

### INTRODUCTION

### To Protect the Public, Agencies Must Restore Science

The COVID-19 pandemic is only one of the crises facing the United States as we look toward a new presidential term starting in 2021. Climate change and racism also threaten public health and well-being and demand comprehensive solutions. Fortunately, US government agencies are staffed with many skilled employees whose leadership and expertise can help us meet these challenges and many others.

In order for federal agencies to advance solutions to public health and environmental problems, their leaders must renew a commitment to scientific integrity and science-based public policies, and they must demonstrate that decisionmakers will respect evidence even when scientific findings are not politically palatable. In recent years, public trust and civil servants' morale have suffered as agencies have ignored, defunded, suppressed, and distorted science. Bipartisan support for scientific integrity safeguards is strong, though, and new agency leadership can make immediate, meaningful changes to restore confidence and position the US government to meet the challenges that face our nation today and in the future.

The following eight memos identify top priorities for agencies to adopt in the next presidential term to advance scientific integrity and science-based public policies. Each memo begins with a brief overview of the scientific integrity issues that agency faces and short descriptions of between two and five priority areas, followed by a list of specific actions recommended for the early days of the next presidential term. The remainder of each document provides additional detail about these priorities and specific recommended actions. The memos are designed so that high-level agency officials can read the first few pages and then pass them on to specialized colleagues who can use the more detailed information.

A companion set of memos—Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term—contains cross-agency recommendations for making independent science a core pillar of an agenda for the next presidential term. It has the support of good-government, public health, environmental, consumer,

#### **MEMOS**

- Department of Agriculture
- Department of Health and Human Services—Public Health: Ensuring Science Drives Policy
- Department of Health and Human Services—Sexual and Reproductive Health, Education, and Services
- Department of the Interior—Restoring Science into Decisionmaking
- Environmental Protection Agency
- National Oceanic and Atmospheric Administration
- Occupational Safety and Health Administration, Mine Safety and Health Administration, National Institute for Occupational Safety and Health
- · Office of Science and Technology Policy

and human and civil rights advocates representing tens of millions of people of varying political affiliations. These two sets of memos complement one another and together provide a roadmap for repairing and rebuilding scientific integrity starting in 2021.

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## Department of Agriculture

This memo outlines the ways in which the US Department of Agriculture (USDA) can ensure it is making science-based policy and program decisions during the next presidential term. Select priorities and steps the agency can take to effectively act on these issues in 2021 are identified.

This memo outlines priorities for USDA to advance its scientific leadership and capacity during the presidential administration beginning in 2021. We recommend that administration officials develop a plan within the first 100 days for repairing and rebuilding the agency's Research, Education, and Economics (REE) mission area, especially the Economic Research Service (ERS) and the National Institute of Food and Agriculture (NIFA), given the staffing losses both agencies incurred due to their abrupt relocation in 2019. In addition, USDA must quickly invest substantial resources in research that helps ensure the sustainability and resiliency of our food and farm systems, especially given the urgency of climate change. This research should be informed by agroecology and social and systems science, and consider environmental, public health, and nutrition science, and the need to ensure food chain worker health and safety. Finally, REE research, as well as policy and program decisions, must be conducted in an inclusive way given the diversity of our food and farm systems.

These priorities are intended to offer a strong starting point for strengthening science and science-based policymaking at USDA in 2021. However, continued fidelity to these particular priority areas will be needed beyond 2021.

#### **Top Priorities for the Secretary of Agriculture**

- Re-establish and advance the scientific capacity of ERS and NIFA. Also, ensure that REE agencies' science informs policy and is carried out without undue political interference.
- Within the REE mission area, prioritize research on how to enhance the sustainability and resilience of US farm and food systems. This research should include a focus on agroecology, systems and social sciences, and human nutrition science.

- Conduct an agency-wide assessment to evaluate the process and degree to which research and science effectively inform the agency's program and policy decisions.
- Increase the diversity of USDA's employees, program
  recipients, stakeholders, and scientific advisory committees. The agency should ensure that program and policy
  decisions are made in an inclusive way. This diversity
  includes, but is not necessarily limited to, race, ethnicity,
  gender, geography, interest group, scientific discipline,
  and sector (such as industry, academia, and nongovernmental organizations).

#### **Key Appointment Positions**

- · Deputy Secretary
- USDA Inspector General
- USDA Chief Economist
- Under Secretary for Food, Nutrition, and Consumer Services
- Undersecretary for Food Safety
- Undersecretary for Natural Resources and Environment
- Undersecretary for Research, Education and Economics (Chief Scientist)
- Assistant Secretary for Civil Rights

#### **Day-One Actions**

- Announce a review of the previous administration's rulemaking and other policy decisions to identify any and all that were not evidence-based and revise or alter such decisions. Required actions will include:
  - Revoking or reversing any proposed or final rules issued in previous presidential terms that reduced or would reduce participation in the Supplemental Nutrition Assistance Program (SNAP), since evidence consistently indicates that the program is effective at alleviating food insecurity. This is especially important given the current economic downturn due to the COVID-19 pandemic.

#### **Actions for the First 30 Days**

- Return science-program leadership positions to Washington, DC, where people who fill them can best interact with and inform policymakers in accordance with their mission.
- Ensure that ERS remains under the purview of the REE mission area. This will help ensure that the USDA secretary and the Office of the Chief Economist are respecting the organizational firewall between ERS and the Office of the Secretary.
- Review the previous administration's rulemaking and other policy decisions to identify any and all that were not evidence-based and revise or alter such decisions.
   Required actions will include:
  - Ensuring that evidence-based child nutrition meal standards consistent with dietary guidelines are being implemented in the National School Lunch Program.
     Again, this is critically important during the COVID-19 pandemic since so many additional families are relying on these meals to meet their food needs.
  - Establishing evidence-based dietary guidelines and implementing them consistently across USDA nutrition programs with the goal of improving nutrition education, sustainability, and health and well-being for all people.
  - Revoking or reversing all "line speed waivers" granted to meat and poultry plants in 2019 and 2020. Withdraw the final rule on swine slaughter inspection and suspend all work on any rules increasing line speeds at meat and poultry plants. These changes are important because meat and poultry plant workers are particularly vulnerable to COVID-19. One potential rationale for these reversals, withdrawals, and suspensions is that the actions did not adhere to the requirements set forth in the agency Information Quality Activities Guidelines data presentation and transparency requirements.

#### **Actions for the First 100 Days**

 Develop a plan to rebuild and advance REE science capacity that defines the agencies' major strategic and tactical goals for the upcoming years, assesses talent and

- trends impacting availability of needed expertise, analyzes the current state of function of the agencies, conducts a gap analysis, and develops a plan for implementing program or policy changes.
- In the president's fiscal year 2022 budget request to Congress, request funding that allows ERS and NIFA administrators to quickly hire back staff so they can, at minimum, operate at their pre-relocation capacities. In addition, provide additional support and opportunity for administrators to advance overall staff capacity, particularly to add capacity for urgently needed research areas, such as on agroecology, interdisciplinary social science, and climate change, as much as possible. This could include additional full-time equivalents for recruitment or additional administrative human resource capacity.
- Across REE agencies, prioritize climate change mitigation and adaptation agricultural research, which spans disciplinary boundaries and includes agroecological, applied economics, integrated human nutrition science and policy, and systems science principles. For example, USDA's Agricultural Research Service (ARS) can devote more resources to researching agricultural practices that enable farmers and ranchers to both mitigate heat-trapping emissions and increase resilience to extreme weather events and other disturbances caused by climate change.
- In the president's fiscal year 2022 budget request, seek increases in discretionary funding for USDA's REE mission area, especially for NIFA's Agriculture and Food Research Initiative (AFRI) and the Sustainable Agriculture Research and Education (SARE) program. Given the importance of AFRI and SARE for identifying and improving tools and practices that help farmers achieve sustainability and resilience, the administration should propose budget increases for both of these programs in its fiscal year 2022 budget request. Furthermore, within these grant programs, increase funding for urgently needed research. Specifically, research that applies principles from agroecology, systems science, and social science should be prioritized. A balance of relatively smaller and larger grants is needed to support both exploratory and more complex field-based research. Additionally, larger grants are needed to support long-term research, particularly for understanding diversified farming systems (e.g., multicrop rotations) and the long-term impacts of climate and management changes.

- Request funding in the president's fiscal year 2022 budget for the USDA's Climate Hubs and Long-Term Agroecosystem Research Network, which could each provide a strong foundation for much-needed, regionally focused science in the years to come.
- Ensure that non-industry stakeholders are engaged in USDA policy and program decisions, especially in decisions about intramural and extramural research. These non-industry stakeholders could include academic or non-academic research institutions, nonprofit organizations, and organizations that represent farmers or other food system stakeholders, as well as women, Black people, Indigenous people, and other people of color, among others.

#### **Actions for the First Year**

- Ensure that ERS and NIFA analyses and research continue to inform the federal policymaking process.
- The USDA's SARE program, which offers farmer-driven grants and programming, should increase its emphasis on climate change mitigation and adaptation. Through its Education and Outreach and Professional Development programming, SARE could improve farmer access to knowledge and resources to build climate resilience.
- Use USDA data collection instruments—such as the Census of Agriculture or the Agriculture Resource Management Survey (ARMS)—to collect more information on the prevalence of agricultural practices that can mitigate heat-trapping emissions or that help farmers adapt to climate change, including practices that preserve soil health (such as cover crops, agroforestry, perennials, and conservation crop rotations).
- Create a public breed and cultivar research coordinator
  position within the REE mission area. This will ensure
  that USDA can continue to maintain and build a diversity
  of crops and livestock breeds with climate-adaptive and
  other beneficial traits that are broadly accessible to all
  US farmers.
- Conduct an agency-wide evaluation of the processes and degree to which science and evidence enter into agency decisionmaking and policy positions.
- In addition to evaluating the process by and degree to which program and policy decisions are evidence-based, USDA should evaluate the processes by and extent to

- which the public can participate or engage in agency decisionmaking. It should also evaluate the costs or benefits incurred by specific populations who are impacted by program or policy decisions.
- Evaluate NIFA's capacity to serve the 1890 and 1994 land-grant institutions (the Tribal Colleges and Universities) and the Hispanic-Serving Agricultural Colleges and Universities.
- Increase emphasis on diversity in evaluating applicants for USDA federal advisory committees (such as the National Agricultural Research, Extension, Education, and Economics Advisory Board). In particular, prioritize applicants who individually or through their organizational affiliation represent farmers who are women, Black, Indigenous, Hispanic, Asian, or part of other racial and ethnic groups that identify as non-White.
- Increase funding and resources for the USDA civil rights division to ensure that historic inequities in policy and program decisions are addressed and/or corrected.
- Invest in research that evaluates the links between soil, plant, animal, and human health.

# Priority 1: Re-Establish and Advance the Scientific Capacity of ERS and NIFA and Ensure that REE Agencies' Science Informs Policy and Is Carried Out without Undue Political Interference

In 2018, Secretary of Agriculture Sonny Perdue announced that he intended to relocate ERS and NIFA to a yet-to-be-determined location. At the same time, the secretary also announced as part of this plan that ERS would be reorganized, moving it out of the REE mission area and into the Office of the Chief Economist under the Office of the Secretary. Many advocates raised concerns about this particular proposal because it would expose ERS to more political influence.

After a lengthy site selection process, *the secretary* announced on June 13, 2019, that ERS and NIFA would be moving to Kansas City, Missouri. Employees were then required to decide whether or not to choose reassignment to the new location no later than September 30, 2019. *USDA* announced that it had signed a 15-year lease for office space in Kansas City on October 31, 2019. Since the relocation was first announced in 2018, both agencies lost approximately 75 percent of their staff and have yet to rehire back the

majority of these positions. We encourage the administration to undertake the following actions as soon as possible.

#### **Administrative Actions**

- Develop a plan to rebuild and advance REE science capacity that defines the agencies' major strategic and tactical goals for the upcoming years, assesses talent and trends impacting availability of needed expertise, analyzes the current state of function of the agencies, conducts a gap analysis, and develops a plan for implementing program or policy changes.
- Ensure that ERS and NIFA analyses and research continue to inform the federal policymaking process.
- Return science-program leadership positions to Washington, DC, where people who fill them can best interact with and inform policymakers in accordance with their mission.
- Ensure that ERS remains under the purview of the REE mission area. This will help ensure that the USDA secretary and the Office of the Chief Economist are respecting the organizational firewall between ERS and the Office of the Secretary.

#### **Budgetary Action**

• In the president's fiscal year 2022 budget request to Congress, include funding that allows ERS and NIFA administrators to quickly hire back staff so they can, at minimum, operate at their pre-relocation capacities. In addition, provide additional support and opportunity for administrators to advance overall staff capacity, particularly to add capacity for urgently needed research areas, such as agroecology, interdisciplinary social science, human nutrition science and policy, and climate change, as much as possible. This could include additional full-time equivalents for recruitment or additional administrative human resource capacity.

#### Priority 2: Within the REE Mission Area, Prioritize Research on How to Enhance the Sustainability and Resilience of US Farm and Food Systems

Agricultural systems in the United States produce among the highest yields of commodity crops globally. Yet food and agricultural production can degrade soil health, pollute air and water, and harm farmers, farmworkers, and rural communities. In addition, while food security and diet are not fully determined by total agricultural output or yields, there are direct links between food production and human health that USDA must investigate more fully. Furthermore, there is scientific consensus that climate change amplifies many of these challenges and is, therefore, an urgent threat to the livelihood of farmers, and food and farm workers, as well as to the resilience of our global food and farm systems upon which US and global consumers rely.

To ensure that US agriculture remains competitive globally and can sustainably produce food, fuel, and fiber for many generations to come, USDA must quickly invest substantial resources, especially with the REE mission area, into research to address environmental, climate change, worker safety, and public health—related concerns such as human nutrition and food insecurity. We encourage the administration to prioritize the following actions under this priority area.

#### **Administrative Actions**

- Across REE agencies, prioritize climate change mitigation and adaptation agricultural research, which spans disciplinary boundaries and includes agroecological, applied economics, integrated human nutrition science and policy, and system science principles. For example, ARS can devote more resources to researching agricultural practices that enable farmers and ranchers to both mitigate heat-trapping emissions and increase resilience to extreme weather events and other disturbances that are caused by climate change.
- The SARE program, which offers farmer-driven grants and programming, should increase their emphasis on climate change mitigation and adaptation. Through their Education and Outreach and Professional Development programming, SARE could improve farmer access to knowledge and resources to build climate resilience.
- Use USDA data collection instruments—such as the
  Census of Agriculture or ARMS—to collect more information on the prevalence of agricultural practices that
  can mitigate heat-trapping emissions or that help farmers
  adapt to climate change, including practices that preserve
  soil health (such as cover crops, agroforestry, perennials,
  and conservation crop rotations).
- Create a public breed and cultivar research coordinator position within the REE mission area. This will ensure that USDA can continue to maintain and build a diversity

- of crops and livestock breeds with climate-adaptive and other beneficial traits that are broadly accessible to all US farmers.
- Invest in research that evaluates the links between soil, plant, animal, and human health.
- Establish inequities research programs at ERS and NIFA
  with two purposes: (1) to build a portfolio of research at
  ERS and NIFA on social and economic inequities across
  sectors of the food system (e.g., farming, farmworkers,
  food processing, distribution, consumer food choices)
  and (2) to improve minority-serving and capacity-building
  competitive programs.

#### **Budgetary Action**

- Seek increases in discretionary funding for USDA's REE mission area, especially for the AFRI and SARE programs. Given the importance of AFRI and SARE for identifying and improving tools and practices that help farmers achieve sustainability and resilience, the administration should propose budget increases for both of these programs in its fiscal year 2022 request. Furthermore, within these grant programs, increase funding for urgently needed research. Specifically, research that applies principles from agroecology, systems science, and social science should be prioritized. A balance of relatively smaller and larger grants is needed to support both exploratory and more complex field-based research. Additionally, larger grants are needed to support long-term research, particularly for understanding diversified farming systems (e.g., multi-crop rotations) and the long-term impacts of climate and management changes.
- Request increased funding for the USDA's Climate Hubs and Long-Term Agroecosystem Research Network could also provide a stronger foundation for critical multiyear, regionally focused science.

## Priority 3: Conduct an Agency-Wide Assessment to Evaluate the Process and Degree to Which Research and Science Effectively Inform the Agency's Program and Policy Decisions

There is a great need to create a formal and consistent process across all of USDA's mission areas that ensures that rules, programs, and policy decisions are evidence-based. The administration should undertake the following priority actions.

#### **Administrative Actions**

- Conduct an agency-wide evaluation of the processes and degree to which science and evidence enter into agency decisionmaking and policy positions.
- Review the previous administration's rulemaking and other policy decisions to identify any and all that were not evidence-based and revise or alter such decisions.
   Required actions will include:
  - Revoking or reversing any proposed or final rules issued during previous presidential terms that reduced or would have reduced SNAP participation, since evidence consistently indicates that the program is effective at alleviating food insecurity. This is especially important given the current economic downturn due to the COVID-19 pandemic.
  - Ensuring that evidence-based child nutrition meal standards consistent with dietary guidelines are being implemented in the National School Lunch Program.
     Again, this is critically important during the COVID-19 pandemic since so many additional families are relying on these meals to meet their food needs.
  - Establishing evidence-based dietary guidelines and implementing them consistently across USDA nutrition programs, with the goal of improving nutrition education, sustainability, and health and well-being for all people.
  - Revoking or reversing all "line speed waivers" granted to meat and poultry plants in 2019 and 2020, as well as withdrawing the final rule on swine slaughter inspection and suspending all work on any rules increasing line speeds at meat and poultry plants. These changes are important because meat and poultry plant workers are particularly vulnerable to COVID-19. One potential rationale for these reversals, withdrawals, and suspensions is that the actions did not adhere to the requirements set forth in the agency Information Quality Activities Guidelines data presentation and transparency requirements.
- Improve coordination across USDA agencies to ensure programs and policies are synergistic and not working at cross purposes. This could be achieved by establishing an agency-wide task force to evaluate where policies or programs might be working at odds with one another and then determining what type of administrative actions could help to better align policies and programs across the agency.

## Priority 4: Increase the Diversity of USDA's Employees, Program Recipients, Stakeholders, and Scientific Advisory Committees

The US food and agricultural system is not monolithic. The system and sectors within it vary by geographic region, by predominant crop grown, by scale or style of production, and by many other characteristics. Likewise, the challenges and obstacles that different sectors, communities, and individuals face within our food and agricultural system are diverse and distinct. Consequently, USDA's staff—and those with whom it engages and consults to make program and policy decisions—must be diverse to ensure that multiple perspectives inform and have influence over the agency's decisions.

#### **Administrative Actions**

In addition to evaluating the process and the degree to
which program and policy decisions are evidence-based,
USDA should evaluate the processes and extent to which
the public can participate or engage in agency decisionmaking. It should also evaluate the costs or benefits
incurred by specific populations who are impacted by
program or policy decisions.

- Evaluate NIFA's capacity to serve the 1890 and 1994 land-grant institutions (the Tribal Colleges and Universities) and the Hispanic-Serving Agricultural Colleges and Universities.
- Ensure that public and private sector stakeholders are
  equally engaged in USDA policy and program decisions,
  especially in decisions about intramural and extramural
  research. These non-industry stakeholders could include
  academic or non-academic research institutions, nonprofit
  organizations, and organizations that represent farmers
  or other food system stakeholders as well as women, Black
  people, Indigenous people, and other people of color.
- Increase emphasis on diversity in evaluating applicants for USDA federal advisory committees (such as the National Agricultural Research, Extension, Education, and Economics Advisory Board). In particular, prioritize applicants who, individually or through their organizational affiliation, represent farmers who are women, Black, Indigenous, Hispanic, Asian, or part of other racial and ethnic groups that identify as non-White.
- Increase funding and resources for the USDA civil rights division to ensure that historic inequities in policy and program decisions are addressed and/or corrected.

#### **ENDORSED BY**

Acadia Institute of Oceanography / Climate Science Legal Defense Fund / Free Government Information (FGI) / Friends of the Earth / Government Information Watch / Greenpeace USA / In the Public Interest / Institute for Agriculture and Trade Policy / International Chemical Workers Union Council / Milwaukee Riverkeeper / MomsRising / Ocean Conservation Research / PHILAPOSH / Revolving Door Project / RICOSH / Society for Conservation Biology North America / Union of Concerned Scientists / Western New York Council on Occupational Safety & Health (WNYCOSH)

# Department of Health and Human Services

Public Health: Ensuring Science Drives Policy

This memo outlines key ways in which the Department of Health and Human Services (HHS) can establish and restore the principles of scientific integrity, as well as repair and rebuild its scientific capacity, during the next presidential term. Specific priorities and steps the agency can take to effectively act on these issues in 2021 are identified.

HHS advances public health by conducting and funding research and by translating evidence into advice. To be effective, it must act based on the best available evidence and retain public trust—but recent events demonstrate that it needs stronger safeguards in order to do both of these things consistently.

To address the public health needs of the nation, other government partners and the public must be able to trust that HHS will supply relevant, sufficiently detailed data quickly and provide actionable recommendations based on evolving evidence. It must also make funding decisions that prioritize strong science to advance public health, uphold transparency, and limit conflicts of interest. Over multiple administrations, and with conditions worsened in the years immediately prior to the COVID-19 crisis, HHS agencies have failed to uphold these high standards in ways that damage public trust. Improvements to policies and practices will help ensure that HHS science can advance public health equitably and sustainably.

#### **Top Priorities for the HHS Secretary**

• Restore and safeguard public trust in HHS.

To restore and safeguard public trust, HHS should strengthen scientific integrity and media policies and create additional procedures to prevent political interference with advice that should be based on public health evidence. The agency should also improve transparency and safeguards against conflicts of interest for industry-funded research.

- Ensure research funding is based on merit and continues without unwarranted interruptions.
  - To support ethical, high-priority research by National Institutes of Health (NIH) scientists and well-qualified grantees, NIH must ensure an effective, transparent process of reviewing research grants in a manner that promotes scientific rigor and guards against political interference. To correct recent inappropriate action, NIH should immediately rescind recent restrictions on research using human fetal tissue.
- Collect appropriate data and act in accordance with the evidence. To enable work that advances health equity, HHS should strengthen data collection to allow for analysis on multiple characteristics and identification of disparities, including by sex assigned at birth, gender identity, sexual orientation, race, ethnicity, national origin, disability status, age, income level, and geographic location. It should also ensure that the Food and Drug Administration (FDA) considers a wide range of rigorously evaluated data as well as clinical trial data, and that FDA uses sufficient evidence to make appropriate and timely decisions about drugs and devices—including any necessary changes for approved products when postmarket data on safety or efficacy demonstrate a need.
- Create policies, procedures, and cultures that ensure equitable work environments and allow all staff members to thrive. HHS must make meaningful changes to dismantle barriers to advancement and address toxic workplace cultures that harm Black employees and other staff who face racism and discrimination. The June 2020 letter supported by more than 10 percent of Centers for Disease Control and Prevention (CDC) employees demonstrates the severity of the situation and provides a roadmap for effective change. Creating workplaces that treat employees equitably and ensure that all can thrive will allow all HHS agencies

to attract and retain skilled, diverse scientific workforces equipped to advance health equity and other public health priorities.

#### **Key Appointment Positions**

- Assistant Secretary for Health
- Principal Deputy Assistant Secretary for Health
- Assistant Secretary for Public Affairs
- Assistant Secretary for Planning and Evaluation
- Assistant Secretary for Preparedness and Response
- Surgeon General
- NIH Director
- National Cancer Institute (NCI) Director
- FDA Commissioner
- FDA Deputy Commissioner
- CDC Director

#### **Day-One Actions**

- Commit to modernizing and restoring independence to the public health agencies, ensuring that they are the premier scientific institutions that they have been throughout the last century. (See Priority 1 below for more detail.)
- Announce rulemaking to rescind 2019 restrictions on federally funded research using human fetal tissue. (Priority 2)
- Announce a plan to reinstate the NIH EcoHealth
   Alliance grant to allow for the continuation of the global research collaboration leading coronavirus studies in
   China. (Priority 2)
- Announce a commitment to transparency of research funding and data for the COVID-19 response. (*Priority 3*)

#### **Actions for the First 30 Days**

- Assign a high-level team to create procedures to insulate scientists producing guidance from political pressure. (Priority 1)
- Make a public announcement that scientists from the National Institute for Occupational Safety and Health (NIOSH) will participate in drafting and approval of any CDC guidance and other major communications on topics that affect worker health. (Priority 1)

- Assign a high-level team to assess and strengthen scientific integrity policies and media policies at each HHS agency. (Priority 1)
- Initiate rulemaking to rescind 2019 restrictions on federally funded research using human fetal tissue. (Priority 2)
- Reinstate the NIH EcoHealth Alliance grant. (Priority 2)
- Publicly announce FDA's first steps for improving its use of rigorously evaluated evidence in approvals and post-market actions. (Priority 3)
- Determine which eliminated federal advisory committees should be restored and publicly announce plans to re-establish them. (Priority 3)
- Release data regarding the quality of tests (both antigen and antibody) and therapeutic agents that have been approved by FDA during the COVID-19 pandemic. (Priority 3)

#### **Actions for the First 100 Days**

- Appoint members and schedule the first meeting of the transdepartmental working group to evaluate foundations, public-private partnerships, and user fees; the working group should be charged with providing oversight and public leadership and engagement. (Priority 1)
- Develop a secretarial-level plan to ensure that each agency is collecting and analyzing data and delivering findings to those who can use them to advance health equity. (Priority 3)
- Assign senior staff to ensure that each agency within HHS
  has standard procedures for the collection, disclosure,
  and maintenance of data across multiple dimensions.
  (Priority 3)

### Priority 1: Restore and Safeguard Public Trust in HHS

During an epidemic or pandemic, public trust is essential to ensuring that members of the public heed advice from experts about behaviors that reduce the risk of infection spread—but problems before and during the COVID-19 crisis have damaged HHS's previous reputation as the world leader in public health. In a move decried by public health experts, CDC relaxed guidelines on worker protections against coronavirus transmission to recommend surgical masks rather than the more-protective N95 respirators—despite accumulating

evidence that the virus can spread via aerosols that surgical masks do not block—and did so without the apparent support and engagement of NIOSH. Reporting later *revealed* that CDC made the change after pleas from hospitals and public officials concerned about employer liability. Guidelines on safe re-opening have been *delayed* and *weakened*, apparently in direct response to political instructions. FDA made emergency approval determinations about *testing* and *treatments* with both *limited data and limited transparency*. Marginalization of science and expertise compromises the independence of our stellar scientific institutions and puts the people of our nation at risk.

Concerns about scientific integrity at agencies across HHS preceded COVID-19 and span numerous administrations. Restrictions on journalists' access to experts at *CDC* and *FDA* have raised concerns about transparency. Use of CDC and NIH foundations to accept industry funding for studies related to those industries' products—such as *alcoholic beverage companies funding research into health effects of alcohol consumption* and the *National Football League supporting studies on concussions*—highlights the potential for conflicts of interest and damaged public trust in research findings. Public-private partnerships and user fees also raise concerns about the potential for inappropriate influence.

The public must be able to trust that the advice they receive from HHS experts is based on evidence rather than on political or funder pressure, and that experts are able to share their expert opinions freely with the media and the public. Data produced by our federal agencies must be more accessible to outside experts. Strengthening scientific integrity policies and procedures, improving conflict-of-interest safeguards, and increasing transparency can help restore damaged public trust and improve HHS's ability to respond to pandemics and advance public health.

#### **Administrative Actions**

• Create procedures to ensure that scientists producing guidance on public health topics are sufficiently insulated from pressure so that their advice to the public reflects informed opinion based on evidence and not compromised by industry or political pressure. This is particularly important for responses to the COVID-19 pandemic, including guidance on testing, safe and effective treatments, personal protective equipment, and vaccine development and safety.

- Commit to restoring the independence and apolitical nature of public health agencies, including CDC, NIH, and FDA, and to supporting the public health and research infrastructure needed.
- Require that when CDC is producing guidance and other major communications on topics that affect worker health, such as personal protective equipment, NIOSH scientists and leadership play an active role in the development and approve the final product prior to public release.
- Ensure that each agency within HHS has a scientific integrity policy that protects the rights of scientists to share data and analysis, prohibits retaliation against those raising scientific integrity concerns, provides clear procedures for addressing alleged violations, and requires ongoing scientific integrity training. (For more details, see the "Agency Scientific Independence" memo in Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term.)
- All HHS officials, including senior scientists, should testify openly and accurately to Congress upon request.
- Ensure that each agency within HHS has a media policy
  that allows scientists to share their expertise publicly
  without political vetting or approval. (For more details,
  see the "Scientific Communications" memo in Restoring Science, Protecting the Public: 43 Steps for
  the Next Presidential Term.)
- Convene a transdepartmental working group to evaluate foundations, public-private partnerships, and user fees that fund CDC, FDA, and NIH research in order to ensure transparency and oversight; identify potential conflicts of interest; share best practices; provide estimates of risks (including risks to public trust) associated with continued receipt of industry funding; and describe options for arrangements that significantly reduce the risk to public confidence and involve public and consumer input and leadership. Those options should include both a) new institutional arrangements that allow for receipt of industry funding with far stronger safeguards against industry influence over research and b) replacement of industry funding with public appropriations. The working group should issue a public report with recommendations within two years.

## Priority 2: Ensure Research Funding Is Based on Merit and Continues without Unwarranted Interruptions

Recent instances in which research funding decisions appeared to have been made for political reasons have imperiled public confidence in HHS and delayed important research, including studies on coronavirus transmission and treatments. To restore public trust and direct public dollars toward research that would advance public health, the administration must ensure that political motivations are not driving grantmaking and research funding decisions.

In 2019, HHS discontinued the funding of future research requiring newly acquired fetal tissue, stating that "promoting the dignity of human life from conception to natural death" drove the decision. NIH senior-level scientists protested the restrictions and pledged to continue funding the existing fetal tissue research. Studies involving fetal tissue remain "the gold standard" for many kinds of research. Medical researchers have relied on fetal tissue for developing vaccines including polio, rubella, measles, chicken pox, adenovirus, and rabies, as well as treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia. Scientists continue to rely on fetal tissue for research for ongoing medical advances for Zika and HIV, as well as COVID-19—despite current restrictions making it difficult for scientists to conduct such studies. The administration must lift these restrictions on research using fetal tissue so that lifesaving research and scientific advances can continue unhindered.

Transparent decisionmaking processes for the review and cancellation of NIH and other research grants must be established and reaffirmed as well. In 2018, HHS *quietly* ended and paused longstanding NIH grants relying on fetal tissue, with no public announcement. This decision was made so abruptly that NIH researchers' cancer and HIV studies were imperiled. We have yet to see the audit the agency conducted during this time that apparently informed the 2019 decision to halt all research involving newly acquired fetal tissue.

In February 2020, HHS *announced* the formation of a new Human Fetal Tissue Ethics Advisory Board to be housed within NIH. In July 2020, the Advisory Board *convened* for the first time. The names of the *members* were released to the public on the morning of this meeting. Of the 15 Advisory Board members, at least two-thirds of them have anti-abortion views and connections that have influenced

their scientific research and policy decisions. A majority of the members have expressed outright opposition to fetal tissue and stem cell research. The Advisory Board released a *report* in August 2020 recommending against funding for 13 of 14 NIH grants using fetal tissue that they reviewed. The only study that was recommended for funding looks into validating alternatives to fetal tissue research. Two members of the panel included a dissent published as a part of the report, stating that the group was designed to "block funding of as many contracts and grants as possible." They closed by warning of detrimental implications of defunding fetal tissue research, including for COVID-19. Although the board's charter specified that it would terminate 30 days after submitting its report, it could have long-lasting repercussions if the HHS secretary terminates funding based on its recommendations.

In April 2020, as the deadly COVID-19 pandemic spread across the world, HHS *abruptly cancelled an EcoHealth Alliance grant* for research in China on how coronaviruses, including COVID-19, move from bats to humans. In doing so, the *administration cited the unsupported claim* that the "virus had escaped from a Chinese laboratory supported by the NIH grant," and vowed to end the funding. The research involved a 15-year collaboration, and the Chinese researchers had already shed light on the pandemic's origins.

Decisions about funding awards must be made by individuals with relevant scientific expertise and be based on transparent criteria that address the merits of the proposed research, investigator qualifications, and the research's potential contributions to public health priorities. Halting research studies before the scheduled completion of grants wastes the resources already devoted to them; while situations such as ethical misconduct might require intervention by the grantmaking agency, solutions such as transferring studies to different investigators or institutions should be explored. Transparency around funding and cancellation decisions is crucial for accountability. Any reviews, audits, and/or cancellations of an agency's research grants must involve the input of that agency's scientists with relevant expertise, and relevant information must be made available to the public in a timely manner.

#### **Administrative Actions**

- Rescind the restrictions published in 2019 on federally funded research using human fetal tissue.
- Reinstate the NIH EcoHealth Alliance grant to allow for the continuation of the global research collaboration leading coronavirus studies in China.

### Priority 3: Collect Appropriate Data and Act in Accordance with the Evidence

HHS provides researchers and the public with many important data sets, but it does not always collect sufficient data to advance its **stated equity aims** or make the most appropriate decisions about drugs and devices.

The stark racial disparities in COVID-19 deaths underscore the importance of collecting race and ethnicity data. Researchers and public health officials should have timely access to public health data sets that allow for analyses along multiple dimensions—e.g., comparing hospitalization rates for Black women to those of White men. In many cases, collecting more complete data will require providing additional resources and technical assistance to grantees who provide data to the agency. Data on individuals should include sex assigned at birth, gender identity, sexual orientation, race, ethnicity, national origin, disability status, age, income level, and geographic location. HHS and all the agencies within itincluding the Administration for Children and Families (ACF), Office of the Assistant Secretary for Planning and Evaluation (ASPE), Agency for Healthcare Research and Quality (AHRQ), CDC, Centers for Medicare and Medicaid Services (CMS), FDA, Health Resources and Services Administration (HRSA), Indian Health Service (IHS), NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA) should ensure that the data they collect are detailed enough to allow for identification of disparities, and then use data analyses to drive policy changes that advance equity. Analyses and responses should identify the role of racism in creating and maintaining health disparities rather than allowing for *persistence of assumptions* that disparities are due to inherent characteristics or actions of affected groups.

In studies on medical products regulated by FDA, required data collection should include not only clinical trial data but also other rigorously evaluated data, including post-market safety reports and studies, electronic health records, and registries that can allow a more complete understanding of drug and device safety and effectiveness. Such evidence has played a key role in recent post-market regulatory actions challenging the safety of medical devices such as Essure and breast implants, as patient experience can help identify what questions should be asked and what additional data are needed.

FDA should strengthen rather than lower their standards for approval of medical products, ensuring consistent and appropriate decisionmaking. This includes examining and limiting the use of biomarkers instead of clinically meaningful endpoints, and limiting the use of non-inferiority as a standard

rather than product superiority or equivalence in safety and effectiveness. The standard of "least burdensome" should also include "least burdensome to patients," not just to the industry sponsor, thus requiring useful information on which product works and for whom. FDA should be transparent about the criteria it uses for making decisions, including approvals of COVID-19 tests (both antigen and antibody) and therapeutic agents.

FDA should make a stronger commitment to monitoring post-market data and acting promptly to alter approvals and labels when evidence indicates changes are warranted.

#### **Administrative Actions**

- Ensure that each agency within HHS is collecting data
  that are sufficiently detailed to detect disparities across
  multiple dimensions, including sex assigned at birth,
  gender identity, sexual orientation, race, ethnicity, national
  origin, disability status, age, income level, and geographic
  location; routinely analyzing data to track progress on
  health equity; and delivering these findings to policymakers who can make changes to advance equity.
- Ensure that each agency within HHS has standard procedures for the collection, disclosure, and maintenance of data, including transparency and release of data to outside experts and the public. (For more details, see the "Data Collection and Dissemination" memo in *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term.*)
- Ensure that FDA uses a wide range of rigorously evaluated evidence—including post-market safety reports and studies, electronic health records, and registries—as well as controlled clinical trials in approval and post-market surveillance, and that it acts to modify approvals as indicated when post-market safety signals emerge.
- Re-establish federal advisory committees that were eliminated pursuant to *Executive Order 13875* but whose scientific advice is still needed, and increase transparency around these committees' composition and member selection. (For more details, see the "Federal Advisory Committees" memo in *Restoring Science*, *Protecting the Public: 43 Steps for the Next Presidential Term.*)

#### **Budgetary Action**

 Propose budgets that include expanded funding for program evaluation and research to gather comprehensive data sets that can be disaggregated by sex assigned at birth, gender identity, sexual orientation, race, ethnicity, national origin, disability status, age, income level, and geographic location. Budgets for grant-funded programs should include sufficient resources to assist grantees with appropriate data collection.

## Priority 4: Create Policies, Procedures, and Cultures that Ensure Equitable Work Environments and Allow All Staff Members to Thrive

When CDC employees sent a letter to agency director **Robert Redfield** on June 30, 2020, calling on him to address workplace racism and discrimination, they stated that "decades of well-meaning, yet under-funded, diversity and inclusion efforts" had yielded "scant progress in addressing the very real challenges Black employees experience at CDC." They highlighted the insufficient numbers of Black scientists in the Epidemic Intelligence Service that serves as a training ground for future leaders and the low number of Black people in the agency's senior leadership, and pointed out that this affects how the agency addresses pressing public health issues: "While African Americans are disproportionately affected by many of the diseases this agency works to control and prevent, astonishingly few African Americans sit at the tables of leadership where critical decisions are made concerning these public health issues." The staff members also warned of "widespread acts of racism and discrimination within CDC that are, in fact, undermining the agency's core mission."

The letter, which has since received signatures from more than 10 percent of the agency's workforce, identifies seven areas for change and makes 33 specific asks. Immediate actions include steps such as an independent review of hiring, grading, and performance evaluation to identify any bias and/or discrimination, and mandatory implicit bias training for all staff within 30 days of onboarding and annually thereafter. Longer-term steps include increasing the proportion of Black

scientists recruited through key training programs; tracking workforce diversity data; and launching external audits of agency policies and culture. While a few of these asks are specific to CDC (such as engaging locally employed staff in the hiring of country leaders in other nations where CDC operates), most could apply to other HHS agencies with minimal changes such as replacing the names of CDC-specific training programs with analogous programs from the relevant agency.

HHS can best meet the public health challenges of the 21st century by ensuring that its agencies welcome and support a diverse group of staffers. To do so, it must make meaningful changes to dismantle the racism and discrimination that Black staff members have called out.

#### **Administrative Actions**

- The secretary should require that CDC leadership provide a point-by-point response to each of the 33 asks in the *June 30 employee letter*, and that other agencies' leadership respond to all the points that could apply to their agency (with minor modifications where necessary). These responses should include details about whether and how the agency plans to address each ask, as well as any additional steps the agencies plan to take to address racism and discrimination.
- Assign senior HHS staff to review the agency responses, recommend additional or modified actions, and follow up regularly with each agency's leadership to ensure they are implementing plans to create equitable policies and work environments.

#### **Budgetary Action**

 Propose budgets that include staff time and other resources for Diversity, Equity, and Inclusion Committees, as well as implicit bias training and cultural sensitivity education for all staff.

#### **ENDORSED BY**

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# Department of Health and Human Services

### Sexual and Reproductive Health, Education, and Services

This memo outlines key ways in which the Department of Health and Human Services (HHS) can establish and restore the principles of scientific integrity, as well as repair and rebuild its scientific capacity, during the next presidential term. Specific priorities and steps the agency can take to effectively act on these issues in 2021 are identified. This memo is complementary to, though not affiliated with, the broader Blueprint for Sexual Health, Rights, and Justice recommendations.

For decades, HHS has taken a science-based approach to family planning and reproductive health, but recent changes have reduced the role of evidence and complete information in several of its related activities. Improvements at the Office of Population Affairs (OPA), Food and Drug Administration (FDA), Office for Civil Rights (OCR), National Institutes of Health (NIH), and other agencies within HHS can ensure that future activities related to reproductive health, education, and services are science-driven and evidence-based.

The ability to determine whether, when, and under what circumstances to have children is an essential component of public health, and decades of research demonstrate the safety, efficacy, and benefits of voluntary, patient-centered family planning. However, FDA decisions on sexual and reproductive health products are too often made with apparent deference to political considerations rather than being driven by evidence, and conditions across HHS have grown dire over the past few years.

Many recent HHS appointees have advanced policies that reduce access to family planning education, services, and methods; cut off promising avenues of research for apparently ideological reasons; appear to put political considerations above patient access to care; and apply different standards to abortion medication than other drugs. They have often done so by ignoring and misrepresenting scientific and programmatic evidence. As a result, millions of people have lost access to reproductive health services and the reputation

of HHS has suffered. At the same time, HHS has fallen short on collecting data that would allow researchers to identify and study inequities in health care and develop solutions to improve sexual and reproductive health equity. Through specific policy actions and an agency-wide commitment to evidence, HHS can improve access while re-establishing an expectation that the agency will use, produce, and consider the best available evidence in its grantmaking, research, enforcement, and drug approval activities.

#### **Top Priorities for the HHS Secretary**

- Use evidence to drive HHS-funded programs on sexual and reproductive health education and services. Changes to sexual and reproductive health programs have ignored evidence and resulted in a loss of services to those who need them. HHS should rescind the domestic gag rule that prevents Title X grantees from providing high-quality, evidence-based family planning care, assess to what extent grantees are providing such care, and use existing enforcement authority to ensure compliance with evidence-based quality standards. It should restore the original evidence-based intent, structure, administration, and implementation of the Teen Pregnancy Prevention (TPP) Program and reactivate and fund the Teen Pregnancy Prevention Evidence Review.
- Ensure OCR rulemaking and enforcement are based on evidence. Recent structural changes and rulemaking at OCR were made based on specious rationale and without evidence that the issues they aimed to address warranted the actions taken. HHS should rescind the unwarranted rules and reallocate resources to ensure that enforcement priorities reflect the current definition of discrimination as well as evidence about the form and scope of civil rights problems.

- Require that evidence rather than political considerations drive drug and device approval and guidance decisions. Across administrations, FDA has appeared to make decisions on sexual and reproductive health–related drugs based on politics rather than evidence, and it has been too slow to respond to post-market surveillance information. The administration must ensure that the same rigorous, science-based standards and internal review processes applied to other drugs and devices are applied to reproductive health products. This should include taking immediate action to remove non-evidence-based restrictions for prescribing and dispensing the drug mifepristone, used in medication abortions.
- Use evidence to advance equity. HHS has committed to advancing health equity, but its data collection and analysis have not supported this goal as well as they should. HHS must ensure that it is collecting data that enable it to identify disparities in access to, and experiences with, reproductive health education and services, including evaluating maternal health data collection and reporting; that it routinely analyzes data to track progress on health equity; and that findings from these analyses reach policymakers who can make changes to advance equity.

#### **Key Appointment Positions**

- Assistant Secretary for Health
  - Principal Deputy Assistant Secretary
  - Deputy Assistant Secretary for Population Affairs
- Assistant Secretary for Planning and Evaluation
- Assistant Secretary for the Administration on Children and Families
- Assistant Secretary for Public Affairs
- Director of the Office for Civil Rights
- FDA Commissioner and Deputy Commissioner
- Administrator, Centers for Medicare and Medicaid Services (CMS)
- Director, Indian Health Service (IHS)
- HHS Office of General Counsel, Associate General Counsel for Civil Rights Division
- HHS Inspector General

#### **Day-One Actions**

- Announce intention of rulemaking to rescind the Title X gag rule. (See Priority 1 below for more detail.)
- Direct FDA to affirmatively suspend the Risk Evaluation and Mitigation Strategy (REMS) in-person dispensing requirement on mifepristone that endangers pregnant people by requiring them to travel during the COVID-19 public health emergency, and drop any pending legal challenges to uphold those restrictions. The suspension should remain in effect until FDA can undertake a comprehensive review. (Priority 3)

#### **Actions for the First 30 Days**

- Take initial rulemaking actions to rescind the Title X gag rule. (Priority 1)
- Issue sub-regulatory guidance to reinforce the expectation that all Title X–funded programs follow Quality Family Planning (QFP) guidelines. (*Priority 1*)
- Take initial steps to reactivate the Teen Pregnancy Prevention Evidence Review. (Priority 1)
- Restore the Office of Adolescent Health and appoint a well-qualified Director of Adolescent Health. (*Priority 1*)
- Begin the process of rescinding the refusal-of-care rule.
   (Priority 2)
- Abandon the HHS/Department of Justice (DOJ) appeal of decisions vacating the refusal-of-care rule. (Priority 2)
- Dissolve the Conscience and Religious Freedom Division within OCR. (*Priority 2*)
- Direct FDA to conduct a comprehensive review of the REMS imposed on mifepristone to eliminate medically unnecessary barriers to access based on well-established evidence, both clinical and real-world, of mifepristone's effectiveness and safety. (Priority 3)
- Declare the administration's commitment to reproductive health drug and device approvals based on scientific evidence free from political interference. (Priority 3)
- Direct departments to appoint leadership within 60 days to demonstrate the administration's commitment to addressing disparities in minority health, women's health, health equity, and LGBTQ+ health. (*Priority 4*)

#### **Actions for the First 100 Days**

- Begin to undo the damage of the domestic gag rule
  by allowing qualified entities that left the program as a
  result of the rule a way to rejoin it, and ensure the grant
  application and award process for Title X supports
  high-quality, science-based services. (Priority 1)
- Commission a rigorous review to assess the impact on clients' access to high-quality family planning care (including the full range of contraceptive methods) as a result of recent changes in the Title X regulatory framework, the effects of COVID-19 on service delivery, and the support needed to fully meet the goals of the Title X program going forward. (Priority 1)
- Ensure the grant application and award process for the TPP Program supports high-quality, evidence-based projects. (Priority 1)
- Assess the extent and status of TPP Program funding that remains unallocated, and direct that funding to evidencebased purposes consistent with the intent of the program. (Priority 1)
- If any decisions vacating the refusal-of-care rule are overturned, HHS should rescind the regulation. (*Priority 2*)
- Rescind the regulation narrowing Affordable Care Act (ACA) Section 1557 and engage in rulemaking using a broad definition of discrimination that aligns with the Bostock decision. (Priority 2)
- Direct divisions that directly address minority health, women's health, LGBTQ+ health, adolescent health, rural health, immigrant health, and health equity to announce plans within one year to enhance data collection and analysis to address health disparities. (Priority 4)

## Priority 1: Use Evidence to Drive HHS-Funded Programs on Sexual and Reproductive Health Education and Services

Over five decades, the Title X program has funded a network of centers that provided high-quality, evidence-based *family planning care*, primarily to adolescents and clients with low incomes. However, the *Compliance With Statutory Program Integrity Requirements* rule issued in 2019—often called the domestic gag rule—requires providers receiving Title X funds to care for pregnant patients in a manner at odds with evidence-based standards of care, as well as

*medical ethics*. Among other things, it prohibits providers from making abortion referrals for patients who desire them, and requires referrals for prenatal care regardless of whether patients want to continue their pregnancies.

When HHS proposed this rule, thousands of commenters warned, citing evidence from a similar action in Texas, that it would drive experienced providers out of the program, and that it would be impossible to replace those providers quickly with others who could provide the high-quality family planning care that the program has long required. HHS responded that it believed new providers who could meet clients' needs would enter the program, but it did not offer compelling evidence. Initial research found that within months of the rule taking effect, there was a 47 percent drop in the program's capacity to serve female patients and reduced access to services for women in at least 390 counties spanning 30 states. Forcing high-quality providers out of Title X exacerbates disparities in access to family planning care, falling hardest on people of color, people living in rural areas, and people struggling to make ends meet. The administration should rescind this harmful rule and restore the integrity of the program, including by assessing whether new grantees are providing high-quality, evidence-based care and meeting the terms of their grants.

Beginning in 2010, the *TPP Program* funded high-quality, evidence-based teen pregnancy prevention grants. A *diverse group of grantees* across the nation replicated a variety of models that have demonstrated a positive effect on teen sexual behavior. Grants also support high-quality innovation and evaluation to continue expanding the evidence base. The first two five-year cycles of grants made vital contributions to the growing body of knowledge of what works to prevent teen pregnancy. This included high-quality implementation, rigorous evaluation, and learning from results. The TPP Program was recognized by *evidence experts* as a leading example of a tiered-evidence approach to evidence-based policymaking.

Since 2017, HHS repeatedly sought to eliminate or undermine the TPP Program by attempting to terminate grants, weakening evidence standards in grant announcements, and diverting funds supporting high-quality evaluation.

While *courts blocked* most of these egregious actions, they harmed ongoing research and the scientific enterprise under way. HHS also stopped funding and updating the *Teen Pregnancy Prevention Evidence Review*, an independent, systematic, rigorous review of evaluation studies that informed TPP grantmaking and provided a clearinghouse of evidence-based programs for other federal, state, and community initiatives.

From 2010 through 2019, the TPP Program was administered by the Office of Adolescent Health (OAH) under the assistant secretary of health. This office, with a well-qualified director and expert staff, was *lauded for high-quality implementation*, including generating unprecedented amounts of research and transparency. In 2019, OAH was merged into OPA, the director position was subsumed into the deputy assistant secretary for population affairs, and significant staff time and technical assistance were diverted to other efforts.

Divisions across HHS—including the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), CMS, FDA, the Health Resources and Services Administration (HRSA), IHS, NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA)—should ensure that their work on sexual and reproductive health is driven by evidence, and this approach should apply to international as well as domestic work. In particular, CDC should recommit to advancing sexual and reproductive health and making contraceptive access a priority, including by serving as an active partner in revisions to *Providing Quality Family Planning Services* (QFP).

#### **Administrative Actions**

- Rescind the Compliance With Statutory Program Integrity Requirements rule (i.e., the domestic gag rule) on the basis of its failure to respond appropriately to evidence-based concerns about its impacts, and replace it with the former regulations until new ones can be created through the standard notice-and-comment process.
- Begin to undo the damage of the domestic gag rule by allowing qualified entities that left the program as a result of the rule a way to rejoin it.
- Assess the rule's impact on clients' access to high-quality family planning care (including the full range of contraceptive methods) and use existing enforcement authority to ensure compliance with evidence-based quality standards, including the QFP guidelines.
- Ensure the TPP Program adheres to rigorous standards of evidence and to complete, unbiased, science-based information in its grant announcements, grant awards, evaluations, and implementation.
- Assess the extent and status of TPP Program funding that remains *unspent*, and direct that funding to evidencebased purposes consistent with the intent of the program.

- Reactivate and dedicate funding for the Teen Pregnancy Prevention Evidence Review.
- Restore OAH as a separate entity, appoint a well-qualified director of adolescent health, and ensure the office has sufficient funding to address the broad scope of adolescent health issues.

#### **Budgetary Action**

 The budget request for the TPP Program should provide adequate funding to support restoration of evidence-based implementation of grants that replicate effective programs and continue to expand evidence. This includes sufficient funding for technical assistance and high-quality evaluation, as well as funding for the Teen Pregnancy Prevention Evidence Review.

#### Priority 2: Ensure OCR Rulemaking and Enforcement Are Based on Evidence

OCR has an important role to play in safeguarding civil rights related to health care, but recent OCR actions based on specious rationales have diverted limited resources from appropriate priorities while employing a narrow version of discrimination that invites abuse. OCR must rescind rules that allow for discrimination based on gender identity and sex stereotyping and reverse damaging and inappropriate changes to its structure and approach.

Created in January 2018, the Conscience and Religious Freedom Division (CRFD) was established in part to investigate health-care workers' claims of discrimination on the basis of religious and moral objections to providing patient care such as abortion or sex reassignment. HHS claimed that an increase in "conscience" complaints (where health-care providers or even those associated with the provision of a healthcare service feel they are forced to provide care that violates their beliefs) merited the creation of CRFD, but that claim is false. In *federal court*, HHS attorneys admitted that prior to January 2018 "there was approximately one complaint per year" that would fall under CRFD's purview. CRFD claimed an increase in "conscience" complaints in FY 2018—however, they still constituted only a microscopic percentage of the 33,194 total complaints OCR received that year. A federal court found that fewer than 10 complaints are fairly characterized as relating to the federal refusal laws that CRFD is charged with enforcing. HHS devoted additional resources and staff to focus on an imaginary "problem" for which there

is no evidence. OCR always had the responsibility and authority to investigate and enforce federal laws that allow health-care providers to refuse to perform certain services, so absent evidence that OCR was unable to do so, the creation of CRFD and disproportionate allocation of staff to it was unwarranted.

The newly created CRFD drove HHS policies, including a refusal-of-care rule that dramatically expands the reach of existing federal refusal laws that enable doctors, hospitals, and other health-care entities to deny people care on the basis of the entities' own beliefs. Another rule that precedes CRFD's creation but uses similar rationale exempts employers and universities that have religious or moral objections to birth control from complying with the provision of the ACA's preventive care mandate that requires insurance plans to cover the full range of approved contraceptive methods. With no evidence to back its claims, HHS made the sweeping statement that the rule "will not affect over 99.9 percent of the 165 million women in the United States." Experts vehemently disagreed, arguing that the rule puts services like contraception, abortion, and HIV treatment at risk catastrophic human costs that HHS failed to assess.

The Health Care Rights Law (Section 1557 of the ACA) is a groundbreaking civil rights law that prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in all health programs and activities receiving federal financial assistance. The Obama administration issued a regulation interpreting Section 1557 to define discrimination on the basis of sex as inclusive of abortion, sex stereotyping, and gender identity. On June 12, 2020, the Trump administration's HHS removed this definition in a final rule amending and superseding the rule issued under the Obama administration. Three days after the Trump administration rule was released, the US Supreme Court affirmed workplace protections for LGBTQ+ people in its **Bostock v. Clayton County decision**, which solidified the interpretation of sex discrimination as including discrimination based on sexual orientation and gender identity. The Trump administration's 1557 rule change was already problematic; the Bostock decision also makes it clear that its definition of discrimination violates federal civil rights law.

#### **Administrative Actions**

- Begin the process of rescinding the refusal-of-care rule.
- Rescind the regulation narrowing ACA Section 1557 and engage in rulemaking using a broad definition of discrimination that aligns with the *Bostock* decision.

 In recognition of the lack of evidence demonstrating its necessity and in accordance with Court findings, dissolve CRFD.

#### **Budgetary Action**

 Allocate rulemaking and enforcement resources based on evidence of problems.

## Priority 3: Require that Evidence Rather than Political Considerations Drive Drug and Device Approval and Guidance Decisions

To fulfill its mission, FDA must make decisions about drugs and devices based on the best available evidence, and regularly update those decisions to ensure they continue to reflect evolving knowledge. Past agency failures in these areas warrant a renewed public commitment to making evidence-based decisions and prompt action to correct past errors.

FDA decisionmaking across a range of reproductive health drugs and devices is an area in which political appointees often make decisions counter to recommendations from scientific experts, with apparent political motivations. In two especially well-known cases, *Plan B* (levonorgestrel emergency contraception) and medication abortion (mifepristone), political appointees across multiple administrations overruled agency scientists and medical experts to restrict or delay access.

During the partial review of mifepristone's label and REMS in 2016, for example, agency officials publicly acknowledged that the commissioner personally overruled the recommendations of reviewers in at least one instance, with other instances of political interference known or suspected to have occurred. Although the label approved in **2016** removed some restrictions on mifepristone, it did not reevaluate requirements that the drug be prescribed and dispensed only by a limited group of providers—despite an extensive international record demonstrating that medication abortion without such restrictions is safe and effective. Now. in the COVID-19 context, FDA has sought to continue to require patients seeking abortions to face unnecessary exposure by traveling to one of the limited sources of mifepristone, despite lifting similar restrictions on other drugs. In July, a federal court **found** that these requirements provide "no significant health-related benefit" and are "unnecessary regulations." FDA must act to eliminate medically unnecessary barriers to access based on well-established evidence, both clinical and real-world, of mifepristone's effectiveness and safety.

Furthermore, in all of its decisions, FDA should use a range of evidence as a complement to-not a replacement for—controlled clinical trials in the approval and post-market surveillance of drugs and medical devices. Rigorously evaluated data, including analysis of post-market safety reports and studies, electronic health records, and registries, can help us better understand a more complete safety and effectiveness profile for both drugs and devices than manufacturer-sponsored clinical trials alone. Preclinical and clinical trials typically have extensive exclusion criteria and controls, which make use in the research setting different from average use. Dismissing data collected in the "real world" means ignoring the voices and lived experience of patients who were not part of the sponsor's studies and may not fit an industry narrative. Such evidence has played a key role in recent post-market regulatory actions challenging the safety of medical devices such as Essure and breast implants.

#### **Administrative Actions**

- Direct FDA to affirmatively suspend the REMS in-person dispensing requirement on mifepristone that endangers pregnant people by requiring them to travel during the COVID-19 public health emergency, and drop any pending legal challenges to uphold those restrictions; the suspension should remain in effect until FDA can undertake a comprehensive review of the REMS.
- Direct FDA to conduct a comprehensive review of the REMS imposed on mifepristone to eliminate medically unnecessary barriers to access based on well-established evidence, both clinical and real-world, of mifepristone's effectiveness and safety.
- Declare the administration's commitment to reproductive health drug and device approvals based on scientific evidence free from political interference.
- Ensure that the same rigorous, science-based standards and internal review processes applied to other drugs and devices are applied to reproductive health products. The secretary must direct FDA to reexamine previous decisions where routine agency processes were subverted in favor of political outcomes.

#### **Priority 4: Use Evidence to Advance Equity**

HHS has *committed to advancing health equity*, but its data collection and analysis have not supported this goal as well as they should. In order to address health inequities in a comprehensive and integrated way, HHS must develop and fund research to better understand the overall health status and the sexual and reproductive health needs and experiences of all communities. It should apply this approach across divisions—including ACF, ASPE, AHRQ, CDC, CMS, FDA, HRSA, IHS, NIH, and SAMHSA—and in both its domestic and international work.

HHS must ensure that it is collecting appropriate data, that it routinely analyzes data to track progress on health equity, and that findings from these analyses reach policymakers who can make changes to advance equity, such as developing and implementing evidence-based interventions that can substantially improve outcomes for historically marginalized groups. Efforts must include those for whom research data are frequently lacking, such as racial and ethnic groups often combined into broad categories, LGBTQ+ people, immigrants, people with disabilities, rural residents, and young people. By improving data collection on abortion, contraception, maternal health, sexually transmitted infections, sexual orientation and gender identity, formal sex education, and social determinants of health for under-researched populations, HHS can meaningfully expand capacity to address sexual and reproductive health inequities. It is important to note that, given the particular personal and political sensitivities surrounding reproductive health in the United States, any moves to improve surveillance must safeguard the privacy, rights, and needs of patients and providers.

Sexual and reproductive health advocates have warned that several recent policy changes will exacerbate health disparities. Such policies include those discussed above (the Title X gag rule, exemptions from the ACA's preventive care mandate, and the newly narrowed interpretation of the ACA's prohibition on discrimination) as well as changes to the Medicaid program (e.g., approval of waivers that let states make changes that limit access to family planning services). Research should examine whether these policy changes have had the predicted detrimental impacts to health equity.

#### **Administrative Actions**

- Clinical and behavioral research studies and surveys sponsored across all relevant agencies must collect data about the sexual and reproductive health of all communities while soliciting specific data on race, ethnicity, immigration status, age, disability status, geographic location, sexual orientation, sex assigned at birth, and gender identity so that data may be stratified on multiple characteristics. Data on literacy and health literacy should also be collected so research and surveys are developed so they can be understood by all populations.
- Assign personnel to conduct analyses of how recent policy changes in sexual and reproductive health have affected disparities across the dimensions listed above.
- If the Data to Save Moms Act (HR 6165) has not passed, take the action described in Section 4 of the bill by creating a Task Force on Maternal Health Data and Quality Measures. As described in the act, the task force should consider Maternal Mortality Review Committee members' participation in trainings on bias, racism, or discrimination; the extent to which states have implemented systematic processes of listening to the stories of pregnant and postpartum women and their family members, with a particular focus on minority women and their families; legal barriers preventing the collation of state maternity care data; the extent to which data are sufficiently stratified by race and ethnicity in the context of maternity care quality measures; the extent to which quality measures consider subjective measures of patientreported experience of care; and recommendations to

- improve maternal health data collection and reporting processes, and maternity care quality measures.
- If the *Social Determinants for Moms Act (HR 6132)* has not passed, take the action described in Section 2 of the bill by establishing a task force that includes representatives of relevant HHS agencies, other federal departments, and community representatives to develop coordinated strategies to address social determinants of health influencing maternal health outcomes.
- Elevate and strengthen existing offices and divisions related to minority health, women's health, health equity, and LGBTQ+ health to ensure that they have the resources and authority to collect and analyze data and ensure that their findings inform policy discussions.

#### **Budgetary Action**

 Propose a budget that includes expanded funding for program evaluation and research to gather comprehensive data sets that can be disaggregated by race, ethnicity, immigration status, age, disability status, geographic location, sexual orientation, sex assigned at birth, and gender identity. Budgets for grant-funded programs should include sufficient resources to assist grantees with appropriate data collection.

#### **Endnote**

1. The Health Information Privacy Division has only 20 full-time equivalents to investigate 78 percent of the complaints OCR receives, while CRFD has 12 full-time equivalents to investigate 4 percent of the complaints OCR receives.

#### **ENDORSED BY**

Acadia Institute of Oceanography / Advocates for Youth / Center for Reproductive Rights / EMAA Project / Equity Forward / Free Government Information (FGI) / Government Information Watch / Greenpeace USA / Guttmacher Institute / In the Public Interest / International Chemical Workers Union Council / Jacobs Institute of Women's Health / Milwaukee Riverkeeper / MomsRising / NARAL Pro-Choice America / National Abortion Federation / National Family Planning & Reproductive Health Association / National Partnership for Women & Families / National Women's Health Network / National Women's Law Center / Ocean Conservation Research / PHILAPOSH / Planned Parenthood Federation of America / Power to Decide / Revolving Door Project / RICOSH / Society for Conservation Biology North America / Union of Concerned Scientists / Upstream USA / URGE: Unite for Reproductive & Gender Equity / Western New York Council on Occupational Safety & Health (WNYCOSH)

## Department of the Interior

### Restoring Science into Decisionmaking

This memo outlines the key ways in which the Department of the Interior (DOI) can and should repair and rebuild its scientific capacity during the next presidential term. It identifies specific priorities and steps the agency can take to effectively act on these issues in 2021.

DOI is tasked with protecting the nation's natural resources and heritage, but recent changes have reduced the role of science and evidence-based decisionmaking within the agency. Improvements to the US Geological Survey (USGS), Bureau of Land Management (BLM), and US Fish and Wildlife Service (USFWS), among other agencies within DOI, can help ensure that science plays a leading role in the management and conservation of natural resources in the United States. This will be critical as DOI plays an important role in addressing two of today's biggest challenges: the climate and biodiversity crises, both clearly requiring science-based policies.

Through specific policy actions and an agency-wide commitment to using the best available science, DOI can recommit to and restore the expectation that the agency will use, produce, and consider the best available evidence in its research and decisionmaking.

#### **Top Priorities for the Secretary of the Interior**

- Restore and advance the use of the best available science and improve transparency in all agency planning and decisionmaking. Issue and implement DOI secretarial orders to ensure planning and management decisions are made with accepted science, good data, environmental analysis, and maximized public input.
- Restore and elevate the role of science in addressing the climate and biodiversity crises across all agency and bureau missions. Provide increased funding for DOI research and programming that focus on greenhouse gas emissions, building the resilience of communities and ecosystems, and land and wildlife conservation.

- Restore Freedom of Information Act (FOIA) functions. FOIA enables researchers, media, and the public access to government information. DOI must restore adequate funding to the DOI FOIA program and direct it to facilitate information sharing to the maximum degree allowed by law. It should revise the 2019 DOI FOIA regulations to reduce control over FOIA retention decisions by political appointees.
- Rebuild scientific capacity throughout DOI.
   Restore the commitment to science and incorporating science into agency decisionmaking.

#### **Key Appointment Positions**

- Director, Bureau of Land Management
- Director, US Geological Survey
- Director, US Fish and Wildlife Service
- Assistant Secretary for Fish and Wildlife and Parks
- Assistant Secretary for Water and Science
- Assistant Secretary for Land and Minerals

#### **Day-One Actions**

- Announce a plan to establish a Science Office and high-level Climate Action Team.
- Announce a moratorium on new fossil fuel leases.

#### **Actions for the First 30 Days**

- Revoke secretarial orders that undermine science-based decisionmaking processes, including Secretary's Orders 3355, 3360, and 3369. (See Priority 1 below for more information.)
- Draft a secretarial order calling to restore scientific integrity and transparency at DOI and enumerating steps the department will take toward those goals.

#### **Actions for the First 100 Days**

- Announce the establishment of a joint Climate Services
   Office with the Departments of Agriculture, Transportation, Defense, and Commerce.
- Appoint leadership for and implement a plan to fully staff the newly established Science Office and office of the Climate Science Advisor.
- Announce the formation of the Climate Crisis Advisory Committee.

## Priority 1: Restore and Advance the Use of the Best Available Science and Improve Transparency in All Agency Planning and Decisionmaking

Anti-science actions have been frequent at DOI in recent years. Multiple reports have documented that scientists at agencies under DOI's purview have been prevented from publishing valid scientific work under their agency affiliation or pressured to alter their work for political reasons. A DOI official repeatedly inserted misleading language about climate change into scientific reports, and the department has interfered directly with the research process by directing scientists not to undertake computer modeling of certain long-term climate impacts, to cite only a few of many examples.

Incidents such as these prevent DOI from using the best available science to protect our natural resources and inform the public. They also contribute to a lack of transparency that damages DOI's credibility and undermines the public's trust that the department's policy decisions are based on sound science. To reverse this trend, DOI should begin by taking the steps outlined below.

#### **Administrative Actions**

• Revoke Secretary's Order 3369, "Promoting Open Science," which uses the guise of transparency to restrict which science can inform agency actions, and could allow the agency to ignore evidence of the need for habitat protections and other safeguards. Require agency actions and rulemaking to rely on the best available science, akin to the mandate to consider the best available scientific and commercial data already required for Endangered Species Act (ESA) listing decisions. Establish performance criteria for transparency in science. Criteria should apply to deliberations involving science, scientific communication, and staff surveys, as well as to scientific studies.

- Strengthen DOI's Scientific Integrity Policy to explicitly
  protect scientists against attempts to censor them or
  pressure them to alter their work, to safeguard scientists'
  ability to freely engage in professional development
  activities such as publishing and presenting at scientific
  conferences, and to include stronger procedural protections for scientists who file complaints about scientific
  integrity issues they encounter.
- Issue a new secretarial order establishing criteria for using the best available science in rulemaking.
- Issue a secretarial order to defer to more protective decisions in cases of scientific uncertainty. (When faced with uncertainty about whether an action will harm an ESA-listed species, for example, assume that it will.)
- Revoke Secretary's Order 3355, "Streamlining National Environmental Policy Act Reviews and Implementation of Executive Order 13807, 'Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects," that, among other things, established arbitrary page limits and time limits for completing environmental reviews even when scientific complexity demands further attention.
- Revoke Secretary's Order 3360, "Rescinding Authorities Inconsistent with Secretary's Order 3349, 'American Energy Independence," that rescinded multiple sciencebased policies on climate change including a departmental manual chapter on climate change, a departmental manual chapter on landscape-scale mitigation policy, a BLM manual section on mitigation, and a 2016 BLM handbook on mitigation.
- Repeal recent changes in ESA regulations that ignore or undermine the role of science, in particular the regulation limiting the scope of "foreseeable future" from its accepted meaning as a horizon as far out as scientists regularly predict natural and human-made processes.

#### **Budgetary Actions**

- Invest in a department-wide effort led by USFWS and USGS to identify imperiled species' strongholds and movement corridors on federal lands. Set priorities and track conservation and recovery work so that agencies can more effectively and transparently meet their statutory obligations under the ESA.
- Restore full funding and personnel for the Climate Science Centers and the climate change mission area

- at USGS, as well as the Landscape Conservation Cooperatives and Science Applications program at USFWS.
- Dedicate funding to establish and staff a Science Office
  within the Office of the Secretary, develop and maintain
  a database to store scientific information used in decisionmaking, and measure progress in achieving science transparency goals by establishing transparency milestones
  for performance plan reporting to the Office of
  Management and Budget.

## Priority 2: Restore and Elevate the Role of Science for Addressing the Climate and Biodiversity Crises across All Agency and Bureau Missions

DOI has a unique responsibility and opportunity to put the United States on the path to aggressive progress on climate change and to address the biodiversity crisis. According to USGS, one-quarter of all US carbon emissions come from fossil fuels extracted from public lands. Reducing future oil and gas production on public lands will protect the environment and the health of wildlife and ecosystems, as well as the communities surrounding these production sites. Furthermore, DOI has management authority for the majority of public lands in the United States and can make biodiversity protection a priority use on multiple-use areas (e.g., BLM lands). DOI can also enlarge the protected areas network (such as through the National Wildlife Refuge System) to lead the way in protecting biodiversity.

It is critical to keep climate change and biodiversity conservation science at the forefront of decisionmaking at DOI. That means taking steps as diverse as prioritizing a leadership focus on science, establishing climate- and biodiversity-specific federal advisory committees, and increasing funding for science programs. DOI should take the following steps.

#### **Administrative Actions**

Assess the ability of DOI programs to address the climate
and biodiversity crises, develop a strategy for reorganizing
these programs as needed to address those crises, and
suspend any current proposals to reorganize departments
or relocate agency personnel pending review of their
impact on the agencies' ability to effectively address
climate issues. Consider options for reassigning idle permitting and leasing staff to restoration and remediation.

- Using the reinstated Climate Policy as a starting point, develop a science-based, DOI-wide climate strategy for optimizing carbon storage on public lands and building resilience across all mission areas.
- Establish a Climate Crisis Federal Advisory Committee
  and install a high-level climate crisis advisor in the Office
  of the Secretary. Take steps to restore an emphasis on the
  use of climate models to project likely future impacts to
  DOI mission areas.
- In coordination with other federal programs and departments, establish a Biodiversity Crisis Federal Advisory
  Committee to provide science synthesis and advice to the secretary to advance a national strategy for conserving biodiversity.
- Meet the obligations of the ESA by fully incorporating climate science into ESA species listing decisions, fiveyear species status reviews, critical habitat designations, and recovery actions. Re-establish the climate change policy revoked by Secretary's Order 3360 so that all decisions address or incorporate the latest climate change information.
- Issue a secretarial order to establish climate and biodiversity action performance measures to be incorporated into the new DOI strategic plan. Task the Office of Policy and Performance with immediately establishing metrics and collecting performance data from each bureau.
   Ensure that each bureau director prioritizes these performance measures by including them in their senior executive performance reviews.
- Work with Departments of Agriculture, Transportation, Defense, and Commerce to establish a joint Climate Services Office to assist land managers, farmers, infrastructure planners, and other climate-vulnerable sectors in planning for climate impacts.
- Assess and reduce the vulnerability of mission-critical infrastructure and facilities to climate change and biodiversity loss.

#### **Budgetary Actions**

 Ensure a real 4 percent budget increase, year over year, for all DOI programs, and ensure that DOI science program budgets are explicitly addressed.  Reinstate scientific programs that have been eliminated or drastically reduced, such as the USGS Library and the USGS climate change mission area, the Climate Science Centers, and the USFWS Landscape Conservation Cooperatives.

#### **Priority 3: Restore FOIA Functions**

FOIA is essential for facilitating access to government information and maintaining transparency. The law is particularly important for ensuring that science is used to inform policy, that nongovernmental scientists have access to government data, and that the public can be made aware of science that can affect their lives. Restoring adequate funding to the DOI FOIA program and reversing the trend in recent years of increasing delays in responding to many FOIA requests are high priorities. DOI should direct staff to facilitate information sharing to the maximum degree allowed by law and, to avoid political interference in the FOIA process, revise its FOIA regulations to ensure that production decisions are made only by career staff.

#### **Administrative Actions**

- Revise DOI's current FOIA guidance to ensure that production decisions are made by career scientists and experts rather than political appointees.
- Establish and empower a FOIA "ombudsman" in the Office of Collaborative Action and Dispute Resolution to resolve high-level concerns regarding FOIA productions.
- Devolve some FOIA operations out to bureaus at DOI to more effectively spread the workload. Eliminate all political review except as a courtesy.
- Expand FOIA office staffing to address the current backlog and to develop a strategy for addressing incoming FOIA requests within 60 days.
- Simplify FOIA production and accessibility by reducing duplication of records (such as long email strings repeated in their entirety with every entry, including attachments), and store records in legible, simplified format.

#### **Budgetary Actions**

 Increase funding to hire additional FOIA office full-time equivalents (FTEs) to process the current volume of FOIA requests, develop a strategy for adjusting staffing as

- needed per workload, and ensure rapid turnaround of incoming requests.
- Increase funding for bureau FOIA offices to accelerate production.

## Priority 4: Rebuild Scientific Capacity throughout DOI

Scientific capacity at DOI has been steadily declining over the past two decades through a combination of cuts, antagonism from Congress, and, at times, neglect and antagonism from the executive branch. Measures that limit scientists' ability to produce research and access expertise undermine the work they do to serve the United States. For example, USGS Director James Reilly reportedly managed grants at the agency's Climate Adaptation Science Centers so closely that they were regularly stalled for months, hindering critical research. Agency scientists have also reported that slowdowns in hiring have hampered scientific work.

Although scientific advisory committees, which typically provide crucial input, have been cut back across the federal government, DOI has been particularly hard hit. In 2017, a shocking 67 percent of DOI's science advisory committees failed to meet as often as required by their charters.

#### **Administrative Actions**

- Restore scientific advisory committees (including the Advisory Committee on Climate Change and Natural Resource Science) eliminated after Executive Order 13875, "Evaluating and Improving the Utility of Federal Advisory Committees." Codify their input into DOI-wide decisionmaking and prioritize the recruitment of independent committee members with scientific expertise.
- Expand and empower USGS Climate Adaptation Science Centers by increasing science FTEs for existing centers, developing strategic work plans with clear objectives for each center, and establishing two new regional centers at universities.
- Expand and empower USFWS Landscape Conservation Cooperatives and the agency's Science Applications programs by increasing science FTEs and reconnecting scientists with the local and regional governments they are intended to support.

- Instruct bureau directors to prioritize rebuilding science capacity and add a relevant measure to the Senior Executive Service performance review.
- Establish goals and performance measures for ensuring a science enterprise that is diverse and inclusive, including expanding hiring practices to be more inclusive and public demographic reporting of hiring and retention rates of employees.
- Establish a Science Office within the Office of the Secretary, led by a high-level scientist. The office should include a rapid-response capacity for dealing with disaster and crisis management regarding DOI assets, responsibilities, and mission.

#### **Budgetary Actions**

- Dedicate funding for stabilizing and increasing the capacity of scientific advisory committees.
- Restore full funding to the science and conservation mission of BLM by re-allocating funds from the permitting side of the agency.
- Provide funding for rebuilding DOI scientific capacity by redirecting funds from the oil and gas permitting programs in coordination with a directive establishing this priority to DOI agencies.
- Reinstate the Landscape Conservation Cooperatives, which were dissolved or placed on hiatus in 2019 despite funding appropriated by Congress.

#### **ENDORSED BY**

Acadia Institute of Oceanography / American Geophysical Union / Climate Science Legal Defense Fund / Defenders of Wildlife / Free Government Information (FGI) / Government Information Watch / Greenpeace USA / In the Public Interest / Inland Ocean Coalition / International Chemical Workers Union Council / Milwaukee Riverkeeper / MomsRising / Ocean Conservation Research / Oceanic Preservation Society / Open The Government / PHILAPOSH / Revolving Door Project / RICOSH / Society for Conservation Biology North America / Union of Concerned Scientists / Western New York Council on Occupational Safety & Health (WNYCOSH)

# **Environmental Protection Agency**

This memo outlines key ways in which the Environmental Protection Agency (EPA) can establish and restore the principles of scientific integrity, as well as repair and rebuild its scientific capacity. Specific priorities and steps the agency can take to effectively act on these issues are identified.

EPA and its mission have been adversely affected by the abandonment and sidelining of science over the past threeand-a-half years. Created in 1970 to consolidate numerous federal programs into one agency, EPA operates under 15 separate laws to protect public health and the environment. Each law spells out an aspect of EPA's mandate and authority. EPA implements these authorities by issuing regulations and guidance, taking enforcement actions, and giving approval to conduct (permitting) certain activities. Science underlies all of these activities and several of the laws specifically require the use of the best available science. Scientists of various disciplines populate all of EPA's program areas, and EPA has an Office of Research and Development (ORD) that conducts basic research on human health and the environment and supports programs by answering critical questions regarding the science underpinning regulatory decisions. ORD also sponsors research in academic laboratories.

The current administration has severely undercut EPA's mission by rolling back standards and diminishing scientific support for the agency's mission. The following high-priority areas need attention.

#### **Top Priorities**

• Eliminate the "transparency" rule. There is no single action that more adversely impacts EPA's ability to do its job than the proposed "Strengthening Transparency in Regulatory Science" rulemaking (83 FR 18768). While the title may sound good, it is a Trojan horse. It is detrimental to high-quality, impartial decisionmaking on behalf of the health and safety of the American public and the environment because it limits the scientific studies that the agency can consider, and allows the agency to

- place less weight on studies that indicate a need for stronger regulations. This rule should be withdrawn.
- Strengthen scientific advisory committees.

  EPA has barred recipients of EPA grants from serving on advisory committees and arbitrarily reduced the number of advisory committees, thereby depriving EPA of expertise. These actions should be reversed to ensure the agency can benefit from experts' advice.
- Strengthen scientific integrity. There have been multiple attacks on science at EPA that range from proposing enormous cuts in funding and attacking the credibility of established science to politically interfering with science communication and assessments. EPA must take action to ensure that science and the work of its scientists are not compromised by political considerations.
- Address rollback of regulations. One of the Trump administration's top priorities was to roll back numerous regulatory requirements based on false claims that they posed a burden on the economy. These rollbacks are not scientifically defensible. The administration has also failed to regulate in cases where the science clearly shows that additional regulation is warranted. The New York Times has reported that more than 60 such rollbacks have already occurred. EPA must swiftly review these rollbacks and prioritize for remedial action those the evidence shows to be inappropriate.
- Enhance staffing and resources. Administration actions over the past three years have led to a hollowing out of the agency as senior civil servants have retired and other staff have left. While EPA's budget has not suffered the severe cuts proposed in each of the recent presidents' budgets, EPA's budget in real dollars has declined by 25 percent since 2010 and inadequate funding and staffing have imposed significant limitations on the agency's mission. Increased funding and staffing are essential to allow EPA to fulfill its mission.

#### **Key Science/Regulatory Appointment Positions**

- Assistant Administrator for Air and Radiation
- Assistant Administrator for Chemical Safety and Pollution Prevention
- Assistant Administrator for Research and Development
- Assistant Administrator for Office of Water
- Assistant Administrator for Land and Emergency Management

#### **Actions for the First 100 Days**

- If the transparency rule has not been finalized, suspend or rescind the proposal.
- If the transparency rule has been finalized,
  - announce that the administrator will use the discretion provided to EPA in the rule to suspend its application pending its revocation, and
  - announce that EPA will draft realistic science-based guidance, not rules, through an open process to ensure the integrity of the decisionmaking process.
- Rebalance scientific advisory committees by reappointing members who have been disqualified by former EPA Administrator Pruitt's directive barring grant recipients from serving on federal advisory committees.
- Advise the president to repeal Executive Order 13875, which reduces the number of federal advisory committees by one-third.
- Reinstate key advisory committees that have been disbanded.
- Identify the deregulatory actions taken by the Trump administration and prioritize for remedial action those the evidence shows to be inappropriate.
- Issue a directive that, in calculating the benefits of a regulation, the agency must follow the standard, wellestablished practice of considering all the benefits, direct and indirect.
- Appoint strong, well-qualified leaders, free of conflicts
  of interest and supportive of the agency's mission, to
  manage the transition of EPA back to a high-functioning
  organization.

- Restore collective bargaining rights to EPA employees and negotiate a new contract in good faith, using the last mutually agreed—upon contract as a starting point.
- Request significant increases in full-time employees (FTEs) and funds to allow EPA to carry out its 21st century responsibilities.
- Restore funding for core science through the Science and Technology (S&T) Account to its 2010 level of \$1 billion (in 2020 dollars).

#### **Actions for the First Year**

- Strengthen the scientific integrity policy to provide greater protection to scientists and their work from political interference.
- Reissue the rule regulating mercury emissions from coal-fired power plants.
- Revise the National Ambient Air Quality Standard for particulates and conduct a review of the adequacy of the current NAAQS for ozone.
- Restore the 2015 definition of "Waters of the United States."
- Ban all uses of the pesticide chlorpyrifos.
- Redo flawed risk evaluations under the Toxic Substances Control Act, including those for asbestos, methylene chloride, and trichloroethylene.
- Ban all uses of methylene chloride.
- Set greenhouse gas standards to transition all on-highway vehicles from gasoline to electricity.
- Evaluate the benefits of reissuing the Clean Power Plan
  with potentially updated goals that take into account
  progress that has already been made in reducing carbon
  emissions and current opportunities for greater reductions.

#### **Ongoing Actions**

- Appoint the best-qualified scientists to committees.
- Restore a culture in which the mission of EPA and its employees are valued. Seek out and develop relationships with current career staff, particularly during the transition, to build trust and momentum and to communicate

- effectively with the career workforce. Include career staff in decision meetings as an important step in building trust and communication.
- Strengthen recruitment and hiring of diverse staff to
  meet critical needs. Given the serious reductions in EPA
  staffing, there is an urgent need to significantly strengthen
  EPA's recruitment and its pace of hiring staff with the
  skills and experience needed to address pressing needs in
  science, technology, analytics, and mission support. Place
  an emphasis on increasing the representation of people
  of color within EPA's workforce to fill historic gaps.
- To avoid "reinventing the wheel," take advantage
  of the historical perspective and expertise available in
  the Environmental Protection Network (EPN), which
  harnesses the expertise of former EPA career staff
  and confirmation-level appointees from multiple
  administrations.

#### **Priority 1: Eliminate the "Transparency" Rule**

EPA has a long-established history of using the latest peer-reviewed science in decisionmaking. EPA's proposed "Strengthening Transparency in Regulatory Science" rulemaking is detrimental to high-quality, impartial decisionmaking on behalf of the health and safety of the American public. (See EPN's comments and testimony on this *proposal* to censor science.) The rulemaking would have far-ranging consequences. It would reverse the decades-old EPA practice of using the best available science in carrying out the responsibilities the US Congress placed on the agency and violate some statutes that require EPA to use the best available science. It would also deprive agency decisionmakers of access to vetted studies published in scientific journals for which some of the underlying data cannot be made publicly available and would require duplicative testing and delays in making regulatory decisions when data cannot be made available for published studies. Epidemiological studies have been critical in setting environmental standards, including standards that have improved air and water quality. However, the proposed rule would prohibit the use of many epidemiological studies because these studies rely on personal information that, if disclosed, would violate the privacy of study subjects. The proposed rule also gives excessive authority to the administrator to pick and choose which studies to include in policy evaluations, regardless of their source or vetting, and without transparent criteria for disclosing the rationale for the decisions.

### Priority 2: Strengthen Scientific Advisory Committees

Federal advisory committees operating under the Federal Advisory Committee Act (5 U.S.C. Appendix—Federal Advisory Committee Act; as amended) provide valuable scientific advice to EPA at a bargain price. On October 31, 2017, then-EPA Administrator Scott Pruitt issued a directive that banned academic scientists who received EPA grants from serving on EPA federal advisory committees. He gave them a choice: either give up their grants and remain on the committees, or keep their grants and resign. The stated reason for Pruitt's policy shift was to obtain independent advice and avoid conflicts of interest associated with the receipt of research funding from EPA. However, no parallel prohibition was made for industry scientists or academic scientists who receive industry funding, so the result has been to increase the number of industry-affiliated committee members while decreasing the number of academics. The Natural Resources Defense Council (NRDC) challenged the directive in court (19cv5174 (DLC)). On February 20, 2020, the court granted NRDC's motion for summary judgment ruling that EPA's action was arbitrary and capricious. EPA has stated that it will not appeal the court's decision. However, the damage from the directive has been done as the committees have already been stacked with pro-industry scientists. Rebalancing committee membership must be a high priority. Procedures for committee selection should be reviewed and modified to ensure that future committee selections are focused on ensuring the highest-quality reviews in all future administrations.

In addition to skewing the composition of federal advisory committees, EPA disbanded some committees. The Particulate Matter Review Panel, a subcommittee under the Clean Air Act Scientific Advisory Committee (CASAC), was disbanded in 2018. As a result, CASAC did not have the expertise to review the new data on health effects relating to standards for fine particulate matter (PM<sub>2.5</sub>). The Ozone Panel met a similar fate. The instatement of such panels is further complicated by Executive Order 13875, "Evaluating and Improving the Utility of Federal Advisory Committees," signed by President Trump on June 14, 2019. The executive order intends to reduce by one-third the number of federal advisory committees. EPA's unilateral action, in conjunction with the order, will reduce the scientific input to EPA's regulatory decision-making. Both of these actions must be corrected swiftly.

#### **Priority 3: Strengthen Scientific Integrity**

From its earliest days, the Trump administration has interfered

with science for apparently political reasons. Examples include the removal of references to climate change from EPA websites, leaving "legacy" uses out of an asbestos risk evaluation, altering a risk assessment to remove evidence that the solvent trichloroethylene damages fetal hearts, preventing scientists from attending conferences and presenting their papers, and routing questions from the press and agency communications through political filters. Putting political values above science at EPA has been most apparent in regulatory decisions the agency has made (see Priority 4 below). The administration should ensure that EPA strengthens its culture of scientific integrity. It can do this by calling on EPA to update its scientific integrity policy to strengthen crucial provisions protecting EPA science from political interference and censorship, and to continue and improve the training it provides its employees about scientific integrity. The administration should also ensure that EPA scientists have the right to communicate the results of their research to each other, to the public, and to the media.

#### **Priority 4: Address Rollback of Regulations**

The *New York Times* reports that the Trump administration is ignoring science and public comments in attempting to roll back 100 environmental regulations. Rescinding many of these unwarranted rollbacks and issuing regulations where the Trump administration has refused to act must be among the top priorities for the agency. EPA must undertake a complete review of the actions taken and refused over the past four years and, for those actions found to be contradictory to scientific evidence or norms, set priorities to move forward based on their adverse impact on human health and the environment. Agency staff should be consulted in the process of setting these priorities; however, the following actions should rank at the top of the list.<sup>1</sup>

Mercury and Air Toxics Standards. EPA reversed the finding that it is necessary and appropriate to regulate emissions of toxic air pollutants. This finding is the legal predicate for the Mercury and Air Toxics Standards (MATS) (85 FR 20838), the highly successful Obama-era regulation of mercury and other toxic pollutants from coal-fired power plants. Mercury, which is best known as a developmental neurotoxicant, damages several organ systems. Although the Trump administration left MATS in place, reversing the

finding invites legal challenges to MATS. This action is also significant because, in an attempt to justify this action, EPA made an unwarranted change to the way it computes health benefits. EPA says that the only benefits that can be counted are those that are directly attributable to decreases in the pollutant being targeted by the regulation. Because EPA only calculated the benefits of reducing mercury but did not calculate the collateral benefit of reducing particulate pollution, the cost of the regulation appears to be greater than the benefit of reducing mercury. However, if the collateral benefits are considered, which had been the EPA practice until this action, the benefits of the rule greatly exceed the costs even without counting most of the mercury benefits. This approach of ignoring collateral benefits is contrary to reason and the public interest. The approach and the EPA finding must be overturned.

**National Ambient Air Quality Standard (NAAQS) for particulates.** As noted above, when EPA disbanded the panel on particulate matter, *an independent panel* made up of nearly every former member of the disbanded panel reviewed data pertaining to the adequacy of the existing standards. Despite a science-based finding that the current suite of primary fine particulate matter (PM<sub>2.5</sub>) annual and 24-hour standards are not sufficiently protective of public health, EPA has refused to take action to lower the standard. The administration should heed the independent panel's science-based finding and take action to adopt the more stringent standards.

Waters of the United States (WOTUS) rule. Published in 2015, the WOTUS rule sought to clarify which waters and wetlands fall under federal jurisdiction and thus are subject to the Clean Water Act. This definition was adopted to ensure that wetlands and tributaries did not pollute the bodies of water into which they drained. In September 2019, EPA promulgated a rule repealing the 2015 rule and in April 2020, the agency promulgated a new definition of waters of the United States that removed federal jurisdiction from at least half of the wetlands in the country and about 20 percent of the streams, leaving the bodies of water into which they drain more vulnerable to pollution. The impact was even greater in the arid West, where as many as 90 percent of streams lost federal water quality protections. The 2015 definition should be reinstated.

**Chlorpyrifos.** The pesticide *chlorpyrifos* is acutely toxic and associated with neurodevelopmental harms in children. Prenatal exposures to chlorpyrifos are associated with lower birth weight, reduced IQ, loss of working memory, attention disorders, and delayed motor development. Acute

poisoning suppresses the enzyme that regulates nerve impulses in the body and can cause convulsions, respiratory paralysis, and, in extreme cases, death. It also has adverse effects on wildlife. Chlorpyrifos is one of the pesticides most often linked to pesticide poisonings. For half a century, staple food crops in the United States—such as apples, citrus, corn, and wheat—have been sprayed with chlorpyrifos. EPA was expected to make a decision in 2017 to ban all uses of chlorpyrifos. But two days before the court-ordered deadline, then-EPA Administrator Pruitt reversed the agency's proposal and refused to ban the pesticide. Under the Food Quality Protection Act, EPA can register a pesticide for use on food crops only if it can make a finding of "a reasonable certainty of no harm." That standard is not met for chlorpyrifos. Chlorpyrifos should be banned.

Methylene chloride. Methylene chloride, commonly used in paint strippers, is highly neurotoxic, acutely lethal, and carcinogenic. There have been more than 50 reported deaths from acute exposure to the chemical. Many more likely have gone unreported. During the Obama administration, EPA worked, under the auspices of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, to assemble a record to support the need for a ban on most commercial and consumer uses of methylene chloride. Despite this overwhelming scientific evidence, the Trump EPA chose to finalize the ban on consumer uses only, relying on ineffective requirements for labeling, protective equipment, and training to protect workers' health. This failure was part of a more comprehensive undermining of worker protections under TSCA. EPA should follow the evidence and ban commercial, as well as consumer, uses of methylene chloride.

Greenhouse gas (GHG) emissions standards for cars. The transportation sector is the largest contributor to US GHG emissions, narrowly edging out the electricity generation sector. The GHG emissions standards enacted during the Obama administration were the biggest single effort to address climate change in the United States. Yet the Trump administration rolled back the standards for cars to mandate fuel efficiency of just 40 miles per gallon (mpg) by 2025 rather than the 54 mpg mandated by the Obama administration. As the Trump administration acknowledges, this rollback will increase GHG emissions by about 900 million metric tons and gasoline consumption by about 80 billion gallons. The administration also admits that the rollback will increase net costs to society (i.e., the rollback costs exceed its benefits). This rollback is completely at odds with both climate science and automotive technology. It will largely benefit the oil and gas industry through higher gasoline costs for consumers, and

roughly half of the auto industry has opposed the rollback since many auto manufacturers have already invested in the technology to meet the more stringent standards. Given that climate change and air quality pose major challenges, the agency should set GHG standards to achieve electrification of on-highway vehicles, maintaining the model year 2022–2026 Obama GHG standards to the extent possible.

Clean Power Plan (CPP). Under the Paris climate agreement, the United States promised to lower the nation's GHG emissions 26 to 28 percent below 2005 levels by 2025. Because power plants account for roughly one-third of US emissions, the *CPP* was seen as a crucial part of that strategy. The plan would have established national carbon emissions performance rates for coal and natural gas power plants while giving individual states some flexibility in finding ways to meet those standards. It would have reduced carbon pollution from the power sector by 32 percent and emissions of sulfur dioxide by 90 percent and nitrogen oxides by 72 percent below 2005 levels in 2030. The rule never took effect, however, as it was stayed as a result of court challenges contending that the rule exceeded EPA's authority under the Clean Air Act, and was later replaced by the Affordable Clean Energy (ACE) rule. The ACE rule, which presents a narrow view of EPA's regulatory authority, is designed to help extend the lifetimes of expensive and heavily polluting coal-fired power plants. A **study** published in *Environmental Research Letters* in April 2019 estimated that the ACE rule would lead to a negligible reduction in GHG emissions compared with a "no policy" scenario. An analysis by NRDC estimates that, given falling costs for clean energy, a stronger rule than the CPP could cut powersector carbon pollution 60 percent below 2005 levels by 2030, and do so at a lower cost than the initial estimated costs of the CPP. If still under review, the ACE case should be stayed, EPA should stop defending the ACE rule, and the agency should evaluate the possibility of a more ambitious regulation than the CPP.

#### **Priority 5: Enhance Staffing and Resources**

Looking ahead, EPA must address a whole new horizon of health and environmental threats, including worsening climate change impacts and the prospect of new pandemics. Meanwhile, the agency must face partially addressed threats that are growing more serious, and reckon with past and ongoing environmental injustice issues exemplified by low-income communities and people of color who are struggling with cumulative exposures to toxic pollution. Unfortunately, EPA has been

substantially hollowed out from inadequate resources and battered staff morale. Employees have been demoralized by the administration's attitude toward the mission of the agency and government workers in general. Instead of protecting human health and the environment, many have been called on to roll back decades of work. In addition, there is concern that the *new labor contract*, imposed by the administration, makes it easier to place employees on a performance improvement plan and subsequently fire them, risking a chilling effect on employees wishing to speak up about violations of scientific integrity.

EPA resources have long been inadequate and have been dangerously declining. Under President Ronald Reagan, EPA's budget was 40–60 percent larger than it is today in inflation-adjusted dollars. The agency's staff was 30 percent larger under President Bill Clinton in 1999 than today's EPA, which has far more congressionally mandated environmental responsibilities. In recent years, drastic cuts have been proposed to EPA's diminishing resources that would further diminish the capacity of the federal government, states, tribes, and localities to protect public health and the environment. EPA should also restore collective bargaining rights to EPA employees.

EPA needs a budget that is in line with its responsibilities in the second decade of the 21st century. It also needs to recruit several thousand new staff members, including scientists in program and regional offices and ORD, while bolstering the diversity of EPA's science experts. Given the beating EPA has taken in recent years and the prevalence of disparaging attitudes in some quarters toward government work and government workers in general, recruiting top talent may be difficult (although it may be helped by the recessionary economy as other options dry up). Still, successful recruiting and retention will require a change in the organizational climate and policy direction at the agency so that the notion of working at EPA once again appeals to people who want to use their knowledge and abilities to serve the public. EPA's fellowship, internship, and grantee programs have been effective at training and recruiting scientists for the agency. These programs should be fully supported and an emphasis should be placed on recruiting people of color into these programs.

What cannot be replaced is the historic knowledge that left with the exodus of workers and retirees in recent years. EPN—with its membership of 500 former EPA employees—can help. EPA officials should not hesitate to contact EPN.

#### **Endnote**

 More information is available at EPN's website on MATS, NAAQS, WOTUS, methylene chloride, and vehicle greenhouse gas emissions standards.

#### **ENDORSED BY**

Acadia Institute of Oceanography / Center for Auto Safety / Climate Science Legal Defense Fund / Environmental Protection

Network / Free Government Information (FGI) / Green America / Government Information Watch / Greenpeace USA / Herndon

Reston Indivisible Science and Environment / In the Public Interest / Inland Ocean Coalition / International Chemical Workers Union

Council / Milwaukee Riverkeeper / MomsRising / National Center for Health Research / NJ Work Environment Council / Ocean

Conservation Research / Oceanic Preservation Society / Open The Government / PHILAPOSH / Revolving Door Project / RICOSH /

Society for Conservation Biology North America / Union of Concerned Scientists / Western New York Council on Occupational

Safety & Health (WNYCOSH)

# National Oceanic and Atmospheric Administration

This memo outlines key ways to establish and restore the principles of scientific integrity, as well as repair and rebuild scientific capacity, during the next presidential term, including specific priorities and steps the agency can take to effectively act on these issues in 2021.

One of the nation's premier science agencies, the National Oceanic and Atmospheric Administration (NOAA) plays a critical role in scientific research and services related to climate change, forecasting natural disasters, understanding atmospheric processes, coastal and ocean environments, and the conservation and management of marine resources. NOAA laboratories and offices are located throughout the country and its data, products, and services are used widely in every state. Some NOAA scientists also play key roles in numerous international diplomacy, research, resource management, and development efforts. All of these roles need to be fully recognized, authorized, and funded by Congress and championed by the administration. Set in the Department of Commerce, NOAA has, at times, failed to receive attention and political support for its mission from departmental leadership. Today, in an era of climate change and promotion of preserving and protecting marine resources in the "blue economy," NOAA and the Department of Commerce have a historic opportunity to connect business development and international trade to low-carbon green (climate-friendly) and blue (ocean-based) economic development.

#### **Top Priorities**

• Restore commitment to scientific integrity and rebuild scientific capacity. NOAA's mission is rooted in conducting unbiased science that supports transparent decisionmaking and that should be reflected in the agency's scientific integrity (SI) policy and staff capacity. While NOAA has a strong existing SI policy, it could be significantly improved by providing full accountability up to the Department of Commerce secretariat and through robust training, communication, and implementation, making it a model agency for scientific integrity in government. NOAA has lost many senior scientific staff members and suffered violations of its SI policy and should commit to rebuilding its scientific integrity and capacity in an inclusive and equitable manner.

- Provide robust and accessible climate change services and leadership. NOAA should be directed to prioritize climate change mitigation and adaptation services so that it can lead the nation in providing critical information to federal, state, and local governments and small and large businesses nationwide on a sustained and authoritative basis about how to respond and adapt to climate change.
- Advance partnerships in ocean science and technology. NOAA should work with other federal agencies, Congress, oceanographic academic institutions, philanthropies, nongovernmental organizations, and businesses to coordinate and fill gaps in our understanding of the ocean, while ensuring the availability of data to the public and ocean stakeholders.

#### **Key Appointment Positions**

- Under Secretary of Commerce for Oceans and Atmosphere (NOAA Administrator)
- Assistant Secretary of Commerce for Environmental Observation and Prediction
- Assistant Administrator for NOAA Fisheries
- Chief Scientist
- NOAA Chief of Staff

#### **Day-One Actions**

 Make a strong endorsement of the principles and actions needed to support scientific integrity and end political manipulation and censorship of science and scientists.
 (See Priority 1 below for more detail.)  Issue an executive order or declaration of intent for the federal government to become a critical information resource for states, tribes, local communities, and businesses on climate change, and designate NOAA as a lead information agency. (Priority 2)

#### **Actions in the First Year**

NOAA should announce a plan for integrating principles
of diversity, equity, and inclusion in its recruitment and
hiring processes, including any modifications to existing
or new fellowship or training programs or other innovative initiatives to foster a diverse and robust scientific
capacity across the agency. (Priority 1)

## Priority 1: Restore Commitment to Scientific Integrity and Rebuild Scientific Capacity

Science and scientific values are mission critical to NOAA given its role providing accurate weather and climate data, managing ocean and coastal resources, and supporting the scientific mission of multiple other agencies. NOAA and the Department of Commerce should become a model for strengthening and implementing SI policy. While NOAA's existing SI policy is considered strong, it doesn't include full accountability up the chain of authority to the Department of Commerce secretariat. The policy should protect NOAA science and scientists even if political interference comes from the department level or originates from outside NOAA proper, and any investigation of such complaints should be able to be conducted in full in a transparent manner.

Under the Trump administration, and due to the demographics of agency staff, NOAA has lost many senior scientists and has been slow to recruit young, diverse talent. It is critical to encourage talented scientists to take up public service and to promote principles of diversity, equity, and inclusion in recruitment and hiring.

#### **Administrative Actions**

 NOAA should become the model agency for scientific integrity in government by: expanding to provide full accountability up the chain of authority to the Department of Commerce secretariat; allowing full public access to science experts and expertise; ensuring that science is not censored or manipulated for political purposes; and fully involving scientists in the policy process. All political appointees as well as career staff should be fully trained

- to understand the purpose, function, and details of the policy. This initiative should guarantee whistleblower protection for NOAA personnel reporting violations of the agency's scientific integrity policy and a fully staffed independent mechanism for the investigation of complaints and enforcement. Such provisions would make it harder to censor NOAA scientists or otherwise prevent them from speaking with the public. This renewed effort should fully incorporate and be responsive to the findings of the multiple investigations of the so-called Sharpie-Gate incident.
- NOAA should rebuild scientific capacity with a diverse staff by employing new recruitment mechanisms, fellowship programs, term-length and rotating assignments from universities and industry (such as those at the National Science Foundation), and other innovative initiatives.
   NOAA can be a leader in this regard through its Sea Grant programs and fellowships, the José E. Serrano Educational Partnership Program with Minority Serving Institutions, and HBCU (historically Black colleges and universities) and joint/cooperative institute relationships.

### Priority 2: Provide Robust and Accessible Climate Change Services and Leadership

NOAA should be directed to prioritize climate change mitigation and adaptation services so that it can lead the nation in providing critical information to federal, state, and local governments and small and large businesses nationwide about how to respond and adapt to climate change. All NOAA line offices have leadership and implementation roles to play in making sure that NOAA is a primary, credible, and expert source of climate information necessary for other agencies, state and local decisionmakers, and private sector partners who require the best scientific information available to make critical decisions. NOAA should prioritize climate services that include data collection and dissemination, long-term monitoring, forecasting, evaluation, and analysis, and public information campaign tools to meet critical national needs.

#### **Administrative Actions**

 Issue an executive order or declaration of intent for the federal government to become a critical information and technical resource for the states, tribes, local communities, and businesses on climate change mitigation and adaptation with NOAA serving as the lead information agency.

- The secretary of commerce should spearhead a voluntary initiative to guide and incentivize businesses in directly confronting the challenges of climate change mitigation and adaptation, facilitating their connection to the full power of NOAA science and services. This should include both green and blue economic components.
- Direct NOAA's Ocean and Fisheries Services to review guidance, policy, and regulation associated with the implementation of resource conservation and management statutes such as the Magnuson-Stevens Fisheries Conservation and Management Act, the Marine Mammal Protection Act, and the Endangered Species Act, among others, to ensure that forward-looking approaches are being employed that maximize climate mitigation and adaptation responses.

## Priority 3: Advance Partnerships in Ocean Science and Technology

Ocean science and technology partnerships can help address some of today's most pressing challenges in ocean management. NOAA should work with other federal agencies, oceanographic academic institutions, philanthropies, nongovernmental organizations, and businesses to coordinate and fill gaps in our understanding of the ocean (including development of a sustained and operational coastal ocean observing system), while ensuring the availability of data to the public and ocean stakeholders. NOAA has an opportunity to advance these collective efforts while also building on historical NOAA data collections, harnessing the collective research that is happening in the ocean. Seamless historic and contemporary data will enable the science community to identify important changes in ocean conditions and health over many decades and predict future change, informing decisions that can help to manage fishery resources, wildlife, and habitats.

#### **Administrative Actions**

NOAA should establish clear best practices in data collection through partnerships with academia, industry, and the federal government. These efforts should be fully responsive to the leadership role on climate change science that NOAA must embrace. These best practices and data collection efforts should ensure new data are comparable to historic data and that they are available in a single location.

• Institutionalize better processes for including end users of ocean data and information in the early stages of research and project development. Ocean observations and biological data are increasingly important to people who rely on the data every day to estimate risk and opportunity, supporting ocean-dependent jobs in coastal and inland communities and safeguarding marine ecosystems. Connecting those people to researchers early in the research planning process is a substantial challenge, yet, when executed, it will help ensure these projects have a greater likelihood of creating lasting and useful products.

#### **Budgetary Actions**

- NOAA should increase funding for data management, reviewing all its data programs, grants, and contracts and, where appropriate, allocating at least 10 percent of project budgets, or those of its contractors or awardees, toward data management. Data programs should develop budgets for at least one full-time data manager. Congress, in consultation with NOAA and data stewards, should make policy changes to ensure that this goal is met. Congress should also increase funding to account for data and staffing needs without compromising baseline funding for other NOAA activities while accounting for the 10 percent across-the-board increase.
- NOAA should increase funds used for data acquisition, data hosting, and access to computational resources, and make this data publicly available. Regional Ocean Partnerships, for example, operate in regions across the country to promote sustainability through science-based management, the usage of publicly available regional ocean data portals, and the provision of a common venue for convening stakeholders. Additionally, the Regional Ocean Partnerships provide a coordinating ground for states, federal agencies, and other regional organizations. Increased funding for NOAA programs such as the Regional Ocean Partnerships will help NOAA address gaps and problems in ocean data, while ensuring effective coordination between federal agencies, states, academia, and stakeholders.
- NOAA should increase funding for the National Marine
  Fisheries Service Science Centers, whose offices are
  responsible for the stewardship of the nation's fisheries
  and living marine resources as well as their habitats. The
  Science Centers provide scientific, technical, and research

support for fish stock assessments, ecosystem-based management, living marine resources, and various regulatory mandates such as the Marine Mammal Protection Act. Since 2009, a fundamental erosion of science has occurred at these Science Centers due to funding limitations. This decline has occurred during a time of great change in our oceans, when resource managers and users

are most in need of timely and complete data to make responsible and business-friendly management decisions. Increasing this funding would ensure more robust and timely scientific surveys that support fish stock assessments, baseline data for national climate assessments, and vital information for environmental impact reviews for offshore renewable energy siting.

#### **ENDORSED BY**

Acadia Institute of Oceanography / American Geophysical Union / Climate Science Legal Defense Fund / Defenders of Wildlife / Free Government Information (FGI) / Government Information Watch / Greenpeace USA / In the Public Interest / Inland Ocean Coalition / International Chemical Workers Union Council / Milwaukee Riverkeeper / MomsRising / Ocean Conservancy / Ocean Conservation Research / Oceanic Preservation Society / PHILAPOSH / Revolving Door Project / RICOSH / Society for Conservation Biology North America / Union of Concerned Scientists / United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) / Western New York Council on Occupational Safety & Health (WNYCOSH)

# Occupational Safety and Health Administration, Mine Safety and Health Administration, National Institute for Occupational Safety and Health

This memo outlines key ways in which the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), under the Department of Labor, and the National Institute for Occupational Safety and Health (NIOSH), at the Centers for Disease Control and Prevention (CDC), can establish and restore the principles ofscientific integrity, as well as repair and rebuild their scientific capacity, during the next presidential term. Specific priorities and steps the agencies can take to effectively act on these issues in 2021 are identified.

In order for the federal government's occupational health agencies to succeed in protecting workers' health and lives while helping the nation's industries establish safe and sustainable modes of production, they must be able to collect and use evidence effectively. For decades, however, insufficient resources and numerous roadblocks have prevented these agencies from fulfilling their potential—and resulted in thousands of workers suffering from preventable injuries and diseases, many of them fatal.

The COVID-19 pandemic demonstrates how years of underinvestment and practices favoring special interests have left OSHA poorly prepared to protect workers' health and industries' ability to function during an occupational health crisis. The agency had been working on an airborne infectious disease standard that could have protected health-care workers and other essential workers, but it was shelved in 2017. When the pandemic struck, OSHA could have issued an emergency temporary standard to protect workers from infectious diseases such as COVID-19, but it opted not to—leaving the nation with no federal requirement that employers implement safety measures to protect their workers.

Out of 3,990 COVID-19-related complaints that OSHA had received as of May 18, 2020, the agency had opened only 310 coronavirus-related inspections. Since COVID-19 was declared a national emergency, the number of daily inspections conducted or overseen by OSHA has fallen from an average of 219 per day to just 73 per day. Moreover, the agency currently has the lowest number of inspectors in its history, and in fiscal year 2018 conducted the lowest number of health hazard-related inspections in 20 years. Workers and their families especially Black, Hispanic, and immigrant familiesare bearing the brunt of the harmful impacts, losing the health that allows them to participate fully in their communities as well as years of life. Preventing occupational injuries and illnesses could save billions of dollars in costs that today are largely borne by workers' families and public programs, and could help our nation's economy to recover.

OSHA, MSHA, and NIOSH function effectively when they collect comprehensive, high-quality data and use it to drive prevention efforts, regulation, and enforcement. However, decades of inadequate budgets and a *growing set of hurdles* erected at the behest of special interests that oppose regulation reflexively have inhibited these agencies' ability to protect the lives and health of workers. By recommitting to collecting and effectively using comprehensive, high-quality evidence to drive their activities, these agencies can help ensure that workers go home safe and healthy at the end of the day, and that we are better prepared for the next pandemic.

#### **Top Priorities**

- Use evidence to drive regulation of major
  hazards and improve preparedness. OSHA and
  MSHA should promulgate rules that evidence indicates
  will have substantial impact on worker health and safety,
  including protections against infectious diseases such as
  COVID-19. Both agencies should make better use of
  NIOSH's expertise on mine safety, chemical hazards,
  infectious diseases, and occupational health surveillance.
- Collect more comprehensive, high-quality data to guide OSHA prevention and enforcement activities, and make data accessible to the public. With comprehensive, high-quality data, OSHA can identify sectors, tasks, and hazards where initiatives, guidance, rules, or enforcement actions can better safeguard workers' lives and health. Making data accessible to the public can allow researchers to identify patterns while letting workers and employers recognize trends in their industries. NIOSH can issue specific guidance for data collection and surveillance programs for workplace injuries and illnesses, including infectious diseases, and for workplace exposures and hazards.
- Ensure appropriate disclosure and analysis of information that informs rulemaking. Industry groups have a *long history* of funding studies designed from the outset to exonerate the potentially hazardous materials that they manufacture, use, incorporate into products, and/or release as waste. Addressing these problems requires both improved disclosure and stronger support for high-quality research that is not influenced by industries whose products or releases are under investigation.
- Better use agency expertise to prepare for the next infectious disease crisis. NIOSH should establish an occupational infection control research program focusing primarily on worker safety to complement the work of the traditional infection control profession, which focuses primarily on patient safety. NIOSH should develop recommendations to ensure better preparedness for future infectious disease pandemics and other crises, and future federal crisis task forces should include NIOSH and OSHA experts to ensure that workplace issues are visible and appropriately addressed.

#### **Key Appointment Positions**

#### **Department of Labor**

Solicitor of Labor

#### **OSHA**

- Assistant Secretary of Labor for Occupational Safety and Health
- · Chief of Staff
- Deputy Assistant Secretary

#### **MSHA**

- Assistant Secretary of Labor for Mine Safety and Health
- · Chief of Staff
- Deputy Assistant Secretary

#### **NIOSH**

Director

#### **Day-One Actions**

- **OSHA:** Issue an emergency temporary standard on COVID-19 and other infectious diseases. (See Priority 1 below for more detail.)
- **NIOSH:** Issue a statement that any face covering not certified as a respirator by NIOSH (or the Food and Drug Administration) does not constitute adequate respiratory protection for workers exposed to airborne infectious agents and other respiratory hazards. (*Priority 1*)

#### **Actions for the First 30 Days**

- **OSHA:** Begin work on a permanent infectious disease standard whose starting point is the California Division of Occupational Safety and Health's (Cal/OSHA) Aerosol Transmissible Disease Standard and that covers transmission via skin and mucous membranes as well. (*Priority 1*)
- **OSHA:** Issue an emergency temporary standard on heat hazards and begin work on a permanent standard. (*Priority 1*)

- **OSHA:** Begin rulemaking to restore to employer injury and illness logs the checkoff column for employers to indicate whether injuries were musculoskeletal disorders. (*Priority 2*)
- **OSHA:** Begin rulemaking to restore the 2016 rule requiring employers to electronically transmit to OSHA injury and illness data they already collect, and use these data to create a publicly available injury data set. (*Priority 2*)
- **OSHA and MSHA:** Meet with the solicitor of labor for advice on how much financial disclosure can be required of commenters without violating the Administrative Procedure Act, and identify steps Congress should take to require such disclosures. (*Priority 3*)
- **Department of Labor:** Assign a team to strengthen scientific integrity policies. (*Priority 3*)
- **NIOSH:** Identify for the CDC scientific integrity officer changes that would strengthen the agency's scientific integrity policy. (*Priority 3*)

#### **Actions for the First 100 Days**

- **OSHA:** Begin regulatory work to address chemical hazards and musculoskeletal disorders. (*Priority 1*)
- **OSHA:** Create a working group with the Environmental Protection Agency (EPA) and NIOSH to establish a truly protective regime for workers against chemical hazards and schedule the first meeting. (*Priority 1*)
- MSHA: Develop a process for identifying relevant NIOSH research and engaging in rulemaking based on it. (Priority 1)
- **OSHA:** Develop and begin implementing a plan to fill all open positions for scientific staff responsible for regulatory development, inspector positions, and the managerial and administrative positions needed to support them. (*Priority 2*)
- OSHA: Assign staff to use MSHA as a model for improving public availability of data on inspections, citation status, and sampling. (Priority 2)
- **OSHA:** Develop and begin implementing a plan to complete the modernization of OSHA's website. (*Priority 2*)
- **OSHA:** Support legislation codifying OSHA's ability to issue citations for recordkeeping violations based on employer records for the past five-and-a-half years. (*Priority 2*)

- **OSHA:** Propose legislation amending Section 11(c) of the Occupational Safety and Health (OSH) Act of 1970 to provide stronger protections for whistleblowers. (*Priority 2*)
- OSHA: Establish a work environment justice task force to address data collection, rulemaking, and compliance needs to eliminate inequities in all industrial sectors. (Priority 2)
- **OSHA:** Develop a secretarial-level plan to ensure OSHA is taking appropriate steps to identify and address racial and ethnic disparities. (*Priority 2*)
- **NIOSH:** Assign staff to develop a comprehensive surveillance program to collect data on workplace exposures and hazards. (*Priority 2*)
- **NIOSH and OSHA:** Create a working group to evaluate health and safety trainings and methods for improving employer behavior. (*Priority 2*)
- NIOSH and OSHA: Create a working group to advance NIOSH's role in providing evidence to support OSHA standards. (Priority 3)
- **NIOSH and OSHA:** Assign a project team to explore regulating chemicals by class. (*Priority 3*)
- **NIOSH:** Begin a process to develop recommendations for employers to apply the hierarchy of controls in advance of the next pandemic so that less personal protective equipment (PPE) is needed. (*Priority 4*)
- **NIOSH:** Create a process to assess the PPE needs of all workers and all hazards for the Strategic National Stockpile for future pandemics. (*Priority 4*)

## Priority 1: Use Evidence to Drive Regulation of Major Hazards and Improve Preparedness

OSHA and MSHA should use evidence from a range of sources, particularly NIOSH research and input from workers and the organizations that represent them, to identify and regulate hazards that pose risks to workers' health and lives. However, procedural barriers and delays prevent OSHA and MSHA from doing so as quickly as they should. These are particularly severe in OSHA's case. According to the Government Accountability Office, the additional procedural requirements established since 1980 by Congress, court decisions, and various executive orders have resulted in *a more* 

protracted rulemaking process that can result in insufficient protections for workers. Evidence of certain hazards is so overwhelming that it demands a regulatory response. Priority hazards for OSHA include the following:

- **Infectious diseases.** Given the urgency of the COVID-19 pandemic—which is unlikely to be resolved by January 2021—OSHA should immediately issue an emergency temporary standard (ETS) to protect against airborne infectious diseases such as COVID-19. Morbidity and mortality in health care, transportation, farming and food **processing** (including **meat** and **poultry** packinghouses), retail, and other workplaces make it abundantly clear that OSHA should have already issued such a standard. The content of an ETS is readily available in the AFL-CIO's petition to OSHA and Virginia's recently issued emergency temporary standard. OSHA should begin work immediately on a permanent infectious disease standard whose starting point should be Cal/OSHA's Aerosol Transmissible Disease Standard, and it should cover transmission via skin (to protect workers against pathogens such as MRSA) and mucous membranes as well.
- **Chemical hazards.** Regulation of chemical hazards by OSHA has not functioned properly since the creation of the agency in the 1970s. According to the inventory of the Toxic Substances Control Act (TSCA), there are more than 40,000 chemicals actively in commerce in the United States. Since its foundation, OSHA has succeeded in updating or issuing new standards for only 29 of them and, by its own admission, those regulations are inadequate. In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act. That act amended TSCA and specifically instructed EPA that workers are a highly exposed population to be protected by EPA through regulations issued under TSCA. Since 2017, EPA has acted in numerous ways to avoid carrying out the law. Among these ways is the systematic sabotage of worker protection. OSHA should work cooperatively with EPA and NIOSH to establish a truly protective regime for workers against chemical hazards. Work could begin with chemicals on the TSCA priority list.
- Ergonomic hazards. In 2001, despite *enormous evidence* that musculoskeletal disorders (MSDs) are caused by workplace exposure to high forces, awkward postures, and repetitive motions, Congress used the Congressional Review Act (CRA) to repeal the newly promulgated ergonomics standard. Since that time,

there have been more than a million work-related MSDs each year. OSHA should work with the solicitor of labor on a strategy to regulate MSDs without violating the CRA. One possibility for this would be industry-specific rulemakings.

• Heat and other hazards related to the climate crisis. As the pace of global climate disruption accelerates, many jobs have become more hazardous. OSHA should immediately issue an ETS to protect workers from heat and begin work on a permanent standard, similar to the Cal/OSHA standard. The climate crisis will also expose workers to more severe impacts of extreme weather events and necessitate that US production shift to new materials and technologies. OSHA and NIOSH should address the full range of worsening hazards and examine the health and safety risks of new materials and technologies as they are being developed, rather than waiting until they are widely used, to discover which ones are safe and which ones harm workers.

Although rulemaking is not as severely hampered at MSHA as at OSHA, the agency has nonetheless acted too slowly in ways that have cost miners' lives. NIOSH produces important research on mine safety and health topics, but MSHA has been too slow to regulate based on it. For instance, NIOSH researchers had recommended *explosibility meters* that could have identified insufficiently protective rock dusting at Upper Big Branch before the devastating explosion there. More recently, MSHA has failed to act on *NIOSH research* indicating that the calculations MSHA uses to detect silica in coal mine dust samples are understating silica amounts. MSHA should develop a robust process to ensure it is aware of relevant NIOSH research and engages in timely rulemaking based on it.

#### **Administrative Actions**

#### **OSHA**

- Issue an ETS on COVID-19 and other infectious diseases.
- Issue an ETS on heat hazards.
- Begin work on a permanent, comprehensive infectious disease standard whose starting point is Cal/OSHA's Aerosol Transmissible Disease Standard, covering transmission via skin and mucous membranes as well.

- Begin regulatory work to address musculoskeletal disorders.
- Begin working with EPA and NIOSH to establish a truly protective regime for workers against chemical hazards.

#### **MSHA**

 Develop a process for identifying relevant NIOSH research and engaging in rulemaking based on it.

#### **NIOSH**

Issue a statement that any face covering not *certified as a respirator* by NIOSH (or the Food and Drug
 Administration) does not constitute adequate respiratory
 protection for workers exposed to airborne infectious
 agents and other respiratory hazards.

#### **Budgetary Action**

OSHA, MSHA, and NIOSH should fill all open positions and propose budgets that include appropriate staffing and compensation levels, including additional scientific staff to develop new standards and guidance, and additional staff to increase enforcement and whistleblower protections. In OSHA's case, this will require funding that is multiples of its current budgetary level. Budget requests should also include funding for initiatives that will allow the agencies to attract and retain a diverse workforce and create welcoming cultures where members of historically marginalized groups can operate effectively in leadership roles. Initiatives can include independent reviews of hiring and evaluation processes, mandatory implicit bias training, empowered and well-resourced diversity and inclusion committees, and other actions recently recommended by CDC employees for their agency.

#### Priority 2: Collect More Comprehensive, High-Quality Data to Guide OSHA Prevention and Enforcement Activities, and Make Data Accessible to the Public

To direct its resources effectively and meet evidentiary thresholds for the promulgation of workplace health and safety standards, OSHA must have comprehensive information about the number, type, and location of workplace injuries and illnesses that occur nationwide, and high-quality

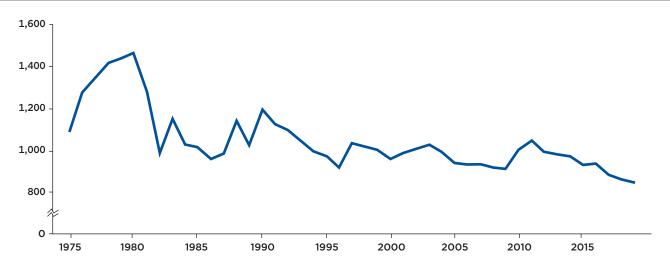
data on workplace exposures and hazards. Such information can help the agency identify areas where guidance, improved enforcement, special emphasis programs, and/or new rules can save lives and preserve health and safety. Past administrative actions—including reversals of rules on data collection—have limited OSHA's ability to collect relevant information and share it with the public. Restoring these rules should be a priority. In addition, OSHA should work with NIOSH to strengthen surveillance of injuries and illnesses, including infectious diseases, and of exposures and hazards, and should look to unions, worker centers, and other worker organizations as partners in gathering and sharing information.

OSHA must make changes both to collect more data and to share the data it has with the public. Posting easily searchable and downloadable data sets online—with sufficient aggregation to prevent identification of individuals—can allow others to augment OSHA's work. Researchers can identify new or previously unnoticed patterns of exposures and injuries; employers can recognize trends in their industries; and workers and advocates can use information, including stories of preventable worker deaths, to push for improvements in their workplaces and communities. Recent court decisions have ordered OSHA to release injury data reported by employers to *journalists* and *the public*, and OSHA has agreed to do so. MSHA does a much better job ensuring public access to data on inspections, citation status, and sampling, and OSHA should use that agency as a model for posting complete data in a timely and accessible fashion.

OSHA's ability to receive high-quality data from employers through electronic submission of injury and illness logs was hampered by the Trump administration's weakening of the rule requiring electronic submission of injury and illness data. OSHA's ability to collect information through workplace inspections is hampered by having *far too few inspectors* (see figure on next page). It would take the agency *165 years to inspect each workplace under its jurisdiction just once*.

OSHA must also be able to use information it has to enforce the law; however, when Congress used the CRA to nullify OSHA's "Volks rule," it deprived the agency of the authority to prevent employers from disposing of or falsifying OSHA log entries that are more than six months old, despite the fact that the standard requires employers to maintain accurate records for the previous five years. Strengthening the inspection workforce and supporting restoration of the Volks rule will allow OSHA to collect more comprehensive data and use the data it has access to.

#### Number of Federal OSHA Inspectors by Year



SOURCE: WORKER SAFETY IN CRISIS: THE COST OF A WEAKENED OSHA

There are **28 occupational health and safety plans** (including six that cover only state and local government workers) operated by US states and territories under the OSH Act. OSHA should use its oversight authority under the act to ensure that these states collect and share data appropriately.

Workers and the organizations that represent them—including unions, worker centers, and councils on occupational health and safety—can be valuable partners in information collection and sharing. OSHA should fully include workers and their representatives in inspections and strengthen whistleblower protections so workers can provide information about health and safety conditions without fear of retaliation.

Research has shown that data from OSHA logs reported to the Bureau of Labor Statistics' (BLS) annual Survey of Occupational Illnesses and Injuries (SOII) and to the OSHA Data Initiative (ODI) undercount occupational injuries and illnesses. An analysis of data collected from OSHA's National Emphasis Program on Recordkeeping (2009–2012) found that 47 percent of the establishments inspected had unrecorded or misrecorded cases. Nearly one-quarter (23 percent) of cases involving days away from work or injury-related work restrictions (called DART for Days Away or Restricted Time) were either not recorded or recorded as non-DART cases. When interviewed, workers identified employers' disciplinary and absentee programs as having the greatest negative effect on injury reporting.

Section 11(c) of the OSH Act prohibits discharging or discriminating against employees who exercise their rights

under the act, including the right to report injuries and illnesses. Unfortunately, *11(c)* has failed to provide adequate protection. Disciplining of employees for the protected activity of reporting injuries and illnesses under the OSH Act has contributed to the undercounting of illnesses and injuries and thus the inaccuracy of SOII and ODI. The president should send legislation to Congress amending 11(c) as follows:

- Lengthen the statute of limitations to 180 days in keeping with the retaliation provisions in the anti-discrimination statutes enforced by the Equal Employment Opportunity Commission. Similar provisions under the Fair Labor Standards Act have an even longer statute of limitations. The OSH Act's 30-day statute of limitations makes it far more likely that workers who face discharge or other retaliation will miss the deadline for filing a complaint, meaning that they will have no recourse.
- 2. Create a right of preliminary reinstatement pending final adjudication similar to the one that exists in the Mine Safety and Health Act, which states that if the complaint was not frivolously brought, the individual should be reinstated pending further litigation. Under 11(c), workers who have been discharged cannot return to their workplace unless the employer settles the case and includes reinstatement, or the solicitor of labor pursues the case in federal court.
- 3. Amend 11(c) to make it procedurally consistent with more recently passed whistleblower provisions of the last two

decades, such as those in the Affordable Care Act and Dodd-Frank Act:

- a. Grant complainants the right to bring their complaints forward to a *de novo* adjudicatory hearing utilizing the existing Department of Labor administrative law judges and Administrative Review Board. The right to bring a case forward should be triggered after a formal finding or after the statutory time for investigation of a complaint has elapsed.
- b. Provide legal representation for complainants.
   The solicitor of labor should have the discretion to provide representation to complainants in meritorious cases. Amend 11(c) so that prevailing complainants can recover attorneys' fees in addition to damages.
   Most of the other anti-retaliation and whistleblower statutes provide for fees for complainants who prevail.
- c. Create a private right to bring a civil action that would allow complainants the option to remove cases from the agency and pursue them in federal court or to pursue administrative adjudication.
- d. To ensure that cases involving dual motives can be successfully litigated by complainants, change the evidentiary standard from "a motivating factor" to "a contributing factor"—the standard in all of the more recent whistleblower laws enforced by OSHA.

In addition to improving its access to and use of existing sources of information, OSHA should work with NIOSH to improve surveillance of infectious disease exposures and hazards, with an initial focus on industries where extensive transmission of COVID-19 has been reported. *NIOSH surveillance initiatives* already address specific exposures (such as to lead and pesticides) and industries (such as longhaul trucking and oil and gas extraction), so the agency is well positioned to provide guidance to OSHA. The two agencies should also collaborate to evaluate health and safety trainings and methods for improving employer behavior.

OSHA should collect and analyze data that can help it identify and address racial and ethnic disparities in occupational health and safety, including through stronger inspections and enforcement actions. With MSHA, NIOSH, and the National Institute for Environmental Health Science, it should establish a work environment justice task force to address data collection, rulemaking, and compliance needs to eliminate inequities in all industrial sectors.

#### **Administrative Actions**

#### **OSHA**

- Prioritize filling open inspector positions, as well as the managerial and administrative positions needed to support them, while recruiting a diverse group of candidates and eliminating bias from the hiring process.
- Restore to employer injury and illness logs the checkoff column for employers to indicate whether injuries were musculoskeletal disorders.
- Restore the 2016 rule requiring employers to electronically transmit injury and illness data—including data from the OSHA 300 log and OSHA 301 forms they already collect—to OSHA, and use these data to create a publicly available injury data set.
- Use MSHA as a model for improving public availability of data on inspections, citation status, and sampling.
- Complete the process of modernizing OSHA's website so it contains useful data—including up-to-date fatality information with workers' names, as well as reports of amputations and hospitalizations—that are easily searchable.
- Propose legislation codifying OSHA's ability to issue citations for recordkeeping violations based on employer records for the past five-and-a-half years (i.e., repeal the CRA resolution that repealed the Volks rule).
- Monitor state plans and ensure all state plans allow workers to file formal complaints online.
- Propose legislation amending Section 11(c) of the OSH Act to provide stronger protections for whistleblowers.
- Establish a work environment justice task force to address data collection, rulemaking, and compliance needs to eliminate inequities in all industrial sectors.
- Develop a secretarial-level plan to ensure OSHA is taking appropriate steps to identify and address racial and ethnic disparities.

#### **NIOSH**

 Issue guidance for data collection and workplace surveillance programs for injuries and illnesses, including infectious diseases, and for exposures and hazards. Work with OSHA to evaluate health and safety trainings and methods for improving employer behavior.

#### **Budgetary Action**

Budget requests should include funding for appropriate
 OSHA staffing—including, but not limited to, inspectors,
 supervisory inspectors, whistleblower investigators, and
 the staff involved with their work—and a high-quality,
 easily searchable website. This will require increasing
 OSHA's budget to multiples of its current level and will
 enable Congress to recognize the investment necessary to
 protect workers. The request should also include sufficient
 funding for NIOSH surveillance work covering injuries,
 illnesses (including infectious diseases), exposures, and
 hazards.

# Priority 3: Ensure Appropriate Disclosure and Analysis of Information that Informs Rulemaking

Industry groups have a *long history* of funding studies designed from the outset to exonerate the potentially hazardous materials that they manufacture, use, incorporate into products, and/or release as waste. This history includes conducting *rigged re-analyses* of studies that have shown these materials to harm workers' health. Addressing these problems requires more effective scientific integrity safeguards, improved disclosure, and stronger support for high-quality research that is not influenced by industries whose products or releases are under investigation.

Strong scientific integrity policies are essential to ensure that agency employees and contractors can raise concerns about instances of inappropriate industry influence and prevent unwarranted interference with their reports and other work products. A *2017 Union of Concerned Scientists analysis* rated the Department of Labor's scientific integrity policy as poor.

Greater transparency about funding sources for research and public comments can help agency personnel assess comments as they prepare regulations and allow for tracking of which stakeholders are responding and whose voices are missing from discussions. OSHA requested that commenters on its crystalline silica and beryllium standards disclose their funding sources, and it should resume the practice.

In addition to identifying and addressing potential conflicts of interest, agencies should seek sources of high-quality evidence that are less likely to be influenced by industries that have a vested interest in the outcomes. This is particularly important for regulating chemical hazards. One next step would be for NIOSH to initiate a project using "criteria" documents and other tools to explore regulating chemicals by class rather than individually. In its early years, NIOSH developed a large number of criteria documents that were intended to form the basis of OSHA standards. Few became standards, and those that did took many years (e.g., the NIOSH Recommended Exposure Limit for Respirable Crystalline Silica was published in a criteria document in 1974 and became an enforceable permissible exposure limit 42 years later). Even when criteria documents do not become standards, they provide valuable information to employers who want to protect their workers and establish that a hazard is "recognized," which means that employers have a duty under the OSH Act to protect workers from it.

In the 1970s, NIOSH produced more than 15 criteria documents per year. In the 1980s, this fell to fewer than three. In the 1990s, it produced fewer than two per year. Since 2000, NIOSH has produced fewer than one every two years. Because NIOSH is not hemmed in by statutory, administrative, and judicial requirements, it can use criteria documents to explore ways of regulating chemicals by class instead of treating each distinct chemical formula as a separate entity requiring a separate rulemaking. Industry should not have the opportunity to edit these recommendations or water them down.

#### **Administrative Actions**

- Ensure the Department of Labor has a scientific integrity policy that protects the rights of scientists to share data and analysis, prohibits retaliation against those raising scientific integrity concerns, provides clear procedures for addressing alleged violations, and requires ongoing scientific integrity training. (For more details, see the "Agency Scientific Independence" memo in *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term.*) CDC's scientific integrity policy should establish the same safeguards for NIOSH.
- NIOSH should play a more prominent role in providing the scientific evidence that serves as the basis for OSHA standards. As an initial step, leaders of both agencies should initiate a project exploring regulation of chemicals by class rather than individually.
- OSHA and MSHA should encourage members of the public who comment on proposed rules to disclose the funding sources and sponsoring organizations of research

mentioned in their comments, and weigh the presence or absence of disclosure when considering comments.

# Priority 4: Better Use Agency Expertise to Prepare for the Next Infectious Disease Crisis

NIOSH has had too limited a role in preparing for public health crises like COVID-19. In response to this pandemic, many employers focused on PPE, which is at the bottom of the *hierarchy of controls* and one of the least effective ways to protect workers. Faced with constrained PPE supplies, the American Hospital Association and other employer representatives *lobbied successfully* for CDC to relax requirements in order to avoid citations for not providing adequate PPE.<sup>1</sup>

NIOSH should have a more visible role in helping the nation prepare for the next pandemic by identifying elements of the hierarchy of controls that should be used to prevent infectious diseases in every workplace (including, but not limited to, health-care workplaces) and by making recommendations so that the PPE in the Strategic National Stockpile will be in adequate quantity and will be adequately maintained so that equipment is not expired or unusable. Adequate quantities of PPE should mean enough for all hazards for all workers. In the COVID-19 pandemic, the problem has not merely been a lack of PPE to protect health-care workers from the novel coronavirus. It has also been a lack of PPE for other hazards in health care, due to the demand in response to the pandemic; a lack of PPE in other occupations, such as grocery store clerks; and a lack of PPE for other hazards, such as silica and lead in construction and pesticides in farm work. OSHA,

MSHA, and NIOSH should participate fully in task forces and public communications related to COVID-19 and to future pandemics. In addition, NIOSH should establish an occupational infection control research program.

The presidential administration should ensure that work-place issues are visible and adequately addressed by including NIOSH and OSHA experts in federal task forces addressing public health crises. When crises are ongoing, these workplace health and safety experts should participate in daily briefings as well as high-level meetings and be consulted when relevant guidance is prepared. Task forces that seek to generate lessons from past crises must include NIOSH and OSHA, even if they were underrepresented while the crisis occurred.

#### **Administrative Actions**

• Include NIOSH and OSHA in federal task forces addressing past and future pandemics.

#### **NIOSH**

- Develop recommendations for employers to apply the hierarchy of controls in advance of the next pandemic so that less PPE is needed.
- Assess the PPE needs of all workers and all hazards for the Strategic National Stockpile for future pandemics.

#### **Endnote**

1. NIOSH is housed within CDC but does not appear to have participated in the decision to relax these requirements.

#### **ENDORSED BY**

Acadia Institute of Oceanography / Food Chain Workers Alliance / Free Government Information (FGI) / Government Information Watch / Greenpeace USA / In the Public Interest / International Association of Machinists and Aerospace Workers / International Chemical Workers Union Council / Laborers' Health & Safety Fund of North America / Milwaukee Riverkeeper / MomsRising / National Center for Health Research / National Council for Occupational Safety & Health / National Employment Law Project / NJ Work Environment Council / Ocean Conservation Research / Open The Government / PHILAPOSH / Revolving Door Project / RICOSH / Society for Conservation Biology North America / Union of Concerned Scientists / United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) / United Mine Workers of America / Western New York Council on Occupational Safety & Health (WNYCOSH)

# Office of Science and Technology Policy

This memo outlines key ways in which the Office of Science and Technology Policy (OSTP) can establish and restore the principles of scientific integrity, as well as repair and rebuild federal scientific capacity, during the next presidential term. It identifies specific priorities and steps the agency can take to effectively act on these issues in 2021.

The pursuit and communication of scientific knowledge free from political interference is necessary for a coherent and effective response to any major challenge. Decisionmakers and the public need timely and accurate scientific information and advice to be able to improve health, spur innovation, and advance the economy. Since its founding in 1976, OSTP, part of the Executive Office of the President, has played an important role in advising the US president on a wide variety of science- and technology-related issues. Yet over the past several years, *scientists have left federal service in droves*, science advice has been sidelined, statistical infrastructure has been undermined, and scientific integrity has been violated, leaving the nation more vulnerable to all kinds of attacks on its health, security, and environment.

The COVID-19 pandemic demonstrates the need for federal policymakers to prioritize and act on science. Reductions in scientific capacity combine with chaos and confusion to impair our nation's ability to adequately protect the population. Fortunately, our nation is still home to a wealth of scientific expertise. Protecting public health during a time of pandemic disease, while addressing long-term challenges such as climate change, requires strengthening the federal infrastructure that governs how agencies use, produce, and communicate science. This is not the time to pause our nation's quest for discovery, solutions, and action. OSTP can play an important role in setting expectations for how information can be shared and how science should inform decisions made by executive branch agencies, leading to more effective policymaking.

#### **Top Priorities**

• Advance scientific integrity in government. With requests, resources, and assistance, OSTP should help all

- scientific agencies within the executive branch adopt policies and practices that safeguard and strengthen scientific integrity.
- Create robust scientific capacity within executive branch agencies. OSTP should develop a task force on rebuilding scientific capacity, assist with strengthening of federal advisory committees, and contribute to improvements in awarding of scientific grants and standardization of international scientific collaborative practices.

#### **Key Appointment Positions**

- Director, OSTP
- Associate Director, Science
- Assistant Director, Scientific Integrity (new proposed position)
- Associate Director, Environment
- Associate Director, National Security and International Affairs
- Associate Director, Technology
- Assistant Director, Social, Behavioral, and Economic Sciences
- · Chief Technology Officer

#### **Day-One Actions**

 Announce the formation of a task force for rebuilding scientific capacity in the federal government.

#### **Actions for the First 30 Days**

- Appoint an associate director for science and assistant director for scientific integrity.
- Issue a memorandum recommending that every agency have an official in charge of scientific integrity.

- Provide advice to the president on a memorandum supporting the policy that scientific grants should be awarded based on scientific merit.
- Assign OSTP staff to work with agencies and provide them sufficient guidance to ensure that cost-benefit analyses are in line with best scientific practices and are not manipulated or used to avoid indicating a need for public protections.
- Assign staff to work with agencies on best practices regarding federal advisory committees.
- Reinstate the National Science and Technology Council Human Subjects Research Subcommittee.

#### **Actions for the First 100 Days**

- Create a subcommittee within the National Science and Technology Council (NSTC) Committee on Science that includes a working group and workplan for improving scientific integrity policies and practices across agencies.
- Assist agencies in the development of media policies that allow scientists to share their expertise publicly without political vetting or approval.
- In conjunction with the relevant agencies and with the Office of Management and Budget (OMB), identify rules and guidance that restrict the use of science in policymaking.
- Create an NSTC working group to improve management of public data.
- Create an NSTC working group to standardize international scientific collaborative practices throughout the federal government.

### Priority 1: Advance Scientific Integrity in Government

Federal scientists are looking for concrete signals that they will be able to do their jobs free from political interference or retribution and that their work will be appropriately considered during the policymaking process. *Recent surveys* show marked increases in political control over the work and communication of science across many environmental and public health agencies and departments. This has tangible consequences on our ability to mitigate and adapt to climate change, keep pollution levels sufficiently low, protect people from

public health threats, support biodiversity, and ensure that consumer products are safe.

The nation will continue to face extraordinary challenges in the coming years and maintaining a high standard of using science in decisionmaking is critical. Scientific integrity improvements are not only inexpensive to implement, but are likely to have additional positive impacts that extend beyond the federal scientific enterprise. Independent science is integral to making sound, effective policy decisions that withstand court challenges.

Many checks on government have eroded over the past several years, including the safety of whistleblowers, the autonomy of inspectors general, and the effectiveness of agency scientific integrity policies. In the next presidential term, the administration should take steps to restore this kind of accountability to bring back public faith in the competence and effectiveness of government. OSTP should coordinate and oversee these efforts and share best practices across agencies.

#### **Administrative Actions**

- Appoint an associate director for science (ADS). The role of the Senate-confirmed ADS has been to support and advocate for basic and translational research at federal agencies and to coordinate across the agencies (often via NSTC) on regulatory matters and emerging issues including behavioral impacts, potential pandemics, open science, and biomedical innovation. The ADS oversees support and attention to broad areas of science, including the social and behavioral sciences, physical sciences, biology and biotech, nanotechnology, research ethics, and space science, as well as broadening participation, education, and training.
- Appoint an assistant director for scientific integrity. The director of OSTP should appoint this new position, which should be vested with sufficient authority to make scientific integrity a priority across agencies. The assistant director will work to build a robust culture of scientific integrity, develop best practices and training modules, work with individual agencies to improve their scientific integrity policies on paper and in practice, develop and implement processes for evaluation of scientific integrity misconduct by agency leaders and White House staff, and charter a scientific integrity subcommittee under the standing NSTC Committee on Science to share resources and to strengthen and unify scientific integrity efforts across the government.

- Request that agencies appoint officials in charge of scientific integrity and direct them to develop and implement agency-specific scientific integrity policies. The president, in consultation with the director of OSTP and in conjunction with OMB, should issue a memorandum that encourages every agency to have an official in charge of scientific integrity at the deputy director level who reports to the highest-ranking civil servant in the agency. These officials should review and improve existing scientific integrity policies at their respective agencies to ensure they are strong and enforceable with clear procedures for training and implementation. The officials should develop agreements with their agencies' inspectors general for addressing misconduct, and work with the OSTP on cross-governmental coordination of scientific integrity practices. These officials should also have the ability to have unfiltered communications with members of Congress.
- Work with agencies to improve scientific integrity policies and practices. OSTP can play an important role in bolstering a culture of scientific integrity by developing best practices and training modules, working with individual agencies to improve their scientific integrity policies on paper and in practice, developing and implementing processes for evaluation of scientific integrity misconduct by agency leaders and White House staff, and convening an interagency scientific integrity committee to share resources and to strengthen and unify scientific integrity efforts across the government.
- Request that federal agencies develop media policies that allow scientists to share their expertise publicly without political vetting or approval. Several federal agencies, including the Department of Energy and National Oceanic and Atmospheric Administration, have media policies that encourage open public communication. OSTP, in conjunction with OMB and the Office of Information and Regulatory Affairs (OIRA), should work with all federal agencies and departments that create or utilize scientific information to develop policies that meet minimum transparency standards.
- Work with agencies to remove any rules that restrict the
  use of science in policymaking. OSTP should work with
  the president to instruct agencies to roll back any rules or
  guidance that exclude public health studies from use in
  policymaking or agency scientific analysis, including rules
  and guidance in place or in process at the Department of
  the Interior and Environmental Protection Agency (EPA).

 Work with agencies to ensure the appropriate use of costbenefit analysis. To the extent that cost-benefit analyses are required, OSTP should ensure that agencies have sufficient guidance to ensure that these analyses are in line with best scientific practices and are not manipulated or used to avoid indicating a need for public protections.

#### **Legislative Actions**

- Support the Scientific Integrity Act. The Scientific Integrity Act requires agencies to develop effective, enforceable scientific integrity policies that will prevent—and establish consequences for—censorship of scientists and political interference in their work. It has bipartisan support and is endorsed by scores of public-interest organizations.
   The administration should signal support for any legislation that improves scientific integrity, and act swiftly to implement any enacted law that protects scientists from political interference in their work.
- Support stronger whistleblower protections. Federal employees need better whistleblower protections in order to feel that they can safely reveal abuses of scientific integrity. OSTP should support legislation enabling whistleblowers to oppose retaliation by appealing directly to federal courts when the Merit Systems Protection Board does not act on an appeal within 90 days. Legislation should also ensure protection and functioning of agency inspectors general by increasing their funding and granting inspectors general for-cause removal protections.
- Support legislation that clarifies the role of OMB in interagency coordination. OSTP and the White House should support legislation clarifying that OMB may not direct agencies to change scientific findings.

#### **Budgetary Action**

Request funding for the newly created position of assistant director for scientific integrity. Additional funding
may also be necessary for scientific integrity officials at all
or some agencies, depending on individual agency budgets.

# **Priority 2: Create Robust Scientific Capacity** within Executive Branch Agencies

Federal scientific agencies are weaker today than several years ago. An aging federal workforce, intentional purges of agency scientists, the politicization of grant funding in certain cases, and actions that sideline and dilute the role of science have conspired to weaken the ability of government agencies to fulfill their public service missions.

Beyond the workforce, the quality of expert opinion sought by government has also deteriorated. EPA removed several highly qualified scientists from its advisory panels after ruling that receipt of an EPA grant made them ineligible to serve—even though the agency made no such prohibition for scientists who receive industry funding. Under the president's executive order to cut one-third of federal advisory committees, many science advisory committees have been disbanded or dismissed, while others meet less frequently or not at all.

In the next presidential term, the administration will need to take immediate and sustained action to make the federal government an attractive place to work, rebuild and diversify the workforce, and improve the quality of science advice to federal agencies. OSTP has a critical role to play in creating, coordinating, and overseeing the conditions that will allow this to happen.

#### **Administrative Actions**

- Develop a plan for filling open science positions quickly and efficiently. OSTP should develop a Task Force for Rebuilding Scientific Capacity with external stakeholders empowered to make recommendations to agencies and the White House on shoring up scientific capacity within federal agencies, with a specific commitment to diversity, equity, and inclusion. This work can complement broader executive branch actions recommended in *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term.*
- Help agencies determine whether and how current, disbanded, and new advisory committees can help fill interagency needs. With guidance from OSTP, NSTC should work with agencies to identify interagency needs that advisory committees can fill and provide advice

- about the best mechanisms for meeting those needs. It should also assist agencies with transparency around the composition and member selection of federal advisory committees and safeguards to ensure that scientific advisory committees can operate with the independence they require. For more information, see the "Federal Advisory Committees" section of *Restoring Science*, *Protecting the Public: 43 Steps for the Next Presidential Term*.
- Support the president in issuing a memorandum to reinforce that scientific grants should be awarded based on scientific merit. To safeguard against the political vetting of research grants, the president should issue a memorandum instructing agencies to allocate funding based on evaluations by experts with relevant qualifications, and based on publicly available criteria.
- Reinstate the NSTC Human Subjects Research Subcommittee (HSRS). While some subcommittees can be time-limited, issues related to the use of human subjects cannot be thought of as a short-term deliverable. Rather, the issue of research ethics needs to be an ongoing effort, as it is complicated by perennial and emerging technological and social issues. In the past, HSRS contributed to transparency and fairness by playing a coordinating role across federal agencies, which allowed agencies to learn from one another, and created opportunities for smaller agencies to have their perspectives represented. Such engagement is especially crucial so that teams working to save lives with COVID-19 prevention and treatment research can uphold the highest ethical standards.
- Standardize international scientific collaborative practices.
   Introduce policies and practices for a secure and collaborative international scientific environment. While we face legitimate threats to research security, the scientific enterprise—across all federal agencies—benefits tremendously from international collaborations.

#### **ENDORSED BY**

Acadia Institute of Oceanography / Center for Auto Safety / Climate Science Legal Defense Fund / Defenders of Wildlife / Federation of Associations in Behavioral & Brain Sciences / Free Government Information (FGI) / Government Information Watch / Greenpeace USA / In the Public Interest / International Chemical Workers Union Council / Jacobs Institute of Women's Health / Milwaukee Riverkeeper / MomsRising / Ocean Conservation Research / Oceanic Preservation Society / Open The Government / PHILAPOSH / Revolving Door Project / RICOSH / Society for Conservation Biology North America / Union of Concerned Scientists / United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) / Western New York Council on Occupational Safety & Health (WNYCOSH)