



BPA IS CLEARLY SAFE, AND HERE'S HOW WE KNOW

Steven G. Hentges, Ph.D.

Polycarbonate/BPA Global Group

American Chemistry Council

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PC/BPA Global Group Introduction

- Global coalition of bisphenol A (BPA) and polycarbonate plastic manufacturers
- Focused on health and environmental aspects of BPA and polycarbonate
- Integrated global structure
 - Global Science Team
 - Regional Communications/Advocacy Teams
 - + China, Europe, Japan, Korea, North America

Introduction to BPA

- Essential ingredient to make polycarbonate plastic and epoxy resins
 - Polycarbonate: High clarity, shatter-resistant, light weight
 - Epoxy: Tough/durable, chemically resistant, good adhesion
- BPA has a 50+ year safety track record
 - One of best tested substances in commerce



Question #1

Which statement best describes your usage of polycarbonate or epoxy resins?

Question #2

Please indicate your perspective about polycarbonate or epoxy resins?

A Little History

- BPA has been of scientific/regulatory interest since the late 1990s
 - Health effects at low doses?
 - Endocrine disruption?
 - Developmental exposure → health effects later in life?
 - Non-monotonic dose response?
 - Safety?



US Government Research Overview

- Comprehensive US government research program underway for > 10 years
 - Designed to resolve remaining uncertainties about the safety of BPA
- 30 studies published to date
 - Human exposure
 - How much BPA are we exposed to?
 - Animal and human pharmacokinetics
 - What happens to BPA when it enters the body?
 - Toxicity
 - Does exposure to BPA cause health effects?
- CLARITY is the capstone to a multi-year, multi-million dollar program

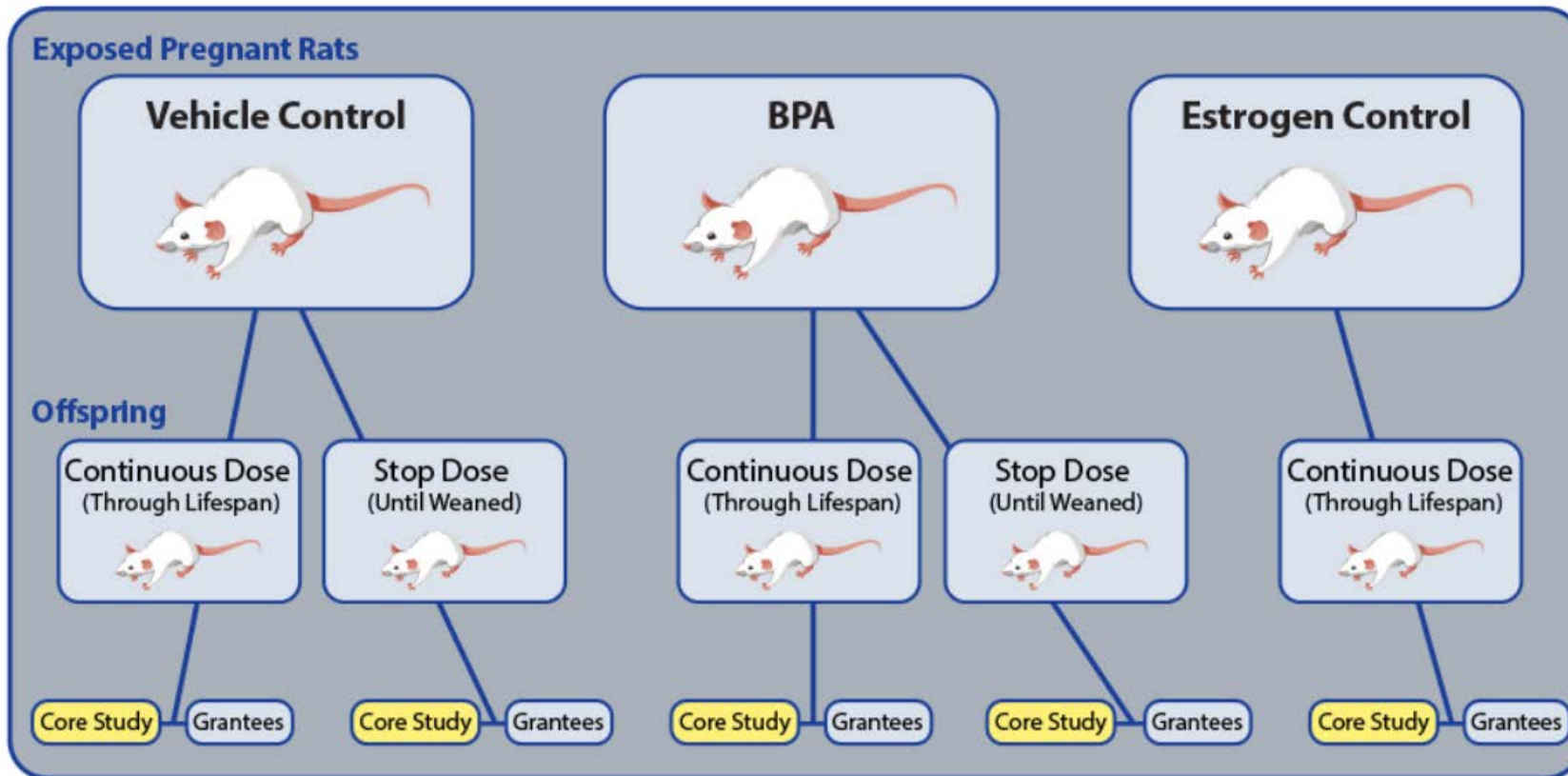


CLARITY - Background

- CLARITY = Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity
 - Cooperative agreement including FDA, NTP, NIEHS and 14 academic scientists
 - All participated in designing the CLARITY study
 - Aimed at bridging regulatory research (FDA) with hypothesis-based research (academic)
- 2 key components
 - Chronic (lifetime) toxicity study conducted by FDA scientists
 - Academic studies on samples from the chronic study

CLARITY - Study Design

Unprecedented study scope and magnitude for BPA



CLARITY - Key Study Features

- Continuous Dose exposure: Pregnancy through offspring lifespan
 - Directly relevant for human exposure
 - Safety?
- Stop Dose exposure: Pregnancy through offspring weaning
 - Developmental exposure → effects later in life?
- Wide BPA dose range: 5 doses spanning human exposure to ~250,000 times higher
 - Health effects at low doses?
 - Non-monotonic dose-response?
- Estrogen control: 2 doses of EE2
 - Validates sensitivity of study for estrogenic effects
 - Endocrine disruption?
- All with high statistical power

CLARITY - Results

Draft NTP report on chronic toxicity study released on February 23, 2018

**Draft NTP Research Report on
the CLARITY-BPA Core Study:
A Perinatal and Chronic Extended-Dose-Range
Study of Bisphenol A in Rats**

Research Report 9
National Toxicology Program

February 2018



CLARITY - Key Conclusions

- Overall conclusions from draft NTP report:

“BPA produced minimal effects that were distinguishable from background”

“In contrast, the high EE2 dose elicited several strong effects in females”

CLARITY - Answers

- Answers to key scientific questions
 - Health effects at low doses? **NO.**
 - Endocrine disruption? **NO.**
 - Developmental exposure → effects later in life? **NO.**
 - Non-monotonic dose-response? **NO.**
 - Safety? **YES.**



CLARITY - Bottom Line

- FDA statement issued on February 23

"our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers"

Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine, FDA



Question #3

What impact might this have on your customers' questions about polycarbonate?

CLARITY - Next Steps

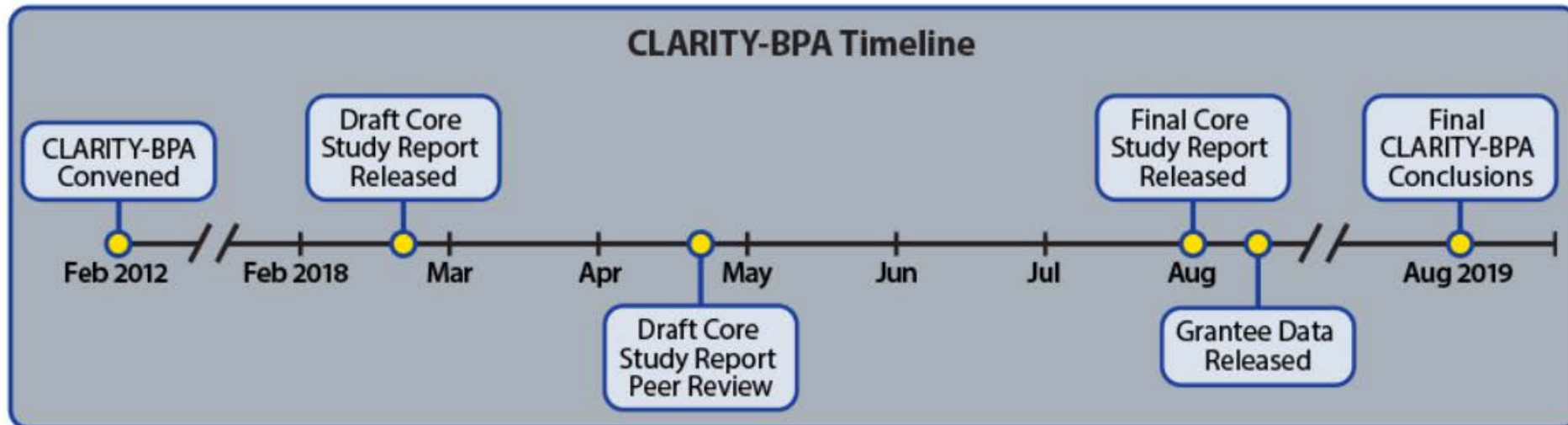
- Scientific peer review organized by NTP now complete
 - Panel of 6 independent scientists discussed findings at April 26 public meeting
 - Supportive of study design and conduct
 - Generally agreed with FDA's overall conclusions
 - Documentation of peer review meeting available on-line:
 - <https://ntp.niehs.nih.gov/about/org/sep/rrprp/past/index.html>
- Final NTP report expected in August 2018
- FDA will publish study in scientific literature, likely later this year

CLARITY - Academic Studies

- 14 academic researchers received animals or biological samples from the CLARITY chronic study
 - To the extent possible, all samples were blinded (i.e., dose groups not identified)
 - Decoding not provided until raw data uploaded to an NTP database
 - Analysis of data only possible after data uploaded and samples decoded by NTP
 - Elaborate procedure to reduce/eliminate researcher bias
- 6 researchers have reported very limited findings in 10 published papers to date
 - Generally consistent with FDA's overall conclusion ("minimal effects")
- Awaiting for others to publish results

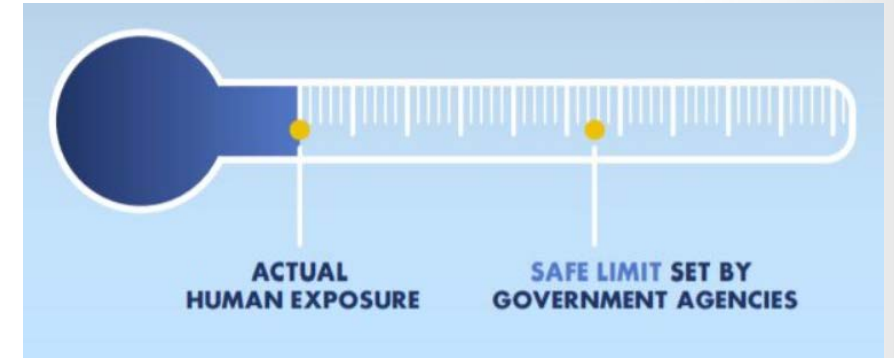
CLARITY – Overall Conclusions

- All raw data (FDA and academic) to be released in August 2018
- NTP will undertake an exercise to integrate results from all CLARITY studies (FDA and academic)
 - Final conclusions expected in August 2019



BPA – Clearly Safe and Here’s How We Know

- Consumer exposure to BPA is extremely low
 - Population-scale biomonitoring studies in US
 - Similar results from numerous studies worldwide
 - BPA is efficiently metabolized and rapidly eliminated from the body
 - FDA pharmacokinetic studies (laboratory animals)
 - NTP pharmacokinetic study (human volunteers)
 - Low toxicity confirmed in large-scale toxicity studies
 - CLARITY study
 - FDA subchronic toxicity study
 - Three large-scale reproductive toxicity studies
- ➔ **No risk of health effects at typical consumer exposure levels**



For More Information

- Key Contact

Steven G. Hentges, Ph.D.

Executive Director, Polycarbonate/BPA Global Group

American Chemistry Council

700 2nd Street, NE

Washington, DC 20002

Phone: 202-249-6624

E-mail: steve_hentges@americanchemistry.com

<http://www.FactsAboutBPA.org> (sign up for e-mail updates)

http://www.science20.com/profile/steve_hentges



Question #4

After participating in today's webinar, has your perspective changed regarding polycarbonate or epoxy resins?



QUESTIONS?
