

Oral Statement of Dr. George Thurston, ScD. to the US EPA Science Advisory Board  
Regarding the EPA's Proposed "*Strengthening Transparency in Regulatory Science*" Rule  
May 31, 2018

Today, I want to highlight the manuscript I submitted for the record, which I wrote 20 years ago, entitled "Mandating the Release of Health Research Data: Issues and Implications" (Thurston, 1998). It was about a similar proposal that was made in July 1997, as an amendment to the US House Appropriations Bill without any hearings. The problems I raised at that time are directly relevant to today's, "Transparency" proposal:

- **First: The Increased Potential for Compromise of Medical Record Confidentiality:**

Data privacy laws prohibit making public the type of data that EPA proposes to make public. Also, in a time of "big data", it is all too easy to crack any de-identification process, especially when lots of publically available spatial environmental data are matched to people in the study. The solving of the Golden State Killer case is one example where a combination of two databases allowed the identification of an individual.

- **Second: A Loss of Researchers' Intellectual Property**

This could involve lost publications and academic career derailment.

- **Third: The Imposition of a Government Unfunded Mandate**

The US OMB has estimated that a similar law considered in the Congress (but was never passed by the Senate) could cost the government up to \$250 million dollars/yr. There would also be data prep costs to the scientists and their institutions.

- **Fourth: Damage to Future Scientific Research**

When people no longer wish to enroll for fear their medical data will be released, new scientific studies could be inhibited.

- \* **Fifth: The Abuse of the Research Data to Undermine Science Credibility:**

This last problem is likely the most dangerous. Past examples of abuse by consultants to a vested interest resulted when the State of Georgia set up an Open Records Law, and the RJ Reynolds Company used it to obtain research data to attack the study findings that the use of cartoon characters (such as "Joe Camel") in tobacco advertising influenced children's product recognition (Burd, 1994). That research was later validated in other studies, but the damage

was done, and the physician involved left research for private practice. Thus, this data release approach has already been tried in the past and shown to be too easily abused by vested interests.

Interestingly, there is also a tobacco industry connection to this issue that occurred just before the 1997 Open Data amendment was presented in the House: a December, 1996 memo from a consultant to the Tobacco industry (Horner, 1996), laying out a strategy to address federal agency science, including a now familiar call for science “Transparency”.

Finally, there is no need for this rule. Independent validation has already been done by groups such as the Health Effects Institute for studies like the ACS and the Six Cities Study (HEI, 2008), and this could be done again in any new cases of concern for data validation without the above risks. Thus, this rule seeks to needlessly solve a purported problem that does not exist.

## References

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- Thurston, G.D. Mandating the release of health research data: issues and implications. *Tulane Environmental Law Journal*. 11(2):331-354 (1998).
- US. Congress. H.R. 1030, Congressional Budget Office Cost Estimate: Secret Science Reform Act of 2015. OMB. March 11, 2015. (Accessed May 6, 2018). See: <https://www.cbo.gov/publication/50025>