

Editorial

Turning the Tables with Mary Jane

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Some of this is about--marijuana. Just so you'll know, there's nothing in here about what we were all doing back in the day (though of course, we never inhaled). The reason to give marijuana some attention here is a legal case that has wedged open an important chapter in the relationship between law and science. It pits some health activists against a law in the United States called the Data Quality Act (DQA). The turnaround is that DQA has usually helped industry fight off regulation. Not this time; here's the background.

Many basic scientists would be uneasy if their primary data--not what's in their publications, but what's in the lab notebooks--would be available for others to fiddle around with and then publish a different conclusion. But in another scientific culture, that's routine. In the U.S. Food and Drug Administration, where science has regulatory outcomes, inspectors go regularly into labs to look at the books.



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Well, these cultures occasionally merge to generate political action. Back in the '90s when the U.S. Environmental Protection Agency was revising the National Ambient Air Quality Standards for ozone and small particles, its staff used the Six Cities Study, a Harvard School of Public Health analysis demonstrating a correlation between particulate concentrations and mortality. Recognizing that Six Cities could escalate the risk of particulate regulation, industry demanded the primary data tapes so that they could reanalyze them. Harvard said no, but soon Congress took over.

First, Senator Richard Shelby (R-AL) introduced an Amendment to the 1999 Omnibus Appropriation Bill charging the Office of Management and Budget (OMB) to guarantee access, under the Freedom of Information Act, to data produced with the use of federally funded research. After two rounds of rule-making, OMB issued a final order putting the Shelby Amendment in regulatory form. That opened the door to the DQA, an amendment to the Paperwork Reduction Act of 1980. OMB, in response, required each agency to establish guidelines ensuring the "quality, objectivity, utility, and integrity" of information it disseminates. DQA's legislative history is sparse, because like the Shelby Amendment, it was tacked onto an appropriations bill in the dark. Its real author was an industry lobbyist named Jim Tozzi, who had also worked on the Shelby Amendment. Thus, the DQA is often called "Son of Shelby."

It should not surprise us that the DQA has seen heavy use. The ink on the OMB regulation had scarcely dried when the Center for Regulatory Effectiveness, headed by none other than Jim Tozzi, urged its constituents to use DQA to challenge the "junk science" offered to support health and environmental regulation. Naturally, the Center for Progressive Reform exhorted its troops to get active on the other side. Who won? It wasn't even close. By 2004, the Washington Post had counted 39 serious challenges under the DQA, of which 32 had been filed by industry or industry organizations.

Now, back to marijuana. Americans for Safe Access (ASA), a group advocating marijuana availability for severely ill patients needing pain or nausea relief, petitioned the Department of Health and Human Services (HHS) under the DQA in 2004. They alleged that HHS made false statements in its publications and its Web site, in particular that marijuana "has no currently accepted medical use in treatment in the United States." ASA cited an Institute of Medicine study that acknowledged benefits from the use of marijuana and cannabinoid derivatives and referenced double-blind clinical trials demonstrating relief from pain and vomiting. HHS delayed a response for months beyond its own deadline, rejected the petition, and then rejected the appeal.

ASA finally brought its case to federal court, asking it to substitute for the agency's false statement one that says, "Adequate and well-recognized studies show the efficacy of marijuana in the treatment of nausea, loss of appetite, pain and spasticity." Will the judge make HHS change, giving ASA the injunctive relief it seeks? We'll have to wait to see whether this case turns the tables on DQA, but it's already clear that HHS has violated its own DQA guidelines--going, you might say, one toke over the line.

10.1126/science.1143936

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