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June 4, 2018

The Honorable Scott Pruitt
Administrator of the Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OA-2018-0259

Dear Mr. Administrator:

With significant concern, I offer the following comments in response to the Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science." Evidence-based research is critical to informed decision-making and the formulation of new regulations and policies. This proposed rule, which would significantly limit the EPA's ability to consider the best available scientific findings, is fundamentally flawed and risks not just erosion of the public trust in the EPA's important work, but also progress on improving the health and wellbeing of our communities and our nation. On behalf of Harvard University, I write to oppose this rule.

As a nation, we benefit from the principle that knowledge created through research, discovery, and science is a public good and that these efforts enrich our understanding of the world around us and provide insights that improve our lives. This work is central to the premise and purpose of universities. Through competitive, peer-reviewed processes, discussion, and debates, we create, preserve, and publicly disseminate the ideas, discoveries, and knowledge that flow from our labs, libraries, and classrooms. These evidence-based outcomes have contributed to decades of economic growth and improved health and wellbeing.

Regulatory agencies are most effective when they have the entirety of the best scientific literature at their disposal for rulemaking to set new standards and policies. Research findings are but one consideration in that process, and evidence is weighed alongside other public needs and perspectives, but science offers invaluable and irreplaceable insight to informed public policy- and rulemaking.

This is certainly true for the EPA, an agency whose mission is to preserve public health and our air, waterways, and land. Industrial activity, energy production, agriculture, and many other realities of modern life challenge this mission and our natural environment. While research universities endeavor to address these challenges through discovery and breakthrough technologies in energy production and storage, medicine and biology, agriculture, and other areas, we also seek answers to the causes of disease and premature death. Routinely, these efforts have served as a resource to policymakers and regulators as they pursue informed and effective governance. This proposed rule will narrow policymakers' access to a significant body of this research, resulting in weaker and less beneficial policies.

Research relies on a multitude of data sources, and one particularly powerful source of discovery in medicine and public health is data from individual patients—their experiences and

health records. Existing law, patient confidentiality standards, and most informed-consent agreements for research participants all protect patients' identities by restricting access to their private information. Frequently, though not in every case, anonymizing and de-identifying information acts as an essential safeguard for patient privacy. Reliance upon studies even when they include private health data that cannot be released to the public is not an exercise in "secret science"; it is responsible science. The proposed rule, with its prohibition against EPA reliance on any study where personally identifiable data cannot be made public, effectively disqualifies the best available science from use in the regulatory process.

The landmark Harvard Six Cities study is one such example. Published in 1993, Six Cities revealed a strong link between air pollution and life expectancy. The study, and others that followed, served as the basis for federal regulations that have reduced fine particulate matter in the air we breathe, and long-term analyses published since these regulations were implemented indicate that the long-term health and economic benefits have been remarkable.

Despite these demonstrated benefits, Six Cities has repeatedly been cited as an example of "secret science," a charge that its science cannot be trusted because some of the underlying data is not available for public scrutiny. Harvard has shared significant information and cooperated entirely in a full independent reanalysis of the data by the Health Effects Institute (HEI), which confirmed the validity of the findings. Through that process and since, Harvard has protected the personal health information and identity of study participants, who were guaranteed confidentiality. That commitment to confidentiality is necessary for contractual and legal reasons, to be sure, but also to assure potential research volunteers that Harvard will always protect their private health information. If not, individuals may be dissuaded from participating in new studies, and the quality of future science would suffer.

Beyond the HEI reanalysis, the findings of Six Cities have been replicated numerous times in many independent studies using different study designs, larger numbers of enrollees, broader geographical distributions across multiple regions of the world, and increasingly sharp analytical tools. The number of studies replicating Six Cities' original findings demonstrate the soundness of the scientific process and have established an extensive foundation of literature whose conclusions are just as important to the weight of evidence as Six Cities itself. To call such science "secret" is to misrepresent the scientific process. Replication of results using different data, not revelation of personally identifiable health data, is the strength by which we should measure our science.

The well-established link between air quality and life expectancy is but one example of critical public health information that could be forced out of policy formation by this rule. Science is not undertaken solely for the joy of knowing; it is an effort to improve ourselves, our lives, and our world. I urge you to reject this proposed policy change and the long-term damage it will do to our health, our communities, and our nation.

Sincerely,



Drew Gilpin Faust

cc: Neomi Rao