THE PROPOSED RULE
Strengthening Transparency in Regulatory Science

"The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation."

83 Fed. Reg. 18768

What Prompted the Rule?

- The HONEST Act

- Prior EPA Actions

- Similar Policies in Other Federal Agencies

"This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand." **83 Fed. Reg. 18769**

EPA's View

"The era of secret science at EPA is coming to an end. The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives."

Former EPA Administrator Scott Pruitt

Should the public have access to the data used by agencies in passing regulations that impose significant economic burdens?

597,083 COMMENTS – POLARIZING VIEWS

"API supports the use of sound transparent science and public policy making"

"The EPA rule on transparency should be viewed as yet another tool in a larger effort to promote transparency and reproducibility within the scientific community."

"[W]e urge the agency to withdraw this unnecessary and burdensome proposed rule."

"[G]overnment agencies should be as transparent as possible, within the bounds of the law, about scientific information relied upon and the justifications for the significant regulatory decisions they make."
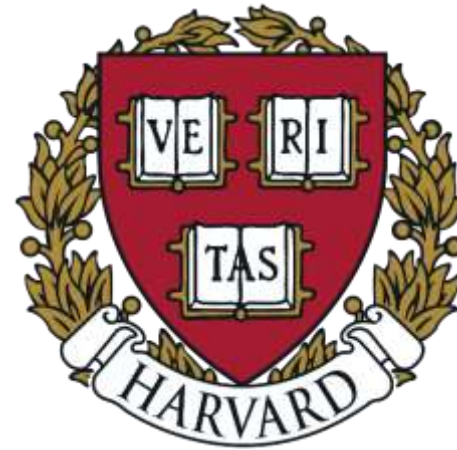
"Most human health studies contain protected health information. This rule threatens the bedrock of what the medical community stands for [and] the health of all of us."

"Our organizations urge EPA to withdraw this proposal and follow the current, effective measures in place."

Renee Salas, researcher with the Harvard Global Health Institute

SUPPORT FOR THE PROPOSED RULE

PROPONENTS' ARGUMENTS

1. Reproducibility Increases Accuracy

2. Exposes "Scientific Mischief"

3. Easier to Challenge

4. Consistent With Statutory Requirements

SHOOK

REPRODUCIBILITY INCREASES ACCURACY

- Reproducibility is the best way to test for scientific accuracy.

- Peer-reviewed publications are NOT necessarily the gold standard in identifying good science.

EXPOSES "SCIENTIFIC MISCHIEF"

- Transparency could reveal the masked flaws in the rulemaking process.

- Reproducibility may expose biased scientific results.

EASIER TO CHALLENGE

- Public exposure of scientific data would reveal whether an EPA regulation is justified.

- The proposed rule could improve regulated industries' ability to challenge costly and impactful regulations.
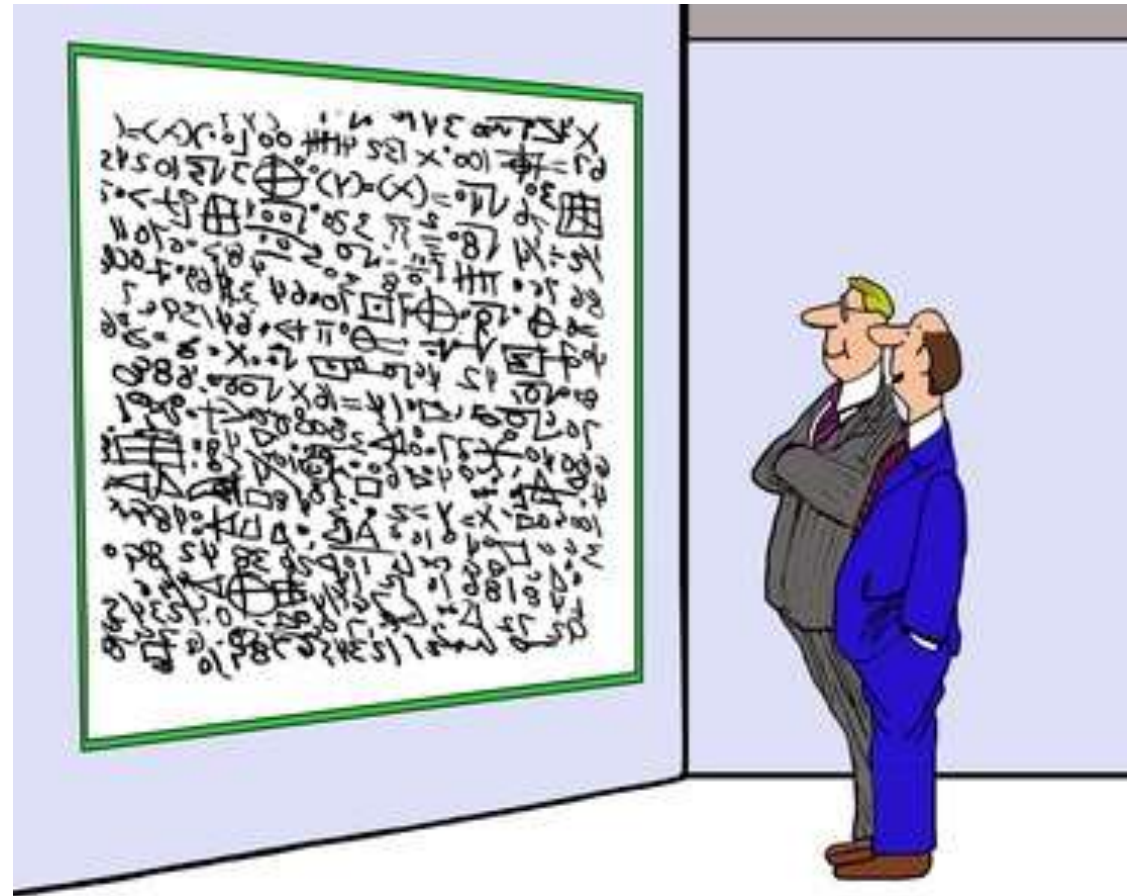
"When you put it like that, it makes complete sense."

CONSISTENT WITH STATUTORY REQUIREMENTS

- It is possible to de-identify personal information while providing underlying data for review.

- The rule contains a key exception.

THE CRITICS' VIEW

A WOLF IN SHEEP'S CLOTHING

The rule may undermine EPA's ability to protect public health.

SHOOK

POTENTIAL RETROACTIVITY

- Could the rule overturn critical scientific reports?

NO STATUTORY AUTHORITY

The proposed rule could prevent EPA from using the "BEST AVAILABLE SCIENCE"

President Harry S. Truman signing the Administrative Procedure Act in 1946

INCONSISTENT WITH THE APA

- Critics assert that the rule is misleading and vague.

- Is the failure to consider peer-reviewed studies "arbitrary and capricious"?

The Final Decision

- The Trump administration's fall 2018 regulatory agenda, released October 16, listed the proposed rule under "long-term actions" with an expected completion date of:

January 2020

Questions?

Maurissa J. Rushton
mrushton@shb.com

SHOOK
HARDY & BACON