Class Action Lawsuits
Can They Advance Epidemiologic Research?

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A recent pollution-related court case and associated research program suggest an important source of funding for research on environmental hazards—one that may have broad relevance to future work in environmental epidemiology. We recently completed such a research project.

Class action lawsuits in the United States claiming health harm from environmental contamination (also known as "toxic tort" cases) have become famous through such popular films as "Civil Action" (Woburn, Massachusetts water contamination with solvents, associated with childhood leukemia) and "Erin Brockovich" (Hinkley, California water contamination with hexavalent chromium associated with cancer). Other well-known cases include polychlorinated biphenyls (PCBs) contamination of soil and water in Anniston, Alabama, and perchlorate contamination of groundwater in Morgan Hill, California.

In many toxic tort cases, community residents allege property damage, mental anguish, and damage to their health. Settlements reached either in court or prior to a trial include payment to community residents (the "'class") and their lawyers, but without resolving the disputed question of whether the exposure actually caused adverse health effects. Rigorous epidemiologic studies are rarely conducted, though both sides typically assemble evidence (often selective and of low quality) and recruit experts who attempt to use scientific evidence to bolster their respective cases. A recent exception to this pattern was a rigorous epidemiologic study of health effects related to steel mill contamination in Taranto, Italy, under guidance from a court, albeit with limited funding (Forastieri et al., ISEE annual conference, Basel, 2013).

A 2004 settlement of a class action lawsuit in West Virginia and Ohio followed an alternative path in a toxic tort case, one that may serve as a model for other such cases. A DuPont manufacturing facility producing PFOA (perfluorooctanoic acid, also known as C8, a fluorocarbon used in the production of Teflon) released the chemical into the surrounding area and contaminated the water supplies. Mean PFOA blood levels in 2005 in affected communities were 82 ng/ml compared with 4 ng/ml in the US population, unambiguously demonstrating that people were exposed to markedly elevated levels of this compound.

In the early 2000s, toxicologic evidence indicated that PFOA was an animal carcinogen and reproductive toxin and that it altered liver enzymes, immunotoxicity, and lipid profiles in rodents. Community residents sued DuPont in 2001 in a class action, alleging damage to the health of residents of the affected area. The 2004 settlement was unusual, in that the opposing sides agreed to establish a panel (the C8 Science Panel), consisting of three epidemiologists (the present authors), who were charged with the task of determining whether PFOA was indeed linked to damage to the health of the residents of this community. The Panel was to generate information needed to make an assessment and reach a judgment about whether disease was "more probably than not" linked to PFOA. The criterion for probable link comes from the common law concept of a cause being more likely than not, as distinct from the criminal law burden of "proof beyond reasonable doubt." Three panelists were appointed to preclude a tie in voting. According to the terms of the settlement, if we found one or more diseases linked to PFOA, a medical panel was to be set up to determine whether there was an effective screening for that disease, in which case DuPont would pay for such screening. Furthermore, at that point, people with the disease in question would be free to sue DuPont for damages.

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The legal settlement recognized that the Science Panel had to have complete independence from the time we were chosen through the dissemination of results. We were selected jointly by the lawyers for plaintiffs and defendants (the "settling parties") to ensure our neutrality. This avoided the danger of each side hiring "their own" epidemiologists, whose work could easily be regarded as biased. Our research was then monitored (although not influenced) by the attorneys from both sides, and research funds were administered by a separate firm and overseen by the Court. We were careful to re-emphasize at critical points our neutrality and independence, in response to pressure from one side or the other, from the judge, from members of the affected community, or from the press. We engaged the services of three prominent epidemiologists to provide initial peer review of our study proposals. Subsequent peer review was ensured by submitting all research supporting our probable link judgments to peer-reviewed journals. We did not reach "probable link" judgments until we were sufficiently satisfied that our results would stand up to journal-quality peer review.

A baseline survey (the C8 Health Project) of 70,000 residents of the five contaminated water districts (the "class") was to be carried out under the settlement. In this survey, affected residents who proved their eligibility based on having been exposed to contaminated water supplies came to recruitment centers to provide a medical history and to donate blood used to measure PFOA and clinical chemistry. The baseline survey was conducted by local contractors not by the C8 Science Panel. That survey was completed in 1 year at a cost of $70 million. Residents were paid $400 for participation, large for an incentive but also considered a form of compensation. Given this incentive, there was a very high participation rate—over 85% of current residents.

As the work proceeded, we had to confront ways in which the terms of the settlement were designed without appreciating the nature of research in environmental epidemiology. The attorneys had envisioned a two-stage process, in which a quick screening study based on inadequate data would trigger a more detailed second-phase study if the initial results were positive. The C8 Science Panel successfully argued that the two-phase idea risked false-positive and false-negative associations, that it would be inefficient to do part of the work and stop before proceeding to completion, and, further, that the various health endpoints (eg, reproductive vs. chronic disease) required multiple studies with different time frames. Furthermore, we argued that we needed additional background studies, including a historical reconstruction of exposure and likely historical blood levels in residents, as well as a study of PFOA half-life to accurately reconstruct exposure. We also argued in favor of longitudinal studies of biological intermediate endpoints, such as liver enzymes and cholesterol, and a cohort study that followed the baseline survey participants. For these additional studies, we needed to invite study subjects to consent to further follow-up by the C8 Science Panel. We finally won that argument, but only part-way through the baseline survey, which in the end limited our ability to ask for consent of all baseline participants (we obtained consent from two-thirds of those eligible). We did not win all arguments. For example, we neither succeeded in including measures of hypertension, height, and weight in the baseline survey nor were we able to collect DNA from the whole sample.

We conducted 12 studies over 5 years (see www.c8sciencepanel.org). These studies were designed and conducted without interference. Our studies included a cohort study with interviews of 32,000 residents and review of medical records for about half of them, a neurobehavioral study of 300 children, a longitudinal study of 800 residents with measurement of clinical and genetic markers, a study of DuPont workers exposed to PFOA, a half-life study of 200 people, several reproductive studies, a geographic study of cancer registrations, and a major exposure-reconstruction effort (fate transport model, residential histories, pharmacokinetic model). The total cost of these studies was around $35 million—far more than would have been possible with funding from federal research agencies.

In the end, in 2012, we made "probable link" judgments for 55 diseases, including 21 cancers and a number of conditions such as hypertension and hypercholesterolemia that are considered diseases even if asymptomatic. Of these, we concluded that six were more probably than not linked to PFOA exposure: kidney cancer, testicular cancer, ulcerative colitis, thyroid disease, hypercholesterolemia, and pregnancy-induced hypertension. To date, we have published 29 papers, with more in development, contributing substantially to the body of research on health effects of perfluorinated compounds (see www.c8sciencepanel.org/publications.html).

Neither the judge nor the plaintiffs were happy with the slow pace of epidemiology. The judge called us to court in 2011 to vent his frustration with our pace. He went so far as to suggest that the settling parties fire us, but fortunately they did not agree. We argued to the court, lawyers, and the public that it was better to take more time and get it right.

We think we were successful. We had very good participation rates from a community that was divided. DuPont is a major employer in the region, and some residents thought the court case (and our research) might run the company out of town for no good reason. Others were suspicious that we might "whitewash" a dangerous chemical. But ultimately we had the impression that most in the community thought we were acting in good faith.

Good community participation was key to the success of our studies, and we took several steps to work toward it. We spoke to the press whenever requested, held several "town meetings" that were widely advertised, and presented interim results often (usually via press briefings) to let people know we were making progress in completing our assignment and to clarify what information we would and would not be able to provide in the end. We hired a local public relations firm to help us with press releases and town meetings, which helped us identify the best mechanisms for reaching the local population.

Will our findings stand the test of time? The Panel endeavored to apply the probable link criterion in deciding if an excess was more likely due to the chemical exposure than chance or bias. As more evidence accumulates, some associations may not be confirmed. Others may be identified that we had missed. Still, we sought to fulfill our charge to deliver a verdict on the array of health outcomes of interest, based on the evidence that could be obtained in a reasonable time frame.

We believe that this undertaking demonstrates that good science with public health relevance can be done even in the middle of a politically and legally tense situation. The process may serve as a model for future toxic tort cases. One key feature, from our perspective, was the joint oversight by opposing parties; this protected us from pressure from either side. There was no doubt that, within the terms of the agreement, each side had an interest in influencing the outcome. But rather than having these opposing interests make the conduct of research more difficult, the opposing goals of the parties actually protected our independence. Ultimately, we believe that we were able to provide evidence that the local population and the scientific community view as unbiased.

An advantage in the toxic tort setting is that such suits involve exposed populations. Exposure above background must be demonstrated for an exposed group to constitute a court-recognized "class." In this case, we were able to study a large population with both high and low exposures (ie, in the normal background range),

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an advantage over most general population PFOA studies that can address only exposure contrasts within the background range.

The typical toxic tort situation requires opposing sides to spend substantial amounts of money recruiting experts and debating the issue, using what is often an insufficient base of informative research. The very fact that these are contentious cases argued in court often indicates that there is insufficient evidence of cause and effect and that thus research is needed. At least one legal scholar has noted the PFOA agreement as a precedent: "in providing for a two-year health study by independent scientists, for example, the PFOA agreement between DuPont and the class action plaintiffs ensured that a great deal of new scientific information on the health risks posed by PFOA would become available to regulatory agencies and the public."[1] This same author notes that "one of the plaintiffs' attorneys hoped that the study would 'provide a real scientific answer to the question ... based on facts and real evidence.'"

It is rational for epidemiologists to argue for support of new research where feasible, to provide a firmer scientific foundation for the legal case and for policy responses to the episode. At the same time, care is needed to ensure that the researchers are protected from special interests of one side or another and that the litigation does not introduce response bias in the population. It is important that investigators be able to select optimal study designs, free from legal restriction. The size of the population and the presence of exposure contrasts are important considerations as well; if the study is underpowered or exposure is homogenous within the exposed population (prohibiting internal analyses of exposure-response trends), false-negative conclusions may be drawn.

However, if these preconditions are met, we believe that the arguments in favor of embarking on these types of studies are persuasive. We would encourage attorneys and expert witnesses to consider this model of funding independent epidemiologic research as a part of the settlement, and we encourage our colleagues to participate when such needs arise.

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REFERENCE

1. McGarity T. *The Regulation-Common Law Feedback*, chapter 11, page 252, in "Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question." Buzbee E (ed.). Cambridge, London: Cambridge University Press, 2009.

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