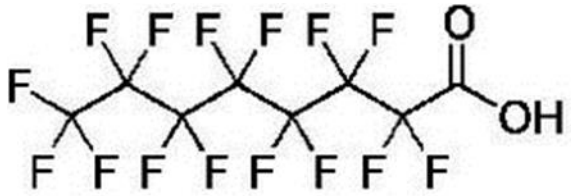

C8 (PFOA) Medical Monitoring Program as Component of a Class Action Settlement

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Objectives

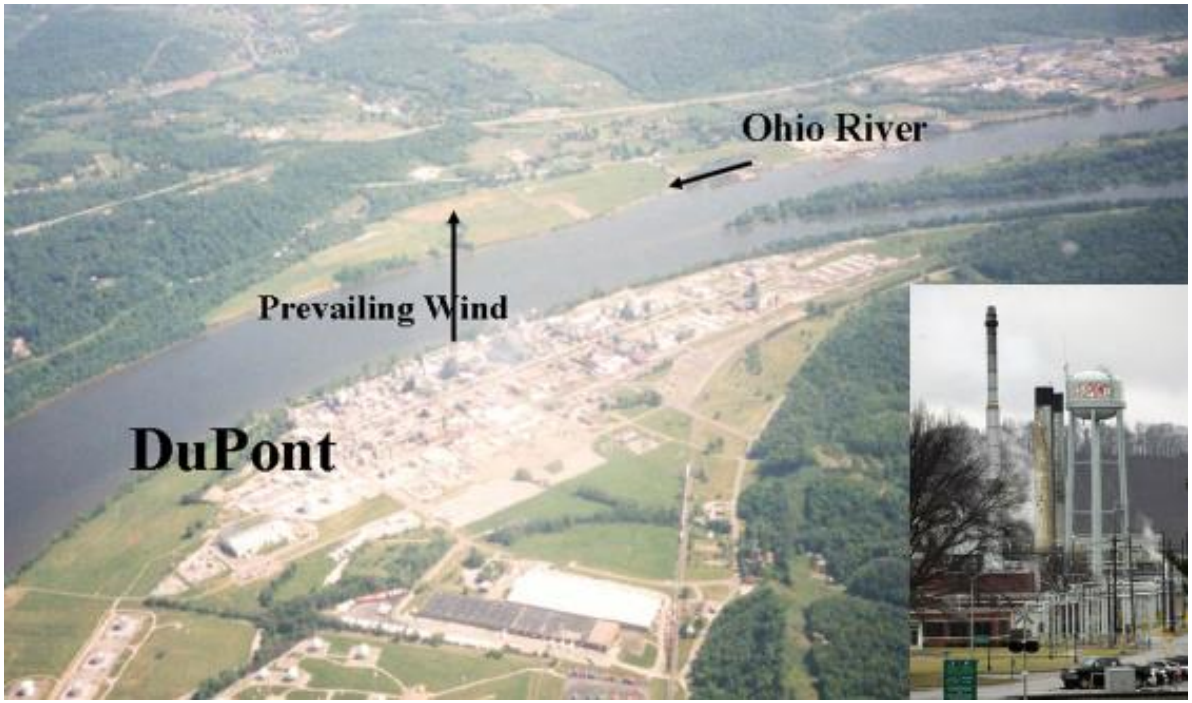
- Describe large-scale environmental exposure to PFOA from DuPont production facility and resulting class action lawsuit
- Identify criteria and directives for developing medical monitoring protocols in context of a class action lawsuit
- Discuss medical and scientific issues that must be considered in developing medical monitoring programs in context of environmental class action lawsuits

Context

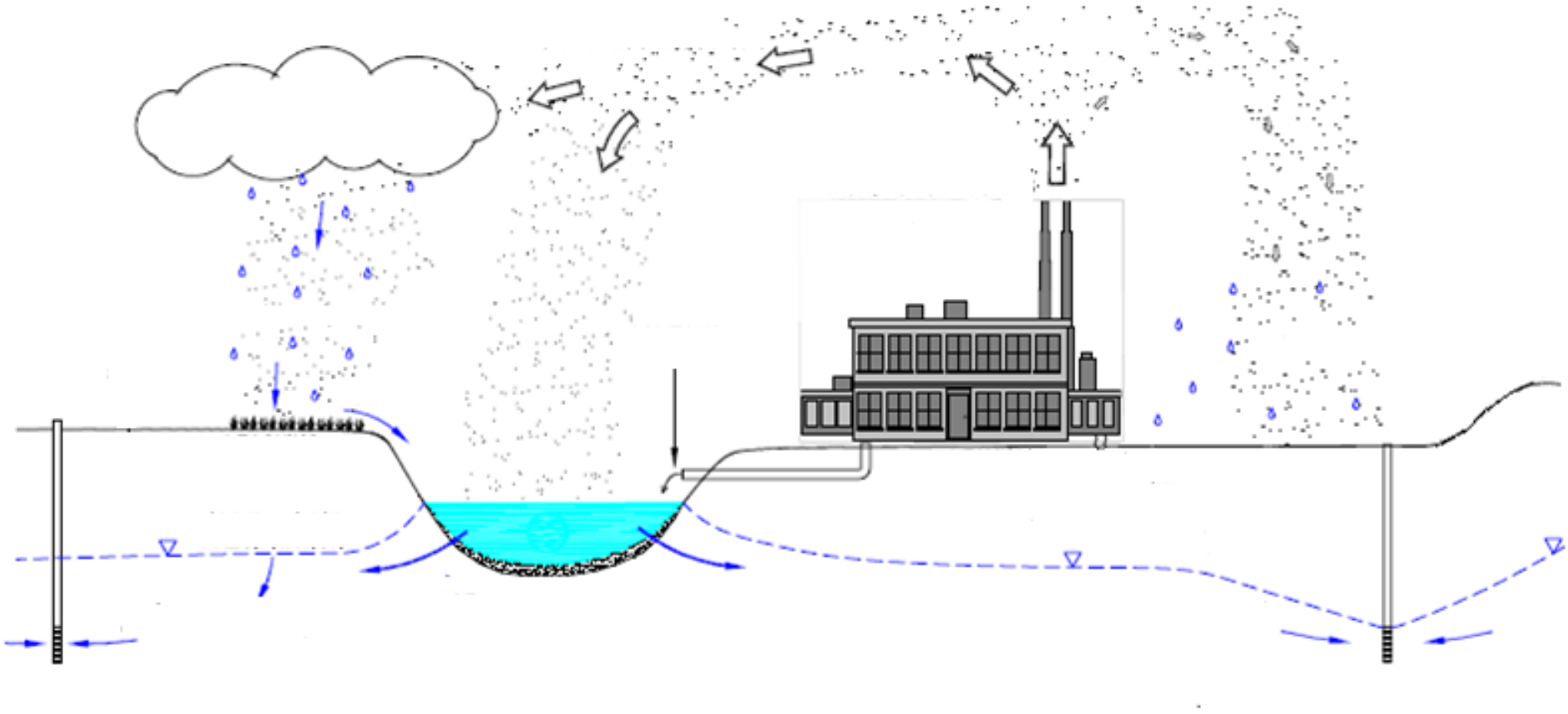
- **Medical Monitoring Claims**
  - Lawsuit in which plaintiffs claim medical testing to detect future health issues for which a plaintiff may be at increased risk due to “tortious” toxic exposure.
  - Variation in allowability and elements by states.
- **Medical Monitoring Class Action Suits**
  - Class action certification varies by courts.
- **West Virginia Supreme Court**
  - Bower v. Westinghouse Corporation
  - Allowed recovery of medical monitoring costs “where it can be proven that such expenses are necessary and reasonably certain to be incurred as a proximate result of a defendant's tortious conduct.”
  - Present physical harm is not a prerequisite to bring a claim for medical monitoring.

DuPont Washington Water Works

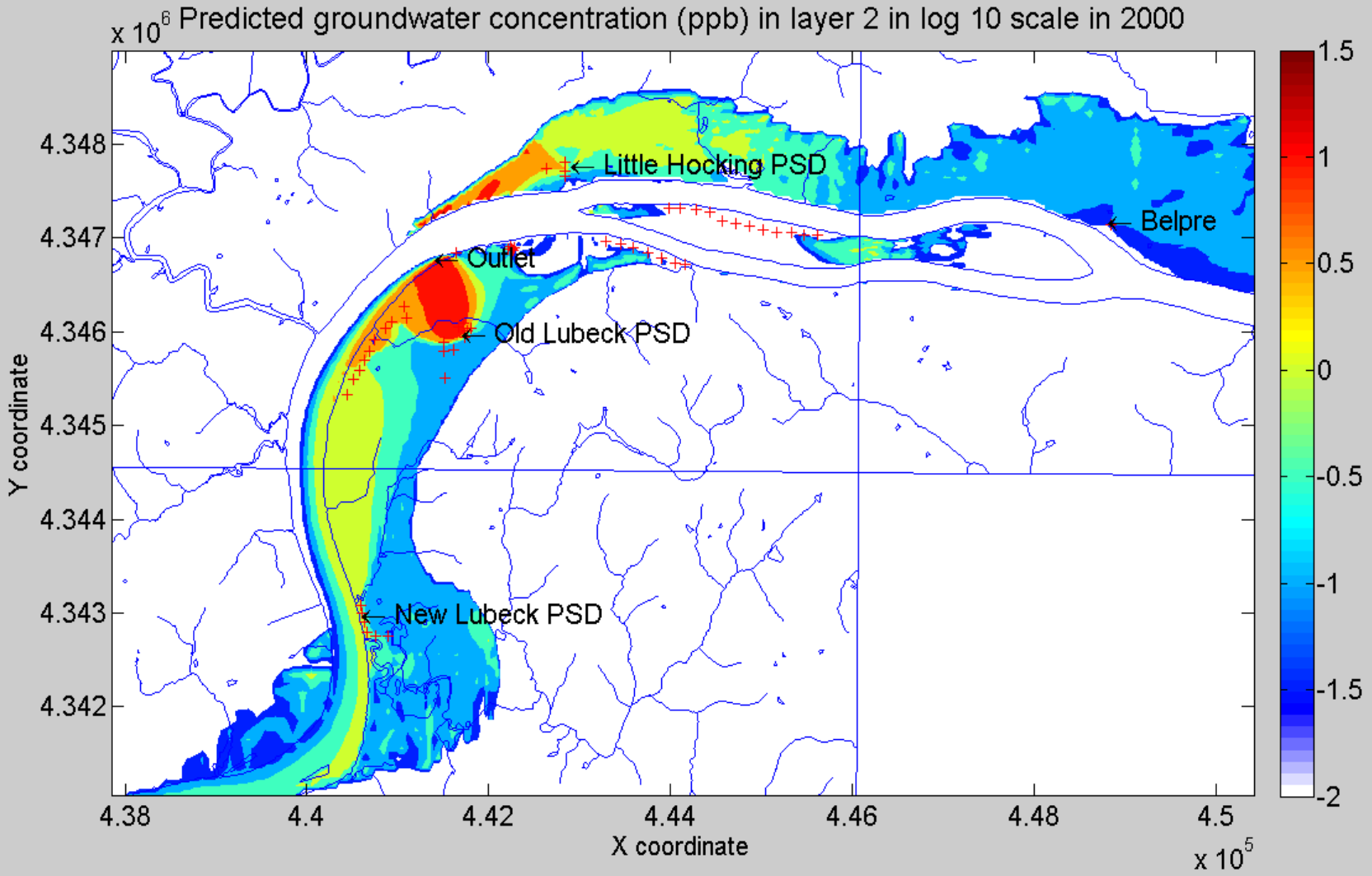
- **Fluoropolymer production plant in Washington, WV**
- Began in late 1950s, peaking in late 1990s
  - Released several hundred tons of PFOA into air and Ohio River; transported into Mid-Ohio Valley water supplies



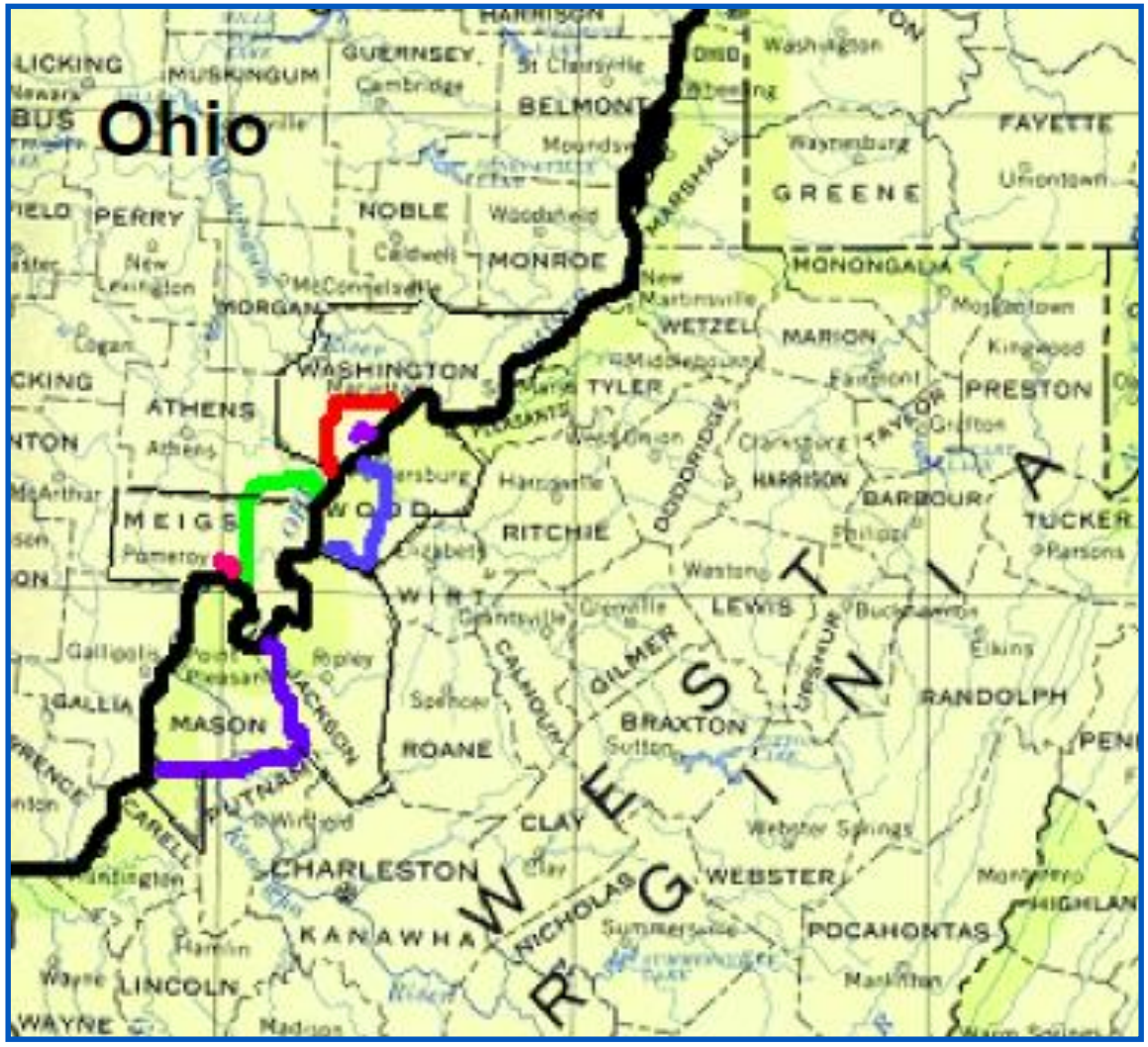
Schematic Transport Pathways



Source: Data Assessment Report, DuPont (2008)

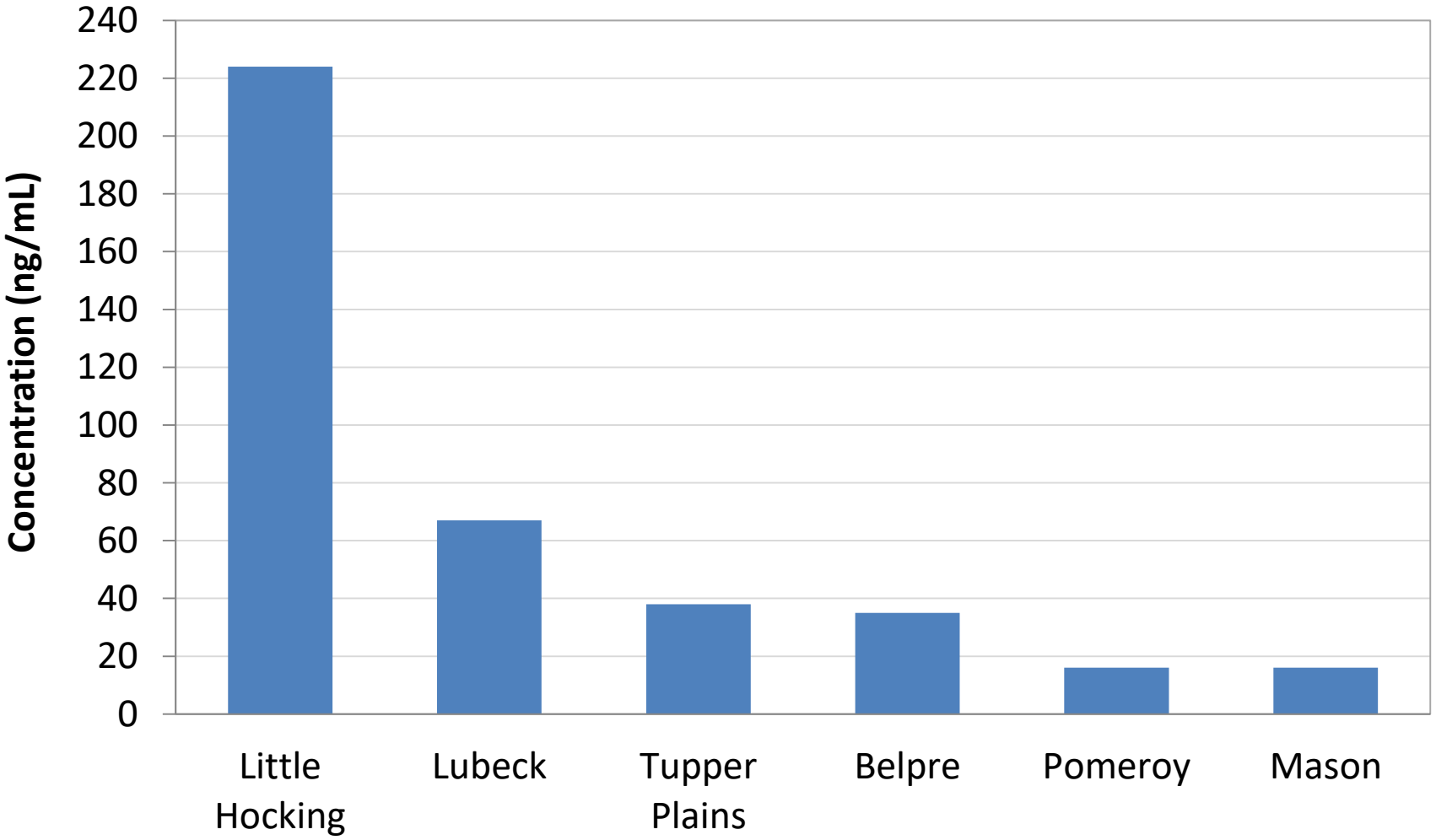

x 10^6 Predicted groundwater concentration (ppb) in layer 2 in log 10 scale in 2000
Little Hocking PSD
Belpre
Outlet
Old Lubeck PSD
New Lubeck PSD
Y coordinate
X coordinate
x 10^5
4.348
4.347
4.346
4.345
4.344
4.343
4.342
4.38
4.4
4.42
4.44
4.46
4.48
4.5
1.5
1
0.5
0
-0.5
-1
-1.5
-2

Six Water Districts of DuPont Lawsuit



Little Hocking, Lubeck, Belpre, Tupper Plains, Pomeroy, Mason

Median PFOA Concentrations by Water District



From: Steenland et al., 2009

C8 Class Action Lawsuit

- Leach, et al. versus E. I. DuPont de Nemours and Company – certified in Circuit Court of Wood County, West Virginia
- Class includes all people within six water districts, or users of private water wells, whose drinking water was contaminated with C8 from Washington Works plant
  - Water districts are Little Hocking, Ohio; Lubeck Public Service District, West Virginia; City of Belpre, Ohio; Tuppers Plains, Ohio; Mason County Public Service District, West Virginia; Village of Pomeroy, Ohio.
  - To qualify a person must have lived in area for at least one year prior to December 3, 2004.
  - Class includes 80,000 individuals.

C8 Class Action Settlement (2005)

- **Water Treatment Project** – filtering and remediation
- **Community Health Project**
  - Cross-sectional study of 69,030 people (2005-06)
- **Science Panel studies** (2005-13)
  - Panel of three epidemiologists to assess whether or not there is a probable link between C8 exposure and human disease in the community
  - Analyzed data from C8 Health Project, conducted additional studies, reviewed literature for animal toxicology and human epidemiological studies
- **Medical Panel** – medical monitoring of Probable Link Conditions (since 2013)

C8 Science Panel Findings

- **"Probable Link"** – based upon weight of available scientific evidence, it is more likely than not that there is a link between exposure to C8 and a particular human disease
  - Criteria: strength and consistency of associations, evidence of exposure-response, possibility of chance associations, and plausibility based on toxicology
- Probable Link establishes "general causation" not particular causation in individual Class Member

C8 Science Panel Findings (cont.)

- **Probable Link Findings**
  - Hypercholesterolemia
  - Thyroid Disease
    - Hyperthyroidism, hypothyroidism
  - Ulcerative Colitis
  - Testicular Cancer
  - Kidney Cancer
  - Pregnancy-Induced Hypertension
    - Gestational hypertension, preeclampsia
- ***No probable link for other diseases***

C8 Medical Panel

- Medical Panel to develop guidelines for medical monitoring for the six Probable Link conditions
- Members were jointly selected by mutual agreement of the Settling Parties:
  - Dean Baker, MD, MPH
  - Melissa McDiarmid, MD, MPH, DABT
  - Harold Sox, MD
- Limited to Probable Link Conditions and must adhere to Settlement Agreement provisions
- Must deliberate in private
- No involvement in Program implementation, oversight or evaluation

Criteria for Medical Monitoring

(from Settlement Agreement)

- **Necessity of Diagnostic Testing**
  - Increased risk of the disease must make it reasonably necessary for Class Member to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of C8 exposure.
  - Diagnostic testing must be something that a qualified physician would prescribe based upon demonstrated exposure to a particular toxic agent.
  - Factors such as financial cost and frequency of testing need not necessarily be given significant weight.
  - Determination may be based, at least in part, upon desires of a Class Member for information concerning the state of his or her health.

Criteria for Medical Monitoring

- **Existence of Monitoring Procedures**
  - Medical Monitoring for the Human Disease(s) addressed in a Probable Link Finding must be available.
  - It is not, however, necessary to show that any treatment currently exists for any Human Disease(s) addressed in a Probable Link Finding.
- **Standard of Care**
  - Medical Monitoring that the Class Member's personal physician would have prescribed for the Class Member even if the Class Member had not been exposed to C8 shall not qualify for reimbursement from the Medical Monitoring Fund.

Medical Panel Approach

- Discussed criteria, strategies, and methods
- Gathered information and wrote protocols
  - PubMed literature search for medical surveillance and diagnostic testing for each condition
  - National Guideline Clearinghouse (http://www.guidelines.gov)
  - MD Consult, “UpToDate” – guidelines, articles
  - Consulted with leading experts on conditions
- Panel discussed and updated protocols
  - Initial protocol report in May 2013
  - Recommendations related to onset of new symptoms in Fall 2013
  - Recommendations related to periodicity and duration of medical monitoring in Fall 2014
  - Updated protocols in Spring 2021

Issues Addressed by Panel

- **Monitoring includes screening & diagnostic tests**
  - "Medical Monitoring" shall mean diagnostic medical examinations, tests or procedures to detect Human Disease.
- **Eligibility for protocols among Class Members**
  - Quantification of risk is not necessary –> did not stratify on water district, estimated PFOA exposure or excess risk
  - Eligibility could be defined by personal characteristics
    - Age – underlying risk can affect positive and negative predictive value of screening tests
    - Sex – e.g., prostate cancer in males
    - Pregnancy status – e.g., pregnancy-induced hypertension
    - Prior diagnosis of condition

Issues Addressed by Panel (cont.)

- **Criteria for periodic medical examinations – different from standard medical screening criteria**
  - Criteria to conduct testing do not conform to standard criteria for screening in a general non-exposed population.
    - Cost and frequency need not given significant weight
    - Not necessary to show that any treatment exists for the probable link condition or that early diagnosis and treatment improves outcomes
    - Medically advisable does not preclude determination based upon desires of Class Member for information
  - However, the screening and diagnostic tests should be standard tests recommended in guidelines, textbooks, and the medical literature.

Issues Addressed by Panel (cont.)

- **Eligibility for screening versus reimbursement**
  - Eligibility for medical screening based primarily on age and sex, assuming all Class Members are at increased risk
  - Payment for screening from Settlement funds or personal medical insurance based on consideration of whether personal clinician would have ordered even if Class Member had not been exposed to C8
    - Had to determine “standard of care” for ordering each medical test in general non-exposed population

Issues Addressed by Panel (cont.)

- **Shared decision-making**
  - Class Members should discuss the screening decision with a health professional as part of screening process.
    - Clinicians should discuss potential risk of diagnostic tests.
- **When to stop screening**
  - Is it possible to model disease risk based on considerations of estimated PFOA exposures, toxicokinetics, disease mechanisms, latency, and duration of elevated risk of potentially reversible conditions in response to changes in PFOA exposure or body concentrations.
  - Would it be possible to monitor target diseases in Class Members to determine when the incidence falls to a level consistent with baseline exposure? Is it pertinent to monitor serum PFOA as a biological indicator of potential risk.

Medical Monitoring Protocols

- **Eligibility**
  - Class Members are eligible to begin participation at any time.
  - Members are eligible regardless of past PFOA exposure, current serum PFOA, place of residence, or water district.
- **General screening**
  - General screening at any time to Class Members who have not yet participated and every three years to participants following their previous general screening.
  - Three categories of Probable Link Conditions:
    - Hypercholesterolemia, Thyroid Disease: screening blood tests
    - Thyroid Disease, Ulcerative Colitis, Testicular Cancer, Liver Cancer: screening by Program questionnaire and age-specific examinations
    - Pregnancy-Induced Hypertension: screening as part of “regular” care
  - PFOA blood test at each round of general screening

Medical Monitoring Protocols (cont.)

- **Symptom-related screening**
  - *Thyroid Dysfunction, Ulcerative Colitis, Testicular Cancer, Renal Cancer*
  - Offered to Class Members who believe they have developed new or substantially changed symptoms.
  - Symptoms and risk factors are evaluated by Program clinicians to assess need for diagnostic testing.
  - Can be screened again as frequently as every six months between general screenings.
- **Pregnancy-related screening**
  - Screening TSH as early as possible during pregnancy and blood test for serum PFOA if not previously measured.
  - Measure blood pressure and test urine for protein at each “regular” prenatal visit. Offer home blood pressure monitor.

Hypercholesterolemia

- **Eligibility** – Class members who have not been diagnosed or taking medications to lower cholesterol
  - The Program Director and Settling Parties decided to offer screening to all participants regardless of age or sex.
- **Screening** – fasting serum lipid profile test; non-fasting is an acceptable alternative. Obtain directly measured LDL-cholesterol if non-fasting triglyceride is greater than 400 mg/dL
- **F/U Screening test** – repeat lipid profile test in 2 to 4 weeks if total serum cholesterol is high or borderline high; average results of two tests
- **F/U Diagnostic tests** – none

Thyroid Disease

- **Eligibility** – Class members age 15 years and older who have not been diagnosed or are being treated for thyroid dysfunction
- **Screening** – Screen for symptoms and serum TSH using Thyroid Cascade Profile test (TSH, free T4, TPO Ab)
- **F/U Screening tests** – If TSH is abnormal and FT4 is normal, repeat tests in 4 to 8 weeks.
- **F/U Diagnostic Tests** – algorithm of diagnostic tests which depend at each stage on findings of earlier tests. Tests include free T4, free T3, TPO antibodies, Thyroid-releasing hormone, T3 suppression test, thyroid stimulating immunoglobin, radioactive iodine uptake test, thyroid gland scan, thyroid ultrasound.

Ulcerative Colitis

- **Eligibility** – Class members age 15 years and older unless previously diagnosed
- **Screening** – symptom and risk factor questionnaire
  - Chronic or bloody diarrhea, abdominal pain, weight loss
  - Risk factors: ethnicity, food intolerance, food poisoning or antibiotic use, foreign travel
- **F/U Diagnostic Tests** – if suggestive symptoms:
  - colonoscopy or sigmoidoscopy biopsy; stool testing for *C. difficile* and other pathogens; other tests as indicted (CBC, ESR, C-reactive protein)

Testicular Cancer

- **Eligibility** – Male class members
- **Screening** – Symptom screening questionnaire
  - Age than 50: questionnaire and testicular exam
  - Age 50 and older: questionnaire, but testicular exam not recommended for asymptomatic males
- **F/U Diagnostic Tests** – ultrasound for males with symptoms or other risk factors
  - if suggestive or abnormal ultrasound:
    - additional imaging with CT abdomen and scrotum, CXR
    - tumor markers (alpha feto-protein, beta human chorionic gonadotropin and lactate dehydrogenase)
    - Inguinal exploration and orchiectomy or testis-sparing biopsy may be considered

Kidney Cancer

- **Eligibility** – Class members 20 years and older
- **Screening** – symptom screening questionnaire
  - Age 20 to 39: symptom questionnaire only
  - Age 40 and older: symptom questionnaire, abdominal examination and dipstick urine test for hematuria
- **F/U Diagnostic Tests**
  - if gross hematuria, or abdominal mass: abdominal CT or MRI and referral to urologist
  - If suggestive or abnormal imaging study, additional tests for assessment of metastatic cancer may include CXR, CT chest, imaging study of brain, or bone scan

Pregnancy-Induced Hypertension

- **Eligibility** – all pregnant Class Members
- **Screening** – Measure blood pressure and urine protein at every prenatal visit; obtain at least one serum TSH as early as possible in pregnancy
  - Offer home blood pressure monitoring device at request of Class Member
- **Standard of Care for screening**
  - Guidelines and medical authorities recommend same prenatal care protocols for high and low risk patients, so the Medical Monitoring Program does not provide reimbursement except for home blood pressure monitoring device

Medical Monitoring Periodicity

- Based on literature review, the Medical Panel concluded that there are no standards on how frequently screening tests should be done.
  - Some guidelines, such as those of the United States Preventive Services Taskforce, discuss these issues and the Medical Panel took them into consideration.
- The Panel recommended that the period between general screening be three years.

Medical Monitoring Duration (when to stop)

- Challenging issue because scientific and medical literature do not provide adequate "evidence-base" for issues, such as biological mechanisms of action, latency and duration of elevated risk even if serum PFOA concentrations return to general population background levels.
- Decisions about when monitoring could be stopped may vary by Probable Link Condition and could be different for individual Class Members.
- As of 2021, the Panel has not made specific recommendations on when monitoring could be stopped for any Probable Link Condition or for individual Class Members.

Ongoing Tasks

- Monitor literature for advances in medical screening and diagnostic tests for probable link conditions
  - Determine if screening and diagnostic protocols are consistent with current standards of medical care
- Conduct literature reviews on scientific knowledge about PFOA exposure, serum PFOA, and associations with health effects
  - Focus on toxicology and epidemiology literature about mechanisms of action, estimated latency periods, and duration of elevated risk following exposure
- Develop recommendations whether monitoring protocols should be revised or monitoring stopped