

POLICY FORUM

SCIENTIFIC INTEGRITY

Ensuring scientific integrity in the Age of Trump

Policies to protect government scientists must be defended

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With the new Donald J. Trump Administration comes uncertainty in the role that science will play in the U.S. federal government. Early indications that the Administration plans to distort or disregard science and evidence, coupled with the chaos and confusion occurring within federal agencies, now imperils the effectiveness of our government. Evidence from the past 20 years demonstrates that, when faced with such threats, supporters of science can take steps to protect the integrity of science in the federal policy-making process. The scientific community will need to connect science-informed policy to positive outcomes and staunchly defend scientific freedom. It must also spotlight political interference in science-based policy development and be prepared to protect scientists—both within and outside the government—against executive or legislative overreach. A range of scientific integrity and transparency policies across federal agencies provides critical tools but must be enforced and protected.

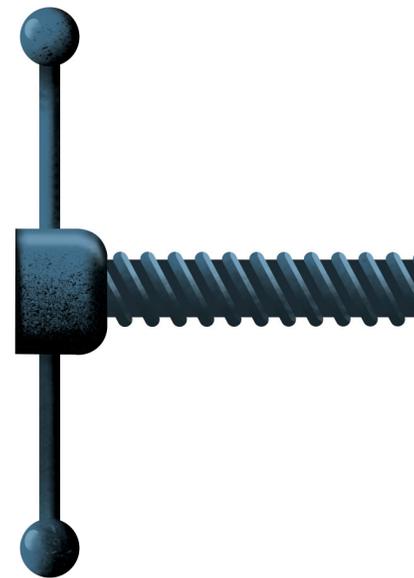
Reliance on science to inform policy decisions, foster economic opportunity, and advance technology stretches back to the founding of U.S. democracy. For decades, both Republicans and Democrats recognized the need for independent science in governance (2). A bipartisan Congress grounded the Clean Air Act, the Endangered Species Act, and many other environmental and public health laws in science, because it knew that a scientific foundation would be essential to their effectiveness. In ways unseen by most people, science is produced, utilized, and disseminated by critical public institutions. It informs the nation's course on everything from deployment of nuclear

weapons to ensuring the safety of food and household products.

Americans still hold science in high regard, which makes it vulnerable to political interference. All modern presidents—both Republicans and Democrats—have politicized science in some way (3). President Barack Obama, for example, clashed with scientists on ozone pollution and emergency contraception—both decisions statutorily mandated to be based on science. But government experts in the George W. Bush Administration found their work suppressed and distorted at all steps in the policy-making process (4). Officials chose science advisory committee members based on who they voted for rather than scientific credentials, prevented federal scientists from publicly sharing their research and expertise, and manipulated scientific reports to help justify policy decisions (5, 6).

GOVERNMENTAL INTERFERENCE

By and large, the scientific community was caught off guard. For years, advocacy for science meant arguing for more funding not defending the integrity of science in the policy process. But eventually, scientists responded to these threats. The Union of Concerned Scientists (UCS) organized 15,000 scientists who made clear that disrespect of science in government was unacceptable and surveyed thousands of scientists across nine federal agencies between 2005 and 2007 to document the state of science in federal decision-making (7, 8). The results showed perceptions and experiences of interference across federal agencies and issue areas—from FDA drug approvals to endangered species. Notably, 1028 climate researchers (60% of respondents on a survey of seven agencies) reported having personally experienced at least one incident of political interference in their work over the previous 5 years. Similarly, 213 scientists (7% of respondents across all surveys and agencies) said that agency decision-makers had directed them to “provide incomplete, inaccurate, or misleading information” to the public.

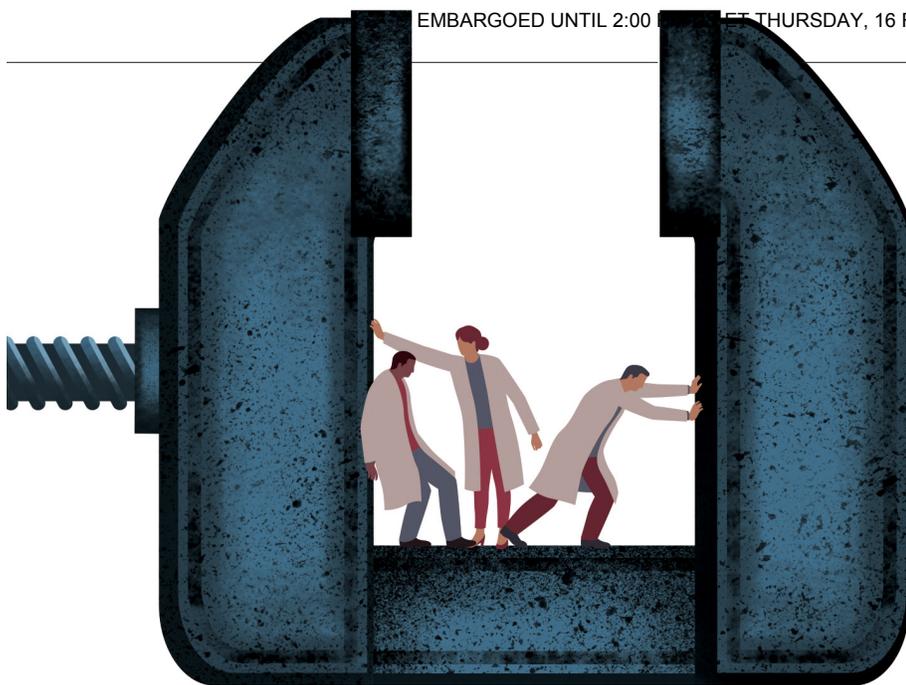


UCS worked with anonymous whistleblowers to reveal political interference in science, resulting in the resignation of high-ranking administration appointees and the correction of the administrative record (9). Scientists and public interest organizations successfully raised the political price of misusing science for political purposes. Informed by these experiences, UCS developed detailed policy recommendations to guide and protect the use of science at federal agencies, including increasing transparency, protecting government scientists from political interference in their work, and improving scientific advice to governments (such as managing external peer review and conflicts of interest on federal advisory committees) (10).

As detailed below, many of these policy recommendations were ultimately adopted by the Obama Administration or passed by Congress with substantial bipartisan support. This was no accident. Scientists mobilized to demand reform. Both the John McCain and Obama campaigns in 2008 committed in writing to restore scientific integrity to federal policy-making. This resulted in the federal government advancing its understanding, policies, and practices around science and decision-making in ways we cannot afford to walk back. Twenty-four executive branch departments and agencies developed scientific integrity policies to guide and protect the process by which agencies utilize and publicly communicate science, including use of nongovernmental scientists for peer review and federal advisory committees (3). Several have dedicated officials to oversee and implement these policies.

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As a result, more federal scientists and some special government employees who serve on federal advisory committees, now have more rights in writing to protect the integrity of their work—rights to share their scientific work with the American people, rights to review official documents based on their research before public release, and rights to participate fully in the scientific community. Many policies explicitly prohibit political appointees and public affairs staff from manipulating agency science.

There are signs of improvement. A 2015 survey of scientists across four federal agencies found that 70% (3539 respondents) were aware of their agency's scientific integrity policy (11). Agency scientific integrity officials report regular informal staff consultations that help staff understand their rights and responsibilities and prevent losses of scientific integrity from developing. The majority of publicly reported scientific integrity allegations across agencies have been found to not have merit or have been resolved within the scientific integrity office, rather than resulting in legal actions. It is hard to imagine that such issues could be resolved as smoothly without the presence of scientific integrity policies and officials to implement them.

These key standards must be retained in order for science-based policies to be credible and legitimate and, thus, to enable the federal government to serve the public, rather than special, interests (12, 13). In fact, many of the policies should be strengthened. Several agency policies, for example, fail to include a provision that provides scientists the right to review, before release, public-facing materials that rely on their

work or list them as an author—an important provision that can safeguard against censorship and tampering with the science.

Recent gains in government transparency thanks to bipartisan efforts in Congress provide other ways to scrutinize the government's use or misuse of science and expose political interference in science. The FOIA Improvement Act of 2016 strengthens the Freedom of Information Act (FOIA) by codifying the presumption of openness that increases public access to government documents and communications. The Whistleblower Protection Enhancement Act (WPEA) of 2012 explicitly protects federal scientists who challenge the censorship of scientific and technical information. Such protections can enable and enrich the use of science in federal decision-making as researchers will be less fearful of retaliation.

ENGAGE, SUPPORT, DEFEND

The public will suffer if politicization of science is normalized. But we need not wait for things to go wrong to defend the role of science in our democracy. We can anticipate where battles may arise.

First, we must demonstrate support for and value of federal scientists' work. This can reduce the likelihood that the Administration will ignore the new scientific integrity policies or otherwise roll back protections for civil servants and discourage Congress from passing legislation that diminishes the role of scientific advice in decision-making. The recently resurrected Holman Rule, for example, allows Congress to reduce a federal employee's salary to \$1. It is easy to see how such a rule could be used to target federal scientists

conducting policy-relevant research, such as climate science or environmental impacts of industrial pollution. Are scientists able to publicly share their expertise, free of intimidation or undue restrictions? Are government data sets remaining intact and publicly accessible? Are government-funded studies being suppressed or altered by political forces? We must continue to monitor and prepare to respond to such abuses of scientists' work. Pressure from the public and the media, political leverage from science-supportive policy-makers, and several legal tools, such as those provided in the WPEA, are available in the event of such losses of scientific integrity.

Second, the scientific community should be prepared to defend the scientific basis for public protections. There are indications that the Trump Administration will attempt to radically alter how science informs regulations that keep Americans safe and healthy. The Regulatory Accountability Act, for example, which is under consideration in Congress, would add dozens of burdensome procedures to how science informs federal rule-making that would, in effect, prevent federal agencies from issuing any science-based rules, as many statutes require. In large part because they are grounded in science, these rules ensure that only drugs proven safe and effective can be put on the market, prevent workers from dangerous environmental exposures, keep our food safe, keep our drinking water clean, and protect our air. President Trump, following the lead of the Republican majority in Congress (14), has emphasized the economic costs of regulations while minimizing or disregarding health, safety, and other benefits that often far outweigh costs (15). Eroding these policies undermines the role that science plays in our government.

Third, we must defend the very process by which scientists engage with decision-makers. Numerous recent, yet unsuccessful, attempts in Congress to undermine the role of science in public policy (16) are now being revisited, this time with a seemingly enthusiastic White House. This directly threatens the work of scientists and substitutes political judgment for scientific judgment. The scientific community must be diligent in scrutinizing Congress for legislative attacks on science and the Administration's efforts to sideline science in federal agencies. And we must connect these actions to Americans' everyday lives.

Finally, scientists can individually engage by providing scientific advice to decision-makers and communicating the importance of their work to those outside the scientific community. They can be conduits of information when scientific integ-

ity is compromised in government. They can fiercely protect university independence. And they can defend peers who become political targets for speaking up (17).

We maintain hope that these concerns will not be realized. But the scientific community is well positioned for what may lie ahead. Already, scientific societies have asked the Trump Administration to appoint a science adviser and more than 5500 scientists have signed a letter asking the Administration to uphold scientific integrity (18). Alarms must sound when science is silenced, manipulated, or otherwise compromised. When science is sidelined from policy decisions, we all lose. ■

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BIOTECHNOLOGY AND LAW

CRISPR, surrogate licensing, and scientific discovery

Have research universities abandoned their public focus?

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Several institutions are embroiled in a legal dispute over the foundational patent rights to CRISPR-Cas9 gene-editing technology, and it may take years for their competing claims to be resolved (1–4).

But even before ownership of the patents is finalized, the institutions behind CRISPR have wasted no time capitalizing on the huge market for this groundbreaking technology by entering into a series of license agreements with commercial enterprises (see the figure). With respect to the potentially lucrative market for human therapeutics and treatments, each of the key CRISPR patent holders has granted exclusive rights to a spinoff or "surrogate" company formed by the institution and one of its principal researchers (5, 6). Although this model, in which a university effectively outsources the licensing and commercialization of a valuable patent portfolio to a private company, is not uncommon in the world of university technology transfer, we suggest it could rapidly bottleneck the use of CRISPR technology to discover and develop useful human therapeutics.

Several patterns emerge from the web of transactions shown in the figure (we make the documents used in our analysis available at <https://dataverse.harvard.edu/dataverse/crisprlicenses>). The right to use CRISPR techniques has been divided into three broad "fields of use": (i) basic, non-commercial research; (ii) development and sale of tools (kits, reagents, and equipment) that aid CRISPR-based gene edit-

ing; and (iii) development, sale, and use of therapeutics and treatments using CRISPR techniques. This last field broadly covers the most commercially significant applications and includes gene editing to develop agricultural products, veterinary medicine, and human diagnostics and therapeutics.

Precisely demarcating these fields of

use—especially for a flexible, broadly applicable technology like CRISPR—and awarding appropriate license grants can be challenging. Nonetheless, the institutions have largely granted nonexclusive licenses with respect to noncommercial research and tools development. This means that licensees, including academic researchers, are permitted to engage in these activities, but do not have the right to mar-

ket and sell products derived from their research. It also means that the CRISPR patent holders are free to grant licenses for their respective technologies to other research institutions. However, in the case of therapeutics and treatments, with few exceptions, exclusive licenses to surrogate companies (Editas, Caribou, or CRISPR Therapeutics) prevent the institution from granting similar licenses to other companies without the surrogate's permission. Caribou's exclusive license covers all fields of use, and it has in turn granted an exclusive license in the field of human therapeutics to Intellia Therapeutics.

SURROGATE LICENSING AND CRISPR

The companies to which the patent-holding institutions grant exclusive licenses effectively stand in as surrogates for the institutions themselves. These surrogates control a large and lucrative field for the exploitation of the licensed technology, and have significant freedom both to exploit it themselves and to seek partners and sublicensees. The surrogates take on the role of the patent owner and retain a lion's share of the resulting profits. Many

"The institutions controlling CRISPR patent rights have delegated [them]... to surrogate companies, which determine...[who] will be able to exploit [them]."

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