Yesterday, the New York Times reported on the administration’s efforts to improve transparency in the science used in making regulatory decisions. The article does present both sides of what is a political policy debate. In the words of “Michael Halpern, deputy director for the Center for Science and Democracy at the Union of Concerned Scientists, a nonprofit advocacy group. … “This is a wholesale politicization of the process.” That is a mistruth. As Steven Milloy, an advocate of the policy points out in his Wall Street Journal opinion piece, transparency of scientific data used in regulatory decisions has been a political football for nearly 30 years.

What does the proposal require?

The current proposal is a modification of proposed regulations written in 2018, which drew over 600,000 stakeholder comments – the majority of which were opposed. While critics claim their concerns were ignored, much of the revision involves providing definitions for what transparency means.

The EPA would require that all scientific articles used in regulatory decisions have their data available to the public to allow for independent validation. That, in turn, is defined as using “exactly the same data to see if the same result emerges from the analysis by using the same programs and statistical methodologies that were originally used to analyze the data.”

The meaning of the world data was also tightened. Data in the new regulations represent the actual data used in the analysis. It is not necessarily the data “straight from the survey or the experiment.” Data input is often a human enterprise (ask any physician or nurse who has to enter data into your electronic health record rather than talking to you), and sometimes the data is
entered incorrectly or left out. It is this dataset, “in which obvious errors have been removed,” the one used in the initial scientific study, that the regulations seek to make public.

Much of the consternation involves this data because, in some instances, it contains confidential/proprietary business information and, equally importantly, personal health information. Many of the comments suggested that this would limit studies considered after all proprietary and health information should be confidential. Public access to the data becomes a trade-off, transparency for privacy. The proposed regulations suggest three alternative approaches. The first would be to require the data to be made public; the second is to use the study in regulatory decisions but weight or prioritize it downward [1]; the third, to allow access to the data using non-disclosure and HIPAA partnership agreements. [2]

In contrast to their initial proposal, the new proposal now includes all scientific studies, not just data and models involving dose-response [3]. Another concern is whether these regulations apply to the regulatory process moving forward or whether they are retroactive. This last point is particularly troubling to some of the stakeholders who point out that early EPA regulations are based on studies that cannot meet the new regulatory standard.

**It is not a done deal**

The new proposals and being sent out for 30-day commentary and if the prior commentary period was any measure, the proposal will be revised. I think this kind of transparency is right, in a regulatory environment or not. External validation, checking someone’s work, is a reasonable approach. We have good evidence that allowing limited or “tiered access” to qualified researchers has served us well as a middle path between complete transparency and privacy. It makes little sense, at least to me, to go back and validate older science already used in regulatory decisions. The scientific methodologies and definitions have changed since then; you cannot step into the same river twice.

What I see missing is some way to assure that the process is free of political influence. Still, I am afraid that policy is inevitably political.

[1] Weighting would include not only the availability of the dataset but

- The soundness of the methodology “or models employed to generate the information.”
- The clarity and completeness of its documentation.
- How variability and uncertainty are evaluated and characterized.
- All factors we should consider for any scientific article, whether used for regulatory guidance or not.

[2] The use of NDA and HIPAA partnerships in sharing data is already well established for federal datasets.

[3] These studies evaluate toxicity. The new proposal includes a greater range of scientific investigations.