PRELIMINARY ASSESSMENT OF PRUITT'S PROPOSED REGULATION TO RESTRICT EPA'S USE OF SOUND SCIENCE: SUMMARY
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Scott Pruitt's proposal to exclude the use of a broad portion of the scientific literature on human health and the environment is inconsistent with scientific practice and sound public policy.

EPA Administrator Scott Pruitt has proposed a regulation that would restrict EPA's use of scientific studies, when the Agency sets rules and other policies and requirements, unless the raw underlying data and the models used to analyze data supporting the study are available for public review.

The proposal disingenuously positions itself as somehow supporting the value of "transparency" when in fact what it does is make it impossible for EPA to consider the full array of well conducted and peer reviewed scientific studies of the health effects of pollution. Assessment of all relevant scientific information is essential in making sound judgments about protecting public health and is a stated requirement in all major environmental legislation.

EPA's regulatory protections over the last five decades have relied on assessments of many thousands of health-related studies of pollutants, including epidemiological, human and animal studies. They include both completed and ongoing epidemiological studies that examine the relationship between concentrations of various pollutants and their effects on people's health. For many of these studies, ethical and legal considerations rightly restrict the release of personal data such as dates of birth and death, health, lifestyle information and subjects' locations.

It appears that EPA has not conducted a full assessment of the potential impacts of a policy to limit peer reviewed science it considers only to studies where raw data are available. Under such restrictions, some of the most useful and influential studies might have to be redone – at great expense and considerable time and resources – in order to sustain some existing regulations. On a practical basis, the level of detail contained in certain human studies would make it impossible to simply redact portions of the information to protect privacy. Even for studies for which the release of data might not pose ethical problems, the underlying data may no longer be accessible years after publication.

A preliminary examination of the potential impacts of the proposed regulation reveals striking examples of rules and programs that might not have been possible if EPA had adopted a data transparency limitation in past regulations. Among them are programs to:

- Reduce or eliminate the exposure of children to lead in paint, gasoline and drinking water
- Develop criteria for how much of a chemical can be present in water before it is likely to harm people, plant and animal life
- Promulgate protective air quality standards for particulate matter and possibly other air pollutants
- Control certain toxic pollutants in air, drinking water and solid wastes
- Approve the registration of pesticides for agricultural and other uses under the federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the federal Food, Drug, and Cosmetics Act (FFDCA)
- Approve increases in production volume and use of commercial chemicals under the Toxic Substances Control Act (TSCA) such that people's health is protected

Rather than exclude company-generated studies containing confidential business information from decisions on pesticides and other toxic chemicals, the proposal includes provisions that would most likely be used to exempt

such studies from meeting the transparency requirements. It is not clear, however, why or how transparency in scientific data should be required for peer reviewed studies supporting air, water and other regulations but not for pesticide or other decisions relying on confidential business information.

Moreover, arbitrary exclusion of a substantial body of air pollution studies would also mean that the benefits estimated for future EPA regulations that reduce fine particles would be substantially lower than indicated by the best available scientific information, thus providing misleading cost-benefit information to the public and policymakers. Existing EPA programs that were adopted to reduce these pollutants are preventing over 50,000 premature deaths each year.

The Pruitt proposal ignores available approaches embraced by the scientific community for alternative methods to ensure the credibility of potentially useful scientific studies. These include both reanalysis by competent third party investigators and replication of studies using different data sets and conducted by different researchers. This was the approach followed when the availability of underlying health data was challenged for two epidemiological studies on fine particles and mortality originally published in the 1990s. Over the years, third party investigators reanalyzed the data and other studies were conducted that replicated the original findings using different data sets. The most recent of these studies, which used a Medicare database available to any research group that can guarantee confidentiality of personal data, found even greater effects of fine particles at levels below EPA's current standards. This powerful study would not be considered under the proposed regulation.

The Pruitt proposed regulation appears to be more aimed at suppressing the use of important scientific information to support regulations and cost-benefit analyses, than addressing any valid concern that study results are faulty because the underlying data are not publically available. His proposal is unnecessary and inconsistent with EPA's nearly fifty-year responsibility to protect public health and the environment.

The Environmental Protection Network has produced a preliminary assessment of the science/policy issues raised by the proposed regulation and a document that evaluates its legal implications.

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