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INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA – UAW

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Submitted via regulations.gov

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington D.C. 20460

Re: Docket # EPA-HQ-OA-2018-0259, Strengthening Transparency in Regulatory Science, Supplemental notice of proposed rulemaking

Dear Administrator Wheeler:

The International Union, UAW, representing one million active and retired workers is grateful for this opportunity to comment on EPA's Supplemental Notice of Proposed Rulemaking "Transparency in Regulatory Decision-making." The UAW believes that the rule as proposed was flawed beyond repair and that the supplement does not better the situation. The UAW respectfully requests that both the proposed rule and the supplement be withdrawn.

Undue burden on human research subjects

The proposal would require that all the data, methods, models, and code from a scientific study be made public before EPA would consider using it in rulemaking. The supplement states that the rule applies to all "influential science" not just science used in rulemaking and that it applies to all data and models, not just dose-response models. The EPA offers two approaches for dealing with data that cannot be made public. One is a tiered-access approach by which data that cannot be made public can be selectively shared for independent validation. The alternative approach offered is a weighted approach where the EPA will not be prevented from using science that relies on nonpublic data, but those studies will be downweighed compared to studies with entirely public data.

Both approaches are deeply flawed. It is difficult to make data public without also making participants identifiable. This is particularly true in some air pollution studies, in which participants' addresses are used to estimate exposure. This means, that in some cases, information about participants' exposures could be used to figure out their addresses[1]. A 2002

[1] Schwartz, J. (2018). Transparency" as mask? The EPA's proposed rule on scientific data. *N Engl J Med*, 379(16), 1496-1497.

study by the National Research Council of the National Academy of Sciences found that, even after the deletion of some personal information from participants, if all the information necessary to reproduce a study's findings remained, it was possible to identify the participants[2].

The tiered approach would permit data that cannot be made broadly public to be shared with a limited number of scientists. If this proposal were to become a final rule, it is possible to imagine that researchers might seek and obtain informed consent from study participants to do this kind of sharing of identifiable information. If they did, it might be more difficult to find willing study participants, especially in communities of color, which have good historical reasons to distrust medical researchers and which are often the most heavily exposed to pollution. Even if researchers were able to seek and obtain consent for this kind of limited sharing in future studies, and even if doing so did not reduce study participation in communities of color or elsewhere, this rule would still exclude a tremendous amount of scientific research conducted before there was any reason to obtain such consent.

The weighted approach is deeply flawed. While it would not totally eliminate a study from consideration for failure to share identifying information, it would downgrade its weight in a rulemaking or as "influential science." This could easily lead to a scientifically perverse result of putting greater weight on a methodologically inferior study just because the researchers shared personally identifying information from their subjects. The rule would incentivize not the best science, but that which most violates privacy.

The principles of conducting human research were first developed as the Nuremberg code as part of the war crimes trials of Nazis. Among the crimes were cruel and unethical experiments practiced on participants who did not have the option to refuse. The three basic elements of the Nuremberg Code (voluntary informed consent, favorable risk/benefit analysis, and right to withdraw without repercussions) became the foundation for subsequent ethical codes and research regulations[3].

In the United States, formal procedures for the ethical treatment of human subjects were developed after national media attention to the Tuskegee syphilis study generated public outrage. The study, funded by the U.S. Public Health Service, investigated the natural history of syphilis in poor, African American sharecroppers. Participants with known syphilis were subjected to tests and procedures done solely for research, but many participants believed these tests and procedures were actually medical care. They were not told that otherwise. When the study began in 1932, there was not a reliably effective treatment that it would have been clearly unethical to withhold. However, as time passed, the antibiotic penicillin, known to be highly effective against syphilis, became available. The investigators decided not to provide penicillin to the unwitting study participants so that they could continue to follow the course of the untreated disease. In

[2] National Research Council. (2002). *Access to research data in the 21st century: an ongoing dialogue among interested parties: report of a workshop.* Washington, DC: National Academy Press.

[3] Rice, T. W. (2008). The historical, ethical, and legal background of human-subjects research. *Respiratory care*, 53(10), 1325-1329.

1972, the study was finally halted after national media attention. The resulting outrage led to the protections for human research studies that we now have[4]. These include protections for privacy and confidentiality that are promised to research participants prior to gaining their consent to participate.

Every year, thousands of people participate in research studies in which they are explicitly informed that they are unlikely to benefit personally, but the benefit will be to humanity in the form of the advancement of science. The Department of Health and Human Services requires that government funded researchers protect the privacy and confidentiality of these participants.

§ 46.111 Criteria for IRB [Institutional Review Board] approval of research:

> (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
>
> > (1) Risks to subjects are minimized…
> >
> > (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
> >
> > > (i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

In this supplemental notice of proposed rulemaking, the EPA states that in order for a study to be accorded full weight in rulemaking or "influential science," the researchers who performed the study will have to violate protections put in place to prevent a repetition of Nazi experiments and of cruel, racist research conducted on African American citizens of the United States. It is the regulatory process itself and the American people who will suffer by being denied regulations based on the best available science if violating human subjects protections is made a condition of giving a study full weight in rulemaking or "influential science."

The Proposed Rule and the Supplement Place an undue burden on private companies that have invested in REACH registration

In order to register a chemical under the European REACH (Registration, Evaluation and Authorization of Chemicals) program so that it can be used in commerce in Europe, private sector companies have to conduct studies of their chemicals (most of these are animal or in vitro studies) and submit them to the European Chemicals Agency (ECHA). These studies are expensive to conduct and are considered by the companies who do so to be an investment for the purpose of gaining access to the European market. Robust summaries of these studies are available to the public, but data, associated protocols, computer codes and models, recorded factual materials and detailed descriptions of how to access and use such information are usually not made available to the public.

[4] Rice, T. W. (2008). *Ibid.*

One reason for this, is that companies spend a lot of money to develop these materials. Requiring information developed at some cost to be made public in this way could give competitors access to the European market without having to make similar expenditures. Thereby giving competitors an unfair advantage. The EPA relied on 20 ECHA Robust summaries for its risk evaluation of Pigment Violet 29 under the Toxic Substances Control Act and on five ECHA Robust summaries for its risk evaluation of 1-Bromopropane. It would not be able to do so under this rule.

Best Possible Science

The proposed exclusion from consideration of any study for which underlying data are not made publicly available is not consistent with sound scientific practice because the scientific community uses other tools to validate studies without access to all underlying "raw data." These include peer review, replication of a study using the same methodology but different data sources, and/or reproduction of a study's conclusions using different methodologies and data.

Sincerely,

Brett Fox, Director
UAW Health & Safety

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