PERRIN CONFERENCES

ENVIRONMENTAL RISK & PFAS LITIGATION CONFERENCE

The New York City Bar Association | June 17-18, 2025

The Human Health Effects of PFAS

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The Human Health Effects of PFAS

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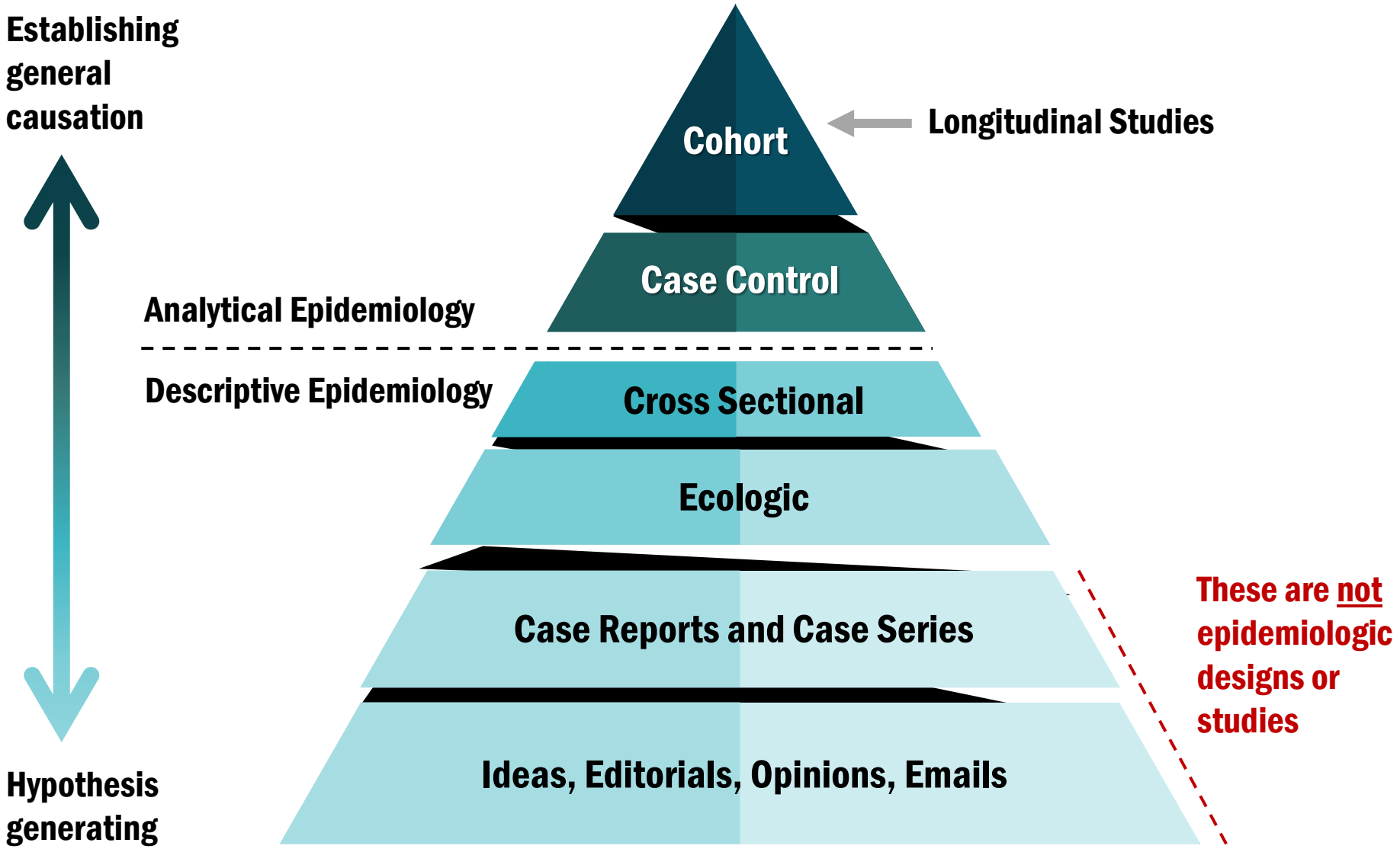
Environmental and Occupational Epidemiological Studies – Hierarchy of Epidemiologic Evidence



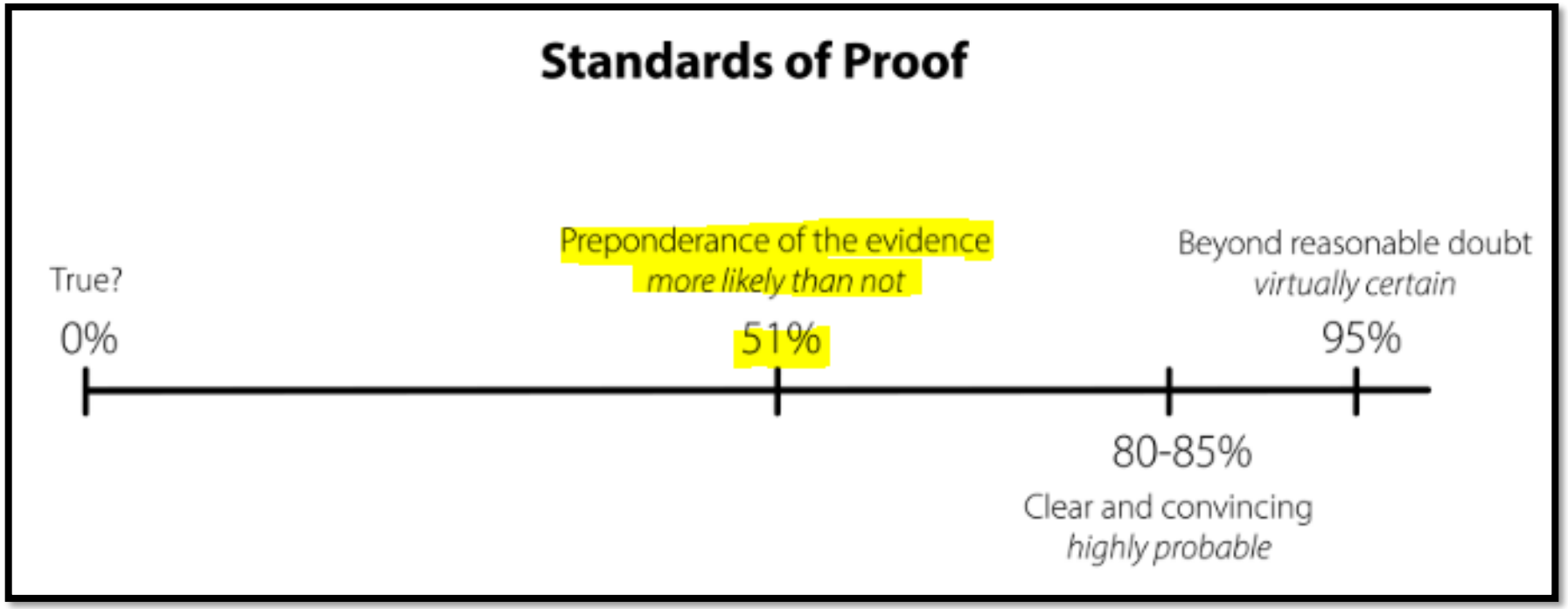
PFAS “Probable Links”

C8 Science Panel

- Direct result of Leach settlement.
- Independent three-member panel (C8 Science Panel) to conduct and evaluate studies to determine whether there is a **"probable link"** between exposure to C8 (PFOA) and ***any*** human disease.

"Probable Link" vs. Legal Causation

1.49 "Probable Link" shall mean that based upon the weight of the available scientific evidence, it is more likely than not that there is a link between exposure to C-8 and a particular Human Disease among Class Members.



The 95% Confidence Interval

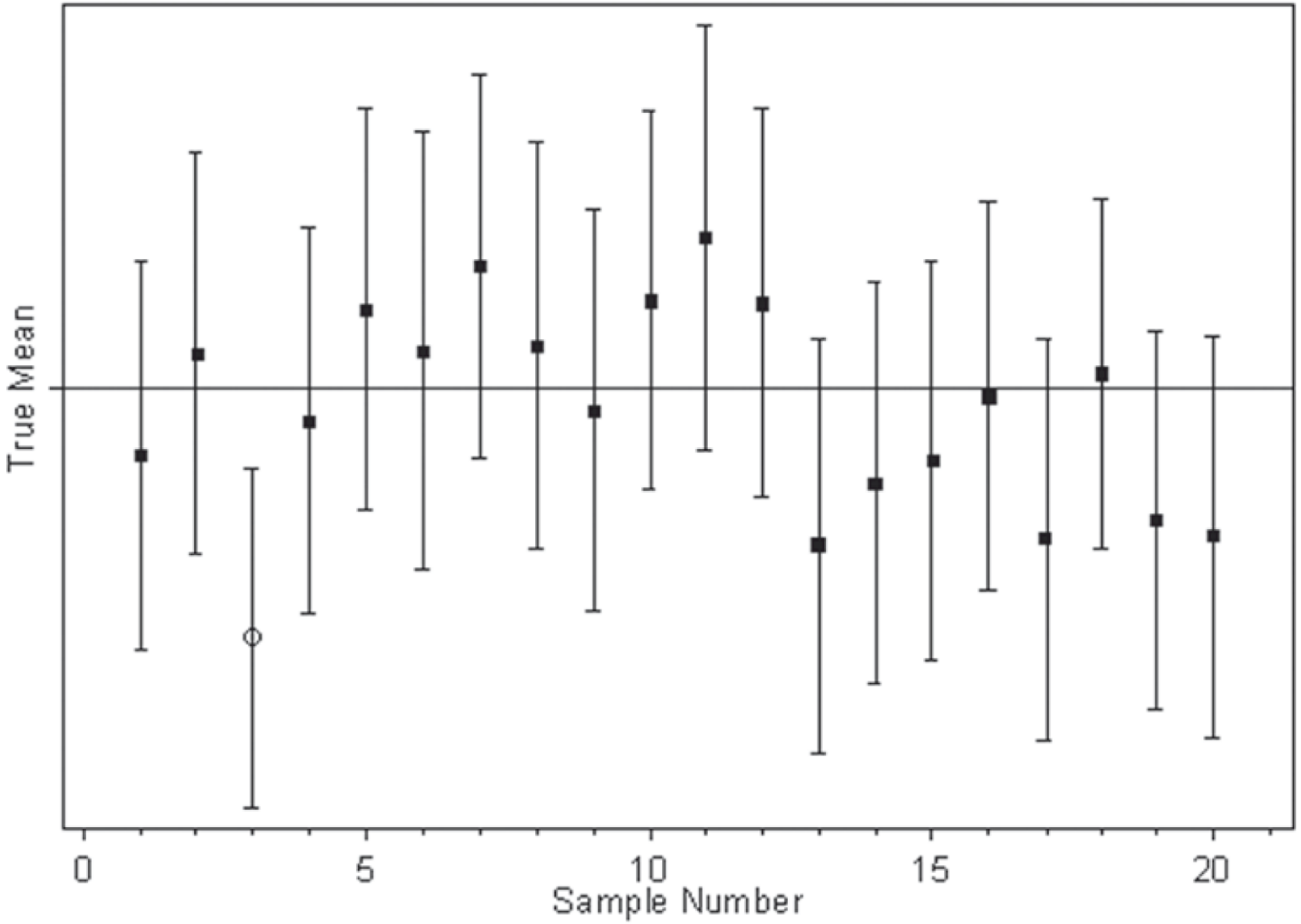
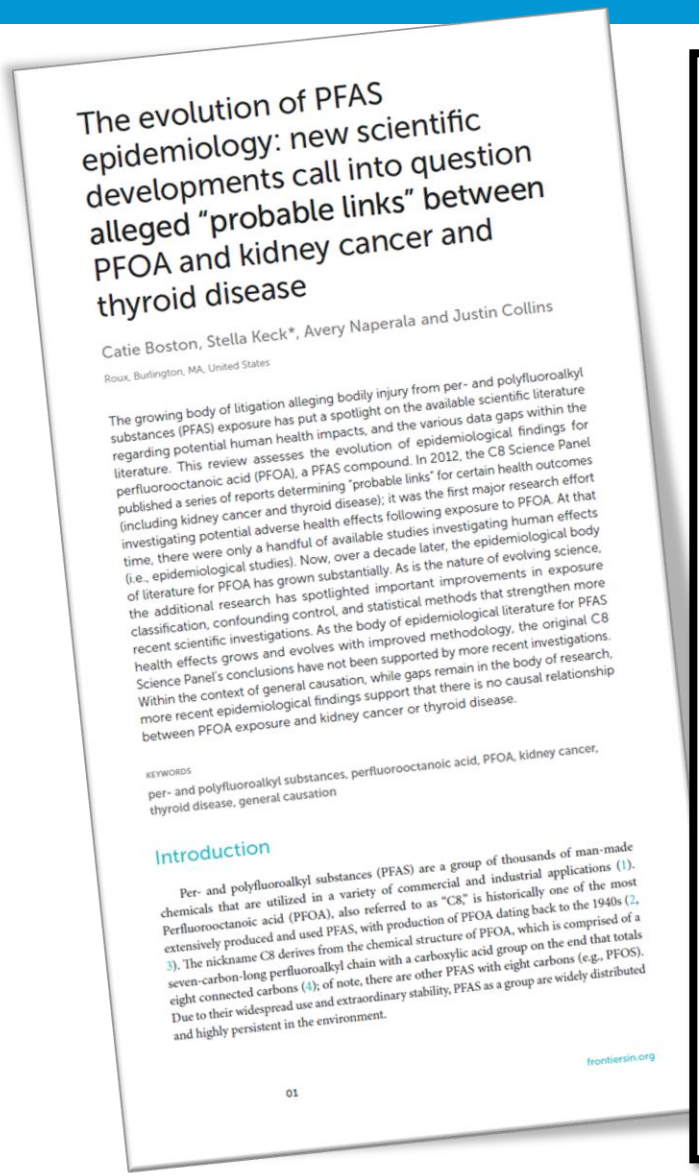


Fig. 1. 95% CI for the population mean for 20 independent samples drawn from the population.

Probable Links Called into Question



The evolution of PFAS epidemiology: new scientific developments call into question alleged "probable links" between PFOA and kidney cancer and thyroid disease

Catie Boston, Stella Keck*, Avery Naperala and Justin Collins

Roux, Burlington, MA, United States

The growing body of litigation alleging bodily injury from per- and polyfluoroalkyl substances (PFAS) exposure has put a spotlight on the available scientific literature regarding potential human health impacts, and the various data gaps within the literature. This review assesses the evolution of epidemiological findings for perfluorooctanoic acid (PFOA), a PFAS compound. In 2012, the C8 Science Panel published a series of reports determining "probable links" for certain health outcomes (including kidney cancer and thyroid disease); it was the first major research effort investigating potential adverse health effects following exposure to PFOA. At that time, there were only a handful of available studies investigating human effects (i.e., epidemiological studies). Now, over a decade later, the epidemiological body of literature for PFOA has grown substantially. As is the nature of evolving science, the additional research has spotlighted important improvements in exposure classification, confounding control, and statistical methods that strengthen more recent scientific investigations. As the body of epidemiological literature for PFAS health effects grows and evolves with improved methodology, the original C8 Science Panel's conclusions have not been supported by more recent investigations. Within the context of general causation, while gaps remain in the body of research, more recent epidemiological findings support that there is no causal relationship between PFOA exposure and kidney cancer or thyroid disease.

KEYWORDS

per- and polyfluoroalkyl substances, perfluorooctanoic acid, PFOA, kidney cancer, thyroid disease, general causation

Introduction

Per- and polyfluoroalkyl substances (PFAS) are a group of thousands of man-made chemicals that are utilized in a variety of commercial and industrial applications (1). Perfluorooctanoic acid (PFOA), also referred to as "C8," is historically one of the most extensively produced and used PFAS, with production of PFOA dating back to the 1940s (2, 3). The nickname C8 derives from the chemical structure of PFOA, which is comprised of a seven-carbon-long perfluoroalkyl chain with a carboxylic acid group on the end that totals eight connected carbons (4); of note, there are other PFAS with eight carbons (e.g., PFOS). Due to their widespread use and extraordinary stability, PFAS as a group are widely distributed and highly persistent in the environment.

frontiersin.org

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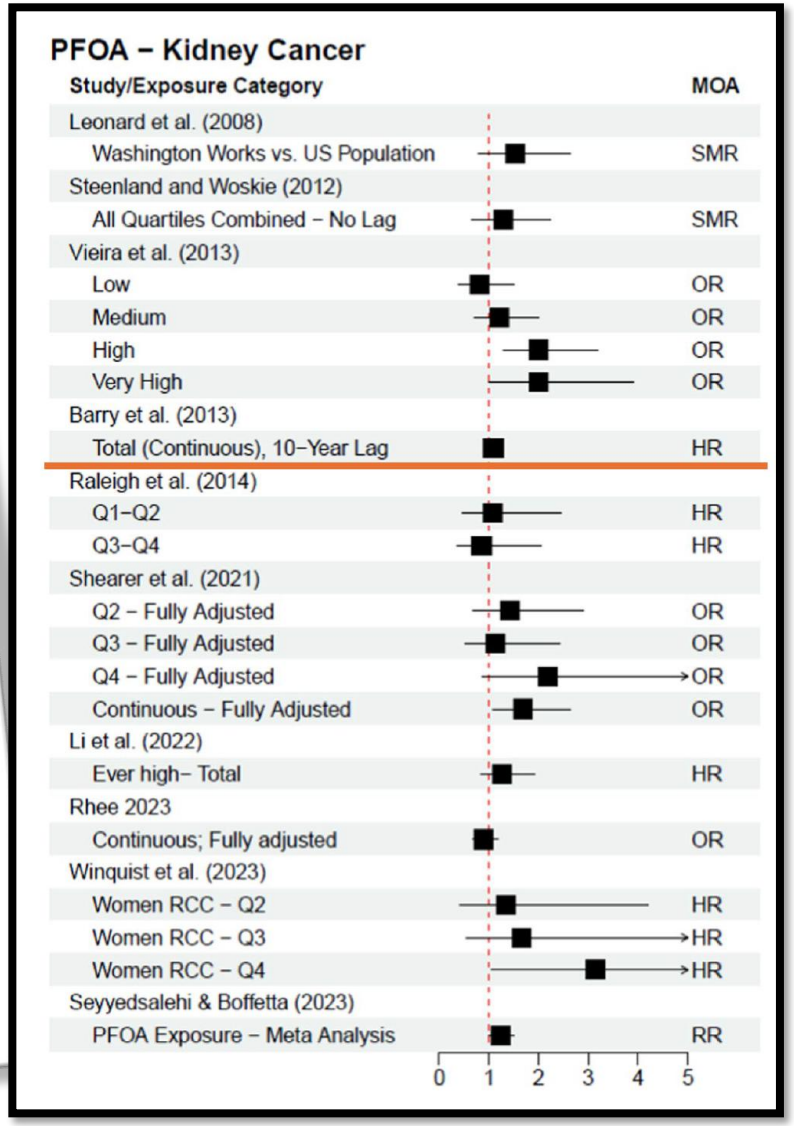
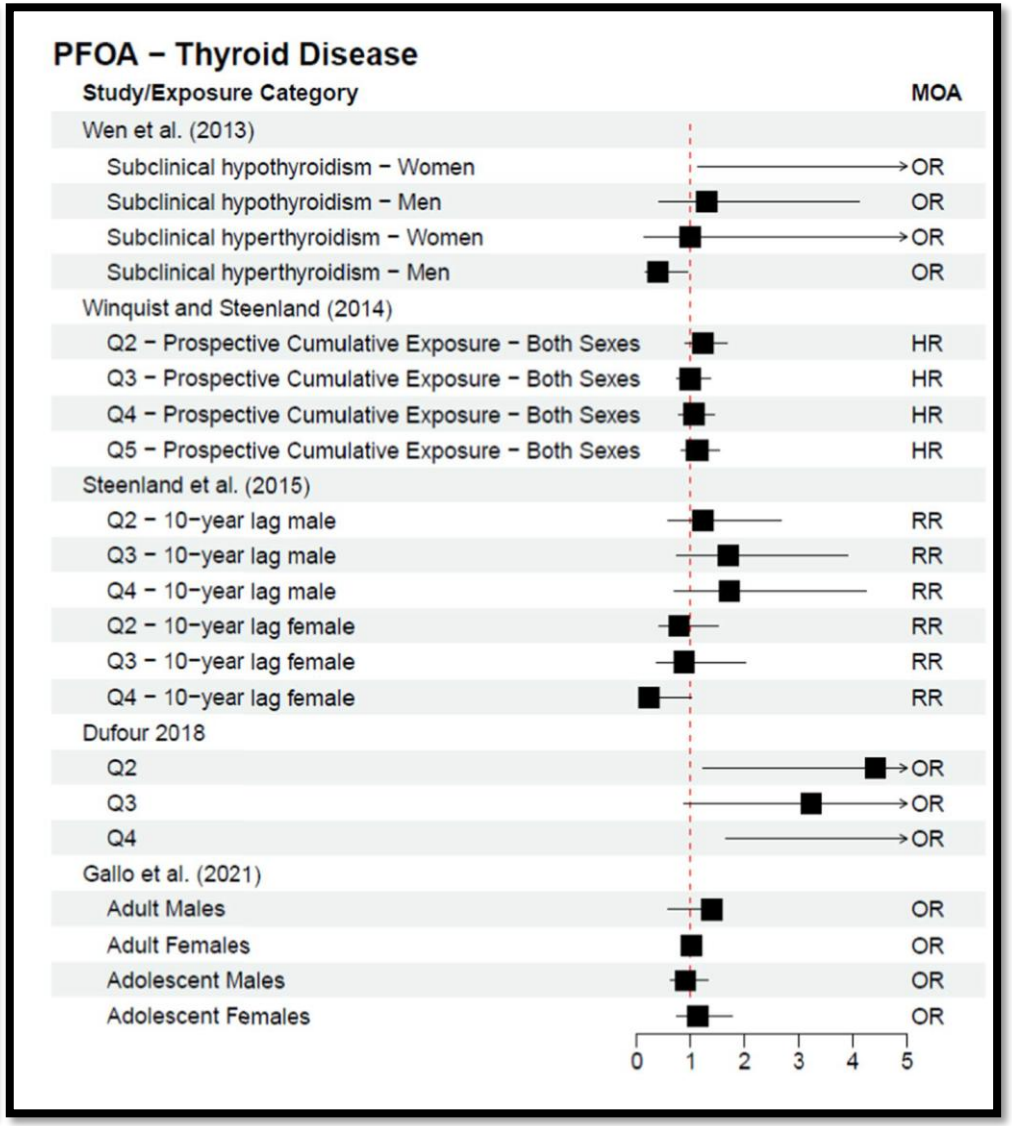
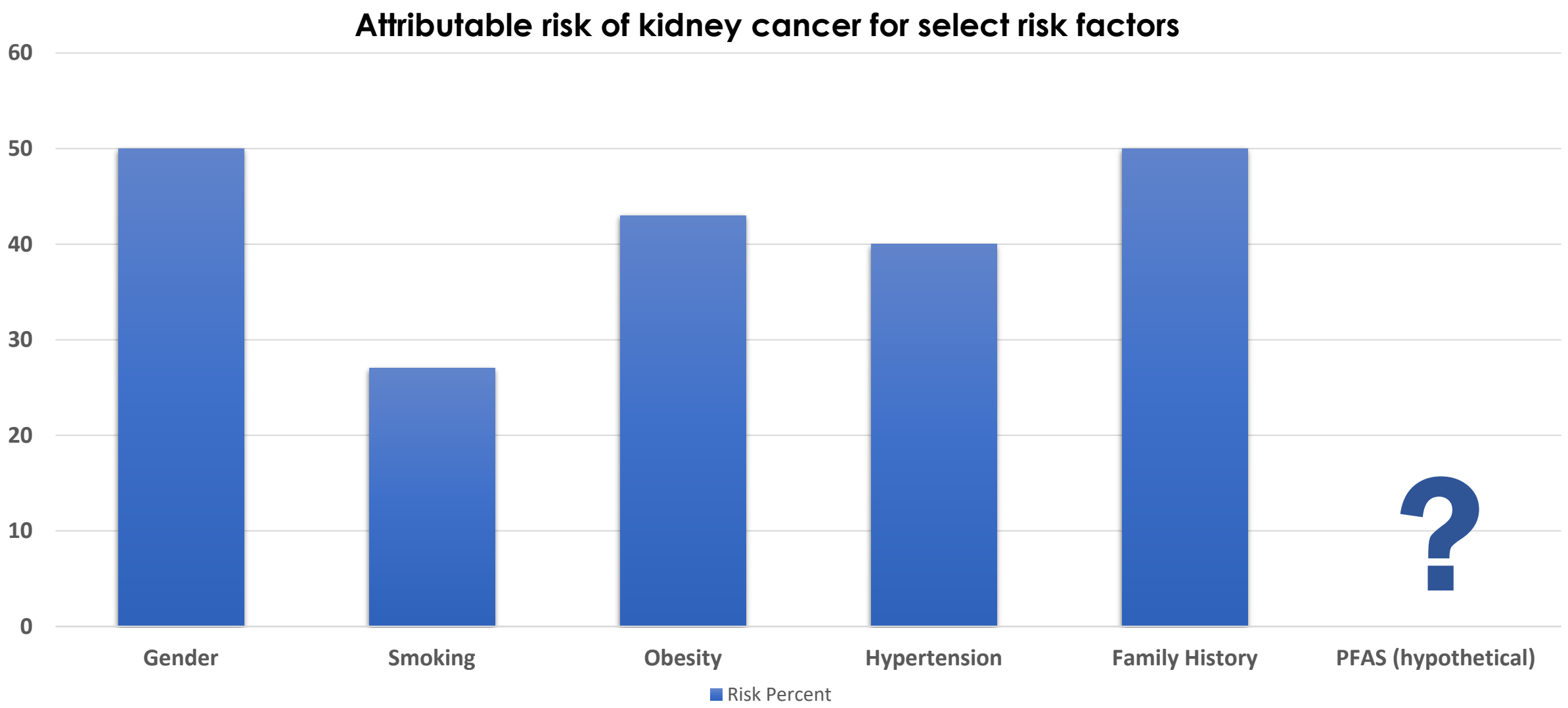
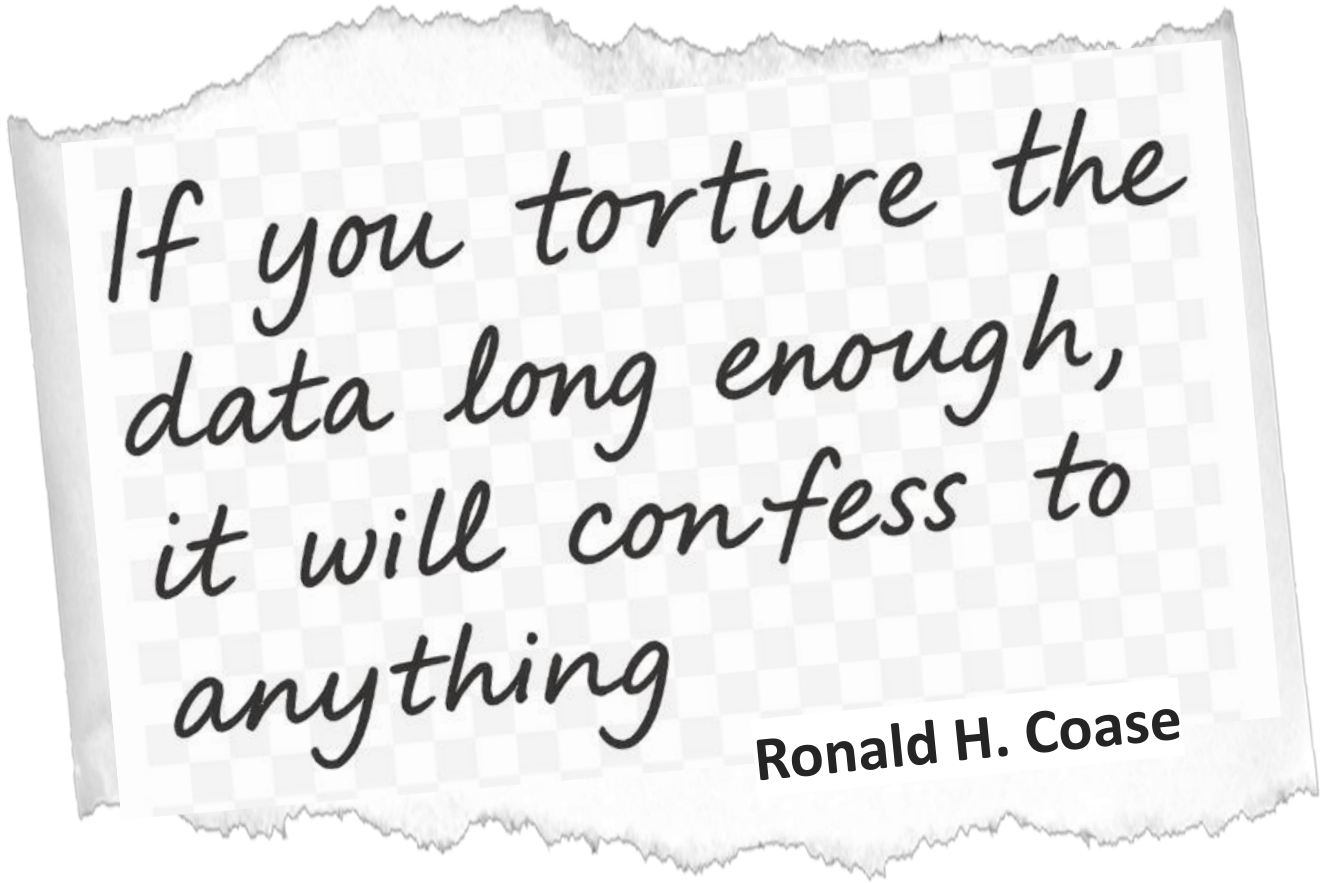




Attributable Risk – Kidney Cancer



Everything is Numbers



- NCBI: > 6,500 articles
- Web of Science: > 8,000 articles
- Scopus: >9,000 articles
- Google Scholar: appx. 174,000

What We Can't See

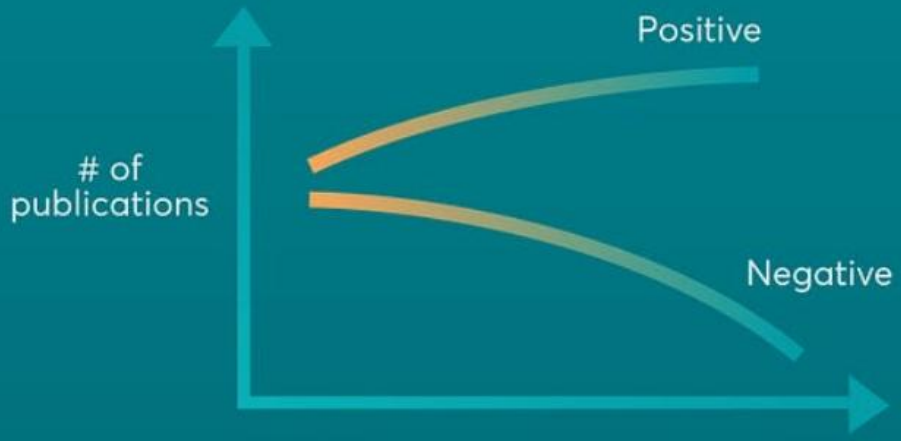
Publishing.

Biased?

THE POSITIVE BIAS

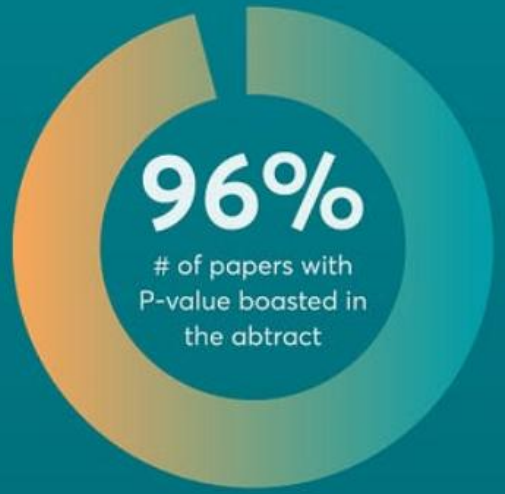
As positive results are more likely to lead to prestigious publications, discarding odd and unexpected findings is common in the scientific publishing system that privileges these "successful" results.

1. The disappearance of negative results



Negative results have been gradually disappearing over the past two decades. Meanwhile, articles primarily and clearly stating positive results have grown 22% between 1990 and 2007.

2. P-hacking or abuse of p-value



The p-value reveals almost nothing about the strength of the evidence, yet a p-value of 0.05 has become the ticket to get into many journals.

Scientific Causation and Legal Causation

General Causation

According to the evidence-based science, is the toxicant capable of causing the injury?

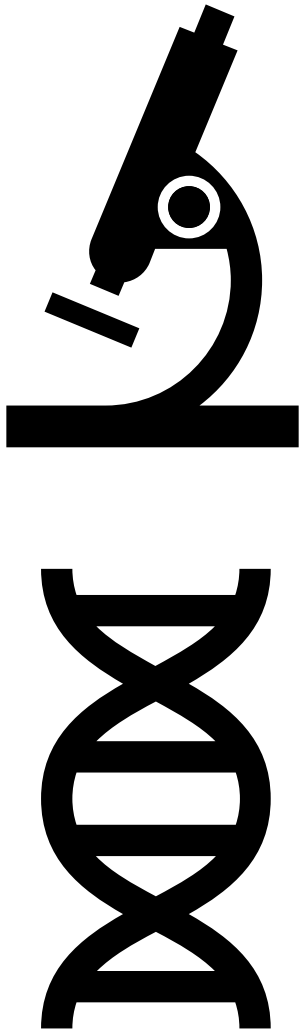
Specific Causation

According to the evidence-based science, is the toxicant, in fact, cause the injury in the present case?

Medical/Scientific Causation

- Jurisdiction dependent
- Rule dependent
- Judge dependent
- Jury dependent

Medical vs. Legal Causation



Causation in Medicine Requires an Analysis

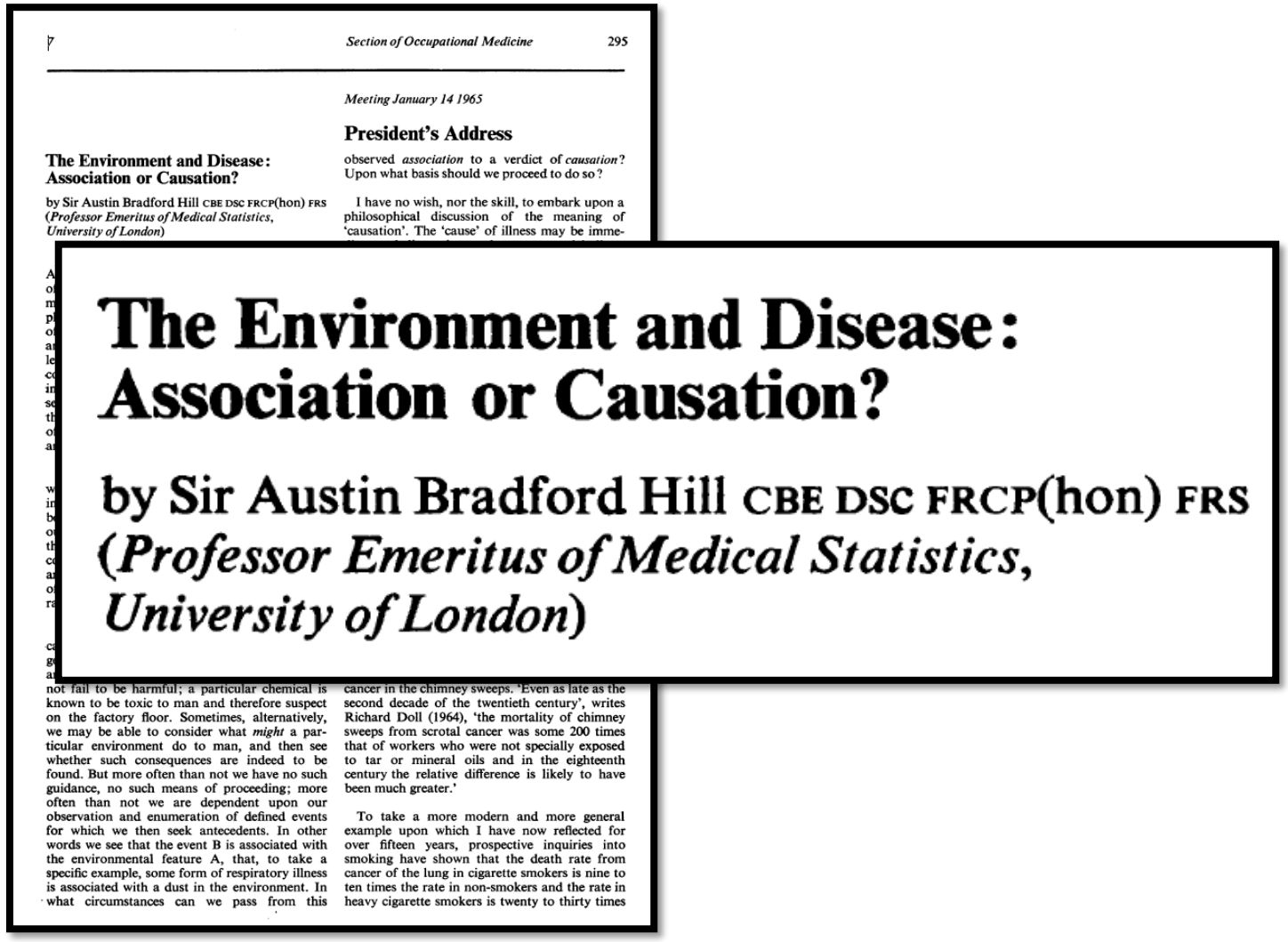
Causation in Law Requires a Determination

"There are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.

Supreme Court's 1993 *Daubert v. Merrill Dow Pharmaceuticals, Inc.*

Thank You!

The Bradford Hill Considerations



7 Section of Occupational Medicine 295

Meeting January 14 1965

President's Address

The Environment and Disease: Association or Causation?

by Sir Austin Bradford Hill CBE DSC FRCP(hon) FRS (*Professor Emeritus of Medical Statistics, University of London*)

observed *association* to a verdict of *causation*? Upon what basis should we proceed to do so?

I have no wish, nor the skill, to embark upon a philosophical discussion of the meaning of 'causation'. The 'cause' of illness may be imme-

not fail to be harmful; a particular chemical is known to be toxic to man and therefore suspect on the factory floor. Sometimes, alternatively, we may be able to consider what *might* a particular environment do to man, and then see whether such consequences are indeed to be found. But more often than not we have no such guidance, no such means of proceeding; more often than not we are dependent upon our observation and enumeration of defined events for which we then seek antecedents. In other words we see that the event B is associated with the environmental feature A, that, to take a specific example, some form of respiratory illness is associated with a dust in the environment. In what circumstances can we pass from this

cancer in the chimney sweeps. 'Even as late as the second decade of the twentieth century', writes Richard Doll (1964), 'the mortality of chimney sweeps from scrotal cancer was some 200 times that of workers who were not specially exposed to tar or mineral oils and in the eighteenth century the relative difference is likely to have been much greater.'

To take a more modern and more general example upon which I have now reflected for over fifteen years, prospective inquiries into smoking have shown that the death rate from cancer of the lung in cigarette smokers is nine to ten times the rate in non-smokers and the rate in heavy cigarette smokers is twenty to thirty times

The Environment and Disease: Association or Causation?

by Sir Austin Bradford Hill CBE DSC FRCP(hon) FRS
(*Professor Emeritus of Medical Statistics, University of London*)

1. Strength of the association
2. Consistency
3. Specificity of the association
4. Temporality
5. Biological gradient
6. Plausibility
7. Coherence
8. Experimental Evidence
9. Analogy

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STATE OF THE SCIENCE OF PFAS TOXICOLOGY

- PFAS overview
- Regulatory updates
- Health effects

HOW ARE PFAS DEFINED?

- 15,000+ chemicals meet definition of PFAS under USEPA

USEPA

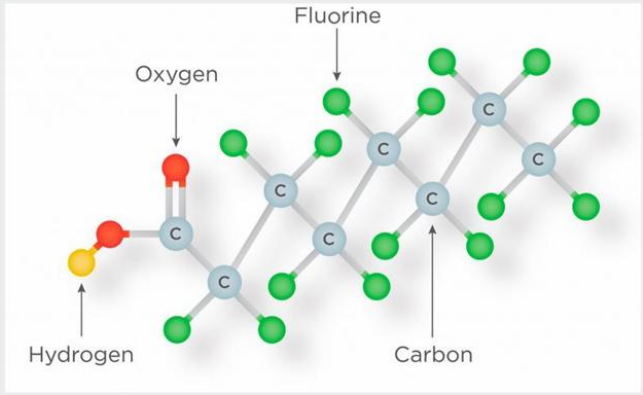
[40 CFR Part 705]

- *"R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons.*
- *R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons.*
- *CF3C(CF3)R'R", where R' and R" can either be F or saturated carbons"*

At least one fully fluorinated carbon atom (CF2)

CALIFORNIA

At least one fully fluorinated carbon atom



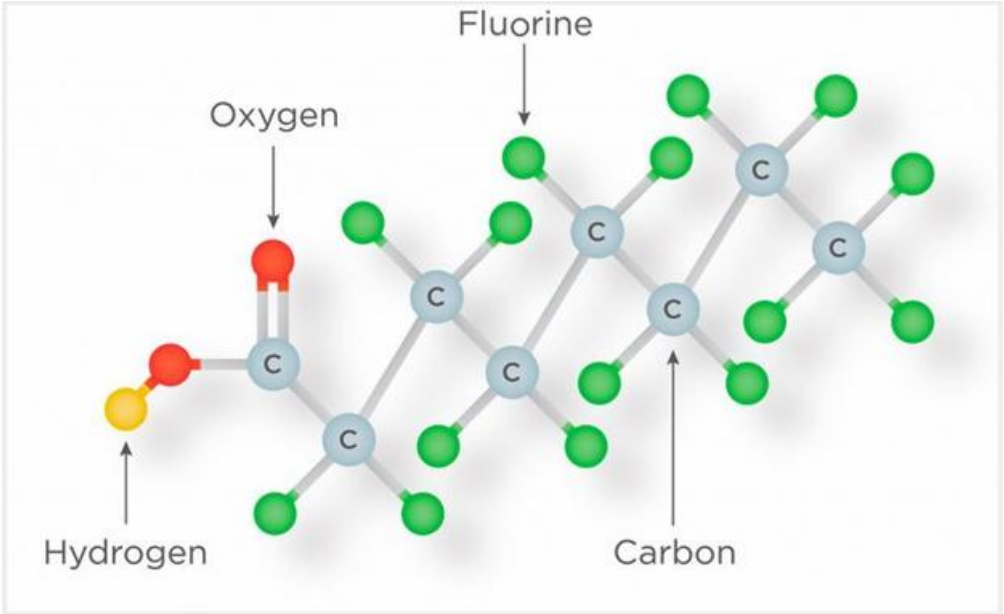
OECD

At least one fully fluorinated methyl or methylene carbon atom

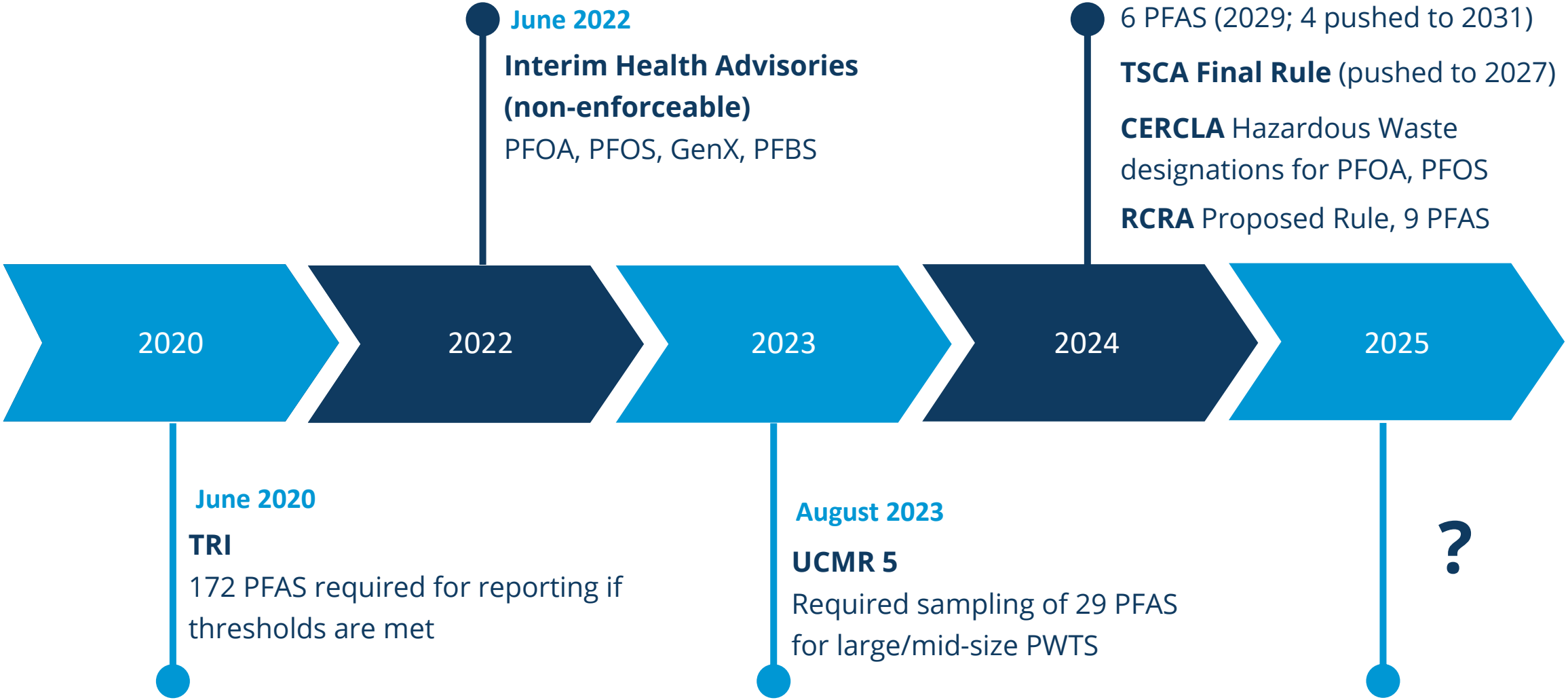
("without any H/Cl/Br/I atom attached to it; with exceptions, any chemical with at least a perfluorinated methyl group ($-CF_3$) or a perfluorinated methylene group ($-CF_2-$)"

WHAT ARE PFAS?

- Synthetic/Not naturally occurring
- Used or detected in multiple products/industries
- PFOA and PFOS are most well-studied
- Widely detected in water, soil, food, dust
- Persistent, bioaccumulative



U.S. PFAS REGULATORY HIGHLIGHTS



E.U. PFAS REGULATORY HIGHLIGHTS

2009

Stockholm Convention

Agreed to ban PFOS (with exemptions)

2019

Stockholm Convention

Ban PFOA AFFF; remove PFOS exemption

2020

Drinking Water Directive

0.1 µg/L, sum 20 PFAS

0.5 µg/L total PFAS

Compliance by 2026

2023

Proposed restriction 10,000 PFAS

Germany, Denmark, Sweden, Netherlands, Norway

2025 estimated final

2024

Packaging/Food Contact Materials

25 ppb per “targeted PFAS”

250 ppb “sum targeted PFAS”

50 ppm total fluorine

PFAS AND HEALTH EFFECTS

Diseases with bellwether tracks

1. Kidney cancer
2. Testicular cancer
3. Liver cancer
4. Thyroid cancer
5. Ulcerative colitis
6. Thyroid disease

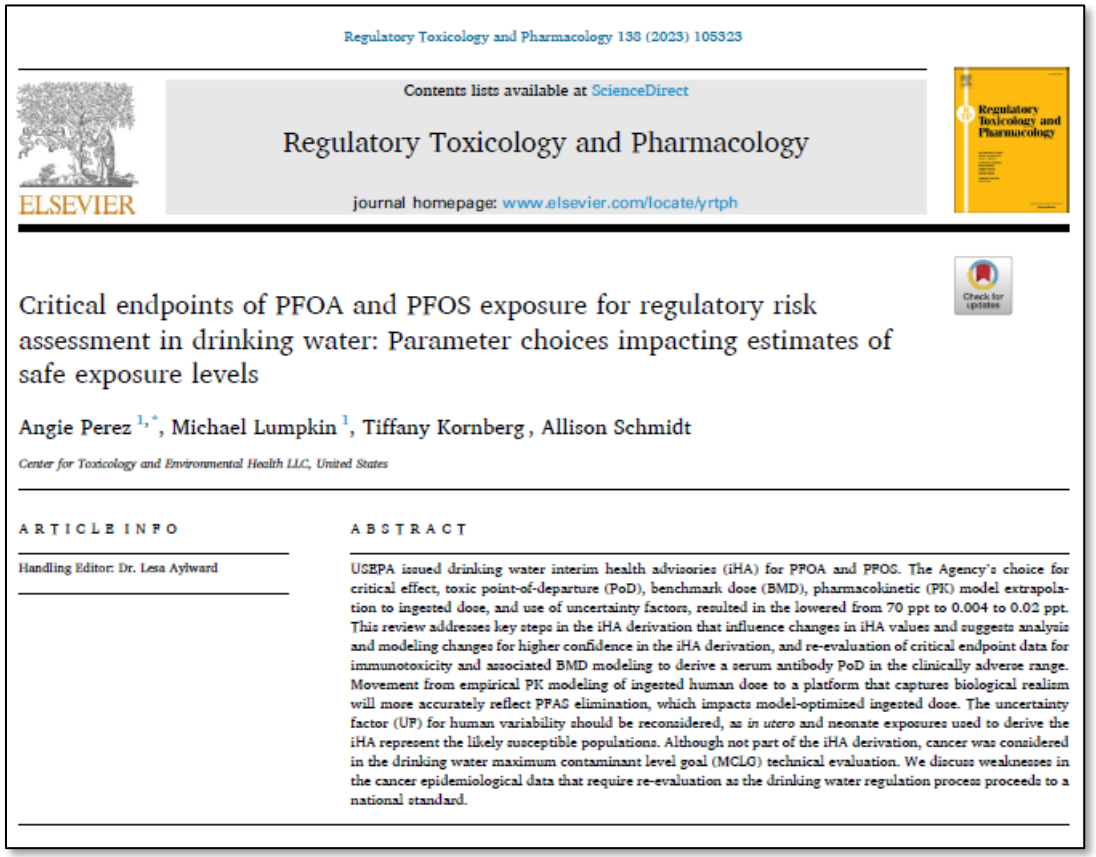
Disease endpoints for MCL basis PFOA/PFOS (USEPA 2024)

Cancer	Kidney cancer (PFOA)
	Liver cancer (PFOS)
Non-cancer	Decreased antibody response (PFOA)
	Decreased birth weight; increased total cholesterol in adults (PFOA, PFOS)

CAUSATION EVALUATION

Do studies meet the burden of "*Probable links*" or "*More likely than not*"

- Findings significant?
- Pharmacokinetic bias?
- Effects specific to exposure?
- Confounders/Covariates?
- Findings clinically relevant?



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journal homepage: www.elsevier.com/locate/yrtph

Critical endpoints of PFOA and PFOS exposure for regulatory risk assessment in drinking water: Parameter choices impacting estimates of safe exposure levels

Angie Perez [1,*], Michael Lumpkin [1], Tiffany Kornberg, Allison Schmidt

Center for Toxicology and Environmental Health LLC, United States

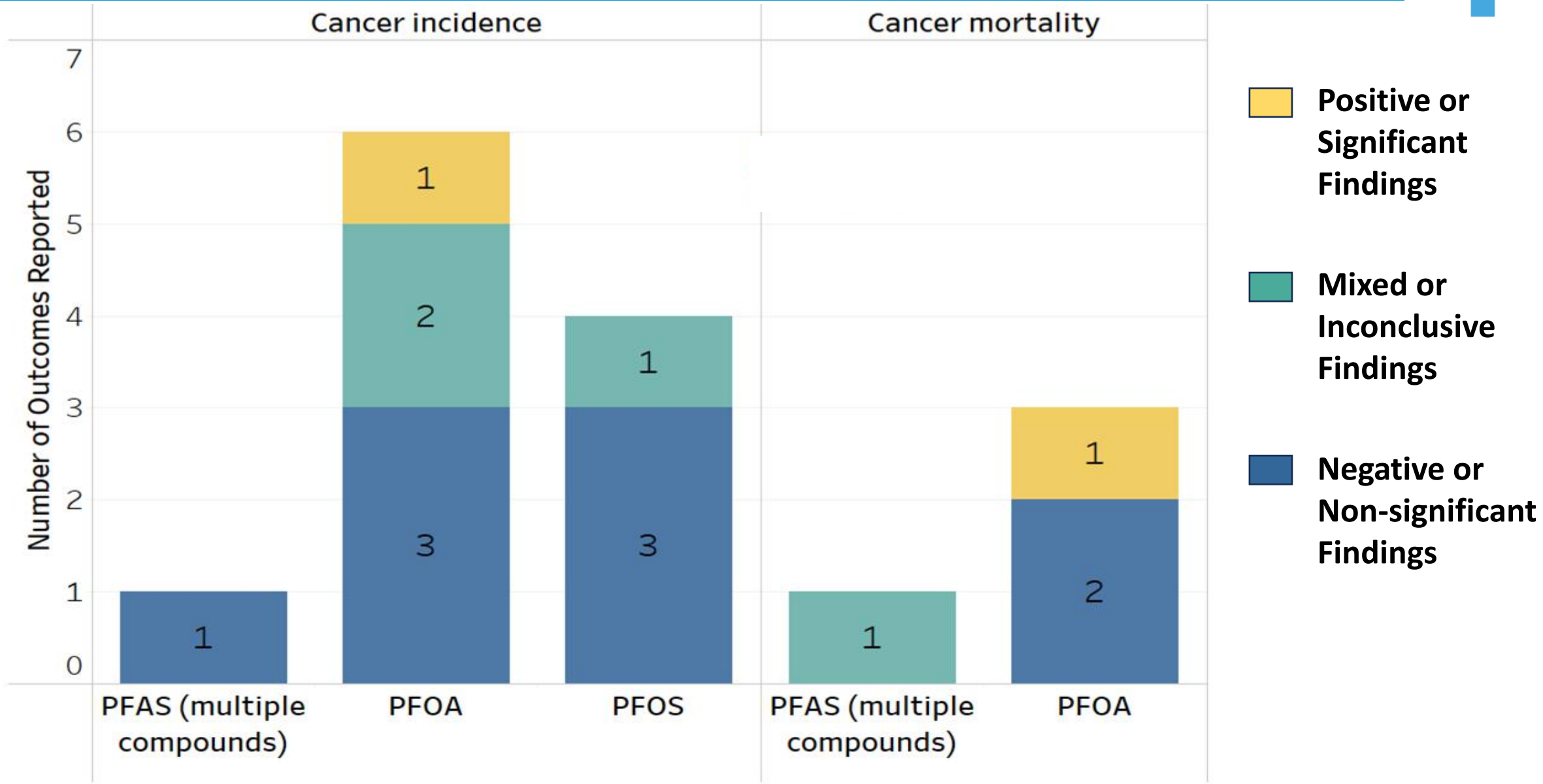
ARTICLE INFO

Handling Editor: Dr. Lesa Aylward

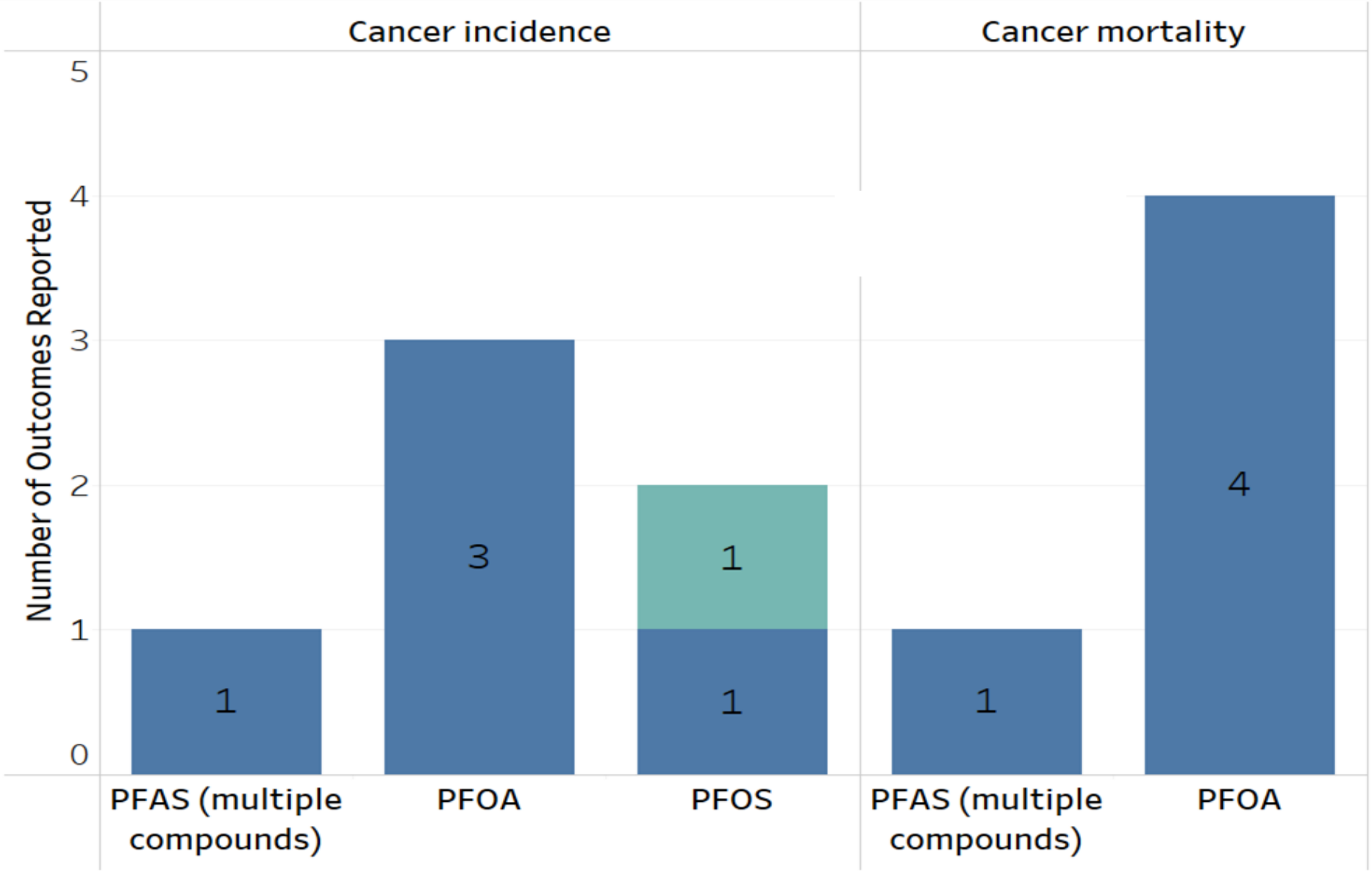
ABSTRACT

USEPA issued drinking water interim health advisories (iHA) for PFOA and PFOS. The Agency's choice for critical effect, toxic point-of-departure (PoD), benchmark dose (BMD), pharmacokinetic (PK) model extrapolation to ingested dose, and use of uncertainty factors, resulted in the lowered from 70 ppt to 0.004 to 0.02 ppt. This review addresses key steps in the iHA derivation that influence changes in iHA values and suggests analysis and modeling changes for higher confidence in the iHA derivation, and re-evaluation of critical endpoint data for immunotoxicity and associated BMD modeling to derive a serum antibody PoD in the clinically adverse range. Movement from empirical PK modeling of ingested human dose to a platform that captures biological realism will more accurately reflect PFAS elimination, which impacts model-optimized ingested dose. The uncertainty factor (UF) for human variability should be reconsidered, as *in utero* and neonate exposures used to derive the iHA represent the likely susceptible populations. Although not part of the iHA derivation, cancer was considered in the drinking water maximum contaminant level goal (MCLG) technical evaluation. We discuss weaknesses in the cancer epidemiological data that require re-evaluation as the drinking water regulation process proceeds to a national standard.

Kidney Cancer: Epidemiology Literature Review



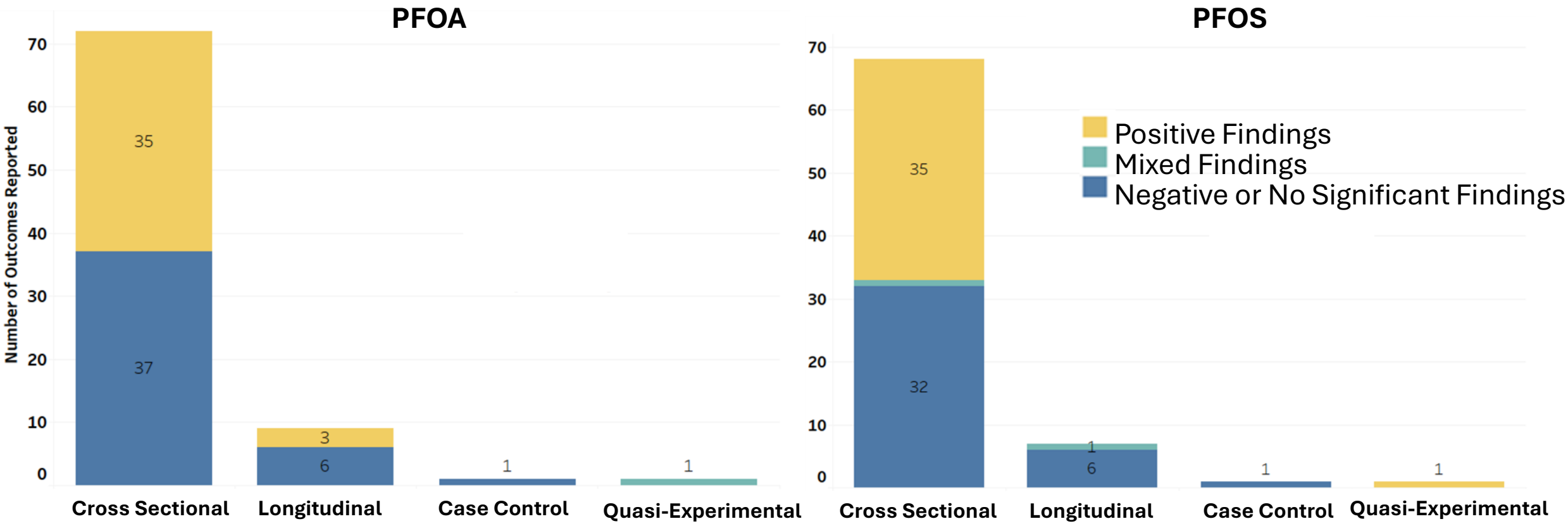
Testicular Cancer: Epidemiology Literature Review



Mixed or Inconclusive Findings

Negative or Non-significant Findings

Cholesterol: Epidemiology Literature Review



Cholesterol: Epidemiology Literature Review

The relationship between PFAS exposure and dyslipidemia: an updated review, meta-analysis, and evaluation of bias

IN PRESS, *European Journal of Epidemiology*
Hussey, MR; Kornberg, TG; Sherrick, JM; Olson, AM; Kind, JA; Perez, AL*

Significance
(Longitudinal studies – study populations over time)

PFOA: 4 out of 7 studies

PFOS: 5 out of 5 studies

NO EFFECT or NEGATIVE EFFECT

Cholesterol: Epidemiology Literature Review

The relationship between PFAS exposure and dyslipidemia: an updated review, meta-analysis, and evaluation of bias

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Prediction Interval
(What is the range of possible effects in new studies)

PFOA **PFOS**	**New studies likely to have NEGATIVE, NULL, or NON-SIGNIFICANT EFFECTS**

Cholesterol: Epidemiology Literature Review

The relationship between PFAS exposure and dyslipidemia: an updated review, meta-analysis, and evaluation of bias

IN PRESS, *European Journal of Epidemiology*
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Heterogeneity
(Do study results differ between similar populations?)

PFOA **PFOS**	**HIGH heterogeneity, likely due to RANDOM ERROR, COHORT DIFFERENCES, or BIAS**

THANK YOU

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JOHN GARDELLA
Co-Owner / Attorney
Chair of PFAS Practice Group

AFFF MDL

Personal Injury Cases

- 6 disease types given bellwether tracks
  - Kidney cancer
  - Testicular cancer
  - Liver cancer
  - Thyroid cancer
  - Ulcerative colitis
  - Thyroid disease

  *highlighted are new additions
- October 2025 – kidney cancer case(s) will be first tried

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Personal Injury Cases - Causation

- July – September 2025: expert reports and start of expert depositions on causation issues for original four injuries
- June 20, 2025: Science Day for thyroid cancer and liver cancer
  - No transcript
  - No cross examination
  - Relaxed format – Judge can ask questions freely
  - Educational in nature for Court

Causation Issues Preview

- Many other causes of diseases
- General causation vs. specific causation
- Science may not be as conclusive as commonly believed
  - IARC: “limited evidence” (PFOA) and “inadequate evidence” (PFOS) for cancer in humans
- C8 Science Panel findings are not conclusive evidence for plaintiffs
  - “Probable links”
  - PFOA only
  - Associations (not causation)

Current U.S. Litigation Trends (Non-MDL)

General Causation Battlefield – Medical Monitoring

- 435% increase in number of PFAS class action lawsuits (excluding AFFF litigation) from 2021 to 2024
  - Land contamination, property devaluation, negligence nuisance, strict liability
  - Many allege medical monitoring claim
- Specific causation not at issue in monitoring cases

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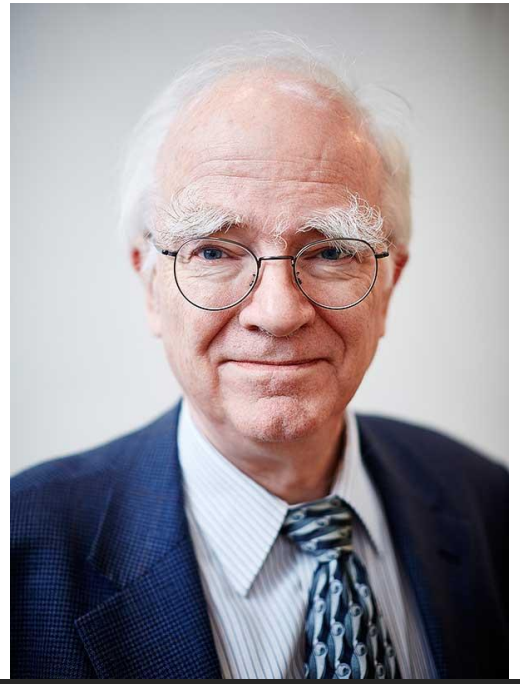
Notable Plaintiffs' PFAS Litigation Causation Experts

Dr. Philippe Grandjean

Head of Env. Medicine, U. of Southern Denmark
Over 200 PFAS articles published
Consultant by EPA SAB for PFAS drinking water regulations



Dr. Alan Ducatman

Dean, School of Public Health, W.V. University
Over 100 PFAS articles published
Administrator for PFAS medical monitoring programs (Hoosick Falls)

Class Action Case Study:

Unknowing PFAS User

- Company recycles cardboard products
- Sends “residuals” (dry waste pellets) to site for composting
- 2022: neighboring private well testing shows elevated PFAS
- Results: EPA enforcement, class action lawsuits by citizens, personal injury lawsuit by two citizens

Specific Causation – Drinking Water

- Primarily cancer cases:
  - Kidney
  - Breast
  - Testicular
  - Thryoid
- Specific causation directly at issue in these personal injury cases
- Watch for evolution of reptile theory by plaintiffs to get around specific causation issues

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Non-MDL Cases To Watch: Causation Impacts

- Hardwick II (Ohio)
  - Originally certified a class of 13,000,000 plaintiffs
  - Overturned on appeal
  - This is the refiled case
- Carey v. DuPont, et al (North Carolina)
  - Class of 100,000 certified
  - General causation, medical monitoring
- State of New Jersey v. DuPont, et al.
  - State seeking over $1 billion for remediation costs
  - General causation issues being litigated
- Miteni trial (Italy): four-year trial, verdict expected June 2025
  - 1968-2018: manufactured PFAS
  - 77 square miles impacted
  - Criminal and civil case
  - Court ruled in May 2025 that death of worker caused by PFAS exposure

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HUNTON

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PFAS Litigation Landscape

- **Legal Theories:** Environmental impacts, public water system damage, personal injury, medical monitoring, property damage and consumer misrepresentation/fraud
- **Plaintiffs:** Federal and state environmental agencies, states (via their attorneys general), municipalities, public water suppliers, and private parties
- **Defendants:** PFAS manufacturers, suppliers of PFAS chemicals, manufacturers of PFAS-containing products, industrial users and disposers, and landfill owners and operators
- **Damages:**
    - Remediation and clean-up costs
    - In personal injury cases, actual/compensatory damages, pain and suffering damages, medical monitoring costs, and/or punitive damages
    - Regulatory/environmental statute violations may result in civil fines and injunctive relief
    - Consumer fraud damages based on “price premium” theory and available statutory penalties

Personal Injury Claims

- Limited outside of the DuPont “C8” Litigation
- Plaintiffs’ ability to prove general and specific causation is limited by existing health effects science
  - No established dose-response (causative) relationship between any PFAS and any particular health endpoint – no “signature disease”
  - Particularly difficult in the consumer product context to trace exposure to any particular consumer product source
- Personal injury claims largely brought in individual suits
- Individualized issues regarding exposure, causation, and harm will predominate over any common issues, creating a barrier class certification

Conklin v. Corteva, Inc., et al.
No. 7:23-cv-1114 (E.D.N.C.)

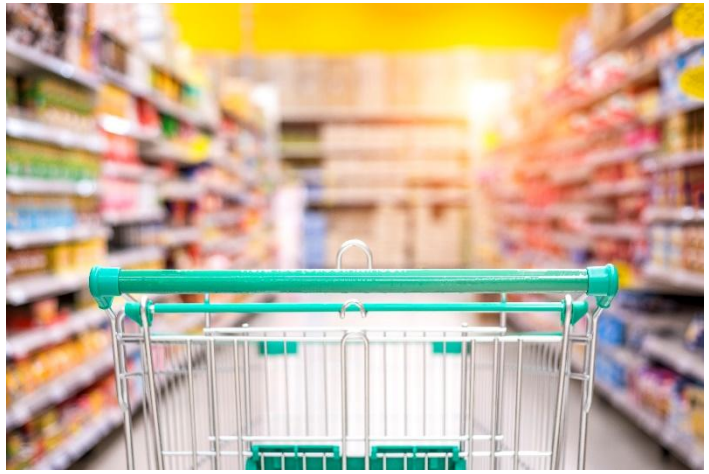
- 60 individual plaintiffs pursuing personal injury and property damage claims against Corteva, DuPont, and Chemours in 8 related EDNC cases

- Claims relate to alleged contamination of the Cape Fear River by DuPont's Fayetteville Works Plant

- Court granted motion for *Lone Pine* case management order requiring plaintiffs to submit expert declarations confirming their injuries and proximate causation

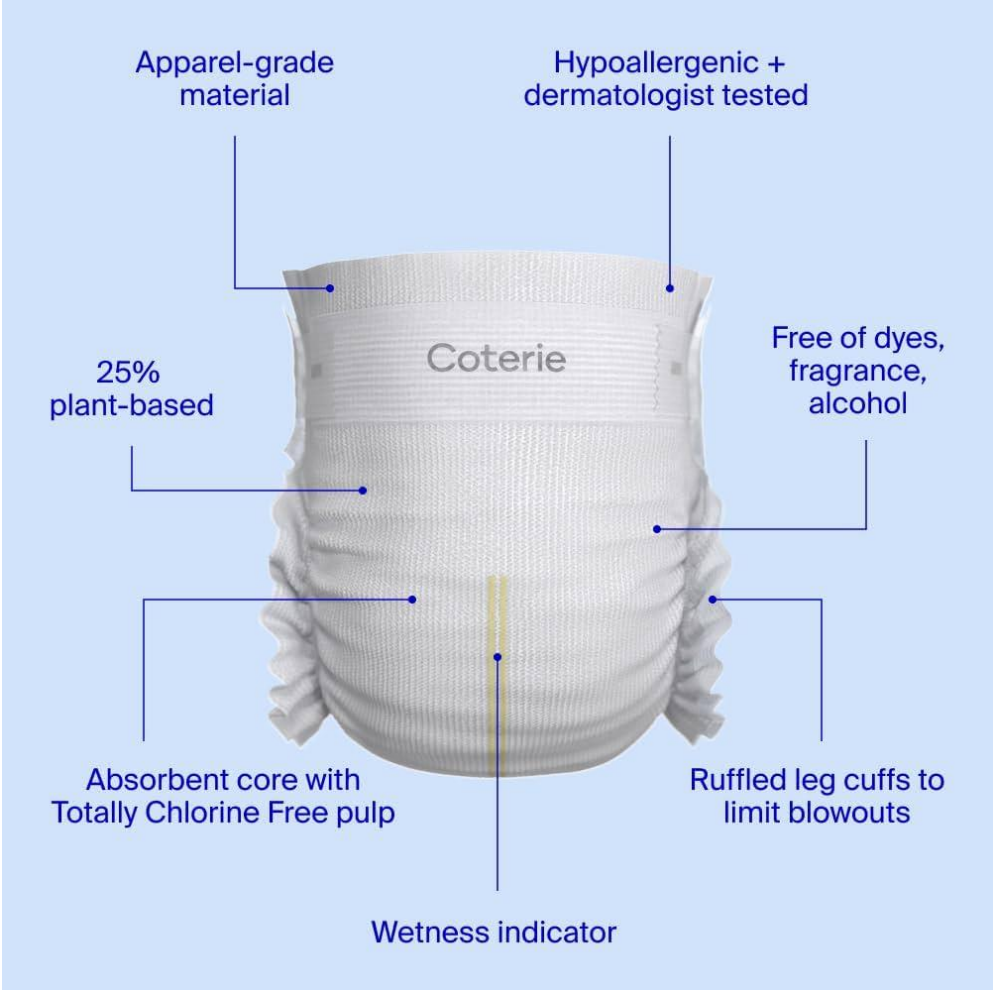
Consumer Product Claims

- Fastest growing area of PFAS claims with significant emphasis on food/beverage products and consumer products
- Putative class actions based on state consumer protection statutes that prohibit false or deceptive advertising practices
- Common facts:
  - Alleged presence of PFAS in a product, and
  - A marketing claim that is allegedly incompatible with the presence of PFAS (e.g., that the product decomposes over time or is “natural” or “environmentally friendly”)



Saedi v. Coterie Baby, Inc.
No. 24-cv-3893 (S.D.N.Y)

- Putative class actions bringing mislabeling claims based on alleged presences of harmful PFAS in baby diapers
- Website explicitly stated products were PFAS-free
- Complaint dismissed for lack of standing because plaintiff did not adequately allege the diapers she bought actually contained PFAS
- Study from independent third-party lab that tested a Coterie diaper before plaintiff received her subscription was not enough to establish standing



Bounthon v. Proctor & Gamble
No. 23-cv-00765 (N.D. Cal.)

- 1 of 3 proposed class actions bringing mislabeling claims based on the alleged presences of harmful PFAS in tampons
- Plaintiffs said they conducted total organic fluorine (TOF) analysis to determine that PFAS present in Tampax products
- Granting motion to dismiss, court found plaintiffs had not plausibly alleged that the presence of organic fluorine indicated that the tampon products contained PFAS
- Even if TOF was reliable, plaintiffs failed to allege PFAS levels were harmful, based on California Health & Safety Code

Bullard v. Costco, et al.
No. 24-cv-03714 (N.D. Cal.)

- Putative class action bringing mislabeling claims based on the alleged presence of harmful PFAS in baby wipes

- Court denied motion to dismiss amended complaint, where plaintiff identified the three specific PFAS chemicals she contends were found in the product, and in what quantities

- "[T]he viability of Bullard's claims does not turn on her ability to prove the identified PFAS in the product are actually unsafe. . . . Having now named the chemicals, Bullard has stated sufficient facts to support a plausible claim of economic injury."

Questions?