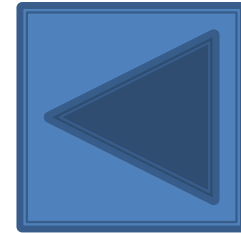


# ***FDA's Active Assessment of Phthalates in Food Contact***



## ***Diagnosis & Prognosis***



**Flexible Vinyl Alliance**

Kevin Ott  
July 16, 2019

# FVA Functions Like a Trade Group: Website/Newsletter/Statistics/Advocacy/Messaging

36 Editions

[www.flexvinylalliance.com](http://www.flexvinylalliance.com)



## FLEXIBLE VINYL: BY THE NUMBERS

### 2011

Vinyl, also known as PVC, is derived from salt (one of the earth's most abundant resources) and natural gas. It is suitable for an almost limitless range of products since vinyl can be rigid and impact resistant enough for pipe or siding, and thin and flexible enough for wall covering, flooring, or upholstery. Vinyl is inherently recyclable and can be made weather and heat resistant, highly durable, and aesthetically pleasing. The superior and proven performance characteristics of vinyl make it a critical material in health care products that are regulated for safety by the U.S. Food and Drug Administration. These products and procedures include intravenous blood bags, kidney dialysis and blood transfusions, cardiac catheters and endotracheal (breathing) tubes.

### \$20 Billion

The flexible vinyl industry is a significant contributor to the domestic economy with an estimated annual value that exceeds \$20B for the North American manufacturing and retail sectors.

### 1000 Sites/47 States

Flexible vinyl related operations throughout the value-added supply chain include more than 1,000 manufacturing sites in 47 states.

### 275,000+ Workers

It is estimated that the flexible vinyl industry employs more than 275,000 domestic workers, and is part of the larger contingent of the plastic-production workforce that exceeds 1 million persons domestically.

### 50 Years of safe use

Flexible vinyl has a long track record as a safe, affordable, durable & sustainable material. Vinyl additives have been studied closely by independent scientists, the federal government, and industry and used safely for more than 50 years.

### 50 Years of saving lives

Wire and cables sheathed with PVC prevent potentially fatal electrical accidents. In hospitals around the world, PVC medical tubing that does not break or leak delivers fluids and medicines to the sick. Vinyl flooring and wall coverings are easy to clean and disinfect, helping prevent the spread of hospital-borne illnesses. The survival of victims of war and natural disasters such as Haiti and Iraq is aided with vinyl products including flexible, flat-topping temporary shelters and field-deployed surgical units. Cars are safer and last many years longer because of durable PVC components and coatings that protect from water and corrosion. PVC products are engineered to be long-lasting with life cycles of 50 years and beyond.

FVA Copyright 2011. [www.flexvinylalliance.com](http://www.flexvinylalliance.com)

**“Getting Smart Around  
Phthalates & PVC: June  
2019” @FVA Website**



**Flexible Vinyl Alliance**

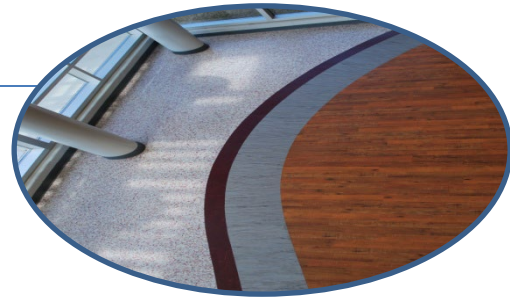
# Flexible Vinyl By the Numbers

- Significant impact on the domestic economy with an estimated annual value that exceeds \$20 billion for the North American manufacturing and retail sectors
- Flexible vinyl related operations within the supply chain include:
  - more than 1000 manufacturing sites in 47 states
  - estimated employment of 275,000 people
- Flexible vinyl is part of the larger domestic plastics industry which employs 900,000 million American workers
- 28-31% of all PVC resins go into flexible PVC products

the flexible vinyl industry is large and is a major employer of American workers



# Seven Pillars of fPVC

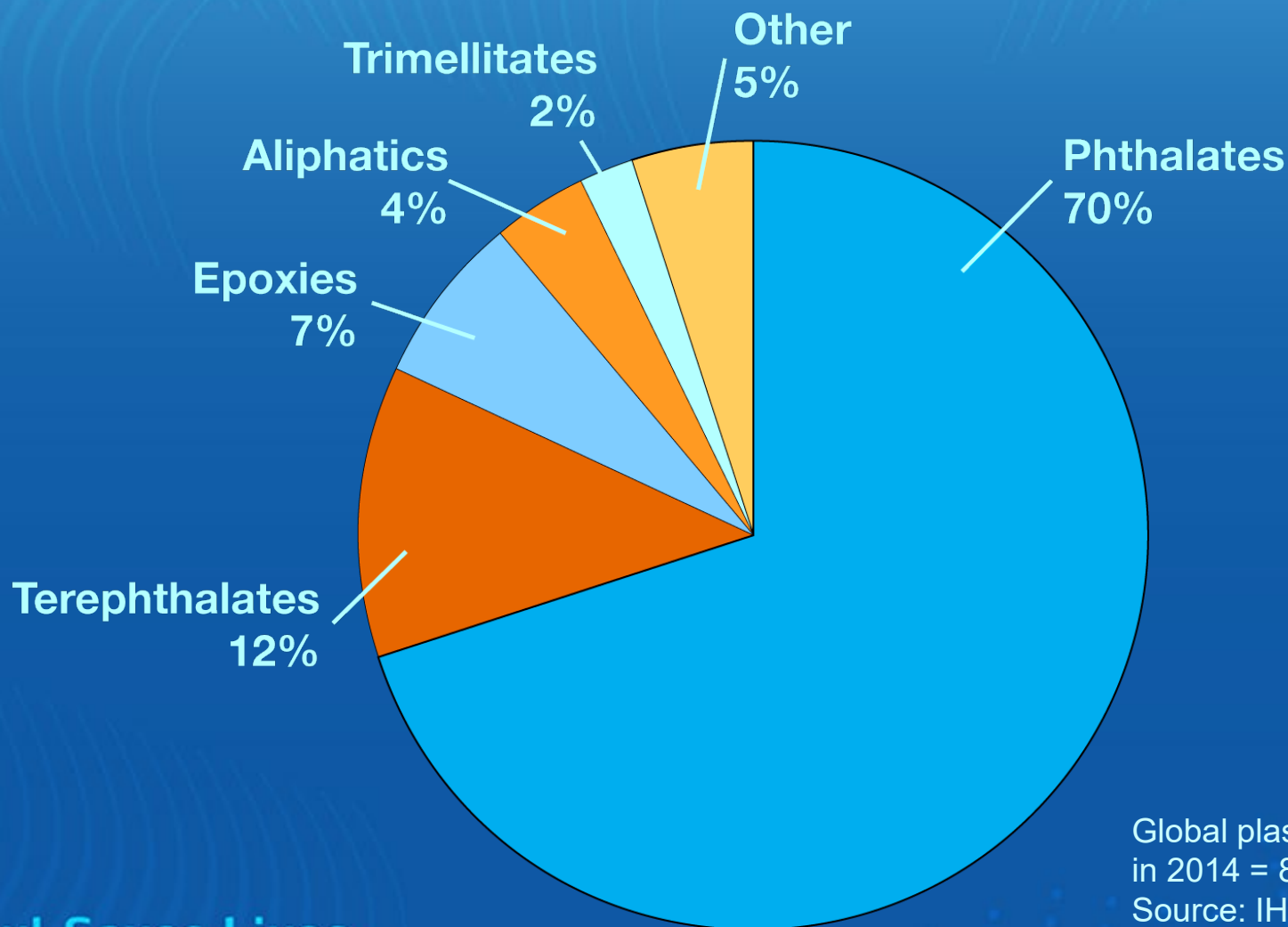


**Flexible Vinyl Alliance**



# THE WORLD OF PLASTICIZERS

Globally, phthalates are still the dominant plasticizer.



Global plasticizer consumption  
in 2014 = 8 million metric tons  
Source: IHS Chemical

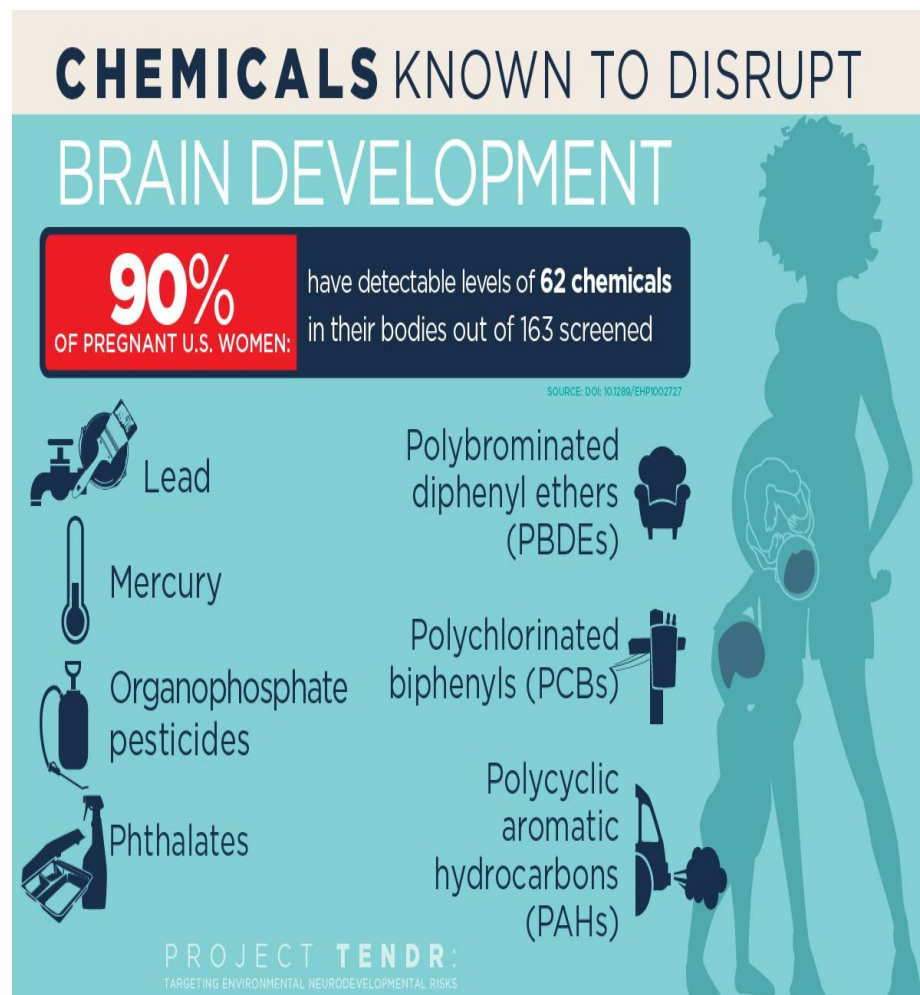
# The “BIG FIVE” Targets: 2019

- *Phthalates*
- *Bisphenol A*
- *PFAS*
- *Flame Retardants*
- *Insecticides*



# Phthalates Are Now “Keeping Bad Company” per Activist Misinformation

- *Phthalates*
- *Bisphenol A*
- *PFAS*
- *Flame Retardants*
- *Insecticides*



# Food as an Epidemic





# *The July 12, 2017 NYT Mac and Cheese Click-Bait Story Based on Junk “Study”*



**Table 1. Macaroni & Cheese Powder Had Highest Phthalates of Products Tested**

Products Tested	Product Description	Number of Varieties Tested	Concentration of TOTAL Phthalates Average and Range, in µg/kg or parts per billion (ppb)					
			In FAT (measured)			In PRODUCT (calculated)		
			Avg.	Low	High	Avg.	Low	High
<b>Cheese Powder</b>	Macaroni and Cheese, dry mix	10	940	365	2,523	106	34	218
<b>Processed Cheese</b>	Slices	5	569	180	1,223	105	38	216
<b>Natural Cheese</b>	Hard, Shredded, String & Cottage	15	216	< 55 *	567	53	< 17 *	203

\* The highest limit of quantification (LOQ) in fat, and in a hard cheese product with a fat content of ~ 30%, for DEHP.



# JOANNA BLYTHMAN SWALLOW THIS

SERVING UP THE FOOD  
INDUSTRY'S DARKEST SECRETS

*'Knows more than anyone else  
about where our food comes from'*  
Nigel Slater









# FDA

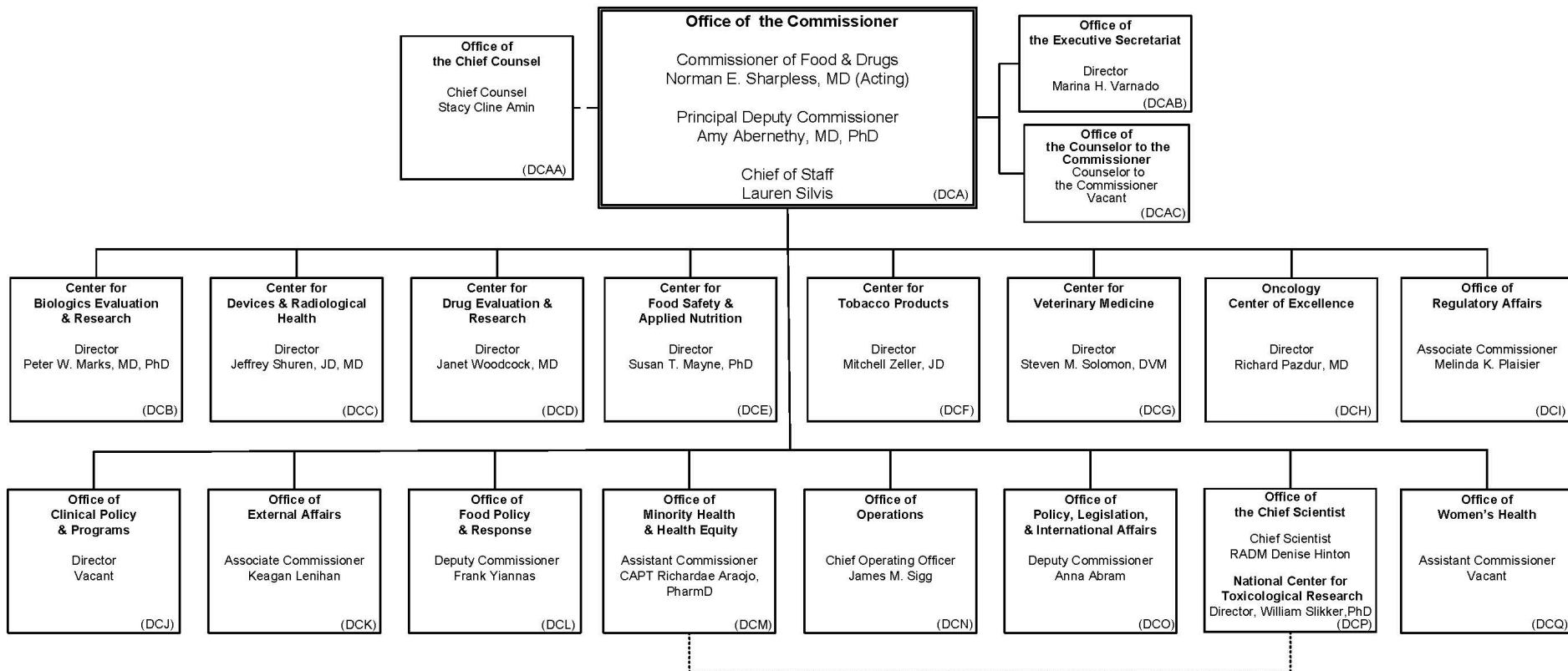


# Patients, Consumers and Industry Agree... FDA's Essential Work Must be Funded



## Department Of Health And Human Services Food And Drug Administration

May 2019



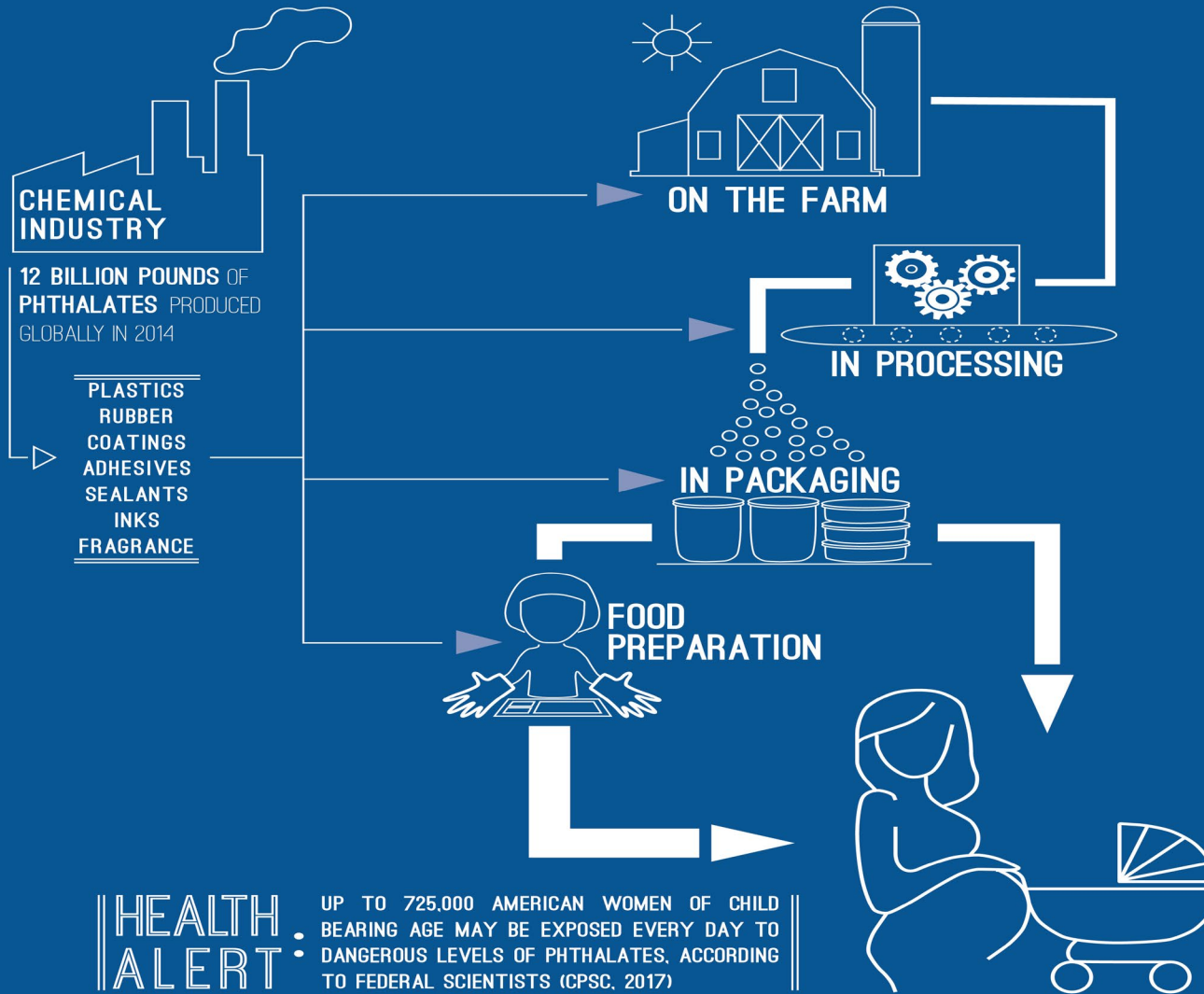
#1 NEW YORK TIMES BEST-SELLING AUTHOR

MICHAEL  
LEWIS



THE FIFTH  
RISK

# HOW ARE PHTHALATES GETTING INTO OUR FOOD?







# Sustaining PVC Means Defending the Material: Which Means Understanding Risk!



- **CHEMICAL PRESENCE**



- **HUMAN HEALTH HAZARD**



**Flexible Vinyl Alliance**

# **Activist Petition: Published May 20, 2016:** **6B4815**

- **Environmental Defense Fund (EDF): \$**
- **Breast Cancer Fund**
- **Center for Environmental Health**
- **Center for Food Safety**
- **Center for Science in the Public Interest**
- **Clean Water Action**
- **Consumer Federation of America**
- **Earth Justice**
- **Learning Disabilities Association**
- **NRDC**
  
- **Seeks to De-Authorize Use of 30 FDA Approved Ortho-Phthalates, including DEHP, DIDP, DINP & DCHP**



INFORM • ADVOCATE • ACT

**Flexible Vinyl Alliance**

## ***THE FVA PETITION OF 2018: 8B4820***

**DEHP, DIDP, DINP, DCHP:**

**Remain Authorized for Food Contact**

**26 Other Abandoned for LACK OF USE  
in Food Contact Applications**

**KEY: Abandonment Request Based on**

**“Not Used” vs. “Not Safe”**





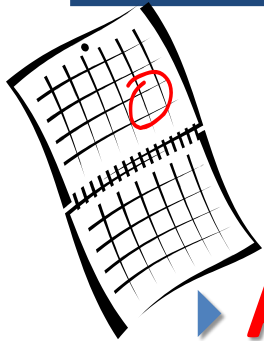
***Flexible Vinyl Alliance***

## ***FVA Ortho-Phthalates Coalition Extensive Procedural Process Since 2016 Includes:***

- Petition Drafting & Filing (83 pp: June 22, 2018)
- Survey of Uses Collected from Industry
- Responses to FDA Technical Inquiries
- Food Additive Master File (Exposure Data)
- FOIA Defense (Successful)/ Affidavits
- Responses to NGO Critiques of our Petition
- Press Release
- Issue Briefs
- Coalition Building

# Scrutiny of Phthalates in Food Contact: Now a Matter of FDA Process (and NGO-Driven Messaging) which has reached the States

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- ▶ **Activist Petition:** De-Authorizes 30 PE's Contact
- ▶ **FVA Petition:** Retains 4 Phthalates; Abandons 26
  - **JUNK SCIENCE:** Orchestrated Attacks using Junk Science, with willing media/lawmaker “partners”
- ▶ **Maine Bill LD 1433:** Enacted June 2019:  
Precedent Setting



# ACTIVISTS HAVE CIRCLED THE WAGONS AROUND FOOD SAFETY

The activist's latest tactics:

“Instead of attacking vinyl itself, its crusaders (have) turned to the many substances that are added to PVC to give it its desired characteristics.....”

Patrick Moore, Confessions of a Greenpeace Dropout



**Vinyl Saves Lives.**

## FDA Scientists Say:

“There have been no studies to date which show any connection between human dietary exposure to phthalates and adverse health effects.”

Source: Investigation of the primary plasticizers present in polyvinyl chloride (pvc) products currently authorized as food contact materials. Article in “Food Additives and Contaminants” Part A: March 2018.







**Attitudes Toward Phthalates Influence  
Customer Specifications of PVC**



**Real Assessments at FDA are Being  
Conducted**

**WE EXPECT A GOOD OUTCOME ON THE  
FDA MATTER!**

# **PLASTICS Supports the Ortho-Phthalates Coalition of the Flexible Vinyl Alliance**

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**For Any Questions:**

**Kevin Ott**

Executive Director

Flexible Vinyl Alliance

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**Flexible Vinyl Alliance**