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IS PUBLIC HEALTH SCIENCE BEING DERAILED IN THE LEGAL AND REGULATORY ARENAS?

Special *American Journal of Public Health* Supplement: How Challenges from Industry Undermine Scientific Evidence and Public Health Protections

Washington, D.C., July 20, 2005, 12:01 a.m. (ET) – Every day in the United States, federal trial judges determine whether juries will hear expert scientific testimony based upon their assessment of its relevance and reliability. While the spirit of this process is to improve the quality of evidentiary science, judges' rulings have resulted in juries being barred from hearing credible scientific evidence offered by respected scientists.

"Scientific Evidence and Public Policy," a special supplement to the *American Journal of Public Health* released today, is the **first time a scientific journal has devoted an entire issue to academic analysis of the conflicts arising in the use of science in regulatory, civil and criminal proceedings**. This special issue examines how recent developments in the legal and regulatory arenas have emboldened corporations involved in civil litigation and regulatory proceedings to accuse adversaries of practicing "junk science." At the same time, the failure to apply rigorous scientific standards in criminal cases has sometimes cost innocent and impoverished defendants their freedom, if not their lives.

This *American Journal of Public Health* supplementary issue is especially timely, coming soon after the widely publicized reports of a former oil industry lobbyist who, while working at the White House, rewrote an Environmental Protection Agency (EPA) report on global warming to overemphasize scientific uncertainty. The Journal supplement documents how corporations are able to preferentially change the rules, emphasizing uncertainty and disagreements among scientists, to avoid regulation and compensation.

Articles in the issue reveal how a little known Supreme Court ruling and a legislative rider passed by Congress with no discussion have provided polluters and manufacturers of dangerous products with new tools to block the use of scientific studies that could lead to better protection of the public's health.

Several papers in the supplement analyze the underpinnings and impact of the 1993 Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals Inc*. that requires federal judges to serve as "gatekeepers" of scientific testimony and decide whether expert testimony is "relevant" and "reliable." While it appears that *Daubert* has discouraged plaintiffs without scientifically sound claims from pursuing them in court, others with strong claims but insufficient resources have also been prevented having their cases heard by juries of their peers.

In one current case, the manufacturers of phenylpropanolamine (PPA) – an over-the-counter drug used as an appetite suppressor as well as a cold and cough remedy – unsuccessfully attempted to exclude expert testimony that PPA greatly increased the risk of hemorrhagic strokes among all individuals taking the drug, because the only epidemiological study conducted had found highly elevated risk of stroke among young women. Immediately after that study, the drug had been pulled from the market, making it impossible to conduct any additional studies.

The supplement also addresses the Data Quality Act (DQA), a largely unknown statutory provision slipped into a thick federal appropriations bill. The DQA allows anyone to challenge the quality of information disseminated by the government, opening the door for parties subject to regulation to challenge every piece of evidence considered by regulators; it has been used by the salt industry to challenge National Institutes of Health recommendations that Americans consume less salt; by the food industry to oppose dietary guidelines that suggest reduced sugar consumption; and by manufacturers of toxic chemicals who do not want their products labeled as "cancer-causing."

The DQA is being used to delay or derail other important public health protections. Using the DQA, opponents of regulation are challenging elements of the EPA's assessment of the risks of perfluoroctanoic acid (PFOA), a chemical used in the manufacture of Teflon. The DQA challenge in 2003 to the federal government's National Assessment of the Potential Consequences of Climate Variability and Change resulted in the White House issuing a disclaimer that the report did not meet federal standards for data quality. The whistleblower who recently exposed the rewriting of the EPA global warming report by the former oil industry lobbyist called this "a chilling statement to the research and assessment community."

The *American Journal of Public Health* supplement includes examinations of the *Daubert* decision and the DQA by several of the nation's leading experts in the use of science in regulation, a renowned philosopher of science, a prominent cognitive linguist and an impressive array of public health scientists, legal scholars and former federal officials.

The papers provide examples and analyses not previously published. For example, the authors of "Legislating 'Sound Science': The Role of the Tobacco Industry" present newly discovered evidence that the tobacco industry played an influential but secret role in designing and promoting the DQA.

The authors of this special supplement provide an important and scholarly assessment of the current use of science in public policy. An important message of the supplement is summarized in the paper by David Michaels, the issue's guest editor and a professor at the George Washington University School of Public Health, and Celeste Monforton, also at the George Washington University School of Public Health.

"Scientific uncertainty is inevitable in designing disease prevention programs. Scientists cannot feed toxic chemicals to people… By magnifying and exploiting these uncertainties, polluters and manufacturers of dangerous products have been remarkably successful in delaying, often for decades, regulations and other measures designed to protect the health and safety of individuals and communities."

David Michaels, PhD, MPH, guest editor of the supplement and a contributing author, can be reached at eohdmm@gwumc.edu.

Support for the supplement was provided through unrestricted funding to the ***Project on Scientific Knowledge and Public Policy*** *(SKAPP)* from the Common Benefit Litigation Trust, a fund established by court order in the Silicone Gel Breast Implant Products Liability Litigation. SKAPP is an initiative of scholars that examines the application of scientific evidence in the legal and regulatory arenas. SKAPP is based at the George Washington University School of Public Health and Health Services; more information is available at www.DefendingScience.org.

The *American Journal of Public Health* is the monthly journal of the American Public Health Association, the nation's oldest and largest organization of public health professionals. APHA is a leading publisher of public health-related books and periodicals promoting high scientific standards, action programs and policy for good health. More information is available at www.apha.org.

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