - c. Purchasing Dept. contacts manufacturers to determine DEHP content
  - d. Nursing and respiratory therapy staff evaluate alternative based on clinical applicability and efficacy
  - e. Preferred product list sent to Purchasing Dept.
3. Expand program





# JMMC Success Factors

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- Easily identified “Cause Champion”
- Changes occurred “under the radar”
- Cost not a large factor
- Readily available alternatives for most products
- Effort required:
  - 40 hours primarily by nursing supervisor over 1 year





# Problematic Areas

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- Premixed IV solutions
  - Parenteral solutions mixed by pharmacy in non-DEHP bags
- Blood Bank
  - Red Cross blood products uses blood bags containing DEHP





# JMMC Plastic Products

Item #	Description	Cat#	DEHP?	Manufacturer
9906	Long-life feeding Tube	730709	No	Children's Medical Venture
5420	Dispensing pin with valve	3548441 3500	No	B. Braun
2695	Neonatal catheter	2184-00	No	Vygon



# JMMC Plastic Products

Item #	Description	Cat#	DEHP?	Manufacturer
34257	Soluset- Microdrip	00131194802	Yes	Abbott
1843	Butterfly Inf 19 X 7/8 X 12	00134590010 1	Yes	Becton Dickinson
3094	Transducer Transpac	00154256001	Yes	Abbott
13062	Tray Exchange Transfusion	07055004110	Yes	Pharmaseal Allegiance

# JMMC Plastic Products

Item #	Description	Cat#	DEHP?	Manufacturer
34257	Soluset-Microdrip	19231-12	No	Abbott-new item
1843	Butterfly Inf 19 X 7/8 X 12	00134590 0101	Yes	Becton Dickinson-use for blood <u>drawing</u> -no risk
48795	Transducer	MX20775	No	Medex-New Item
13062	Tray Exchange Transfusion	07055004 110	Yes	Pharmaseal Allegiance- No alternative. No longer used, change in practice



# NICU Replacement Summary

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- Survey found:
  - 31 plastic items
  - Only 5 contain PVC/DEHP and are used in exposure scenarios
  - Others are used for extraction procedures
  - One was eliminated procedurally

Only 4 items need to be replaced



\*+H365MX453HL05\*

LOT NUMBER

**33G210044**



\*+\$33G2100445W\*

**Non-DEHP T Connector  
w/Swivel M.L.L.**

SINGLE USE

**STERILE**

AND FLUID PATH NONPYROGENIC UNLESS  
PACKAGE IS DAMAGED OR OPENED.

SLIDE CLAMP IS SPECIFICALLY DESIGNED FOR EASE OF REMOVAL. PREVENT INADVERTENT REMOVAL.

CAUTION: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

CAUTION: CONNECTORS MAY HAVE LOOSENED DURING  
SHIPMENT. MAKE SURE ALL FITTINGS ARE SECURE BEFORE  
USING. AVOID OVERTIGHTENING AND STRIPPING.

**Latex Free**

MADE IN USA

0618

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# DEHP Resources

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- Sustainable Hospitals:  
[www.sustainablehospitals.org](http://www.sustainablehospitals.org)
- Health Care Without Harm:  
[www.noharm.org](http://www.noharm.org)
  - Audit Form:  
<http://noharm.org/details.cfm?type=document&id=741> :
  - Alternative List:  
<http://www.noharm.org/details.cfm?type=document&id=591>

