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 post-market 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 it—including 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 comprehen-

sive 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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