

C8 Study Overview

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Epidemiologic Evidence Prior to 2005

- Cross-sectional studies of occupationally exposed workers at 3M
- Few correlations found between serum levels of PFASs and blood chemistry – lipids, thyroid hormones, etc.
- Little knowledge, research interest, or concern
- Discovery of widespread environmental contamination and subsequent lawsuits stimulated research that has continued

PFOA in Public Water and Private Wells near DuPont Plant

- Detection of elevated PFOA in water supplies near the DuPont Plant in the Mid-Ohio Valley due to air emissions and river discharges led to a class action lawsuit
- Settlement mandated:
 - Filtration of water to remove PFOA
 - C8 Health Project, a survey of exposure and clinical markers in exposed population
 - Formation of C8 Science Panel to study and evaluate link of PFOA to disease

Serum Levels of PFOA

- Background range of 4-5 ng/mL in US at this time (subsequently declined)
- Mid-Ohio Valley mean = 82.9, median = 28.2
- Dominant determinant is water district and duration of residence
- Additional predictors of elevated exposure are older age, male, private well user, grows own vegetables

The C8 Science Panel

Tony Fletcher, London School of Hygiene & Tropical
Medicine

David Savitz, Brown University

Kyle Steenland, Emory University

- Selected by agreement between the “Settling Parties” - DuPont and the Plaintiffs/Class
- Charge: Determine if there is a “**Probable Link**” between C8/PFOA exposure and any human disease - would lead to medical monitoring program
- Conduct research needed to determine whether Probable Link is present between PFOA and disease

Definition of “Probable Link

- Given available scientific evidence, is it more probable than not that a *connection* is present between C8 (PFOA) exposure and human disease?
- Using a 50% threshold, judge whether a probable link is present based on toxicology, epidemiologic evidence from others, and epidemiologic studies by C8 Science Panel
- Given association and taking into account bias and random error, is a causal effect likely to be present?

Rationale for Conducting New Research on PFOA Health Effects

- Limited evidence from prior studies
- Well-defined exposure that could be accurately reconstructed
- Some, not all, health concerns easily measured
- Large enough population to study
 - Around 70,000 exposed to varying degrees, sufficient for most common diseases

C8 Science Panel Research Program

Overall objective: conduct research needed to reach informed judgment on probable links

- Half-life assessment after cessation of exposure
- Exposure reconstruction using modeling
- Cohort follow-up on community and worker populations to assess disease retrospectively and prospectively
- Cross-sectional analyses of serum PFAAs and blood chemistry
- Ecologic exposure studies of birth outcomes and cancer
- Neurodevelopment in children

Health Outcomes Judged to Have Probable Links

- Elevated cholesterol
- Ulcerative colitis
- Thyroid disease
- Testicular cancer
- Kidney cancer
- Pregnancy-induced hypertension

Research Subsequent to C8 Science Panel

- Immunologic effects
- Infant birth weight
- Thyroid hormones
- Serum lipids