



November 13, 2019

United States House of Representatives  
Committee on Science, Space and Technology  
The Honorable Eddie Bernice Johnson, Chairwoman  
The Honorable Frank Lucas, Ranking Member  
Washington, DC 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

Thank you for taking the time to hold today's hearing on the U.S. Environmental Protection Agency's (EPA) "Strengthening Transparency in Regulatory Science" proposed rule.

As the world's largest nonprofit funder of Parkinson's disease (PD) research, The Michael J. Fox Foundation (MJFF) is dedicated to accelerating a cure for Parkinson's and improved therapies for those living with the disease today. In funding more than \$900 million in research to date — including on toxicity of environmental exposures — the Foundation has fundamentally altered the trajectory of progress toward a cure. It is estimated that one million people in the United States have PD, which costs the U.S. government and American families \$52 billion every year.

Before I comment on the proposed rule, let me be clear: The Michael J. Fox Foundation believes transparency is critical in scientific research. Our Foundation supports a general policy of open data sharing among the scientific community and believes this practice speeds discovery and replication and deepens the public's trust in findings. In addition, access to underlying raw data and initial analysis allows scientists to check each other's work and can help catch errors or overlooked factors.

Our Parkinson's Progression Markers Initiative study makes all de-identified data available to the research community, which has downloaded data from the study nearly 5 million times and used it in more than 150 published papers. We encourage our funded researchers to make data available based on the nature of the study and, very importantly, the feasibility of adequate de-identification. Stripping data of personally identifiable information is vital in protecting a study participant's privacy. There must be a balance between research transparency and protecting patient confidentiality.

As overall justification for the proposed rule, the EPA claims it is following the accepted practice of many science organizations, including many scientific journals. However, we believe this is a misleading claim. Major journals in the field only require data be made confidentially available to other researchers for the purposes of reproducing or extending analysis. No major journal requires scientists to publish raw data to the public in all cases. In a joint statement in response to the proposed rule, the editors-in-chief of *Science*, *Nature*, *Cell*, *Proceedings of the National Academy of Sciences*, and the *Public Library of Science* stated that the proposed rule will

exclude important studies from consideration in the rulemaking process and adversely impact the decision-making process.<sup>1</sup>

The types of studies most vulnerable to exclusion — epidemiological studies that investigate how, when and where disease occurs in populations — form the bedrock of knowledge for determining the environment's impact on human health. Exclusion of these studies from EPA review stands to affect every decision made at the agency from National Ambient Air Quality Standards to chemical registration and regulation in consumer products and pesticides. The EPA already requires studies to be peer-reviewed — a gold standard of science — to verify and validate research. The effect of this rule, overall, will be to restrict EPA's access to science rather than make it more transparent. Our specific concerns are outlined below.

Thank you for the opportunity to testify.

### **De-identified does not mean unidentifiable**

As stated in the proposed rule, the agency aims to ensure that "more of ... the science ... is available to the public for validation," while also "reduce[ing] the risk of unauthorized disclosure and re-identification."<sup>2</sup> There are many studies where it is impossible to de-identify data to a level where both the data is usable and the privacy of participants in the study is properly protected. Environmental exposure data often must be specific to a house, street or neighborhood. For example, a 2009 study showed that consuming water from a private well located in an area with historical pesticide use was associated with an increased risk of Parkinson's disease.<sup>3</sup> Due to the nature of wells — typically serving a limited number of people within a very small radius — the detail needed to perform the study renders proper de-identification impossible. Simply knowing that a person lives near a particular well, coupled with a demographic detail such as their age, gender or race could expose the identity of a person with Parkinson's.

Individuals with Parkinson's often do not publicly disclose their disease when first given a diagnosis. Many of them also want to participate in clinical studies toward better treatments and a cure for themselves and for future generations. The EPA's rule puts these individuals at great risk of having their Parkinson's or other diagnoses exposed. Such exposure could, for example, result in unfair job loss, which then causes loss of income, insurance, and other supports necessary to maintain quality of life.

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<sup>1</sup> Jeremy Berg, et.al, Joint Statement on EPA Proposed Rule and Public Availability of Data, Science Magazine, May 4, 2018, at 501.

<sup>2</sup> Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30).

<sup>3</sup> Nicole Gatto, et al., Well Water Consumption and Parkinson's Disease in Rural California, *Envtl. Health Persp.*, Dec. 2009, at 1912-1918.

### **Rule forces unneeded expense on the public**

Even if there was an acceptable way to mask personal data while maintaining enough information to comply with the rule, costs of such anonymizing are unnecessary and expensive. When Texas Congressman Lamar Smith's *Honest and Open New EPA Science Treatment Act of 2017 (Honest Act)*<sup>4</sup> — a bill with content very similar to the currently proposed rule — was under consideration, the Congressional Budget Office estimated it could cost up to several million dollars a year to comply.<sup>5</sup> This money could be better spent on a number of priorities such as more research into the causes of disease.

### **Chilling impacts to science**

If the EPA's rule takes effect, it could introduce selection bias that may slow studies and alter results, and thereby affect regulatory decisions. Large-scale population studies rely on many people — often numbering in the thousands — to reveal sensitive or private information. These studies may have difficulty recruiting or retaining volunteers if the researchers are required to make de-identified data publicly available, as some may be more hesitant to share their information. Those who are willing to participate may be different from others, which could introduce confounding variables and bias that may question the study's results.

The proposed rule stands to affect every program and statute that the EPA administers. Here we highlight the three most directly relevant to the EPA's role in regulating environmental exposures with potential to cause Parkinson's disease.

### **Parkinson's disease research in pesticide determinations**

All pesticides distributed or sold in the United States must first be registered by the EPA and reregistered every 15 years<sup>6</sup>. In order to be registered, the *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)* requires the applicant show that its proposed pesticide does not cause unreasonable risk to human health or the environment.<sup>7</sup> The applicant typically provides studies that comply with the EPA's testing guidelines along with its application materials. The EPA reviews the data provided and performs some of its own work, including human health and ecological risk assessments, on a chemical.<sup>8</sup> Additionally, under the *Food Quality Protection Act*, which amended FIFRA, the EPA must

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<sup>4</sup> H.R. 1430, 115th Cong. (2017)

<sup>5</sup> Cong. Budget Office, HONEST Act Cost Estimate (2017).

<sup>6</sup> Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1513, 1514-35 (1996)

<sup>7</sup> Env'tl. Prot. Agency, FIFRA and Federal Facilities (2018), <https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities>

<sup>8</sup> Env'tl. Prot. Agency, Human Health Risk Assessment (2016), <https://www.epa.gov/risk/human-health-risk-assessment>

find a pesticide poses a “reasonable certainty of no harm” before it can be registered for use on food or feed<sup>9</sup>.

For example, the herbicide paraquat is currently undergoing reregistration review. As part of that process, the EPA is looking at studies relevant to the chemical’s health concerns, including the connection with Parkinson’s disease.<sup>10</sup> Over the past few decades, studies consistently show a correlation between exposure to pesticides and Parkinson’s disease, but that full breadth of data may not be reviewable by the EPA under the current proposal. For example, a meta-review examined 40 studies and concluded, “epidemiologic studies suggest a relatively consistent association between exposure to pesticides and an increased risk of developing [Parkinson’s disease], despite differences in study design, case ascertainment and definition, control selection, and pesticide exposure assessment.” Many of these studies would be excluded from consideration under the proposed rule as they (i) gathered personally identifiable data that precludes data sharing, (ii) did not obtain consent for data sharing, or (iii) were foreign studies that do not comply with U.S. data protection regulations.

In addition, relevant studies have design characteristics that make them vulnerable to non-compliance and exclusion. Specifically, two studies of California’s Central Valley found years of exposure to a combination of herbicides paraquat and maneb increased the risk of Parkinson’s disease later in life. Another study found that Central Valley residents under age 60 who lived near fields where the pesticides paraquat and maneb were used between 1974 and 1999 had a Parkinson’s rate many times higher than other residents in the region. Parkinson’s is rare enough such that, in many communities, data that would need to be disclosed, such as behavioral factors (e.g., occupation, tobacco or alcohol use, how long a study participant has lived in the area), will render individuals easily identifiable. To protect patient privacy, scientists may not want to make even de-identified data public.<sup>11</sup> Without these and similarly designed studies, the EPA is likely to miss relevant information in its review.

### **Parkinson’s disease research in TSCA determinations**

The *Toxic Substances Control Act (TSCA)* is the EPA’s primary authority for regulating non-pesticide chemicals. Under TSCA, the EPA can secure information on new and existing chemicals and regulate chemicals it determines pose an unreasonable risk to public health or the environment.<sup>12</sup> All studies used would be subject to the proposed rule.

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<sup>9</sup> Food Quality Protection Act of 1996, Pub. L. No. 104-170 § 408(b)(2)(A)(ii), 110 Stat. at 1516 (1996).

<sup>10</sup> Paraquat Dichloride Human Health Mitigation Decision, 82 Fed. Reg. 118 (Env’tl. Prot. Agency Jan. 1, 2017) (notice of availability).

<sup>11</sup> Nat’l Inst. of Health, HIPPA Privacy Rule (2007), [https://privacyruleandresearch.nih.gov/pr\\_08.asp](https://privacyruleandresearch.nih.gov/pr_08.asp)

<sup>12</sup> Env’tl. Prot. Agency, Summary of the Toxic Substances Control Act (2017), <https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act>

In late 2016, the EPA moved to ban toxic chemical trichloroethylene (TCE) due to health risks, including a risk of Parkinson's disease,<sup>13</sup> though this action is still pending<sup>14</sup>. The original recommendation was based on hundreds of studies, many of which would not be considered under the proposed rule.

For example, one study sent questionnaires to 134 people who had formerly worked on a site with heavy and long-term exposure to TCE. Fourteen had signs of Parkinson's disease, and an additional thirteen showed mild features of the condition — far more than expected, given the population.<sup>15</sup> Another asked twin pairs about exposure to solvents including TCE and showed a significant association between TCE exposure and Parkinson's disease risk.<sup>16</sup>

In these relatively small studies, a distinctive characteristic — people who all worked together and twins, respectively — combined with the most basic additional medical information could render the participants identifiable. Both TCE studies are highly cited, and the findings have been replicated. To exclude this evidence that TCE exposure is a risk factor for Parkinson's disease does not serve the best health interests of the American public.

Furthermore, the proposed rule does not comply with the letter of TSCA. TSCA and other statutes administered by the EPA requires the agency use the "best available science"<sup>17</sup> and none require the agency access to raw data. TSCA additionally requires that the EPA consider all information that is reasonably available to the administrator.<sup>18</sup> As drafted, the proposed rule violates these statutes because it would force the agency to ignore some of the best information available.

### **Parkinson's disease research and the Clean Air Act**

The Clean Air Act authorizes the EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and to regulate emissions of hazardous air pollutants. The EPA works with local governments to reduce air pollution and uses scientific studies

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<sup>13</sup> Press Release, Env'tl. Prot. Agency, EPA Moves to Ban Certain Aerosol Degreasers and Dry Cleaning Spot Removers as the First Major Regulatory Action under Chemical Reform Law (Dec. 7, 2016) (on file with the author).

<sup>14</sup> Unified Agenda of Regulatory and Deregulatory Actions, Trichloroethylene 83 Fed. Reg. 1935, 1937. (Jan. 12, 2018)

<sup>15</sup> D.M Gash, et al., Trichlorethylene in Parkinsonism and Complex I Mitochondrial Neurotoxicity, *Annals of Neurology*, Feb. 2008, at 184-192.

<sup>16</sup> Samuel M. Goldman, et al., Solvent Exposures and Parkinson's Disease Risk in Twins, *Annals of Neurology*, June 2012, at 776-784.

<sup>17</sup> Frank R. Lautenberg Chemical Safety for the 21st Century Act Pub. L. No 114-182 (codified as amended at 15 USC §2625 (h)) available at: <http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim>

<sup>18</sup> *Id.* at §2625 (k).

that could be impacted by the proposed rule to revise its national air quality standards and NAAQS on a regular basis.<sup>19</sup>

Very little is currently known about air pollution and its impacts on the brain. Recent studies have linked particulate exposures to Parkinson's disease including a large study done in Denmark. This study included several thousand people with and without a current diagnosis of Parkinson's disease. Using extremely specific (within 5-50 meters of the front door) geo-coding to estimate participant's exposure to contaminants, the study estimated that ambient air pollution from traffic increased risk of developing Parkinson's disease by nine percent.<sup>20</sup> Researchers found an increased risk of Parkinson's disease after exposure to particulate matter in studies from Taiwan<sup>21</sup> and South Korea<sup>22</sup> as well.

In addition to challenges in usefulness of data if enough information is redacted to protect privacy, these studies face a hurdle because they were performed internationally. In the Danish study, participants are protected by European Union (EU) law. Going forward, an EU study's compliance with the proposed rule will need to be reconciled with the new General Data Protection Regulation,<sup>23</sup> which is seen as more restrictive than the United States' *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*<sup>24</sup>. Many studies that involve people located in the EU will have a difficult time both complying with the new directive and providing enough information to the EPA to be considered.

Studies from other countries are useful in evaluating U.S. policies. People in other countries are exposed to chemicals at different rates than in the United States, which can show threats not yet discoverable in our country. For example, average particulate matter concentrations in South Korea and China are several times higher than in the United States,<sup>25</sup> making relatively subtle effects stand out more easily. Studies done in other countries can help researchers determine whether an effect is dependent on dose or length of exposure. The inability to review and use international research in determinations will virtually guarantee the EPA is missing major findings and important data.

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<sup>19</sup> Env'tl. Prot. Agency, Clean Air Act Overview (2017), <https://www.epa.gov/clean-air-act-overview>

<sup>20</sup> Beate Ritz, et al., Traffic-Related Air Pollution and Parkinson's in Denmark, *Env'tl. Health Persp.*, Mar. 2016, at 351-356.

<sup>21</sup> Chiu-Ying Chen, et al., Long Term Exposure to Air Pollution and the Incidence of Parkinson's Disease: A Nested Case-Control Study, *PLOSOne*, Aug. 15, 2017, at 1-14.

<sup>22</sup> Hyewon Lee, et al., Short-term Air Pollution Exposure Aggravates Parkinson's Disease in Population-based Cohort, *Scientific Reports*, Mar. 16, 2017, at 1-14.

<sup>23</sup> Council Directive 2016/679 2016 O.J. (L119) 1, 88 (EC).

<sup>24</sup> Int'l Ass'n of Privacy Prof'l, GDPR Matchup: The Health Insurance Portability and Accountability Act (2018), <https://iapp.org/news/a/gdpr-match-up-the-health-insurance-portability-and-accountability-act/>

<sup>25</sup> Katherine Ellen Foley, Every Country has Terrible Air Pollution, but these are the World's Worst, *Quartz Media*, Sep. 28, 2016, <https://qz.com/794542/air-pollution-map-by-country-fine-particulate-matter/>



In addition to its threat to patient privacy or inclusion of informative studies, this proposed rule also grants too much power to one individual. As written, the proposal grants the EPA administrator broad authority to exclude individual studies. This could have wide-reaching impact depending on the preference of the administrator at the time and allows the administrator to overrule scientists regarding their own research. Allowing politically appointed officials to make decisions about whether a study qualifies for an exception is dangerous. The administrator already has broad authority to decide what action to take on an item. It should not have the power to hide evidence that does not support the action.

The EPA should consider all relevant, peer-reviewed data when making decisions that impact Americans' health, and the proposed rule's exceptions process clearly undermines this goal. If the proposed rule takes effect the EPA should, at least, require that exceptions decisions are made by experts in the area of research. For example, a panel of non-partisan, unaffiliated expert scientists could make recommendations on exceptions.

Overall, the proposed rule will force the EPA to make decisions based on less information, which will compromise its mission to protect human health. As a non-profit organization dedicated to improving the lives of people with a chronic illness, we put patients and families at the heart of everything we do and expect nothing less of the federal government. Decisions made at the EPA impact hundreds of millions of people. Please ensure that the agency continues to balance the need for scientific integrity and transparency with its duty to protect the country's welfare.

Thank you for the opportunity to testify.

Sincerely,

Todd Sherer  
Chief Executive Officer  
The Michael J. Fox Foundation for Parkinson's Research  
New York, NY and Washington, DC