SCIENCE EXPERIMENT

Industries Are Using a Landmark Case and a 2001 Law to Block Regulation, Critics Say

MARK HANSEN

Since 1986, every aspirin bottle sold in this country has carried a label warning that consumption by children with viral illnesses increases the chances of contracting Reye’s syndrome, a rare but potentially deadly disease.

The Food and Drug Administration mandated the warning after scientific studies showed that children with colds, flu or chicken pox who took aspirin were more likely to develop Reye’s syndrome than those who didn’t.

Experts regard that development as a public health tri-umph, but a bittersweet one. The warning labels have helped save lives. But, they say, many children became disabled or died from Reye’s syndrome while the aspirin industry fought the government’s efforts. The industry had argued that the scientific evidence for such a warning was incomplete, unclear or uncertain.

The aspirin industry didn’t invent the strategy of questioning the underlying science, says David Michaels, an epidemiologist at George Washington University. Corporations have successfully used that tactic for decades, says Michaels, an assistant secretary of energy in the Clinton administration who is writing a book on the subject.

But the strategy has become so common that it is almost unheard of for the science behind a proposed public health or environmental regulation to go unchallenged, no matter how strong or conclusive the evidence is, according to Michaels and other experts in public health and environmental law.

A LOT ON THE LINE

“When there’s a lot on the line financially,” says Wendy Wagner, a University of Texas law professor who specializes in environmental and regulatory law, “it’s always going to be in a corporation’s interest to challenge the underlying science—sometimes illegitimately.”

Industry officials say it is ludicrous to suggest that corporations raise scientific uncertainty to delay or defeat government regulation. The uncertainty is real, they say, and it ought to be acknowledged.

“Our position is that every ounce of scientific information that is part of the public debate should be open, available and accessible to everyone,” says Bill Kovacs, vice president for environment, technology and regulatory affairs for the U.S. Chamber of Commerce.

But academics are taking a closer look at two legal developments that, they say, may have exacerbated the trend. Both have altered people’s understanding of how scientific evidence is gathered.

One is the U.S. Supreme Court’s landmark 1993 decision, Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, which requires federal judges to act as gatekeepers and to admit only evidence that they find relevant and reliable.

The other is the 2001 Data Quality Act, which allows anyone who believes that information disseminated by a federal agency is not of sufficient “quality, objectivity, utility or integrity” to request that the information be corrected.

Those two developments, the critics argue, allow—if not encourage—a piece-by-piece examination of scientific evidence rather than the weight-of-the-evidence approach that most scientists prefer. The result, they say, is that opponents of regulation can pick and choose pieces of data to attack the entire premise of a regulation.

For example, Michaels says, take the cases involving Parlodel, a lactation-suppressing drug taken by non-nursing new mothers in the 1980s and early 1990s.

Citing case reports and animal studies showing that Parlodel can cause a rapid rise in blood pressure in humans, the FDA asked the drugmaker in 1985 to include
warning labels. Yet when several women later sued the
drugmaker, claiming Parlodel was responsible for their
injuries, their cases essentially were thrown out of court
for lack of scientific certainty, Michaels says.
“Applying the Daubert rule, those judges demanded a
level of certainty that was virtually impossible to pro-
vide,” he says.

Emboldened, antiregulatory interests are expanding
the application of Daubert principles to judicial review of
federal regulations, experts say.

Michaels cites the chamber’s 2002 call for an executive
order requiring all federal agencies to apply the Daubert
standards in the administrative rule-making process.

Public health advocates should be wary, Michaels and
others say. “The legal, economic and political obstacles
faced by regulators will increase dramatically when
Daubert-like criteria are applied to each piece of scientific
evidence used to support a regulation,” Michaels says.

The Data Quality Act also gives antiregulatory inter-
ests a new tool, experts say. The statute, which began as
a little-noticed rider in a thick appropriations bill, has
opened the door to contest every piece of evidence con-
sidered by regulators. What’s more, the act contains no
equivalent Rule 11 sanctions for filing a frivolous claim.

“There’s no cost or penalty to mounting such a chal-
genve, whether there’s any merit to it or not,” Wagner says.
“But the potential rewards can be huge. At the very least,
it can delay regulation or liability. At best, it can succeed.”

Already, Michaels says, the salt industry has used the
statute to challenge government recommendations that
Americans consume less salt. It has also been used by
the food industry to oppose dietary guidelines that sug-
gest reduced sugar consumption, and by the manufactur-
ers of toxic chemicals that do not want their products
labeled as cancer-causing.

JUNK SCIENCE?

STEVEN MILLOY, A LAWYER AND BIOSTATISTICIAN WHO
runs a Web site devoted to exposing what he calls junk
science, JunkScience.com, concedes there is an inkling
of truth to what Michaels and others are saying. But he
dismisses much of it as “exaggerations, distortions and ma-
nipulations of the truth” by those who are anti-industry.

All Daubert does is allow judges to set up panels of ex-
erts to advise them on scientific matters in litigation,
Milloy says. “It’s not a tool to deprive plaintiffs of what-
ever relief they merit.” And all the Data Quality Act
does, Milloy adds, is allow the public to question the re-
lability of scientific data used to establish public policy.

Opponents “view it as a way of harassing well-meaning
scientists,” he says. “We view it as a way of checking up
on the people who want to use junk science to regulate
how we live.”

Milloy also questions Michaels’ objectivity because his

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work is supported by the Project on Scientific Knowledge and Public Policy, which receives funding from the Common Benefit Trust, a fund that he says was created to pay the expenses of plaintiffs lawyers in silicon-gel breast-implant litigation.

“As far as him throwing rocks at everyone,” Milloy says, “you know what they say about people who live in glass houses.”

The chamber’s Kovaes says Daubert has helped improve the quality of science used in court by giving judges a “little bit of control” over so-called experts who are willing to testify to anything.

“It means they can’t violate the laws of physics anymore,” he says. “It puts some measure of science into the process so they can’t just make things up.”

And Kovaes says the Data Quality Act helps ensure that studies that form the basis for government policies are evenhanded, free of bias and reliable. The act is also supposed to help ensure that the public has meaningful access to the data needed to test and reproduce the government’s results, he says.

The latter point is being tested in court. The chamber has joined the Salt Institute in a lawsuit charging that the government violated the act by failing to release the scientific data that led to its recommendation that Americans reduce their salt intake to avoid the risk of high blood pressure. The plaintiffs contend that a diet with too little salt may actually increase the risk of cardiovascular and other health ailments in some people.

Last year, a federal district judge in Virginia granted the government’s motion to dismiss, holding, among other things, that the plaintiffs lacked standing to sue. An appeal is pending before the 4th U.S. Circuit Court of Appeals at Richmond, Va.

Georgetown University law professor Paul Rothstein, who specializes in criminal law and evidence, says it is in an industry’s interest to raise questions about the science underlying a proposed government rule or regulation. And since science is never absolutely certain, he says, such questions can always be raised.

Rothstein agrees that some courts have taken Daubert too far, rejecting evidence that suggests a causal relationship because scientists demand more before they are willing to conclude that a relationship has been proved. Other courts have gone the opposite way, finding a causal link between a substance and an injury when the science supporting such a link is tenuous.

But Rothstein thinks it is a misreading of Daubert to suggest that it requires a piece-by-piece examination of the evidence and not a weight-of-the-evidence approach. “Daubert specifically says it means to require that the evidence conform to the scientific method. Nowhere does it say anything about a ‘piece-by-piece approach,’” he says.

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