March 16, 2015

U.S. House of Representatives
Washington, DC 20515

Dear Representative:

We are writing to express our opposition to H.R. 1030, the Secret Science Reform Act of 2015, and H.R. 1029, the EPA Science Advisory Board Reform Act of 2015. Our organizations are dedicated to saving lives and improving public health.

Science is the bedrock of sound regulatory decision making. The best science underscores everything our organizations do to improve health. We strongly believe in a transparent and open regulatory process. A vital element of research is patient confidentiality. Physicians and researchers have earned the trust of their patients by steadfastly maintaining patient confidentiality. Patient confidentiality is a clear legal and ethical obligation.

The Secret Science Reform Act of 2015 will compel the U.S. Environmental Protection Agency to either ignore the best science by prohibiting the agency from considering peer-reviewed research that is based on confidential patient information or force EPA to publicly release confidential patient information, which would violate federal law. This is an untenable outcome that would completely undermine the ability of the EPA to perform its responsibilities under the Clean Air Act and myriad other federal laws. The legislation will not improve EPA's actions; rather, it will stifle public health protections.

The kind of information disclosure envisioned in this legislation exceeds that required by peer-reviewed journals. We believe much of the intent of this legislation is already achieved through the current peer-review process required by all academic journals. The vast majority of peer-reviewed journals require manuscript authors to register any trial using human subjects with clinicaltrials.gov. This public registry collects key information on the study population, research goals and methods that allow outside reviewers and scientists to either challenge or attempt to reproduce study results. Additionally, the peer-review process and publication of results invites the broader scientific community to debate study findings. Trial registry and manuscript publications are only part of the process by which scientific endeavors operate in a transparent environment.

Private organizations, public charities, research universities, the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs, corporations and many other entities conduct medical research. Many of these organizations compile large longitudinal data sets that track patients over a period of time. These data serve as the basis of many studies that permit epidemiologists to track disease and risk factor information for large patient populations.

The published peer-reviewed information from such data often inform regulatory decision making at the EPA and other federal agencies as well as future research. Not only do these data inform regulatory action, they help inform efforts to educate the public about the magnitude of a disease, risk factors and steps individuals can take to improve their health. In order for EPA to set the most appropriate standards, it must be informed by the best information.

Understanding the impact of air pollution on human health and the magnitude of harm caused by pollution at specific levels helps the agency meet its obligations under the Clean Air Act. Absent these data, it is unclear upon what basis the agency could make sound decisions.

H.R. 1029, The EPA Science Advisory Board Reform Act of 2015 will also undermine the scientific basis for EPA policy, specifically by compromising the integrity of the panel that reviews that science. EPA's Science Advisory Board (SAB) is composed of independent scientific and technical experts who are tasked with evaluating the science and providing advice that EPA uses to inform its decision making. The current law provides for balanced panels and experts with diverse backgrounds.

This legislation would impose a hiring quota on the SAB that would require ten percent of members to be selected for qualifications other than their scientific expertise. This bill will compromise not only the scientific integrity of the SAB, but also its independence, as the quota would open the door for representatives of the regulated industries to serve on the board.

Further, the bill will also, in some cases, prohibit SAB members from participating when their own research is involved – even indirectly. This requirement could block participation of the "best and the brightest" researchers in a particular field at the very time their expertise is needed to accurately inform the regulatory process.

Finally, the SAB is currently governed by the Federal Advisory Committee Act and already has a public comment system in place. H.R. 1029 would add on the burdensome requirement that the SAB respond to individual comments in writing, a requirement that could be so time-consuming as to render the board unable to carry out its function.

We urge the U.S. House of Representatives to stand up for sound science and public health protections, and vote NO on both H.R. 1030 and H.R. 1029.

Sincerely,

Harold Wimmer
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American Lung Association

Georges C. Benjamin, MD
Executive Director
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