Public Health and the Law

Fluorides, Facts and Fanatics: Public Health Advocacy Shouldn't Stop at the Courthouse Door

TOM CHRISTOFFEL, JD

During the past several decades, public health professionals have worked hard to educate both the public and policy makers that great care should be taken to scrutinize safety when large populations are routinely exposed to new substances or to common substances in new ways. An Illinois court accepted this principle when it declared that:

> Because public health is at stake the burden [of proof] is *that if* the addition of artificial [substances] to the public water supply *may* have adverse health effect, that must be weighed against the benefits alleged to determine [appropriate standards].[1]

But last fall the Illinois Supreme Court rejected this cautious approach and held that, even where evidence for safety and for benefit is completely lacking, courts should not be the forum to seek protection from alleged health risks. The justices said debate regarding adverse health effects produced by substances introduced into the environment should occur in the legislature, and those unhappy with the result should not be allowed to shift the debate into the courts.[2]

These conflicting judicial opinions offer some important lessons for public health professionals. Ironically, they involve one of the most thoroughly documented successes in public health: community water fluoridation.

Background

Fluoridation of community drinking water was first undertaken in the United States in 1945. Today close to one-half the population of the United States drinks water from community water supplies that have fluoride contents near the optimal level of one part per million (ppm), either naturally or through the addition of fluoride compounds.[3] Numerous studies have borne out the safety and effectiveness of fluoridated drinking water in preventing dental caries.[3–6] A 1982 *Science* article on fluoridation summarized the situation:

> During the past 40 years a large body of research has attested to the efficacy, cost-effectiveness, and safety of fluoride therapy in community water fluoridation, school water fluoridation, fluoridation of dentifrices, professional topical application, and self-administered rinses and tablets. A former US Surgeon General called fluoridation, along with pasteurization, water purification, and immunization, one of the four most important public health measures of our time.[7]

Address reprint requests to Tom Christoffel, JD, Associate Professor, School of Public Health, Health Sciences Center, University of Illinois at Chicago, P.O. Box 6998, Chicago, IL 60680.

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Yet despite the clear evidence and the strong support of dental and public health professionals, fluoridation of public water supplies remains under continual attack by some extremely vocal groups which are associated with the political far right and/or with various unorthodox health claims. "The most active and effective" group, according to *Consumer Reports,* "is the National Health Federation, whose roots run deep into the soil of medical quackery."[8] This opposition has ended or prevented fluoridation of the water supply in numerous municipalities, including Los Angeles, CA, and Levittown, NY, prevailing in at least two-thirds of more than 1,000 local fluoridation referenda.[3,9–11] Rejection of fluoridation has generally been based on campaigns in which opponents argue that fluoridated water can cause fluoride poisoning, allergic reactions, sterility, birth defects, genetic damage, and/or cancer. Use of the courts to invalidate fluoridation programs has had considerably less impact. The courts of the various states have almost routinely upheld fluoridation of public water supplies as a legitimate exercise of state policy power.[3,6,12] In one leading case, the Illinois Supreme Court ruled in 1964 that fluoridation of water was reasonably related to, and suitable and necessary for, the protection of the public's dental health.[13]

It therefore came as a minor surprise when an Illinois trial judge ruled in 1982 that the Illinois law authorizing the fluoridation of public water supplies[14] was an unreasonable exercise of the police power and therefore unconstitutional and invalid.[1] But it did not seem at all surprising when the Illinois Supreme Court subsequently reversed this judgment.[2] At first glance it would appear that a lower level judge, perhaps confused by the scientific concepts involved or perhaps pursuing idiosyncratic beliefs, simply reached a conclusion as intellectually unsound as the anti-fluoride case itself, and that the state Supreme Court acted as a voice of reason and responsibility in overturning the decision. Yet a careful reading of these judicial opinions reveals a quite different situation.

The Anti-fluoridation Case

The lawsuit was brought by the Illinois Pure Water Committee, Inc., and its executive director, alleging that at the levels prescribed by the state fluoridation law (1.0 to 1.2 ppm) a fluoride compound is a "poisonous, noxious and deleterious substance which results in higher incidences of a) various types of cancer; b) aggravation of bone disease; c) aggravation of kidney disease; d) mongoloid births; e) chromosomal and genetic damage in humans; and f) allergic, intolerant and toxic reactions in many sensitive individuals."[2] The plaintiffs therefore argued that the fluoridation

law was unconstitutional as an unreasonable exercise of the state's police power.

To support their case, the plaintiffs presented a series of witnesses well known in the anti-fluoridation effort. The trial judge noted that:

> The plaintiffs witnesses were fanatical in their approach to the litigation and bias permeates the plaintiffs case. . . . The presentation of scientific evidence in this case followed the same basic pattern throughout the trial. The plaintiffs would present evidence of inquiries, experiments and studies that showed fluoride to be a potential health hazard. The defense would then attack the quality of the research and would present evidence showing that the conclusion arrived at by the plaintiffs were erroneous. Plaintiffs would in turn attack defendants conclusions and so it went.

Most notable among the witnesses for the plaintiffs was John Yiamouyiannis, PhD, a biochemist who was at the time serving as Science Director of the National Health Federation. Dr. Yiamouyiannis testified that fluoride compounds inhibit enzymes responsible for the repair of damaged DNA molecules *in vivo*. In the face of defendant's challenge of this assertion, "Dr. Yiamouyiannis admitted that he has done no study of enzyme inhibition and that his conclusions were based on inference." Dr. George Waldbott, an allergist and long-time anti-fluoridation crusader, testified for the plaintiffs that based upon his clinical experience fluoridation could cause allergic and intolerant reactions, including nausea, vision problems, mental slowness, constipation, and bruises. On cross-examination he admitted that he had no formal research training, and that his studies were not double-blind, but relied on personal intuition.

The real heart of the plaintiffs' case came in testimony by Dr. Dean Burk, a cytochemist, who together with Dr. Yiamouyiannis presented the results of their comparison of the 10 largest US cities with fluoridated water and the 10 largest US cities without fluoridated water. They claimed a 4–5 per cent greater increase in cancer death rates in the fluoridated cites over a period of 15 years. Defendants pointed out that Drs. Burk and Yiamouyiannis both lacked formal training in epidemiology and statistics, that this was in fact their first epidemiological study, and that they undertook it as active opponents of fluoridation. Defendants argued that the study lacked any clear hypothesis, was non-random, did not use the best available statistics, ignored confounding variables such as education and employment and historical considerations, adjusted for age, sex, and race variables separately, failed to identify and differentiate cancers according to site and affected area, and—even then—produced a statistically insignificant result.

The Trial Court Rationale

The existing literature is overwhelming in its acceptance of fluoridation as a safe and effective way of preventing dental caries. As an American Dental Association spokesman put it in 1977 Congressional testimony, "Fluoridation may well be the most thoroughly studied community health measure of recent history."[15] Moreover, the trial judge's opinion makes it clear that he was not impressed with the quality of the testimony presented by witnesses for the plaintiffs in their effort to discredit fluoridations. How, then, could the judge have ruled in favor of the plaintiffs? Was this a neanderthal-like reaction to emotionally charged evidence? Is the decision a warning sign of "anti-scientific" court rulings to come?

Generally, public health regulations will be upheld as constitutional if it can be reasonably shown that they are needed to protect and promote the public's health, safety, and general welfare. The courts have repeatedly upheld state public health powers even when individual rights are significantly infringed by the operation of that power and even when no immediate public health danger threatens. In one of the classic statements on the subject, *Jacobson v. Massachusetts,*[16] the United States Supreme Court upheld the authority of state government to compel immunization by imposing a fine for noncompliance. However, the Court did note in that case that "the police power of a state . . . may be exerted in such circumstances, or by regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression." It is not enough for a court to disagree with a legislative judgment; the plaintiff must provide evidence that the legislature has gone too far. The most compelling standard to emerge from the *Illinois Pure Water Committee* case was one of undue risk: legislation which exposes the public to the risk of unhealthy side effects is unreasonable and should be invalidated.

Judges decide cases by applying the law to the facts presented to them. Judge Ronald Niemann, the trial judge, was aware that "There are hundreds of studies and experiments, perhaps thousands, involving the effect of fluoride on living systems." Yet despite 40 days of testimony, involving 11 witnesses and 151 exhibits, "the Court received very little of the vast area of knowledge that has assimilated since the 1940s." The judge noted that:

> It is disappointing to the Court that of available evidence on the subject matter very little was presented for the record. The State was satisfied with trying to discredit the plaintiffs case and not presenting witnesses and studies to help enlighten the Court when it appears much quality data was available. . . . Not once were the roles reversed with the defendants presenting their own *independent* evidence which tended to show that fluoridation of public drinking water is safe.

The judge was therefore faced with that small part of the plaintiffs' case which had not been fully or successfully refuted, "together with the failure of the State to adequately explain the scope of the risks to the public. . . ." As far as the court was concerned, this shifted the burden of proof from the plaintiffs onto the defendant government "to justify its intrusion into the life and health of the individual."

What was the judge to do under such circumstances? The facts missing from the record were not "generally known with certainty by all the reasonably intelligent people in the community."[17] Judge Niemann may have been tempted to do his own research, but this approach is narrowly proscribed for judges. In fact, the judge bemoaned the inability of the current adversary system to deal with this information problem. "It may be," he observed, "that the Court system will need a specialized group of judges in the future who are trained in the technical field underlying the litigation such as bio-chemistry or statistics. At the very least, the rules of evidence need to be altered to permit scientific treatises or experiments under Judicial Notice or as hearsay exceptions."[18]

Judge Neimann took as his guiding principle the view that "decisions that touch the environment and affect the lives and health of all are entitled to a special claim of judicial protection requiring more precision and persuasion than presented by the State in this case." He felt compelled to

rule as he did by the State's failure to provide any evidence regarding the safety of fluoride. He noted that:

> There are important interests resting on the scientific and/or technical judgments of the State. The Court cannot weigh the reasonableness of the State action because of the absence of evidence from the State of Illinois as to how it tests the effects of artificial fluoridation on the public at large. . . . This record is barren of any credible and reputable, scientific epidemiological studies and/or analysis of statistical data which would support the Illinois Legislature's determination that fluoridation of public water supplies is both a safe and effective means of promoting public health. . . . To carry the burden of proof in this case the plaintiffs evidence need not be conclusive that fluoride will cause adverse health effects. Because public health is at stake the burden is *that if* the addition of artificial fluorides to the public water supply *may* have adverse health effect, that must be weighted against the benefits alleged to determine if it is a reasonable exercise of the police power afforded the State.

The judge briefly commented on asbestos, on Love Canal, of PBBs entering the food chain in Michigan, and on toxic shock syndrome. In all of these instances, he suggested, government should have taken a "harder look" when the possibility of harm to humans was first raised. He concluded, "The Court is not satisfied, on the record in this case, that the state has taken a hard enough look at the long term effects on humans of artificial fluoride when added to the Public Water Supply. . . . The legislation that exposes the public to the risk, uncertain in its scope, of unhealthy side effects of artificial fluoridation of the public water supply is unreasonable. . . ." and therefore an unconstitutional exercise of the police power.

The State Supreme Court Decision

Appellate courts are generally limited to reviewing whether the lower court has correctly applied the law, and are required to accept the factual determinations made by the lower court. Here the lower court ruled as it did because of a lack of evidence regarding safety, and the Supreme Court could not get safety information on its own. At the same time, however, it faced a lower court decision which invalidated an important public health program.

The Court's way out of this seeming dilemma was simply to "find that plaintiffs have not sustained their burden of showing that the fluoridation statute is so unreasonable as to be invalid." The high court noted that it accepted the long-established "principle that courts will not interfere with legislation falling within the orbit of a municipality's police power unless there is a palpably arbitrary or unfair exercise of the power."[19]

> We construe the circuit court's . . . [opinion to say] . . . that plaintiffs have shown, not that the risk was so great that fluoridation was unreasonable, but that the question was shown to be debatable. Under these circumstances plaintiffs have failed to show an unreasonable exercise of the police power. . . .
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> On this record, we conclude that the evidence shows, at most, the existence of a debate upon the dangers and benefits of fluoridation . . . "At best there is room for difference of opinion, and . . . it is enough to say it is an area in which the legislative judgment must prevail."

Comparing the Two Decisions

From a public health perspective, the Supreme Court decision reached the proper result: fluoridation of public water supplies may continue in Illinois, whereas the lower court decision would have had at least temporarily ended the practice. But judicial opinions are prized more for their rationales than their results, and the Illinois Supreme Court decision establishes a troubling precedent. Stripped of the peculiar fact situation involved, i.e., the State's failure to present relevant and readily available evidence, the decision holds that the police power of the state allows the state to engage in practices of potentially harmful effect to the entire population without any legal obligation either to establish the safety of the practice or to demonstrate significant benefit from the practice. If this were an issue in which the safety decision had to be made by weighing the best available scientific evidence, then the court's deferral to the legislative judgment would be understandable, and consistent with accepted doctrines regarding the appropriate scope of judicial review. But here, *where there is nothing in the record to support the legislature's rationale,* the Illinois Supreme Court seems to be rejecting any role for the courts as safeguards for protecting the public's health. In the long run, therefore, the appellate court's decision may be more damaging to public health than the lower courts invalidation of the fluoridation law (which the legislature could always have re-enacted in light of the safety evidence the court lacked).

There is another important reason for favoring the wisdom of Judge Neimann's approach. The anti-fluoridation activists have a clear strategy. They are not concerned with drawing conclusions from data, but use data to create an aura of scientific controversy. Simply refuting the anti-fluoridationist's arguments plays into their hands by highlighting the "debate". It is important, instead, to emphasize the positive, to stress the fact that this is not an area of unsettled controversy but rather a matter that has been well studied and in which conclusions regarding safety and efficacy are clear. Moreover, it is important to emphasize that *failure* to fluoridate carries a certainty of increased dental caries such that the caution factor works in both directions. Public health professionals must be clear and *consistent* in promoting two key ideas: 1) that society should take great care to scrutinize safety when large populations are exposed to new substances or to common substances in new ways; and 2) that there are public health policies of proven worth and safety and these should be strongly supported in all forums, including the courtroom, as forcefully and as frequently as possible.

In *Illinois Pure Water Committee,* the dental and public health experts participated by successfully refuting virtually all of the bad science presented in the plaintiffs' case. Yet they lost, and lost on what should have been a winner. Similar losses have been occurring on an even broader scale in local anti-fluoridation referenda. This suggests that it is not enough to merely refute misinformation, and may not even be enough to simply provide scientific facts while staying distant from the political-legal-media battle. To function solely as a source of expert information is to abdicate responsibility and guarantee losing. In the case of *Illinois Pure Water Committee,* it meant prolonging the ordeal and winning final victory at the expense of a state supreme court decision that is bad precedent for public health protection. To be effective, public health professionals must be advocates, whether they like it or not. They should use every possible forum to push the public health agenda. Facts will not persuade on their own; they must be put to use. Whether they are used wisely or not is up to the public health community.

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Call for Abstracts for
APHA Late-Breaker Epidemiology Exchange Session

The Epidemiology Section will sponsor a Late-Breaker Epidemiologic Exchange on Wednesday, November 20, at APHA's Annual Meeting in Washington, DC. The Exchange will provide a forum for presentation of investigations, studies, methods, etc., which have been conceived, conducted, and/or concluded so recently that abstracts could not meet the deadline for submission to other Epidemiology Sessions. Papers submitted should report on work conducted during the last 6–12 months.

Abstracts should be limited to 200 words; no special form is required. Abstracts should be submitted to

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Abstracts must be received by October 1, 1985.