In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Secretary Robert F. Kennedy, Jr.

Questions for the Record
House Subcommittee Committee on Energy and Commerce
The Fiscal Year 2026 Department of Health and Human Services Budget Hearing
June 24, 2025

Attachment — Additional Questions for the Record

The Honorable Earl L. "Buddy" Carter

1. Every year, I am proud to partner with my colleague Rep. Chellie Pingree on a bipartisan letter in support of funding for federal antimicrobial resistance programs. In the U.S., antimicrobial resistance (AMR) contributes to nearly 173,000 deaths annually and just six of the worst resistant pathogens increase U.S. health care costs by $4.6 billion annually. In Georgia, CDC's Antibiotic Resistance Solutions Initiative provides over $4 million in funding to support expert staff to prevent and detect resistant infections. I appreciate that the President's Budget Request provides level funding for CDC AMR programs.
    a. How will you maintain our nation's ability to effectively address AMR?

Response:
CDC leads the U.S. public health fight against antimicrobial resistance (AR) in support of the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria. CDC's investments through the AR Solutions Initiative strengthen our ability to prevent infections, rapidly detect antimicrobial resistance threats, and respond to control their spread, preserve the effectiveness of antibiotics through increasing appropriate use, and innovate new strategies and products. CDC continues to work closely with other federal departments and agencies, jurisdictional public health departments, and academia and other partners to address antimicrobial resistance, including through multisectoral coordination, detection and surveillance, infection prevention and control, and antimicrobial stewardship. Through investments in every state health department (as well as in some large cities and territories), the U.S. can better fight new and emerging antimicrobial resistance threats. CDC's current AR Investment Map provides transparency for AR funding across the U.S. states and is updated annually.

2. I was pleased to see that the proposed budget includes funding to support the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB), as this important entity brings together clinicians, scientists, and other experts to inform our federal approach to the major threat of AMR. PACCARB's late January meeting was canceled.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Can you let us know when this meeting will be rescheduled?

Response:
I remain committed to supporting PACCARB and the Department is currently in the process of scheduling the next meeting.

3. The budget request for the proposed Administration for a Healthy America (AHA) includes $119 million for a new Prevention Innovation Program, with a track dedicated to addressing chronic conditions, including by promoting access to healthy foods and implementing nutrition-driven programs in partnership with community organizations.
    a. How do you plan to leverage the MAHA Initiative, and specifically the Prevention Innovation Program, to implement and scale these policy goals?

Response:
The Prevention Innovation (PI) program will provide communities with new and practical ways to support the goals of the Administration to Make America Healthy Again (MAHA). The PI program will support the goals of the MAHA initiative by addressing the root causes of America's escalating health crises, focusing on maternal health delivery gaps and chronic conditions that lead to poorer health outcomes in rural areas. This request supports three tracks: one for maternal health, one for chronic disease, and one for Tribes (where applicants could support programs in either maternal health or chronic disease). The intent of the PI program is to improve overall health, reduce dependence on medications and other treatments, and ensure that people have access to resources and other clean and healthy environmental and lifestyle options.

4. There is growing concern about our reliance on foreign sources for essential medicines, including adversarial countries like China.
    a. Would you support prioritizing U.S.-made medicines in federal procurement programs— such as those run by the Strategic National Stockpile?

Response:
Purchasing critical medical countermeasures (MCMs) domestically reduces the risk of relying on international partners. A Strategic National Stockpile (SNS) that relies on foreign manufacturing and production of critical products is not the best choice or best course of action for national security. When and where possible, the SNS looks to domestic sourcing for products to include in the stockpile. All SNS procurements are made in compliance with federal acquisition regulations (the Buy American statute is implemented at FAR part 25 and requires contracting and procurement, when possible, with domestic suppliers). For awareness, the SNS does hold some products that are not commercially available and for which there is limited or no domestic manufacturing capacity.

As part of the Administration's priority to Make America Healthy Again, we need to bolster domestic manufacturing capability. Offshoring of manufacturing has been a

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

decades long process and it cannot be reversed immediately. My Department is committed to working with Congress to identify efficient ways to improve domestic manufacturing capabilities.

b. How do you believe CMS can better leverage its existing authorities to reward domestic manufacturing—whether through preferred formulary placement, enhanced reimbursement, or other value-based incentives?

Response:
I have directed the Department to fulfill President Trump's goals of lowering drug prices and putting America first, within the confines of the law. Through the Most Favored Nation agreements, these contracts include price targets for certain drugs as well as commitments in to invest in domestic manufacturing.

5. The Children's Hospitals Graduate Medical Education program (CHGME) provides freestanding children's hospitals with federal graduate medical education funding to support the training of pediatricians and pediatric specialists. Nationally, CHGME funds the training of over 8,390 physicians annually and approximately 55 percent of all pediatric residencies. This program delivers nearly $8 million annually to Children's Healthcare of Atlanta to help cover a substantial amount of the costs of training the next generation of pediatricians and pediatric specialists.
    a. What are your plans to continue this program while prohibiting funding for children's hospitals that provide transgender treatments or procedures to minors?

Response:
My Department is implementing President Trump's Executive Order protecting children from surgical and chemical mutilation and dangerous ideologies not backed by science. We have already stopped millions of dollars in taxpayer funding through NIH for woke studies including those that subject children to these gender experiments. Additionally, we are in the process of completing a comprehensive review of these procedures for kids using gold-standard science, which has preliminarily indicated that these procedures are not supported by the evidence.

The FY 2026 President's Budget requests $10 million to continue the Pediatric Specialty Loan Repayment Program (PS LRP), this program provides loan repayment to a range of physicians, pediatric subspecialists, and child and adolescent behavioral health providers who work in a Health Professional Shortage Area, a Medically Underserved Area, or serve a Medically Underserved Population. Additionally, the PS LRP provides eligible health professionals up to $100,000 for loan repayment in exchange for a three-year, full-time service commitment.

6. Mr. Secretary – you have expressed concern regarding the public health and national security risks posed by our country's reliance on medicines manufactured in China. I

share your concern and was pleased to see that FDA's 2026 legislative agenda includes recommendations to provide additional transparency into the source of API entering this country.

a. What steps are you prepared to take to halt the importation of illicit medical products entering the United States?

Response:
FDA works with U.S. Customs and Border Protection and focuses on areas that present the most substantial threat to our drug supply. Import entries for FDA-regulated drugs imported into the U.S. are electronically screened, and the products that appear violative are subject to detention and refusal of admission into the country. FDA's actions at the border help to ensure that imported drugs meet FDA's rigorous standards for quality, safety and effectiveness just as drugs made in the U.S. must do. The U.S. government works with foreign regulatory counterparts, when possible, to disrupt or close illegal operations involving the production and distribution of counterfeit drugs.

7. Given the FDA's prior acknowledgments of in/at-home opioid analgesics disposal technologies achieving the Agency's stated goal (Docket No. FDA-2022-N-0165), a 2019 GAO Report confirming no regulatory barriers, and the SUPPORT Act's clear directive to expand patient access to disposal solutions— does FDA intend to recommend in/at-home drug disposal products in any forthcoming OA REMS Guidance?

Response:
FDA is actively studying commercially available in-home disposal systems and evaluating other data to develop appropriate specifications for such systems that would enable the Agency to require holders of approved applications for opioid analgesics to make them available, in addition to mail-back envelopes, for pharmacies and other dispensers to choose to provide patients under the OA REMS.

8. Additionally, will the FDA forgo with the prior Administration's redundant assessment issued in October 2024 since in/at-home solutions have been recognized as safe, accessible, and effective?

Response:
Unlike mail-back envelopes, commercially available in-home disposal systems are not currently regulated by any federal agency.

To that end, in June 2024, FDA commissioned a study by the University of Maryland's Centers of Excellence in Regulatory Science and Innovation (CERSI) to gain an understanding of the mechanisms of action, ingredients, safety, usability, and capability of commercially available in-home disposal systems. Completion of this study is expected in 2026.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

While this study progresses, we are also planning to engage the public on what specifications these products should meet in order to make them an appropriate disposal option for inclusion in the OA REMS.

a. Lastly, will the FDA consider recommending less outdated methods like flushing or mixing with unpalatable substances, given environmental concerns, overwhelming patient preference for in-home solutions, and years of evidence supporting their public health impact?

Response:
FDA has developed a comprehensive approach to enable patients to dispose of their unused medications, including opioid analgesics, safety and securely. This approach includes a range of options to meet patients' needs and preferences. FDA first recommends that patients use a take-back option, like a pharmacy kiosk, take-back event, or mail-back envelope, to dispose of unused or expired opioids and is actively exploring other options, including in-home disposal systems. If a take-back option is not readily available, FDA recommends most opioids be flushed (i.e., 11 opioids that are on FDA's "Flush List"). FDA does not recommend that any opioid on the Flush List be mixed with unpalatable substances and disposed of in household trash.

9. I know you've long been a critic of NIH's gain-of-function research. Since Fauci-funded gain of function research in Wuhan likely caused COVID, I have been leading bipartisan legislation to cut funding for this dangerous research. So, I was very pleased to see that NIH suspended all funding for gain of function research as part of your work to implement President Trump's May Executive order.
    a. What are the next steps in your effort to improve oversight of dangerous gain-of-function research?

Response:
NIH is actively engaged across the Administration to develop a new, risk-based oversight framework that empowers Federal departments and agencies to identify and prevent dangerous gain-of-function research risks, incorporates independent top-down oversight, strengthens enforcement, and significantly increases transparency and accountability. The safety and security of the American public is paramount, as is maintaining their trust in science. NIH will adhere to and enforce this new, more stringent oversight policy and will maintain our suspension on dangerous gain-of-function research until new systems and processes are in place. The NIH has made to improve the tracking and managing of foreign subawards and promoting maximal transparency in institutional reviews for biosafety. Additionally, NIH will devote substantial efforts to promote a culture of biosafety, biocontainment, and biosecurity vigilance, including new outreach efforts and improved tools for effective implementation and bolstering public trust.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

10. As we look to further make HHS the gold standard for science, could you share the data and science that HHS has assessed to determine that artificial color additives in our food and beverage are unsafe?
    a. Are there any plans to share this data publicly?

Response:
The MAHA Report released in May 2025 notes that the scientific community has conducted a number of studies raising concerns about the association between petroleum-based synthetic dyes and health conditions such as attention deficit hyperactivity disorder, obesity, and diabetes. The MAHA Report contains a list of citations to the studies and articles referenced in the text, including:

- **McCann, D., Barrett, A., Cooper, A., Crumpler, D., Dalen, L., Grimshaw, K., ... Stevenson, J. (2007). Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: A randomized, double-blinded, placebo-controlled trial. The Lancet, 370(9598), 1560–1567.**
- **Miller, M. D., Steinmaus, C., Golub, M. S., Castorina, R., Thilakartne, R., Bradman, A., & Marty, M. A. (2022). Potential impacts of synthetic food dyes on activity and attention in children: A review of the human and animal evidence. Environmental Health, 21(1), 45.**
- **Nigg, J. T., Lewis, K., Edinger, T., & Falk, M. (2012). Meta-analysis of attention-deficit/hyperactivity disorder or attention-deficit/hyperactivity disorder symptoms, restriction diet, and synthetic food color additives. Journal of the American Academy of Child and Adolescent Psychiatry, 51(1), 86–97.e8. https://doi.org/10.1016/j.jaac.2011.10.015.**
- **Bakthavachalu, P., Kannan, S. M., & Qoronfleh, M. W. (2020). Food Color and Autism: A Meta-Analysis. Advances in neurobiology, 24, 481–504. https://doi.org/10.1007/978-3-030-30402-7_15.**

11. At the end of his Administration, President Biden moved to finalize a policy that will lead to less lifesaving research and innovation. The NIH Intramural Research Access Program Access Planning policy requires "access planning" clauses as a condition of NIH licensing. While intended to ensure patient access to therapies, in reality, the policy does the opposite, and will only create ambiguity and uncertainty in the drug development process. Previously, when the federal government imposed "reasonable pricing" conditions on agreements between federal labs and external parties, NIH leadership found that the pricing clause deterred industry from engaging in potentially beneficial scientific collaborations with government scientists, without providing any significant benefit to the public.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Do you believe the NIH Access Planning Policy will similarly discourage these collaborations?
b. How might a reduction in these collaborations impede the development of future medical technologies that benefit patients?

Response:
My Department seeks to drive effective partnerships that foster a shared commitment to transforming knowledge into improved health for all. The agency continues to explore a variety of approaches and evaluate data generated from current and prior policy initiatives, such as the reasonable pricing efforts in the 1990s. My Department will continue to work with patients, industry partners, and other interested individuals to craft and refine approaches that advance the NIH mission and drive biomedical innovation.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Gus M. Bilirakis

1. The President's "Statement of Drug Policy Priorities" calls for innovation in research and data. What new regulatory-science initiatives, such as model-informed drug development or adaptive trial designs, does FDA plan to launch in Fiscal Year (FY) 2026 to accelerate development programs for non-opioid treatments while continuing to ensure safety and efficacy?

Response:
FDA has long supported development of non-opioid pain treatment, including by issuing draft guidance aimed at encouraging development of non-opioid analgesics for acute pain. FDA also intends to issue draft guidance aimed at encouraging development of non-opioid analgesics for chronic pain. We will continue to work with sponsors to accelerate development of non-opioid treatments for both acute and chronic pain.

Additionally, to fulfill SUPPORT for Patients and Communities Act Sec. 3002, FDA has awarded cooperative grants to support the development and dissemination of clinical practice guidelines for the management of acute pain conditions.

2. The President's FY 2026 budget proposal includes a reorganization of the National Institutes of Health (NIH), aimed at streamlining operations and improving coordination across related research areas. As part of this restructuring, several existing institutes and centers would be consolidated, including the National Eye Institute (NEI), which would move to the National Institute on Neuroscience and Brain Research. Will NEI continue its existing research objectives under this plan?

Response:
The National Eye Institute (NEI) supports vision research through 1,700 research grants and training awards to support scientists at more than 250 medical centers, hospitals, and universities. NEI also conducts intramural laboratory and patient-oriented clinical research at its facilities in Maryland.

The key principle of restructuring is to empower collaboration across scientific disciplines to increase knowledge. We will continue to collaborate on biomedical research to address unique geographic and cultural health challenges regardless of the structure of NIH.

3. Early hearing detection and intervention programs are an effective means to ensure that newborns, infants, and young children with hearing loss are identified, diagnosed, and connected to intervention services. Without diagnosis and treatment, children risk missing important developmental milestones related to communication, language, and social skills.
    a. What initiatives will HHS pursue to promote early hearing detection?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The FY 2026 President's Budget request for Birth Defects, Developmental Disabilities, Disabilities and Health, is $157.8 million. The FY 2026 request supports the planned HHS realignment of these activities from CDC to AHA. The budget request continues support for activities to promote the health and development for people with disabilities, including $10.8 million for CDC's Early Hearing Detection and Intervention surveillance program.

4. Newborn screening is one of our nation's most successful public health programs, serving nearly 4 million infants each year and saving thousands of babies' lives. Through timely detection and treatment within the first few days of life, the national newborn screening program provides American children the best chance at a healthy life, a purpose that aligns with the Administration's vision for a healthier America. The agency's proposed budget states that "Newborn Screening for Heritable Disorders" will be eliminated by HRSA.
    a. Does HHS plan to continue broader newborn screening initiatives at other agencies through the reorganization?

Response:
Newborn screening is primarily a state-based program, with each state's public health department maintaining its newborn screening panel. HHS is reviewing the overall process of reviewing conditions for newborn screening, and we look forward to working with Congress on ways to improve newborn screening and child health.

The FY 2026 President's Budget prioritizes programs that provide states and communities with the flexibility to target funding towards the services needed most, such as through the Title V Maternal and Child Health (MCH) Block Grant. The Title V State MCH Block Grant Program, a partnership between the federal government and states, awards formula grants to 59 states and jurisdictions to address the health needs of mothers, infants, and children, as well as children with special health care needs in their state or jurisdiction. Nationwide, the Title V MCH Block Grant reaches 98% of infants and gives states the flexibility to meet their unique health needs, including support for infant screening.

This funding requested in the FY 2026 President's Budget will support programs to measure the impact of birth defects, disabilities, and blood disorders and put research findings and recommendations into public health action to foster a safer, healthier population. Programs span across three focus areas, infant health and child development, health and development for people with disabilities, and blood disorders and other programs.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Dan Crenshaw

1. Earlier this year the administration issued an executive order that called for you and the FDA Commissioner to look at administrative and legislative recommendations to improve the process by which prescription drugs can be reclassified as over-the-counter medications, including recommendations to optimally identify prescription drugs that can be safely provided to patients over the counter. This is commonly referred to as switch.
    a. How can we work together to make sure FDA approaches its work on OTC medicines, including switches, in a common sense and least burdensome manner to make sure we realize the full potential of OTC benefits for American consumers?

Response:
Pursuant to Executive Order 14273 (April 145, 2025), FDA is actively working to ensure its policies and processes are supporting the goal of increasing access to over-the-counter products, which will lower costs and improve access for patients.

FDA has an existing process for prescription-to-nonprescription switches of particular drug products. Through the existing process, a sponsor may seek approval to market an approved prescription drug product as nonprescription. A sponsor of an approved prescription drug product may initiate this proposed change in the drug's marketing status through the New Drug Application process. The Agency will approve an application proposing a prescription-to-nonprescription switch of a particular drug product (which may be a proposed full switch or partial switch, such as only for certain strengths and/or conditions of use), if FDA determines that the previous prescription status is not necessary for the protection of the public health and the application demonstrates that the drug is safe and effective for nonprescription use as directed in proposed labeling, provided all applicable requirements for approval are met.

I appreciate your interest in this subject and look forward to working with you further on this important priority.

2. Cigarette smoking and secondhand smoke exposure still account for nearly half a million deaths in the United States each year. Smoking-related death and disease cost the United States $600 billion each year and contribute to significant health challenges.
    a. What opportunities do you see for innovation in smoking cessation therapies to be part of the administration's work to Make America Healthy Again?

Response:
Nicotine is a highly addictive substance, making nicotine dependence a very challenging condition to treat. That is why, as Secretary, I am working to make more smoking cessation products available. Over the past five years, the FDA has reviewed over 26 million applications, the vast majority for e-cigarette products. The FDA is prioritizing ending the

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

backlog of applications that built up at the Center for Tobacco Products under the Biden Administration

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Troy Balderson

1. We are in a new era of Alzheimer's treatment, and access to timely and accurate diagnoses is more critical than ever. Today, only half of those living with Alzheimer's disease are diagnosed, and of those, only half are told of their diagnosis. The initial diagnosis of Alzheimer's is made by primary care providers in 85% of cases. However, because they are not dementia specialists, most report they do not feel prepared to provide care for those diagnosed. Virtual (online) dementia education and training programs connect multidisciplinary dementia care experts with professional care providers in a free continuing education series of interactive, case-based video conferencing sessions. They have been shown to successfully help address knowledge gaps felt by many primary care providers nationwide - especially in rural communities - allowing patients to get the most accurate advice from providers in their community that they know and trust.
    a. With the growing shortage of healthcare providers that disproportionately impacts rural communities like my district, what steps are you currently taking to ensure that primary care providers are able to diagnose Alzheimer's and other dementia and deliver high-quality care for those already diagnosed - including care for the 236,200 Americans living with Alzheimer's in my state of Ohio?

Response:
Through the Teaching Health Center Graduate Medical Education (THCGME) program and the National Health Service Corps (NHSC) loan repayment and scholarship programs, HHS is supporting efforts to encourage primary care clinicians, including geriatricians who play a crucial role in the diagnosis and management of Alzheimer's disease and dementia. The FY 2026 President's Budget requests $175 million in mandatory funding for THCGME to support up to 1,273 resident full-time equivalent slots in FY 2026. The FY 2026 President's Budget request for the NHSC includes $128.6 million in discretionary funding and $345 million in proposed mandatory resources to support clinician scholarship and loan repayment.

The Budget also provides continued funding for the Rural Health Care Services Outreach Grants, which support collaborative models to deliver basic health care services to rural areas and are uniquely designed to meet rural needs.

2. Secretary Kennedy, I was pleased to see that you recently stated that it's time to let U.S. biotech flourish, not tie it up in red tape. Over the past decade, the biotech industry has invested over a billion dollars in central Ohio, supporting thousands of gene therapy, life sciences, and research and development jobs in and around my district. America leads in biotechnology innovation, but China is investing untold amounts of capital and resources in their biotech to dominate the United States.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. To advance U.S. innovation and cell and gene therapy development, how will you ensure that the most innovative treatments are available to the patients who need them - so patients and their physicians are empowered to choose the right treatment available today and in the future?

Response:
FDA is committed to supporting innovation and continued progress in the development of cell and gene therapies. Cell and gene therapies offer the remarkable potential of single-dose precision treatment that can stabilize or cure rare, serious, and life-threatening diseases with unmet medical needs.

I recognize that utilizing the regulatory flexibilities in our toolbox is key to advancing medical breakthroughs to tackle rare diseases. In addition to the accelerated approval pathway, the FDA is looking into a regulatory approach for rare diseases. By enhancing communication between sponsors and our reviewers, learning from data other than from controlled trial data (e.g., real world data), and utilizing the Agency's recently launched Elsa artificial intelligence (AI) tool to facilitate the evaluation of premarket applications, the FDA aims to be a nimbler agency that can bring much needed treatment options to the rare disease community.

CMS is also working to improve access through the Centers for Medicare and Medicaid Innovation Cell and Gene Therapy (CGT) Access Model. The CGT Access Model aims to improve health outcomes for people with Medicaid who could benefit from innovative new cell and gene therapies by supporting outcomes-based agreements between states and manufacturers that will provide for treatments within a framework that lowers prices for states and ties payment to outcomes.

3. With advances in genetic testing, we can now diagnose over 400 rare diseases and conditions in newborns. However, most newborns do not receive genetic screening, leading to a situation where children with rare diseases often spend 7 to 11 years searching for a diagnosis.
    a. What actions can Congress and the Department of Health and Human Services (HHS) take to review the recommended newborn screenings that have the potential to save lives and reduce costs to the healthcare system?

Response:
Newborn screening is primarily a state-based program, with each state's public health department maintaining its newborn screening panel. HHS provides the Recommended Uniform Screening Panel (RUSP) as a resource to help guide states in their development and management of their screening program HHS is reviewing the overall process of reviewing conditions for newborn screening, and we look forward to working with Congress on ways to improve newborn screening and child health.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Richard Hudson

1. During President Trump's first term, the SNS was pulled from CDC because CDC was failing at managing this critical asset. We all know this administration appreciates success stories, and, under President Trump, the SNS proved more successful when placed under ASPR. Any plans to move ASPR, SNS, or BARDA under either the CDC or any other entity, such as the new Office of Healthy Futures, would be devastating for our country's public health security, and undercut the decisions made under President Trump during his first term.
    a. What was the rationale for this specific decision in the proposed reorganization? And have there been any efforts to reconsider?

Response:
The SNS will remain aligned and coordinated with: the Biomedical Advanced Research and Development Authority (BARDA), the Center for Industrial Base Management and Supply Chain (IBMSC), and the operation and leadership of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This alignment of functions supports the development, acquisition, and stockpiling of medical countermeasures needed during public health emergencies.

2. Since 2009, FDA has collected $9 billion to regulate tobacco and nicotine products, which statutorily includes enforcement against illegally marketed imports. But because of President Biden's failed tobacco policies, more than 85% of the U.S. market is illegal, with the majority of illicit nicotine products coming from China.
    a. Will you commit to restoring order to the marketplace, fixing President Biden's failures, and delivering on the promise of the Tobacco Control Act?
        i. Last month in Senate HELP you committed that the administration would "wipe them out" when referring to disposable Chinese vape products – what have you done so far and what is in the works to follow through on this?
        ii. What is the current status and future plans for the multi-agency task force with the Department of Justice to combat illicit vapor products in the U.S?

Response:
FDA is focusing on curbing the influx of illegal Chinese vaping products while streamlining the review process for legitimate smoking-cessation devices. The agency is prioritizing the seizure of illicit vapes at ports and accelerating the review of products that address nicotine dependence.

FDA's Center for Tobacco Products (CTP) actively monitors industry compliance with the law through surveillance, inspections, and investigations, and continues to harness market intelligence and other data to inform our enforcement strategies. FDA has issued over 780 warning letters to firms for manufacturing, selling, or distributing unauthorized new

tobacco products, as well as more than 860 warning letters to retailers for selling these products. In addition, FDA has filed CMP complaints against 87 manufacturers and over 175 retailers for violations of the FD&C Act related to unauthorized tobacco products. FDA will continue to follow up with those who violate the law until they come into compliance. Additionally, FDA is currently working with Federal partners on new initiatives to stop illegal products from entering U.S. commerce.

Further, FDA has launched an initiative to increase voluntary compliance from retailers. This includes a regularly updated list of e-cigarettes authorized by the FDA, a Searchable Tobacco Product Database of over 17,000 tobacco products that may be legally marketed in the United States, and new tobacco retailer education materials. These materials have been shared with more than 300,000 retailers nationwide.

3. There is extensive research showing loss in pharmaceutical sales and profits is directly linked to a loss in innovation and a decrease in research and development from policies from the IRA. The U.S. is a world-leading nation for pharmaceutical R&D and has been since the 1980s when European nations reverted to most-favored nation pricing.
    a. What steps are you and your team taking to ensure we aren't stifling innovation while hurting and reducing access for American patients – already made more challenging by the IRA policies?
    b. Will you commit to working with Congress, as outlined in President Trump's executive order, on fixing the IRA's disastrous Medicare Drug Price Negotiation Program and extending the period small molecule drugs are eligible for negotiation after FDA approval to align them with biologics?
        i. Do you have a timeline on implementing this EO?

Response:
President Trump has made it a priority to ensure other wealthy nations finally begin to pay their fair share for prescription drugs. My department is working tirelessly to ensure that Americans enjoy lower prices for prescription drugs while helping our trade partners hold peer nations to account.

Medicare drug price negotiations are required by statute and HHS is following the law. President Trump's executive order to lower prescription drug prices improves upon Medicare drug price negotiation and increases transparency into the process while taking other monumental steps to create a transparent, competitive, and fair prescription drug market for Americans.

4. In FY 2024 and FY 2025 (as of April 15, 2025), FDA permitted 252 shipments of semaglutide API from 19 Chinese facilities—sufficient for approximately 1.5 billion doses—for compounding and further manufacturing, including 16 shipments from five

unregistered facilities. Nine Chinese companies accounted for 95% of the imported API, which is typically produced via chemical synthesis and contains peptide-related impurities and trace metals not found in FDA-approved semaglutide made by recombinant DNA technology, posing significant patient safety and immunogenicity risks. Moreover, FDA registration of these facilities does not indicate agency approval or recent inspections, with only 53 drug and device inspections conducted in China in FY 2023.

a. What comprehensive measures is HHS implementing to:
    i. Strengthen FDA's border screening to prevent unlawful shipments from unregistered or non-compliant Chinese facilities, including verifying Good Manufacturing Practice (GMP) compliance and valid manufacturing licenses?
    ii. Enhance FDA's coordination with Customs and Border Protection to intercept non- compliant shipments?
    iii. Prioritize safety evaluations of semaglutide products derived from Chinese API and consider restricting imports of chemically synthesized semaglutide API until safety concerns are resolved?

Response:
FDA reviews shipments of imported drugs to determine whether they comply with applicable standards and are admissible into the U.S. Products that appear to be non-compliant are subject to detention and refusal.

Surveillance inspections for registered active pharmaceutical ingredients (API) and finished dosage forms from drug manufacturers are prioritized by the CDER risk-based Site Selection Model (SSM). The SSM uses risk factors, based on statutory requirements and emerging risks to prioritize inspectional assignments from all eligible CDER-regulated sites. The Agency's risk-based oversight has enabled us to effectively identify violations, take action, and address issues, ultimately contributing to a more secure supply chain.

FDA also actively monitors the internet to identify unsafe online pharmacies and websites offering misbranded and/or unapproved drugs for sale to U.S. consumers and has issued warning letters to stop and prevent the distribution of illegally marketed GLP-1 drugs. For instance, FDA has issued warning letters to companies that have illegally sold unapproved drugs containing semaglutide, tirzepatide, or retatrutide that are falsely labeled "for research purposes" or "not for human consumption" but were nevertheless marketed for use by American consumers. FDA has urged consumers not to purchase these products, which are of unknown quality and may be harmful to their health. FDA's Office of Criminal Investigations has also worked with the Department of Justice to bring actions against parties for introducing unapproved and misbranded drugs into interstate commerce, including GLP-1 drugs.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Under current law, for drugs that are not subject to premarket approval requirements, a category that includes over-the-counter monograph drugs and API used to make compounded drugs, FDA typically does not have a formal, designated opportunity to inspect manufacturing facilities (including those in China) before such drugs are first shipped to or distributed in the United States. Furthermore, the original manufacturers of API and finished products are not always readily identified in labeling, such as when the label only indicates the repackager or distributor. As a result, it can be challenging to ensure that all non-application drug manufacturers' facilities are compliant with applicable requirements prior to initial distribution.

FDA continues to monitor adverse events and complaints related to compounding of GLP-1 receptor agonist drugs. The Agency has conducted systematic sampling and analysis of foreign-sourced GLP-1 APIs entering domestic commerce. Our laboratory testing evaluates these bulk drug substances across multiple critical quality parameters, including identification testing to confirm the identity and authenticity of the API, potency analysis to verify therapeutic strength and consistency, and in-vitro immunogenicity assessment to evaluate potential safety risks. The agency has identified some areas of concern for the API used in compounded GLP-1 drugs. FDA has issued public warnings regarding specific GLP-1 drug products that are inappropriate for use in compounding operations. These communications serve to protect public health by alerting healthcare providers and patients to identified risks. FDA is also actively working with its state regulatory partners and continues to communicate with compounders and the public regarding these concerns.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Neal P. Dunn, M.D.

1. Secretary Kennedy, FDA must play the role of a reasonable and transparent regulator so that law- abiding U.S.-based companies win in the marketplace against law-breaking Chinese competitors. Under the Biden FDA, the Center for Tobacco Products (CTP) oversaw a regulatory regime that failed catastrophically on multiple fronts. Since 2020, FDA has failed to effectively review thousands of Premarket Tobacco Product Applications (PMTAs) for flavored ENDS products. Many applicants have had their PMTAs languishing at FDA since as early as 2020, thousands of days after FDA's 180-day statutory deadline by which they must review them. I have heard from stakeholders who have PMTAs pending before FDA for years for flavored products which contain age-gating and anti-counterfeiting technology to ensure that they may not be used by anyone under 21 and the pods within them may not be counterfeited. Companies with compliant, science-backed products are ready to launch with proper oversight, yet they remain trapped in FDA's review backlog. Indeed, the PMTA for one such product, the Glas G2 system, has been sitting first in the prioritized queue for "products with merit" (e.g., those that include age-gating technology) for almost four years. Such applications deserve a fair and prompt response from FDA.
    a. Please give us a timely update as to the status of Glas's application with the CTP/FDA.

Response:
CTP is working diligently to reduce review times and has made significant progress. The volume of applications received nearly simultaneously has been unprecedented for FDA, with CTP receiving applications for millions of products over the course of just a few weeks in 2020. Despite this challenge, CTP has resolved applications for more than 26.5 million of the nearly 27 million premarket tobacco products received to date. FDA cannot confirm nor deny the existence of pending applications. To protect confidential commercial information, the FDA does not comment on potentially pending applications. Questions about potential products beyond those contained in the FDA's searchable tobacco product database of authorized products may be directed to the manufacturer.

2. Secretary Kennedy, as I'm sure you are aware, the Commerce Department is currently conducting an investigation under Section 232 into the national security risks posed by imports of pharmaceutical drugs and ingredients. I applaud this Administration for taking a serious look at pharmaceutical supply chains, for far too long our country has been dependent on adversaries like China for manufacturing some of our most critical medicines. While there are a number of ways to address the national security risks, I've heard that the Administration is considering tariffs in the near future. In fact, recent reporting indicates that several health insurers for individual and small group plans have told state regulators that they are being forced to raise enrollee premiums by 3% or more – beyond the standard annual premium increases – to account for the anticipated tariffs. If

tariffs are used, I hope the Administration will ensure that any tariffs are tailored to the national security threat and avoid unintended consequences for drug costs and patient access.

a. Can you provide an update on the status of this investigation?

Response:
My Department through FDA and ASPR consulted with the Department of Commerce on the 232 investigation into the national security threats associated with the reliance on imported pharmaceuticals, providing insights into which medicines are considered essential and information on where the active pharmaceutical ingredients for those products are manufactured.

b. How is the Administration ensuring that any remedy minimizes impacts on patients and drug prices?

Response:
The President has committed to lowering the price of drugs for all Americans. While we work to address any national security threats posed by over reliance on imports of finished pharmaceuticals and active pharmaceutical ingredients, we must ensure that all the dollars in the American healthcare system are devoted to working for the patient – including lowering the price of drugs by ensuring transparency in costs, providing accountability to middlemen, looking for innovative way to provide high-cost drugs at low prices, and making sure other countries pay their fair share for the costs of developing prescription drugs. The Trump Administration has taken historic action to lower the cost of drugs and exploring ways to ensure Americans no longer pay more for medications than patients in other economically comparable countries. Utilizing the Most Favored Nation framework, the Trump Administration is putting pressure on other nations to pay their fair share while driving down drug prices.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Diana Harshbarger

1. Secretary Kennedy, with much of my East Tennessee district being rural, I'm proud to serve as co-chair of the Congressional Bipartisan Rural Health Caucus. Rural Americans often face limited access to healthcare due to a shortage of providers, long travel distances, and insufficient infrastructure. This lack of access often leads to poorer health outcomes, with rural populations experiencing higher rates of chronic diseases and lower life expectancy compared to their urban counterparts.
    a. How does the HHS FY 2026 budget invest in and help strengthen rural healthcare?

Response:
The FY 2026 President's Budget request includes $145 million for the Rural Communities Opioid Response program to maintain prevention, treatment, and recovery services for substance use disorder, and $101 million Rural Health Care Outreach program. The outreach program includes $12 million for the Rural Maternity and Obstetrics Management Strategies (RMOMS) program to increase access to maternal and obstetrics care in rural communities. In addition, the Budget provides $12.7 million for Rural Residency Planning and Development to expand the number of rural residency training programs with the goal of increasing the number of physicians choosing to practice in rural areas.

The FY 2026 President's Budget request includes $128.6 million in discretionary funding and $345 million in proposed mandatory resources for the NHSC to continue to support recruitment of a health workforce that is well prepared to meet patients' needs.

2. Everyone agrees that we need to bring pharmaceutical manufacturing back to the United States. But I don't want us to overlook the fact that domestic production is already happening — including for hypothyroidism medication, which is a daily essential for millions of Americans. If we don't reduce regulatory barriers, domestic manufacturers of this product won't be able to sustain operations in the U.S.
    a. So, what more can we be doing — not just to bring manufacturing back — but to ensure it remains viable in the long term?

Response:
My Department is committed to taking steps that can help reduce America's reliance on foreign drug manufacturing and ensure that Americans have a resilient and strong domestic drug supply. The FDA PreCheck program aims to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability and facilitating the construction of manufacturing sites in the United States.

FDA is also developing the Quality Management Maturity (QMM) Program, which aims to encourage drug manufacturers to implement quality management practices that go beyond

current good manufacturing practice (CGMP) requirements. FDA also has programs to actively support the adoption of Advanced Manufacturing Technologies, which can help domestic production be more efficient and flexible. Through its Emerging Technology Program, FDA works directly with industry to resolve regulatory uncertainties and accelerate adoption of innovative platforms. Additionally, the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative is intended to prepare a regulatory framework to support the adoption of advanced manufacturing technologies that could start to bring benefits to patients over the next 5-10 years.

In addition, the Commissioner's National Priority Voucher program will review and potentially select recipients who file applications for approval of certain drugs and biological products that are aligned with U.S. national health priorities, including those that onshore drug development and manufacturing.

3. One of the bright spots at the FDA is that its Center for Tobacco Products (CTP) is fully funded by user fees and NOT appropriated taxpayer dollars. There's an opportunity at CTP to address the most preventable cause of death and disease in the United States — smoking. My state of Tennessee consistently ranks among the states with the highest adult smoking rates in the country. Currently, there are only 74 authorized smoke-free products and devices compared to thousands of combustible cigarettes, the most harmful way to consume nicotine.
    a. Knowing your focus on Making Americans Health Again — and I'm a proud member of the House MAHA Caucus — will you work with Congress on reforming the CTP to help ensure more timely approval of applications for smoke-free nicotine products, that are considerably less risky than cigarettes …. which will also help address the illicit tobacco and nicotine problem we face in the United States?

Response:
FDA supports providing options and resources for adults who smoke cigarettes to quit smoking or completely switch to a tobacco product that is less harmful. To date, FDA has received premarket tobacco product applications (PMTAs) for nearly 27 million products, of which the Agency has resolved approximately 26.5 million, the majority of which are for e-cigarettes. FDA has authorized 34 e-cigarette products, as well as 20 nicotine pouch products. By law, FDA can grant marketing authorization for a new tobacco product subject to a PMTA only if there is evidence that marketing the product would be appropriate for the protection of the public health. This standard requires FDA to consider the risks and benefits to the U.S. population as a whole – including the benefits to adults who currently smoke cigarettes and completely switch to a potentially less harmful product or significantly reduce their cigarette use. FDA weighs these benefits against the risks of the product, including to any youth and adults who are not current users of tobacco products.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

FDA is actively assessing the PMTA review process and determining ways to streamline the process to improve the efficiency of reviews without sacrificing scientific rigor. In addition, FDA will continue to engage with industry to facilitate quality submissions that includes the information needed to conduct the analysis required by law.

4. Over 90% of Americans live within 5 miles of a pharmacist yet many do not have access to basic care.
    a. Would you support expansion of the work of the pharmacist in the Medicare program?

Response:
In 2019, under the first Trump Administration, CMS sought input and recommendations from stakeholders regarding the elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. While Medicare payment rates and coverage criteria—including the types of care providers are covered to administer—are largely established in statute, HHS and CMS are working together to ensure Medicare beneficiaries have access to the drugs they need.

5. Secretary Kennedy, I applaud your leadership in recently working with CMS Administrator Mehmet Oz to secure from the health insurance carrier industry a pledge to streamline and improve the prior authorization processes for Medicare Advantage, Medicaid Managed Care, Health Insurance Marketplace® and commercial plans covering nearly eight out of 10 Americans. It's my understanding this pledge relates to medical claims.
    a. Do you think that PBMs can and will undertake similar reforms for outpatient prescription drugs?

Response:
President Trump has made lowering the price of prescription drugs a top priority of this Administration and is committed to reevaluating the role of PBMs. The Administration is looking at how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans.

6. Prior authorization for prescriptions drugs is often experienced as a barrier at the check-out counter, with the patient and the pharmacist left holding the proverbial empty bag.
    a. Will HHS deploy the Office of the National Coordinator for Health Information Technology (ONC) meaningful use criteria to help drive and automate prior authorization data submission to the point of prescribing in the exam room, thus expanding access and increasing convenience for patients?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Currently, ASTP/ONC is working to issue an updated HTI final rule (HTI-4), that will update the certification criterion for electronic prescribing. Additionally, in June, health insurers committed to HHS to improve the prior authorization processes by reducing the number of medical services subject to prior authorization and expanding the number of real-time responses to reduce delay in care for patients. Also, CMS is developing a proposed rule that would propose new requirements to streamline processes for the prior authorization for certain drugs for Medicare Advantage organizations, state Medicaid fee-for service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans offered on the Federally-facilitated Exchanges.

7. Secretary Kennedy, I want to share two tragic real-world examples that highlight the grave stakes we're facing with respect to the chemical abortion drug mifepristone. In Texas, a woman's ex- boyfriend secretly slipped her abortion pills in an effort to terminate her pregnancy without her knowledge or consent. In Louisiana, a mother obtained abortion pills and used them to end her daughter's pregnancy — again, without the pregnant woman's consent. These abuses only happened because the Biden administration's FDA removed the in-person dispensing requirement, allowing abortion pills to be shipped through the mail and prescribed via telehealth without any physical screening or oversight. The original REMS protocol required that mifepristone be dispensed in a doctor's office, precisely to prevent coercion, fraud, and medical negligence. With these horrific stories in mind, I have several questions about your pledge to conduct a comprehensive review of the FDA's handling of mifepristone.
    a. Will your proposed FDA review examine whether the Biden FDA's removal of in-person dispensing requirements has enabled coercive or criminal abuse — like in these Texas and Louisiana cases?
    b. Will the review include an investigation into why the original REMS — designed to ensure in-person prescribing and follow-up — were removed by the Biden administration's FDA, despite concerns about complications from unsupervised use?
    c. Given your past critiques of regulatory capture and pharmaceutical industry influence, do you believe the Biden administration FDA's relaxation of mifepristone REMS was driven by political or ideological pressure, rather than scientific rigor [particularly in light of the FDA's removal of adverse event reporting requirements]?
    d. Given that the Biden administration FDA eliminated both prescriber oversight and mandatory adverse event reporting (except in cases of death), how will your review ensure a full accounting of post-approval safety data for mifepristone, and what steps would you take to restore transparency and public trust?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

e. You've said science, not politics, should drive public health policy. So if independent data shows higher rates of emergency room visits following mifepristone use since REMS changes, will you support reinstating the original REMS that required in-person, physician- supervised dispensing of mifepristone to protect women from exploitation?

Response:
The Department generally does not comment on matters that are the subject of pending litigation.

Although HHS generally does not comment on matters that are subject of pending litigation, we can provide the following information regarding FDA's oversight of adverse event reporting and post-marketing safety data. When FDA receives new information regarding adverse events, the Agency reviews the new information, and as appropriate, takes necessary action. FDA continuously reviews reports of adverse events to, among other things, determine whether they are known risks or whether they are signals of emerging safety concerns. FDA carefully evaluates the scientific data, leveraging rigorous science to make informed decisions.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Cliff Bentz

1. Thank you for your tireless work to return HHS to once again being the gold standard of science and restoring the trust of the American people in the agency. I know and admire your commitment to improving the health of our children and grandchildren, which is why I support you and the Make America Healthy Again Movement. Unfortunately, tooth decay is a significant public health concern in my home state of Oregon, particularly among children. However, it's come to my attention that some manufacturers have exploited a regulatory loophole which allows their dental products to come to the market without going through proper safety and effectiveness testing before being used on kids. It's critical that children are not used as guinea pigs for products whose safety and dosage have never been established under new drug application standards. A March 21st citizen's petition on this issue urges FDA to rescind all 510(k) clearances for Silver Diamine Fluoride (or SDF for short) devices and reclassify them as drugs. Manufacturers heavily market these SDF devices off-label for the treatment of severe early-childhood caries, and many Oregon dentists—and parents—currently assume FDA has approved them as drugs for kids.
    a. While there haven't been any warning letters issued yet or action on the citizen's petition, will you and the Commissioner quickly work to stop this illegal marketing and correct widespread public misperception that these products are FDA-approved for kids when they haven't been?

Response:
FDA carefully considers and evaluates the scientific and other information that has been submitted in a citizen petition, but we generally do no comment on issues that are implicated in a pending citizen petition before the response is issued. After the Agency has considered the scientific data and other information in the administrative record, FDA will either grant or deny the petition, in whole or in part, or grant such other relief or take other action as the petition warrants. At that time the Agency will issue a response to the petitioner. FDA's responses to citizen petitions are available in the public docket and posted on regulations.gov, and responses to petitions submitted to the Center for Devices and Radiological Health (CDRH) are also available on CDRH's website. Our congressional liaison will share the response with your office once available.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Erin Houchin

1. I've heard from numerous stakeholders that a necessary first step to ultimately utilizing AI to better manage patient electronic health records is to address the lack of a common data standard.
    a. Is CMS taking any strides toward creating a common data standard to improve efficient record exchanges? How can Congress be helpful in that effort?

Response:
My Department is building the infrastructure and engaging with the healthcare ecosystem to create apps and services that will promote the integration of AI in the healthcare system. CMS is currently working with major healthcare and information technology firms to begin laying the foundation for a next-generation digital health ecosystem. I look forward to working with the numerous companies interested in working collaboratively with CMS, and I will continue working with President Trump and my colleagues across HHS and other federal departments to expedite the progress being made through this initiative.

2. Indiana is a national leader in pharmaceutical production and exports, and the industry continues to expand its research and development and manufacturing efforts. A consistent theme I hear, however, is manufacturers face a lengthy and complicated approval process with uncertain timelines, making it extremely difficult to expand production to include raw materials.
    a. What are HHS and FDA doing to accelerate U.S. pharmaceutical domestic manufacturing and minimizing regulatory roadblocks while maintaining high safety standards?

Response:
My Department is committed to taking steps that can help reduce America's reliance on foreign drug manufacturing and ensure that Americans have a resilient and strong domestic drug supply. The FDA PreCheck program aims to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability and facilitating the construction of manufacturing sites in the United States.

FDA is also developing the Quality Management Maturity (QMM) Program, which aims to encourage drug manufacturers to implement quality management practices that go beyond current good manufacturing practice (CGMP) requirements. FDA also has programs to actively support the adoption of Advanced Manufacturing Technologies, which can help domestic production be more efficient and flexible. Through its Emerging Technology Program, FDA works directly with industry to resolve regulatory uncertainties and accelerate adoption of innovative platforms. Additionally, the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative is intended to prepare a regulatory framework to support the adoption of advanced manufacturing technologies that could start to bring benefits to patients over the next 5-10 years.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

In addition, the Commissioner's National Priority Voucher program will review and potentially select recipients who file applications for approval of certain drugs and biological products that are aligned with U.S. national health priorities, including those that onshore drug development and manufacturing.

b. How can Congress encourage the FDA to think creatively to facilitate earlier FDA involvement with new US-based sites to speed the availability of medicines made in the US?

Response:
My Department looks forward to working with Congress to address any gaps in regulatory authority in this area.

3. The Area Health Education Centers (AHECs) have long served as a critical pipeline for recruiting, training, and retaining health care professionals in underserved areas. These local programs have always had an emphasis on primary care for rural and underserved communities.
    a. As we continue to address workforce shortages in rural communities what are the Department's plans moving forward to support our rural communities and AHECs?

Response:
The FY 2026 President's Budget request includes $145 million for the Rural Communities Opioid Response program to maintain prevention, treatment, and recovery services for substance use disorder, and $101 million Rural Health Care Outreach program. The outreach program includes $12 million for the Rural Maternity and Obstetrics Management Strategies (RMOMS) program to increase access to maternal and obstetrics care in rural communities. In addition, the Budget provides $12.7 million for Rural Residency Planning and Development to expand the number of rural residency training programs with the goal of increasing the number of physicians choosing to practice in rural areas.

The FY 2026 President's Budget request includes $128.6 million in discretionary funding and $345 million in proposed mandatory resources for the NHSC to continue to support recruitment of a health workforce that is well prepared to meet patients' needs.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Frank Pallone, Jr. (D-NJ)

1. Multiple news reports are indicating the impact of delays or elimination of FY2025 prevention funding that Congress appropriated as part of the continuing resolution. For example, Centers for Disease Control and Prevention (CDC) tobacco grants were supposed to go out to states in April to support tobacco quitlines, youth prevention programs, and tobacco cessation campaigns. States have yet to receive this funding, and some are already ceasing programs and laying off employees.
    a. Is it the position of the Department of Health and Human Services (HHS) that you do not have to spend funds that Congress appropriated for FY2025?

Response:
My Department and CDC continue to meet its statutory responsibilities and are committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

    b. The entire Office of Smoking and Health at CDC was eliminated as part of Reductions in Force (RIFs). How does HHS intend to implement funding for programs such as this without the technical experts at CDC?

Response:
My Department and CDC are committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

    c. When will the Office of Management and Budget release FY2025 funding to HHS agencies?

Response:
This Administration is committed to being good stewards of taxpayer funding. HHS continues to meet its statutory responsibilities and is committed to ensuring that funds are used efficiently. My Department is following the law to execute funding.

2. The FY2026 budget request proposes moving components of CDC, such as Overdose Data to Action (OD2A) program, to the Administration for a Healthy America (AHA).
    a. Are you proposing that the CDC experts would also transfer?

Response:
There was a 17.1% decline in overdose deaths in the 12 months ending in October 2025, demonstrating the success of the Trump Administration's efforts to end the influx of illegal fentanyl into the United States that proliferated under the Biden Administration's open border policies. Substance use disorder and overdose prevention remain a top priority for

the entire department. The Opioid Overdose Prevention and Surveillance program request in the Fiscal Year 2026 Congressional Justification for the Administration for a Healthy America will continue to support overdose prevention under OD2A-S and OD2A: LOCAL.

b. Would existing programs, such as OD2A, which have helped contribute to a significant decline in overdose deaths in the past year, look different under AHA?

Response:
The FY 2026 AHA Congressional Justification requests $475.6 million for the Opioid Overdose Prevention and Surveillance program, which will fund overdose prevention and support for 49 states, the District of Columbia, and 40 localities through the Overdose Data to Action in States (OD2A-S) and Overdose Data to Action: LOCAL (OD2A: LOCAL) initiatives.

c. How would AHA programs interact with CDC laboratories, which help states identify contaminants and emerging threats in the drug supply?

Response:
As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure. The Administration is actively discussing how to best incorporate the data and laboratory infrastructure between programs proposed to move to AHA and capabilities expected to remain at CDC. HHS is happy to keep Congress informed as decisions are made.

3. As the Administration's vision of expanding the U.S.' role in the world as artificial intelligence innovators and changemakers develops and takes shape, how is HHS' expected role and contribution to that vision going to be impacted by the reorganization?
    a. Are there sufficient staff and resources remaining to ensure HHS can continue fully participating in and supporting the responsible development and use of artificial intelligence tools in health care?

Response:
My Department is building the infrastructure and engaging with the healthcare ecosystem to create apps and services that will promote the integration of AI in the healthcare system. The purpose behind the reorganization of HHS is to maximize efficiencies and streamline functions. The reorganization at HHS will improve our role and contribution in the development and use of artificial intelligence tools in healthcare.

4. With the significant increase in cybersecurity attacks on health care systems recently, and given HHS' charge to work with the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA) on cybersecurity issues, how is HHS' expected role and contribution to that work going to be impacted by the reorganization?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Are there sufficient staff and resources remaining to ensure HHS can be a full and equal partner to CISA in strengthening our nation's cybersecurity protections?

Response:
HHS serves as the Sector Risk Management Agency for the HPH sector and ASPR coordinates the breadth of HHS' cyber resilience and response efforts supporting the sector. Through ASPR's HPH Cybersecurity Division, ASPR manages collaboration and information sharing with other HHS divisions, the healthcare industry, state, local and federal interagency partners (including the Cybersecurity and Infrastructure Security Agency or CISA) through a variety of efforts and mechanisms. While relatively small compared to CISA, the HPH Cyber Division continues to help the HPH sector through efforts to bolster preparedness and provide cyber incidence response support.

The cyber threat against our sector continues to grow and become more complex. ASPR is focused on encouraging implementation of high-impact cybersecurity practices articulated in the voluntary HPH Cybersecurity Performance Goals (HPH CPGs), which help healthcare institutions advance their cyber resilience. The HPH Cybersecurity Division's placement alongside the Secretary's Operations Center, Office of Data, Analytics and Information Advantage, and other key ASPR assets strengthens HHS' cyber response capabilities.

5. In April, your department chose to temporarily withhold title X funding from 16 grantees, many of which are located in states represented on this dais. While at the end of June HHS chose to restore funding for some grantees, Planned Parenthood grantees are still having their funds withheld. Title X, the only federally funded family planning program, provides critical health care services, including cancer screenings, treatment for sexually transmitted infections, and pregnancy tests for nearly three million women.
    a. Given, that this funding freeze is occurring while Republicans have just voted to eliminate funding for Planned Parenthood, the largest provider of reproductive health services including cancer screenings, how will you ensure women have access to the critical reproductive and preventative care they need to live healthy lives?

Response:
My Department remains deeply committed to ensuring the availability of health care services to all Americans who need it. There are other programs across the Department that perform similar services, such as Section 330 grants, which fund health centers, and Medicaid. These services will continue to be a part of HHS's toolkit to ensure that we support women seeking care.

6. Approximately 3.4 million Americans live with epilepsy, and 1 in 26 will develop epilepsy at some point in their lifetimes. The CDC epilepsy program is the only public

health program specifically related to epilepsy with a national scope and community programs that research, test, and share strategies to improve the lives of people with epilepsy and their loved ones. These programs include seizure first aid, mental health and chronic disease self-management, health professional training to aid primary care doctors in treating epilepsy, and surveillance and data collection. Despite the importance of these programs, the CDC epilepsy program staff were part of the RIFs, and to our knowledge, no CDC epilepsy program staff remain. We are extremely concerned about this and what it means for the future of the CDC epilepsy program. Congress appropriated $11.5 million in Fiscal Year 2025 for the CDC epilepsy program, and we want to make sure that these funds are being spent to continue the program's critical work.

a. Can you give us an update?

Response:
CDC worked diligently to ensure that fiscal year 2025 awards for CDC's national education efforts for symptom management and school staff training on seizure identification in children were provided to grantees in a timely manner.

7. The Congressional justification for the new Administration for a Healthy America detailed how many existing chronic disease prevention programs currently housed at CDC would not be moved to AHA but rather completely eliminated. If these eliminations go through, millions of children and their families can expect to lose critical services, like CDC's growth charts that pediatricians use to track a child's growth and ensure our kids grow up healthy. This is just one example of the cost- effective and critical public health programs and services your new agency appears to completely disregard.
    a. How do you expect to reach your goal of decreasing rates of childhood obesity if you are eliminating the very programs that help pediatricians advise families on their children's health?

Response:
Chronic diseases are the leading causes of death and disability in the nation and account for an overwhelming majority of our country's annual health care costs. Preventing chronic diseases and promoting healthy behaviors that limit risk factors for disease are the key to helping us all live longer, healthier lives. Chronic disease prevention remains a priority for my Department.

The Budget includes the reorganization to establish the Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans, including by addressing the root causes of chronic disease.

8. CDC's chronic disease prevention programs provide states, localities, tribes, and territories with millions of dollars in grant funding to prevent costly medical conditions like obesity, hypertension, and type 2 diabetes. These dollars are also accompanied by

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

CDC's expert technical assistance, data monitoring, and epidemiological surveillance of chronic diseases.

a. Under the proposed Administration for Healthy America, would these services move to a new division or be eliminated completely?
b. If they are going to be moved, how will public health officials be able to carry out these critical prevention programs with a significantly decreased budget?

Response:
Chronic diseases are the leading causes of death and disability in the nation and account for an overwhelming majority of our country's annual health care costs. Preventing chronic diseases and promoting healthy behaviors that limit risk factors for disease are the key to helping us all live longer, healthier lives. Chronic disease prevention remains a priority for my Department. The Budget includes the reorganization to establish the Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans, including by addressing the root causes of chronic disease

9. HHS has eliminated all staff for CDC's Office of Smoking and Health, despite tobacco being the leading cause of preventable death in the U.S. This will lead to dramatic reductions in capacity in many state quitlines and the Tips from Former Smokers campaign, which has prevented an estimated 129,000 early deaths and saved $7.3 billion in smoking-related healthcare costs.

    a. How does eliminating the Office of Smoking and Health advance America's health?

Response:
The FY 2026 President's Budget proposes to reform the CDC to focus the agency on its core mission. The CDC supports infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. The Budget includes the reorganization to establish the Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans, including by addressing the root causes of chronic disease.

10. The Make America Healthy Again (MAHA) report, released in May, stressed the need to address the root causes of the childhood chronic disease crisis and not just the symptoms. However, the report noticeably ignored tobacco, one of the biggest risk factors for chronic disease and the number one cause of preventable death in the United States. Smoking is not mentioned as a chronic health issue for children despite decades of research that smoking kills more people than alcohol, AIDS, car accidents, illegal drugs, murders, and suicides combined. 2.25 million high school and middle school students smoke and 38.1% of kids aged 3-11 are exposed to secondhand smoke. Your job cuts

have eliminated the CDC Office on Smoking and Health and portions of the FDA's Center for Tobacco Products.

a. Is tobacco control and prevention a priority for HHS? What specifically will FDA, CDC, and AHA do to reduce smoking and tobacco use in the United States?

b. How will you protect children from the harms of tobacco use if you have eliminated the federal infrastructure that collects data on tobacco use to identify the emergence of new threats and dangerous trends in youth tobacco use, and that provides enforcement against illegal e-cigarette products that target children in their marketing?

Response:
My Department remains steadfast in its mission to protect and promote public health. HHS agencies continue to carry out their responsibilities, including work on tobacco control, with the highest level of integrity and commitment to the American public. This work includes comprehensively regulating the manufacture, distribution, and marketing of tobacco products.

11. Alcohol is the most common drug used by people younger than 21 in the United States and about 4000 young people die from excessive alcohol use each year. Additionally, alcohol-associated cancer deaths have doubled in the United States since 1990. Teenage alcohol consumption, particularly binge drinking, can alter brain development, including cognitive function, and can triple a teenager's risk of developing alcohol use disorder in adulthood. Alcohol can exacerbate anxiety, depression, and other adverse mental health conditions, which the MAHA report also highlighted as a critical problem for America's youth, yet did not mention alcohol use as a risk to the chronic health of children.
    a. How do you and HHS plan to address alcohol use in children and young adults?

Response:
My Department remains committed to reducing and preventing underage drinking by supporting community-driven plans and maintaining numerous resources on this topic available to the public online across our agencies.

b. Is it accurate that the upcoming Dietary Guidelines will no longer recommend limiting alcohol intake?

Response:
HHS and USDA committed to a rigorous, transparent, and science-driven process in developing the 2025–2030 Dietary Guidelines for Americans (DGAs). The Scientific Report of the 2025 Dietary Guidelines Advisory Committee (DGAC) is a key scientific input to this process. While the DGAC report is advisory in nature, along with public comments and federal agency input collected, are used to inform the DGAs. the result of this process will

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

be Dietary Guidelines that provide Americans with information they need to live healthier lives.

12. Given the clear data that connects regular physical activity to the decrease of chronic disease, how do you propose to encourage more physical activity for those who cannot afford sports, a gym, or live in areas where there are no safe places to recreate?

Response:
Physical activity, encompassing moderate-to-vigorous exercise, aerobic fitness, and reduced sedentary time, is critical for child health and well-being. The Administration for Children and Families, in partnership with President's Council on Sports, Fitness & Nutrition (PCSFN) will promote greater physical activity in afterschool and out-of-school time programs, including programs receiving childcare subsidies. In addition, my Department, with the Department of Agriculture and the Department of Education, the PCSFN will work with States and schools across the country on a Make American Schools Healthy Again awareness campaign that provides tools to implement best practices such as increasing physical activity and improving nutrition options.

13. At your nomination hearing, you emphasized the importance of addressing chronic disease. Yet since taking office, the NIH—central to researching Alzheimer's and other dementias, heart disease, and developing life-saving treatments and drugs—has faced deep funding cuts and damaging layoffs.
    a. How do you plan to fulfill your commitment to combat chronic disease when the nation's leading research agency is being stripped of the resources it needs to make Americans healthier?

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. NIH is working to find better ways to prevent, treat, and cure chronic diseases. NIH-funded research has highlighted crucial roles of diet as it relates to chronic disease including obesity, type 2 diabetes, cardiovascular disease, and many cancers. Specifically related to obesity, NIH will support collaborative efforts among basic science, clinical, and translational investigators to advance innovative nutrition and obesity research. Building on groundbreaking research—such as a clinical trial that found restricting food intake to earlier in the day aided in weight loss—NIH will further advance the translation of discoveries into clinically applicable practices that support healthier communities.

14. The Advisory Committee on Immunization Practices (ACIP) is comprised of medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States. Historically, ACIP members have undergone a thorough application process including letters of support from experts and peers, interviews,

background checks, and disclosure of personal or financial conflicts of interest. This process has taken up to two years for nominees to be approved to join ACIP. ACIP members are required to make annual financial disclosures, divest from vaccine manufacturer stock, and recuse themselves from votes in which they may have a conflict of interest.

a. Secretary Kennedy, when you dismissed 17 ACIP members, you alleged the committee was "plagued with persistent conflicts of interest." What evidence do you have that these 17 former members have conflicts of interest that influenced their work at ACIP?
b. Will the new members be held to the same standards for conflicts of interest, including, if appropriate, with regards to financial interests in treatments or supplements that are marketed as alternatives to vaccines for certain conditions?
c. Secretary Kennedy, what application and review process did you use when naming the eight new ACIP members?
    i. Why was this process done secretly, despite your calls for a more transparent ACIP?
d. Some of the new ACIP members have no experience in vaccinology or related public health issues. How can the American people and public health professionals be reassured that the new members are ready to undertake ACIP's crucial responsibilities?

15. Despite announcing your decision to terminate the 17 members of the ACIP on June 9th, you didn't publicly announce that you also terminated career staff in The National Center for Immunization and Respiratory Diseases (NCIRD) who provide support to the Advisory Committee on Immunization Practices. These staff are responsible for vetting nominees for membership and evaluating conflicts of interest. They also organize meeting materials and data that ACIP members use to make informed vaccine recommendations. In addition to the terminations, several scientists from the NCIRD have resigned in the past week citing concerns that the data they provide would not be used "...objectively or evaluated with appropriate scientific rigor..."[i] As a result, the revised agenda for the June 25th ACIP meeting lists "TBD" for many of the presenters.
    a. Can you explain your decision to terminate career staff within NCIRD supporting ACIP? You claim members were conflicted but provide no evidence. Regardless, what are you doing to prevent conflicts of interest for new members?
    b. Many of members of ACIP you terminated had extensive expertise in immunology and public health. At least one of the appointees, Retsef Levi, has no medical training and has publicly stated he has little vaccine expertise. (source) How were these appointees selected and vetted for membership?
    c. Eliminating experienced CDC staff and members of ACIP with deep expertise in vaccines, immunology, and public health will impair ACIP's ability to make

evidence-based recommendations. What is your plan for ensuring ACIP has the requisite expertise and experience to fully evaluate vaccine data?

Response (14-15):
The Advisory Committee on Immunization Practices (ACIP) serves as a body of external experts who advise the CDC on the use of vaccines for the control of diseases. Established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended, the ACIP is a federal advisory committee charged with providing advice and guidance to the CDC Director regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. It is comprised of outside advisors appointed by the HHS Secretary, who develop recommendations for U.S. immunizations for consideration by the CDC Director, including the ages at which vaccines should be given, dosing regimens, and precautions and contraindications for individual vaccines.

Current information regarding ACIP and its activities may be found at the ACIP website, located at https://www.cdc.gov/acip/index.html.

16. When a new vaccine is developed, it goes through multiple rounds of research and testing over the course of many years. These clinical trials often use placebo groups. This research data is submitted by vaccine manufactures to the FDA, which reviews the safety and efficacy of a vaccine and determines whether or not the vaccine should be licensed. After a vaccine is marketed, the CDC and the FDA continue to monitor it to make sure the vaccine remains safe. When a safe and effective vaccine against a disease already exists, having a placebo study would leave trial participants unprotected against a dangerous illness. Experts believe it would be unethical to give someone a placebo when an effective vaccine already exists. Placebo-controlled trials can also last many years and are not feasible or necessary for vaccines updated every year. For example, a two-year placebo- controlled trial for an annual flu shot would already be outdated at the completion of the trial. As flu shots are only slightly tweaked each year, there is no need for a full-scale placebo trial for each new iteration.
    a. Secretary Kennedy, you've called for all new vaccines to undergo placebo trials. Do you understand this is contrary to commonly accepted ethical principles?
        i. Would you permit any vaccine marketing to proceed where placebo groups are neither ethical nor practical?

Response:
The use of placebo-controlled clinical trials for vaccines is not new. FDA's guidance document for including a placebo control arm as part of clinical testing considers many advantages and disadvantages of placebo-controlled trials (e.g., see E 10 Choice of Control Group and Related Issues in Clinical Trials Section II.A.6 and 7), including, but not limited to ethical and practical issues.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

17. As of July 8, 2025, there have been 1,267 measles cases in 2025 in 38 states. Of those 1267 confirmed cases, 88% of patients were either unvaccinated or vaccination status was unknown. There have been three confirmed deaths from measles in 2025. In contrast, there were a total of 285 cases in all of 2024. In 1963, the first measles vaccine was licensed. Before the vaccine was available, more than 400,000 measles cases were reported in the United States each year. By 2000, measles had been eradicated in the U.S. by one of the most effective vaccines we have.
    a. Mr. Secretary, do you unequivocally support the administration of the MMR (measles- mumps-rubella) vaccine to children and adults?

Response:
The most effective way to prevent the spread of measles is the MMR vaccine.

18. Back in the 1970s and early 1980s, the chances of a child living past her 5th birthday in low-income countries were tenuous at best. Despite the rapid public health achievements over the previous century for wealthy countries like the U.S., many of those same innovations were slow to reach the far corners of the planet. The lack of clean water, sanitation, and basic health interventions such as vaccines against child killers like polio, measles, tetanus, and whooping cough meant that children born to the poorest 20% of the global population were dying at an unimaginable rate. In the mid-70s, less than 5% of all children in developing countries had access to any of the vaccines that were commonly administered in rich countries.

    By 2024, thanks to the visionary leadership of the United States and our partners, the number of children under 5 years of age who die from preventable disease and malnutrition globally continued to drop– going from 12.8 million children per year in 1990 — or roughly the entire population of Ohio — to 5 million. Immunization were saving an estimated 4.4 million lives every year. But now all of that is at grave risk.

    The administration and DOGE have dismantled the world's leader in global health, the US Agency for International Development and undercut our international leadership at CDC. The president's budget request decimates foreign assistance by 84%, forgetting that disease knows no borders. While the terror of a child dying from a preventable disease in our country is thankfully rare, the poor judgement of people leading our country when they eliminated USAID and cut CDC off at the knees internationally is putting our children in danger.

    Mr. Kennedy, our nation has much to be proud of with regard to our global health legacy and you have promised to ensure that the CDC will have strong support to continue its world-class efforts to end the threat of vaccine-preventable diseases around the world, and yet you and the rest of the administration have failed to live up to that promise, both

in funding and in policy. The administration has pulled out of WHO and proposed in its FY26 budget eliminating funding for GAVI and UNICEF which provide life-saving vaccines and treatment for malnutrition to the poorest children in the world. And you personally have undermined the effectiveness of CDC by firing its Advisory Committee.

a. So how do you plan to ensure the CDC has reputable personnel, resources and infrastructure it needs to address diseases around the world and keep us safe at home without USAID and your administration's proposed elimination of funding for GAVI, UNICEF, lab and surveillance apparatus around the world?

Response:
The FY 2026 President's Budget request includes $293 million for CDC Global Public Health Protection for CDC to continue its mission to prevent, detect, and respond to global health threats before they reach U.S. borders.

19. On May 27th, 2025, you, along with National Institutes of Health (NIH) Director Jay Bhattacharya and Food and Drug Administration (FDA) Commissioner Marty Makary announced that COVID-19 vaccines had been removed from the childhood immunization schedule and from the recommended schedule for pregnant women. Earlier in May, Makary and FDA's Director of the Center for Biologics Evaluation and Research Vinayak Prasad released an FDA policy position restricting COVID-19 vaccines to adults 65 and older and those at high risk for severe COVID-19. These changes combined mean that people who are not over 65 or in a high risk group and want to be vaccinated against COVID-19 can no longer obtain the vaccine. In March of 2025, you said in a Fox News interview: "we will make sure anyone who wants a vaccine will get one."
    a. So which is it?
    b. Will you and HHS allow individuals to get vaccinated against COVID-19 and other diseases if they want to be, including by ensuring insurance coverage for these vaccines?
    c. Or do you and HHS as a whole believe the government should be able to prevent people from being vaccinated even if they want to be vaccinated?

Response:
On May 27, 2025, HHS announced that the COVID vaccine for healthy children and healthy pregnant women had been removed from the CDC recommended routine immunization schedule. For healthy children ages 6 months to 17 years who are not moderately or severely immunocompromised, the CDC now advises shared clinical decision-making. Vaccines for which the CDC advises shared clinical decision-making remain covered by commercial health insurance as well as government programs.

Shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months

and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

For pregnant women, the schedule no longer includes a recommendation for the COVID vaccine.

20. The Health Resources and Services Administration (HRSA) is the principal federal agency charged with increasing access to basic health care for medically underserved populations. Over 31 million Americans received health care from HRSA-funded health centers in 2023, and HRSA's Bureau of Health Workforce protects Americans by ensuring an adequate health workforce through grants, scholarships, loans, and loan repayment. HRSA is set to be consolidated into the newly proposed Administration for a Healthy America (AHA), along with other offices such as the Office of the Assistant Secretary for Health, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Agency for Toxic Substances and Disease Registry (ATSDR), and the National Institute for Occupational Safety and Health (NIOSH). This consolidation's stated aim is to more efficiently coordinate chronic care and disease prevention programs and harmonize health resources for low-income Americans. However, reports have indicated that at least 20% of HRSA's staff have been laid off and the President's budget would reduce the agency's budget by $1.7 billion dollars including $1 billion in cuts to workforce programs.
    a. Can you explain the decision to fire these staff? Can you explain specifically how the administration plans to ensure that the work being done by HRSA is supported and not disrupted during this restructuring?

Response:
The proposal to consolidate HRSA and other public health agencies into the new Administration for a Healthy America (AHA) is designed to streamline operations, enhance coordination across public health programs, and better align efforts to improve health outcomes nationwide.

I remain committed to ensuring that staffing changes prioritize maximum efficiency across government programs and minimize waste, fraud, and abuse. The reductions in force are intended to centralize key HRSA administrative functions.

    b. How do you intend to guarantee an adequate supply of medical professionals to meet Americans' growing health needs after a $1 billion dollar reduction to workforce programs?

Response:
Through the Teaching Health Center Graduate Medical Education (THCGME) program and the National Health Service Corps (NHSC) loan repayment and scholarship programs, HHS is supporting efforts to encourage primary care clinicians. The FY 2026 President's

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Budget requests $175 million in mandatory funding for THCGME to support up to 1,273 resident full-time equivalent slots in FY 2026. The FY 2026 President's Budget request for the NHSC includes $128.6 million in discretionary funding and $345 million in proposed mandatory resources to support clinician scholarship and loan repayment.

The Budget also provides continued funding for the Rural Health Care Services Outreach Grants, which support collaborative models to deliver basic health care services to rural areas and are uniquely designed to meet rural needs.

c. With the layoffs at HRSA dissolving the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), the Recommended Uniform Screening Panel (RUSP), which is a standardized set of 12 conditions to screen for as a part of state universal newborn screening programs, is at risk.
    i. As the architect of this RIF, how do you intend to ensure states have the necessary funding, staffing, and resources to properly evaluate new conditions for the newborn screening panel without compromising their ability to safeguard the most vulnerable?

Response:
Newborn screening is primarily a state-based program, with each state's public health department maintaining its newborn screening panel. HHS provides the Recommended Uniform Screening Panel (RUSP) as a resource to help guide states in their development and management of their screening program. HHS is reviewing the overall process of reviewing conditions for newborn screening, and we look forward to working with Congress on ways to improve newborn screening and child health. The FY 2026 President's Budget prioritizes programs that provide states and communities with the flexibility to target funding towards the services needed most, such as through the Title V Maternal and Child Health (MCH) Block Grant. Nationwide, the Title V MCH Block Grant reaches 98% of infants and gives states the flexibility to meet their unique health needs, including support for infant screening.

21. The CDC's National Center for Injury Prevention and Control (Injury Center) has served as a leader in preventing Adverse Childhood Experiences, or "ACEs" since the 1990s. The Injury Center's funding and expertise supports states and local communities across the country in tracking and combating ACEs through research and initiatives including Preventing ACEs Training Modules. CDC research finds that preventing ACEs could reduce suicide attempts among high school students by nearly 90% and mitigate persistent feelings of sadness and hopelessness. Secretary Kennedy, you've previously indicated a commitment to addressing the youth mental health crisis.
    a. If this is your commitment, why has the CDC's ACEs program been slated for elimination through President Trump's FY 2026 Budget Request?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
The FY26 President's Budget proposes transferring activities of the CDC National Center for Injury Prevention and Control to AHA to streamline operations, enhance coordination across public health programs, and better align efforts to improve health outcomes nationwide. The Administration for a Healthy America will be the primary federal agency committed to transforming the health of all Americans.

22. CDC research also finds that as the number of ACEs an individual experiences increases, the risk for chronic illnesses (such as asthma, diabetes, childhood and adult obesity, and cancer) across the lifespan also increases.
    a. Secretary Kennedy, given your focus on addressing chronic disease, are you aware of the connection between ACEs and long-term chronic disease risk?

Response:
ACEs can have lasting effects on health and well-being, influencing life opportunities into adulthood. They can trigger a harmful biological stress response known as toxic stress, which alters children's brains and bodies and impacts lifelong health. ACEs elevate the risks of injuries, sexually transmitted infections, and involvement in sex trafficking. They also are associated with maternal and child health issues, including teen pregnancy, pregnancy complications, and fetal death. Furthermore, ACEs are associated with a higher incidence of chronic diseases and leading causes of death, such as cancer, diabetes, heart disease, and suicide. Preventing ACEs would reduce many chronic health conditions.

    b. Do you support eliminating the CDC's ACEs program and terminating state and local efforts to address one of the key drivers of chronic disease in this country, as proposed in the FY2026 budget?

Response:
The FY 2026 President's Budget proposes to reform the CDC to focus the agency on its core mission. The CDC supports infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. The Budget establishes the Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans.

23. The Administration for Community Living (ACL) successfully brought together aging and disability programs from across the federal government to help older adults and those with disabilities age in place and be active members of their communities.
    a. What is the rationale behind combining ACL with the Administration on Children and Families?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

b. Why were key ACL programs cut in the FY26 budget that older adults depend on such as falls prevention, chronic disease self-management, and Alzheimer's prevention?
c. As part of the recent reorganization, CDC's healthy aging branch, which includes programs to increase early detection and diagnosis of dementia, has been eliminated. How will the Administration for a Healthy America address older adult health?

Response:
The health and well-being of many Americans has long been in decline and this Administration is taking bold steps to better fulfill our promises and make Americans healthy again. My Department is seeking to centralize shared services across the Department, such as human resources, procurement, and technology. While changes at ACL are still underway, please be assured that these changes are designed to minimize waste, fraud, and abuse, and ensure that HHS critical mission services and benefits, like those in ACL, are reaching key constituents. Facilitating collaborative workstreams between ACL and ACF constituencies will allow the Department to improve its focus of better addressing the needs of older adults and people with disabilities. The Budget does provide $2.5 million in discretionary funding for falls prevention and $16.8 million in discretionary funding for Alzheimer's Disease Program Initiative.

The Budget proposes shifting CDC's Alzheimer's Program to the newly established Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans. HHS will continue the fight against diseases such as Alzheimer's with a particular focus to help communities better understand the burden, while identifying the causes and remedies for combatting this affliction.

24. Medicare accounts for about 14% of federal spending. Given the CDC estimates that 9% of Medicare spending on older adults goes to non-fatal medical expenses for falls and that these medical expenses cost our country an estimated $80 billion, how is it cost effective to eliminate (and not replace) the CDC's unique and evidence-based work ($3 million cost) on older adult falls that provided resources, training and tools to healthcare professionals to make older adult fall prevention a routine part of clinical practice and initiated and maintained the Still Going Strong campaign that educated older adults and healthcare professionals about how to reduce fall risk?

Response:
The FY 2026 President's Budget request proposes to continue funding the Fall Prevention program, which awards grants to community-based organizations, states, tribal organizations, and universities for falls prevention measures. The FY 2026 request also provides funding for the National Falls Prevention Resource Center and maintains funding for the Preventive Health Services program. States may use these funds to support falls

prevention programming as well. Finally, the FY 2026 request also continues the Innovation Lab, which is specifically focused on falls prevention research.

25. How will the elimination of programs at CDC's National Center for Environmental Health such as the National Asthma Control Program, National Environmental Public Health Tracking Network and Trevor's Law (which tracks cancer clusters), as proposed in the FY2026 budget, keep America healthy?

Response:
To better address the health of all Americans, the Budget establishes the Administration for a Healthy America (AHA). As part of this proposal, the Budget shifts CDC's National Center for Environmental Health (NCEH) to AHA. Improving efficiencies and focusing on new priorities will make HHS more responsive and efficient while ensuring that critical health services remain and are improved.

26. There is an ongoing lead poisoning crisis in schools in Wisconsin, but CNN reports that all of CDC's lead experts had been dismissed.
    a. Have all the staff been rehired, and if so, how will staff be able to quickly respond to the crisis?

Response:
On June 11, 2025, staff of CDC's Childhood Lead Poisoning Prevention were reinstated. Since this time the Childhood Lead Poisoning Prevention program has resumed regular meetings with the Milwaukee Health Department (MHD) to assess current needs and determine how CDC can provide essential assistance. CDC is actively collaborating with the MHD to develop a screening questionnaire to facilitate additional blood lead testing in the field, while also reviewing data from the health department's lead screening clinics and historical blood lead levels to identify patterns and trends. CDC, in conjunction with the Agency for Toxic Substances and Disease Registry (ATSDR), is also working to develop a webinar for area healthcare providers.

    b. With the Childhood Lead Poisoning Program slated to move to AHA, will these employees be transferred to the new agency?

Response:
The proposed reorganization will refocus CDC's core mission on infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. The proposed Administration for a Healthy America (AHA) will lead on chronic disease and maternal and child health activities for HHS. As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

27. The reconciliation bill would claw back up to $16 million in grants from the Inflation Reduction Act to reduce air pollution and monitor and improve indoor air quality in schools. This provision would disproportionately affect children and schools in low-income, disadvantaged, and tribal communities who routinely report higher instances of asthma, lead poisoning, and obesity.
    a. What actions is your department taking to monitor and improve indoor air quality in schools?

Response:
CDC's National Center for Environmental Health (NCEH) includes functions related to the monitoring and improvement of indoor air quality in schools. NCEH worked with the National Institute of Standards and Technology (NIST) to develop a ventilation calculator to show how to decrease virus particles in homes, which was later adapted for use in schools. NCEH continues to enhance this tool by discussing its expansion to address additional air quality concerns, such as wildfire smoke, pollen, and mold.

28. The Administration has stated that the reorganization will enable CDC to protect Americans from health threats and epidemics. Yet some of the reported programs that have been severely cut or eliminated are critical to community readiness for outbreaks emergencies, such as laboratories focused on viral hepatitis, immunization outreach, staff for the Strategic National Stockpile, and HIV and TB elimination. In addition, during local emergencies, state and local partners often request assistance from CDC, and CDC convenes a multidisciplinary team to provide technical assistance or deploy to the field.
    a. How is the Administration determining which infectious diseases are a threat and which are not?

Response:
The FY 2026 President's Budget streamlines and prioritizes activities to reduce waste and support efficiency. The renewed focus of CDC will better focus the agency on its core mission to protect Americans from communicable health threats. This work is in close partnership with partners at the state, tribal, local, and territorial (STLT) level who are able to best identify how resources can help their local communities. As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure.

Further, CDC uses the Threat and Hazard Identification and Risk Assessment (THIRA) process as one tool to help determine which public health emergencies pose the greatest risk. CDC's process is modeled after the Federal Emergency Management Agency's more general THIRA but modified to be a collaborative, public health-focused risk assessment. Through the THIRA, CDC is able to effectively identify, assess, and prioritize threats and hazards, develop deliberate plans to respond, and assess agency capabilities. More general

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

THIRAs are conducted every three years, and results are based on a 10-year history of CDC Emergency Operations Center-supported events and a hazard impact assessment conducted by CDC subject matter experts.

Additionally, at the state, tribal, local and territorial level and as part of CDC's Public Health Emergency Preparedness (PHEP) program requirements, recipients must complete and submit a risk assessment during the five-year period of performance. The information from the risk assessment helps CDC understand the unique risks of each jurisdiction, while also enabling the jurisdiction to focus their preparedness efforts on the public health threats of greatest consequence to their jurisdiction. CDC's infectious disease programs often conduct pathogen-specific risk assessments to help determine the most imminent or impactful threats. These risk assessments allow CDC to work with the STLT jurisdictions and CDC field staff to provide flexible resources towards the most significant health threats and focus training on highest-risk incidents and align planning initiatives with the most current threat and hazard landscape.

b. What is the plan when – as we have seen numerous times – an emergency response requires experts in environmental health (such as East Palestine and wildfires), maternal and child health (such as Zika) or chronic disease (such as flu and COVID)?

Response:
During an emergency response, CDC relies on subject-matter specific expertise from across the agency, including staff who have expertise in non-infectious diseases. CDC will continue to utilize subject-matter experts from across CDC – now more easily identified since the introduction of CDC's ReadyResponder program, which catalogs the availability and skillsets of CDC staff for use in emergency responses. CDC also historically works closely with other HHS and federal agencies to respond to large-scale emergencies. In the event of a reorganization, CDC will need to continue to work closely with any new agencies to ensure that necessary staff from across the federal government can be rapidly utilized in any public health response, as needed. As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure.

c. The President's budget eliminates all funding for state and local public health emergency preparedness.
    i. What is the plan if there is an emergency that crosses state lines, such as a natural disaster or outbreak?

Response:
The 2026 President's Budget will continue to support and maintain a readiness standard to aid communities in need by acting as backstop for our State, Local, Tribal, and Territorial

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

(SLTT) partners in times of crisis. As proposed in the Budget, the new CDC Center for Preparedness and Response, comprised of the Administration for Strategic Preparedness and Response (ASPR) programs such as the National Disaster Medical System, will continue to support and provide access to existing platforms and tools focused on preparedness and response.

Additionally, CDC remains a critical partner in the nation's public health system and CDC's capacity for surveillance, technical assistance, and rapid deployment remains robust. Additionally, CDC continues to support state and local health departments through investments in longstanding programs like the Public Health Emergency Preparedness (PHEP) cooperative agreement. Recognizing that public health threats cross jurisdictions, the PHEP cooperative agreement encourages cooperation, coordination, and collaboration between recipients, preparedness partners, and the federal government.

HHS is committed to ensuring that state, tribal, local and territorial jurisdictions are prepared for the next public health threat.

ii. What if one state invests in preparedness but the next one doesn't?

Response:
When developing the PHEP cooperative agreement, CDC identified 15 preparedness capabilities that are the foundation of a strong preparedness program. Through years of PHEP investments, jurisdictions have built, and are now maintaining, these necessary preparedness capabilities. Although this investment has established a baseline preparedness network across the nation, the jurisdictional cost of maintaining a robust preparedness program is significant. Public health threats require a robust, coordinated response, which will be weakened if jurisdictions do not continue to invest in their preparedness capabilities.

29. Considering recent public health emergencies, how are you ensuring that children's health needs are prioritized during crises like pandemics or natural disasters?

Response:
CDC administers the congressionally mandated Children's Preparedness Unit that works toward meeting the needs of children during a disaster. As a lesson learned from the COVID pandemic, the unit was merged with the School Preparedness Unit in 2022 to form the Children and Schools Preparedness Unit (CSPU) to ensure that the needs of schools and other youth serving settings (e.g., daycares and camps) are included in future responses. Experts in this unit develop evidence-based guidance, tools, and data systems to ensure the needs of children and school are met during disaster preparedness activities as well as during active, public health responses.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

30. In March, as part of the implementation of the President's executive order "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," the Department announced that the Administration for Strategic Preparedness and Response (ASPR), responsible for national disaster and public health emergency response, will transfer to the Centers for Disease for Control and Prevention (CDC). That reorganization plan also included consolidating 10 regional agencies into 5 regional agencies. One important program under ASPR supported by the HHS regional offices is the National Special Pathogen System (NSPS), which supports the preparedness needs of hospitals and health care providers to treat patients with special pathogens, including Ebola and other emerging and high consequence infections. This funding is critical to maintain US capacity to manage emerging infectious threats and protect the safety of our healthcare workers and the community. Emerging infectious diseases pose an ongoing threat to the US healthcare system, with one recent example being the case of Lassa viral hemorrhagic fever diagnosed in a returned traveler in Iowa in October 2024.
    a. In light of this reorganization, what is the current status of grants provided under the HPP and PHEP to hospitals, local and state public health and health departments, along with the NSPS to special pathogen treatment centers?

Response:
HHS is committed to ensuring that state, tribal, local and territorial jurisdictions are prepared for the next public health threat. All Public Health Emergency Preparedness (PHEP) recipients have received funding for the Year 1 budget period for the 2024-2028 PHEP Cooperative Agreement. As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure.

    b. Will that grant money continue to flow to hospitals and health systems following the reorganization?

Response:
There are no plans to change or modify grant recipients. All Public Health Emergency Preparedness (PHEP) recipients have received funding for the Year 1 budget period for the 2024-2028 PHEP Cooperative Agreement.

    c. Will the Department commit to notifying the Committee and grantees [30 days] prior to the Department implementing any changes to grants awarded under NSPS?

Response:
My Department will keep Congress informed on relevant progress updates.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

31. Medicaid and CHIP cover over 37 million children. That includes eight in ten children in poverty and nearly half of all children and youth with special health care needs. These programs are crucial for providing health coverage to children.
    a. How are you ensuring these programs remain fully funded, accessible, and comprehensive for children and their families, including parents who are eligible for affordable coverage only because of the Affordable Care Act (ACA) Medicaid expansion?
32. Since the implementation of the Children's Health Insurance Program (CHIP) in 1997, it, along with Medicaid, has helped reduce the rate of uninsured children from 15% to the current rate of 5.4%. However, over 4 million children remain uninsured, with many eligible for but not enrolled in Medicaid or CHIP.
    a. Given Medicaid and CHIP's success in reducing the number of uninsured children, what specific strategies are you employing to close the remaining coverage gaps?
33. According to a National Survey on Children's Health conducted by the U.S. Census Bureau, about 14.1 million children in the U.S. have special health care needs, representing 19.4% of all children. Medicaid is the largest payer for these children's health services.
    a. What is your plan for ensuring that access to coverage for children with special health care needs and their families is not impacted by cuts to Medicaid under now-enacted H.R.1, including access to care at children's hospitals that currently rely on Medicaid state-directed payments up the average commercial rate to conduct workforce programs and provide certain services?
34. Immigrant children in the U.S. face barriers to accessing essential health care services.
    a. Do you support ensuring access to care is protected for immigrant children and pregnant women, including all immigrant women and children provided coverage under the state option known as "CHIPRA 214" or the "ICHIA" option?
35. Nearly all children in foster care are eligible for Medicaid. These children often have more complex health needs than their peers, with higher rates of chronic health conditions, developmental delays, and mental health issues.
    a. What specific measures are you taking to ensure that foster youth receive comprehensive care through Medicaid?
36. EPSDT is a mandatory benefit under Medicaid that provides comprehensive and preventive health care services for children under age 21. However, studies show that many eligible children do not receive all recommended EPSDT services.
    a. What actions are you taking to ensure robust enforcement of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit in Medicaid, which is crucial for children's preventive care?
    b. What specific steps will you take to improve enforcement of the EPSDT benefit?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response (31-36):
I share your interest in ensuring that eligible children have access to the services they need, including Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services, which ensure that eligible children and adolescents receive Medicaid coverage of a comprehensive array of preventive, diagnostic, and treatment services, including dental, mental health, and specialty care services. That's why HHS and CMS are working to strengthen Medicaid so it can continue serving eligible populations, including foster youth, pregnant women, children, and the disabled.

A top priority for strengthening Medicaid is to ensure the program's long-term sustainability by slowing the growth of Medicaid costs, implementing commonsense work requirements, addressing federal cost-sharing distortions, and fixing provider payment disparities. The House-passed H.R. 1 would put the Medicaid program on a more sustainable path, reducing the program's growth rate from 6.3 percent to 4.7 percent. Incorporated throughout these efforts is a strong focus on reducing waste, fraud, and abuse to ensure Medicaid benefits remain available for those who are truly eligible.

37. H.R. 1, which is now law, and that the Trump Administration urged Congress to enact, includes a provision to require states to condition eligibility for Medicaid for the Medicaid expansion population on compliance with work reporting requirements. The requirements include exempting people with substance use disorders from the requirement to meet the work (or "community engagement") standard.
    a. Exactly how will the Secretary ensure that people with substance use disorders who, if not for the work reporting requirement would be eligible for Medicaid, retain their coverage? Please explain how a state would know what individuals have a substance use disorder in order to exempt them.
    b. If the state would use medical data relating to provision of substance use disorder treatment services, how will the State get that data?
        i. What processes will states need to undergo to ensure compliance with existing privacy laws and regulations related to the sharing and use of data regarding substance use disorder, including under 42 CFR Part 2?
        ii. Will states be required to provide any assurances or safeguards about the use of that data; for example, will that data be kept from law enforcement?
    c. How, if at all, will states be required to attempt to identify and exempt individuals who have a substance use disorder but are not receiving treatment?
    d. How long will this exemption remain in effect for someone with a substance use disorder?
        i. For example, if someone has a substance use disorder for which they received treatment in January and it is now June, is that individual exempt from the "community engagement" standard?

ii. What if it is now the following January (one year later)? Or the January after that (two years later)?

38. The work reporting requirement in H.R. 1 also includes a requirement for states to conduct "ex parte verifications"--in other words, automatic verifications--of compliance with the work reporting requirement, that someone is "deemed" compliant with the requirement, or that someone is exempt from the requirement because they are a "specified excluded individual," such as people with disabilities and conditions.
    a. For each of the "community engagement" standards (relating to completion of a satisfactory number of hours worked, in school, etc.), what data will HHS require states to use to satisfy this ex parte standard?
        i. How will HHS ensure that states are using these data sources?
        ii. How will HHS monitor the effectiveness of use of these data sources and state operations?
    b. For each of the "mandatory exceptions for certain individuals," what data will HHS require states to use to satisfy the ex parte standard?
        i. How will HHS ensure that states are using these data sources?
        ii. How will HHS monitor the effectiveness of use of these data sources and state operations?
    c. For each of the "specified excluded individuals," what data will HHS require states to use to satisfy the ex parte standard?
        i. How will HHS ensure that states are using these data sources?
        ii. How will HHS monitor the effectiveness of use of these data sources and state operations?

Response (37-38):
Work requirements would empower able-bodied adults to take personal responsibility, build economic mobility, and preserve Medicaid for those in true need. Work requirements protect taxpayer dollars, lessens dependence on welfare, strengthens families and communities, and studies have shown that work can improve physical and mental health.

39. You have indicated that HHS will practice "radical transparency." With respect to sections 71107 (relating to frequency of redeterminations for individuals eligible on the basis of Medicaid expansion) and 71109 (relating to work reporting or "community engagement" requirements), what information will HHS provide the public regarding the effect of these provisions on enrollment, and the cause of terminations of coverage.
    a. For example, once these provisions take effect, will CMS publish data regarding the number of individuals who are disenrolled from Medicaid and, of those, the number whose coverage was terminated for procedural reasons?
    b. Will CMS monitor this data to identify potential concerns related to compliance with federal eligibility and renewal requirements, such as the requirement to conduct "ex parte" renewals?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
CMS regularly posts Medicaid and CHIP enrollment data and will continue to provide such data.

40. Section 71116 of H.R. 1, related to state directed payments, includes a "grandfathering" provision that determines which state directed payments will be established up to the average commercial rate, and reduced to 100% of the Medicare rate, or 110% of the Medicare rate, whichever applies. That provision requires the Secretary to determine which states made a "good faith effort" to receive written prior approval of a state directed payment and are subject, along with already approved state directed payments to the "grandfathering".
    a. How will the Secretary determine which states made a "good faith effort"?

Response:
The House-passed H.R. 1 aims to hold states accountable for paying their part of the financial partnership and ending manipulative funding schemes practiced by some states. My Department will continue to work with Congress as they consider H.R. 1.

41. H.R. 1, as initially passed by the House and which the Trump Administration urged Congress to enact, included a provision to nullify rules that protect children's access to care in CHIP.
    a. Is it the Administration's position that states should be permitted to terminate health coverage for eligible children, and lock them out of coverage for up to three months, if a parent does not make a premium payment for the child's CHIP coverage on time?
    b. Is it the Administration's position that eligible children should be subject to up-to-90-day waiting periods before enrolling in CHIP—that is, a 90-day period of forced uninsurance?
    c. Is it the Administration's position that states should be permitted to place arbitrary and lifetime dollar limits on services for children enrolled in CHIP?

Response:
Provisions included in the House-passed H.R. 1 would give my Department commonsense tools to preserve coverage for vulnerable populations while bolstering sustainability of the programs for current and future enrollees.

42. Via H.R. 1, Congress recently enacted major cuts to Medicaid and the ACA that will result in increases in the number of Americans without insurance and higher costs for hospitals.
    a. How will you ensure the security and longevity of our health care and public health systems as these hospitals face increased Medicaid shortfall and

uncompensated care, while also having payments such as those provided via Medicaid state-directed payments reduced?

Response:
The House-passed H.R. 1 aims to hold states accountable for paying their part of the financial partnership and ending manipulative funding schemes practiced by some states. Many of the reforms included in the legislation are targeted towards able bodied adults and illegal aliens, helping ensure Medicaid is targeted to U.S. citizens and those most in need. Additionally, the bill would reform the ACA to prevent fraud, waste, and abuse. Further, the House-passed H.R. 1 would put the Medicaid program on a more sustainable path, reducing the program's growth rate from 6.3 percent to 4.7 percent.

43. Medicaid—and in particular Medicaid expansion—Given the current threats to Medicaid, how will you and your Department ensure access for millions to lifesaving preventative services, such as blood pressure screenings, cholesterol checks and tobacco cessation counseling?

Response:
I believe that we need to Make America Healthy Again, and this starts with a focus on prevention and management of chronic disease. That's why my Department is leading a coordinated transformation of our food, health, and scientific systems. This strategic realignment is expected to help ensure that all Americans—today and in the future—live longer, healthier lives, supported by systems that prioritize prevention, wellbeing, and resilience. As I testified, we will preserve legacy programs like Medicare and Medicaid, as foundations of the MAHA agenda. The House-passed H.R. 1 would do just that, focusing on strengthening and preserving Medicaid for generations to come.

44. More than half of children who identify as Native American, Black, Hispanic, or multiracial have Medicaid as their source of health insurance. Children of color in the United States face an array of health disparities, including higher rates of chronic conditions such as asthma, obesity, diabetes, and hypertension.
    a. How are you addressing racial and ethnic disparities in children's health outcomes, particularly within the Medicaid and CHIP programs?

Response:
My mission as the Secretary of the Department of Health and Human Services is to enhance and protect the health and well-being of all American people. A critical part of these efforts is ensuring that the Medicaid program is well administered, effective, and available for vulnerable beneficiaries while we work to modernize our tools to reduce fraud, waste and abuse. The House-passed H.R. 1 would strengthen Medicaid for children who rely on it.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

I believe that we need to Make America Healthy Again, and that's why HHS is realigning the department with a key goal of addressing the chronic disease epidemic. CMS supports the goal of making all Americans healthier, including children. I am making a commitment to every American to ensure that their health needs are reflected across CMS programs.

45. Medicaid ensures access to preventative care for tens of millions of Americans. Under the Affordable Care Act (ACA) Medicaid expansion, approximately 20 million adults had coverage for preventive services without cost-sharing. Yet, recently enacted H.R. 1 cuts Medicaid, particularly in states that have expanded Medicaid.
    a. How will you and your Department ensure access to lifesaving preventative services, such as blood pressure screenings, cholesterol checks and tobacco cessation counseling as states that have expanded Medicaid face significant decreases in federal Medicaid funding?

Response:
I believe that we need to Make America Healthy Again, and this starts with a focus on prevention and management of chronic disease. That's why HHS is leading a coordinated transformation of our food, health, and scientific systems. This strategic realignment is expected to help ensure that all Americans—today and in the future—live longer, healthier lives, supported by systems that prioritize prevention, wellbeing, and resilience. Additionally, preventative services will still be covered by Medicaid. As I testified, we will preserve legacy programs like Medicare and Medicaid, as foundations of the MAHA agenda. The House-passed H.R. 1 would do just that, focusing on strengthening and preserving Medicaid for generations to come.

46. The Maternal, Infant, and Early Childhood Home Visiting program provides essential support for young children and their families at critical times in their lives and is administered jointly by the Health Resources and Services Administration and the Administration for Children and Families. The job cuts levied across the Department of Health and Human Services have negatively impacted staffing in these offices.
    a. How will HHS continue to provide home visiting services to the children and families that need them in this environment?

Response:
The MIECHV Program is funded by mandatory appropriations, which currently extend through the end of fiscal year 2027, and is funded at $612.9 million in FY 2026, with sequestration. This is $47 million higher than the FY 2025 funding level, with sequestration. As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

47. CHIP covers approximately 7 million children and pregnant women. Given the critical role of CHIP in maternal and child health, what steps are you taking to ensure its continued funding and expansion?
48. The U.S. continues to face alarming rates of infant and maternal mortality, particularly among communities of color.
    a. What are you doing to support robust funding for programs like Medicaid, the Children's Health Insurance Program or CHIP, the Maternal and Child Health (MCH) Block Grant and other initiatives to reduce racial disparities in maternal and infant health outcomes?
49. The U.S. has the highest maternal mortality rate among high-income countries, with around 80% of maternal deaths considered preventable. The President's proposed HHS budget eliminates vital funding for Maternal Mortality Review Committees (MMRCs), which play a key role in identifying causes of maternal deaths with the goal of preventing future deaths. Your team has stated that maternal health remains a top priority for President Trump.
    a. Given this, how does the administration plan to effectively address the maternal mortality crisis while cutting funding for such vital programs?

Response (47-49):
The FY 2026 President's Budget invests in programs to improve maternal health outcomes, particularly in underserved and rural areas, prioritizing programs that provide states and communities the flexibility to address local maternal and child health needs. This includes a new Prevention Innovation Program funded at $119 million as part of the Make America Healthy Again initiative to address the root causes of America's escalating health crises, including a track specific to maternal health challenges.

The President's Budget also continues investments in the Maternal and Child Health Block Grant, the State Maternal Health Innovation program, the Alliance for Innovation on Maternal Health program, the Integrated Services for Pregnant and Postpartum Women program, the Screening and Treatment for Maternal Mental Health program, and the Maternal Mental Health Hotline to provide support and referrals to pregnant and postpartum women facing mental health challenges.

The Budget also continues investments in rural maternal health through the Rural Maternity and Obstetric Management Strategies program, which provides start-up funding to test out new approaches to supporting, enhancing, and expanding maternal and obstetrics care in rural communities.

50. Prior to layoffs in early April, the Pregnancy Risk Assessment Monitoring System (PRAMS) played the critical role of monitoring and collecting national data on maternal health and maternal mortality to inform interventions that reduce rates of infant and maternal death.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Now, as the U.S. continues to have the highest maternal and infant mortality rates among high income countries, how do you rationalize these cuts and what will be done to prevent more mothers from dying from pregnancy related causes?

Response:
Pregnancy Risk Assessment Monitoring System (PRAMS) activities are currently ongoing at CDC, including funding for the 2025 data collection cycle.

The FY 2026 President's Budget reforms the CDC to focus the agency on its core mission. The CDC supports infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. Under the proposed reorganization, CDC's National Center on Birth Defects and Developmental Disabilities and HRSA's Maternal and Child Health Bureau will be consolidated under the Administration for a Healthy America. This will improve data gathering and streamline the Department's maternal health programs to better serve Americans. All states use HRSA Maternal Child Health (MCH) Block Grant funds for women and maternal health activities such as promoting well-woman visits, increasing access to prenatal and postpartum care, supporting Maternal Mortality Review Committees (MMRCs), and enhancing systems of care for maternal mental health.

51. Your department announced that it would eliminate the congressionally-directed and funded LGBTQ+ youth option of the 988 Suicide and Crisis Lifeline. This option has served nearly 1.3 million LGBTQ+ youth callers since it began in 2022 and comes at a time when LGBTQ+ youth continue to experience drastically worse mental health challenges and rates of suicide than other populations. Research shows that in 2024, 39% of LGBTQ+ youth seriously considered attempting suicide, and this number climbed to 46% for transgender and non-binary youth. Contrary to your explanation for this devastating change, specific populations require specific solutions and approaches to prevention, which is why, for example, researchers now include women in addition to men in clinical trials. There was actually a time when that wasn't the case.
    a. How will your department address the great mental health needs of LGBTQ+ youth if it eliminates programs that literally save their lives?

Response:
I remain committed to reducing suicide among all Americans. The 988 Lifeline provides individualized, responsive care to all help seekers. The 988 crisis contact centers that respond to 988 calls, chats, and texts receive training in responding to all Americans at elevated risk for suicide. Guidance documents, practice simulations, trainings and webinars are available to all 988 counselors across the network. Help seekers from various high-risk populations are represented in video examples as part of 988 counselors initial required training. I have confidence in the ability of 988 centers to effectively assess, intervene, and refer all callers at elevated risk.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

52. There has been a growing push to restrict adolescents' access to critical health services such as mental health care and reproductive health care without parental consent.
    a. How are you addressing the needs of vulnerable adolescents who require confidential access to health services and respecting their ability to receive critically important services, such as mental health care and substance abuse treatment?

Response:
I am strongly committed to protecting the rights of parents within the practice of pediatric medicine. In most cases, parents have a right to access their children's protected health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Under the HIPAA Privacy Rule, a parent is the personal representative of his or her minor child where the parent has the legal authority to make health care decisions for the child. When providers ignore parental consent or keep parents in the dark about their children's care, HHS will act decisively. We will use every tool at our disposal to protect families and restore accountability.

53. Recent studies show that improving pediatric readiness in emergency departments could save over 2,100 children's lives annually.
    a. What specific steps are you taking to ensure all emergency departments achieve high levels of pediatric readiness?

Response:
ASPR manages the Pediatric Disaster Care program, which has funded three Pediatric Disaster Care Pediatric Centers of Excellence (COE) multi-state cooperative agreements, that targeted the development and sharing of appropriate planning and response capabilities to support the specific needs of children during public health emergencies and disasters, such as mass casualty incidents.

    b. Will you commit to promulgating a regulation that makes pediatric emergency readiness a condition of participation for hospitals in Medicare and Medicaid to ensure that children receive high quality emergency services in our nation's hospitals?

Response:
CMS is committed to ensuring that vulnerable pediatric populations receive evidence-based care that meets the highest quality standards, including emergency services. In the CY 2025 Medicare Hospital Outpatient Prospective Payment System Final Rule, CMS revised Medicare regulations to improve emergency readiness for hospitals and CAHs that provide emergency services. Hospitals and CAHs with emergency services are required to have adequate provisions and protocols to meet the emergency needs of patients (90 FR 94592-93).

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

54. In an emergency, children require specialized care that many hospitals are not adequately prepared to provide.
    a. What are you doing to ensure that HHS strengthens pediatric emergency readiness requirements and provides funding to equip hospitals to properly care for children in critical situations?

Response:
CMS is committed to ensuring that vulnerable pediatric populations receive evidence-based care that meets the highest quality standards, including emergency services. In the CY 2025 Medicare Hospital Outpatient Prospective Payment System Final Rule, CMS revised Medicare regulations to improve emergency readiness for hospitals that provide emergency services. Hospitals with emergency services are required to have adequate provisions and protocols to meet the emergency needs of patients.

55. The FY26 NIH budget identifies the Food is Medicine Centers of Excellence – for which NIH approved the concept in 2023 but has yet to receive funding – as responding to the need to bridge nutrition support and clinical practice to address diet-related chronic diseases.
    a. How will you support and prioritize comprehensive food is medicine research at NIH?

Response:
Approximately one million people die annually in this country from diet-related chronic diseases, and this number continues to rise. Diet-related chronic diseases also disproportionally affect underserved communities and exacerbate health conditions. Under my leadership, HHS is committed to integrating nutrition education and research in medicine. For example, in May 2025, NIH and FDA announced a joint Nutrition Regulatory Science Program (NRSP). Under NRSP, the agencies will implement and accelerate a comprehensive nutrition research agenda that will provide critical information to inform effective food and nutrition policy actions to help make Americans' food and diets healthier.

56. The budget request for the proposed Administration for a Healthy America (AHA) includes $119 million for a new Prevention Innovation Program, with a track dedicated to addressing chronic conditions, including by promoting access to healthy foods and implementing nutrition-driven programs in partnership with community organizations.
    a. How do you plan to leverage the MAHA Initiative, and specifically the Prevention Innovation Program, to implement and scale food is medicine services?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Prevention Innovation (PI) program provides communities with new and practical ways to support the goals of the Administration to Make America Healthy Again (MAHA). The PI program supports the goals of the MAHA initiative by addressing the root causes of America's escalating health crises, focusing on maternal health delivery gaps and chronic conditions that lead to poorer health outcomes in rural areas. This request supports three tracks: one for maternal health, one for chronic disease, and one for Tribes (where applicants could support programs in either maternal health or chronic disease). The intent of the PI program is to improve overall health, reduce dependence on medications and other treatments, and ensure that people have access to resources and other clean and healthy environmental and lifestyle options.

57. The HHS food is medicine initiative has served as a critical resource to food is medicine researchers, practitioners, and other stakeholders since its launch in FY 2024 by publishing an online knowledge hub, coordinating food is medicine programs across federal agencies, and developing partnerships with community-level and national FIM leaders.
    a. How do you intend to support and expand HHS's food is medicine efforts through this initiative?

Response:
My Department will work with USDA, ED, VA, and Department of Defense to improve access to whole, healthy foods in government-funded nutrition programs and meals, including in school meals, prisons, and VA hospitals, and ensure the availability of nutritious whole food for populations in need. HHS and FDA will continue efforts with USDA to develop a uniform definition for "Ultra-processed Food" to support potential future research and policy activity.

HHS, the VA, and USDA will study the impact of programs that implement food and lifestyle interventions to improve health outcomes and decrease costs. The NIH Office of Nutrition will coordinate research initiatives to improve rigorous studies and maximize impact, including through largescale randomized control trials.

58. As HHS embarks on its Make America Healthy Campaign, how do you propose to meet people where they are – such as for low income people or schools that may not have the resources for scratch cooking or the increased cost of healthy food?

Response:
The Make America Healthy Again Commission will have a holistic approach and rely on input from a variety of Departments and Agencies across the government to improve the health of all Americans.

59. Secretary Kennedy, you have repeatedly vowed to "radically transform" the US food system. What specific transformational changes do you intend to make?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
My Department has already made steps to radically transform our food supply and implement the MAHA agenda. The FDA is working with industry to phase out all petroleum-based synthetic dyes from the nation's food supply, I directed the FDA to close the GRAS loophole that has allowed ingredients and chemicals to be introduced into the food supply without notification to the FDA or public, and we are working with our colleagues at USDA to update the Dietary Guidelines for all Americans.

60. How does HHS plan to promote initiatives aimed at addressing social risk factors such as food insecurity (such as Food Is Medicine) given the Department's plans (e.g., FY2026 IPPS) to remove social risk screening measures across its programs?

Response:
HHS, the Department of Veterans Affairs (VA), and USDA will study the impact of programs that implement food and lifestyle interventions to improve health outcomes and decrease costs. The NIH Office of Nutrition will coordinate research initiatives to improve rigorous studies and maximize impact, including through largescale randomized control trials.

HHS and USDA will launch an education campaign based on the updated Dietary Guidelines for Americans. The campaign will prioritize whole foods including protein foods, fruits, and vegetables, minimizes highly processed foods and added sugar, and brings awareness to strategies to improve health.

61. Given the current threats to Medicaid, how will you and your Department ensure access for millions to lifesaving preventative services, such as blood pressure screenings, cholesterol checks and tobacco cessation counseling?

Response:
I believe that we need to Make America Healthy Again, and this starts with a focus on prevention and management of chronic disease. That's why HHS is leading a coordinated transformation of our food, health, and scientific systems. This strategic realignment is expected to help ensure that all Americans—today and in the future—live longer, healthier lives, supported by systems that prioritize prevention, wellbeing, and resilience. As I testified, we will preserve legacy programs like Medicare and Medicaid, as foundations of the MAHA agenda. The House-passed H.R. 1 would do just that, focusing on strengthening and preserving Medicaid for generations to come.

62. What is the Administration's outreach and enrollment strategy for the upcoming 2025 Marketplace Open enrollment?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Does the Administration plan to operate all call centers to assist consumers with open enrollment and does the Administration intend to continue to conduct targeted outreach?

Response:
HHS and CMS are committed to promoting a health care system that will provide access to quality care while ensuring Americans across the country are equipped with the information they need to make healthcare decisions that work best for them and their families. Unfortunately, under the Biden Administration, CMS estimates that in 2024 alone, as many as 4.4 million Americans were improperly or fraudulently enrolled in Obamacare plans, many of whom were taken advantage of by unscrupulous agents and brokers. My Department is committed to rooting out waste, fraud, and abuse to ensure taxpayer-funded programs are helping those who need them the most.

63. In early 2025, the Trump administration issued an executive order, which seeks to strengthen hospital price transparency requirements and enforcement, which builds upon efforts from President Trump's first term and from the last administration.
    a. What specific actions is the Administration undertaking to strengthen enforcement and in particular the requirement for hospitals to post their prices in dollars and cents with no exception?

Response:
This Administration remains committed to delivering a more transparent, affordable, and patient-centered health care system. On February 25, 2025, the White House issued Executive Order 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information," to empower patients with clear, accurate, and actionable healthcare pricing information. My Department is actively working to implement this Executive Order and provide Americans with maximum price transparency from both insurance companies and hospitals.

64. As you well know, the MAHA Commission's recent report – which was an extremely flawed document - has significant implications for producers and consumers.
    a. Given the concerns raised about the lack of public input in the drafting of the report, will you commit to correcting the record by opening a formal comment period to allow stakeholders the opportunity to provide valuable feedback and ensure the kind of radical transparency you ensured us would be a part of this process?

Response:
The Make America Healthy Again Commission prioritizes collaboration with top experts across government and industry in order to provide Americans with the information necessary to make the best decision for their health. We must shift the focus of healthcare

from disease management to disease prevention. The MAHA plan encourages healthy eating, regular exercise, and routine health screenings to reduce preventable chronic diseases like heart disease and diabetes.

65. The most effective tool we have to address drug company abuses and lower costs is the Medicare negotiation program which not only saves Medicare millions of dollars but also helps save lives through improved access to medications and reduced drug rationing.
    a. How do the cuts and changes in your proposed budget impact the robust staffing and programmatic support needed to ensure the lowest negotiated prices for drugs covered under Medicare?
    b. Additionally, what impact will these cuts, including cuts to public awareness campaigns related to drug negotiations, have on education for seniors who will significantly benefit from lower drug costs?

Response:
CMS is committed to ensuring that Americans with Medicare have access to affordable, lifesaving medications. Medicare drug price negotiations are required by statute and HHS is following the law. HHS will continue to build off the historic efforts of President Trump's first term to lower prescription drug prices and continues to deliver on his promise to put American patients first as outlined in his Executive Order "Lowering Drug Prices by Once Again Putting Americans First."

On May 12, in accordance with the EO's directive to the Secretary, CMS issued Draft Guidance on the Medicare Drug Negotiation Program for the third cycle of negotiation and manufacturer effectuation of negotiated MFPs in 2026-2028 (May 12 draft guidance). This guidance describes requirements and parameters for the third cycle of negotiations and the first cycle of renegotiations for the Negotiation Program. In addition to soliciting comment on ways to increase transparency in the Negotiation Program, CMS solicited feedback to improve implementation of the IRA's requirement that drug manufacturers provide access to the MFP for selected drugs to pharmacies, mail order services, and other dispensing entities, including alternative solutions for sharing verified data or for routing refund payments from manufacturers to dispensing entities. The comment period for the May 2025 draft guidance closes on June 26, 2025.

Additionally, President Trump has taken historic action to lower the cost of healthcare. This Administration is focused on lowering drug costs and exploring ways to ensure Americans no longer pay more for medications than patients in other economically comparable countries. Utilizing the Most Favored Nation framework, the Trump Administration is putting pressure on other nations to pay their fair share while driving down drug prices for Americans.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

66. Your budget request for AHA includes new MAHA programs that can reduce the burden of chronic disease and decrease long-term spending on health care. The budget also notes that Community Health Centers are at the forefront of Making America Healthy Again through preventing disease by increasing access to integrated nutrition and wellness coaching services.
    a. How will supporting Community Health Centers in expanding access to primary care advance your MAHA goals?

Response:
The FY 2026 President's Budget includes a $6.1 billion investment in Health Centers, including a $1.8 billion in discretionary funding and $4.3 billion in proposed mandatory resources. This funding supports approximately 1,400 Health Centers operating more than 15,000 service sites nationwide and provides comprehensive medical care and support services such as health education, transportation, and screenings to over 31 million people.

67. MedPAC suggests 55% of Medicare patients have difficulty accessing primary care. Seniors are the fastest growing demographic at Community Health Centers. How will HHS help Congress improve the FQHC PPS to increase seniors' access to care at Community Health Centers?

Response:
HHS acknowledges the rapidly growing senior population and the importance of working to increase seniors' access to quality and comprehensive primary care services. We are happy to work with your office to fix antiquated payment systems within FQHC PPS.

68. The THCGME program & Nurse Practitioner Optional Fellowship programs are training the next generation of primary care providers at Community Health Centers. Clinicians trained at health centers are more likely to work in rural & underserved areas than those trained at hospitals. 7 Republicans & 8 Democrats on this Committee have THCGME programs in their district and 5 bipartisan Committee members have NP optional fellowship programs.
    a. How will AHA help this Committee ensure all THCGME & NP optional fellowship programs at Community Health Centers have long-term funding?

Response:
Through the Teaching Health Center Graduate Medical Education (THCGME) program and the National Health Service Corps (NHSC) loan repayment and scholarship programs, HHS is supporting efforts to encourage primary care clinicians. The FY 2026 President's Budget requests $175 million in mandatory funding for THCGME to support up to 1,273 resident full-time equivalent slots in FY 2026. The FY 2026 President's Budget request for the NHSC includes $128.6 million in discretionary funding and $345 million in proposed mandatory resources to support clinician scholarship and loan repayment.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Budget also provides continued funding for the Rural Health Care Services Outreach Grants, which support collaborative models to deliver basic health care services to rural areas and are uniquely designed to meet rural needs.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Diana DeGette (D-CO)

1. President Trump launched the Ending the HIV Epidemic in the U.S. (EHE) initiative to reduce HIV infections in the U.S. by scaling up diagnosis, treatment, prevention, and response. In your appearance before the Committee, you admitted to sanctioning the termination of HIV prevention studies and funding for a clinical trial of an HIV vaccine because there isn't a vaccine yet.
    a. How does your Department plan to eliminate HIV/AIDS using "currently available approaches" if it's not supporting research or clinical trials of emerging treatments or prevention measures?

Response:
HHS is committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

My Department will continue to support activities to prevent and treat HIV. The FY 2026 President's Budget requests $2.5 billion for the Ryan White HIV/AIDS Program, including $165 million for the Ending the HIV Epidemic in the United States Initiative (EHE). The Budget also includes $157 million to continue EHE activities in Health Centers and $220 million to continue EHE activities formerly carried out by CDC. AHA will administer these programs and lead the coordination of EHE and other HIV/AIDS related activities formerly carried out by CDC, HRSA, and OASH under one entity.

2. Certain funding mechanisms within the NIH and other OPDIVs have been terminated if they were determined to have violated executive orders and other administration priorities, even if some research or prevention activities funded under the mechanisms are unrelated to those topics or violations.
    a. Will the NIH shift grants away from certain funding mechanisms (such as cancer moonshot) and move to other funding mechanisms so the research and clinical trials that may be impacted can continue without delay or termination?

Response:
My Department is committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities. The FY 2026 President's Budget requests $4.5 billion for the National Cancer Institute at NIH.

Additionally, NIH is sharpening its focus on chronic health issues that affect Americans, including chronic childhood diseases and nutrition. We are also prioritizing next-generation tools such as artificial intelligence, alternative testing models, and real-world data platforms. NIH empowers its Institutes, Centers and Offices to make funding

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

decisions that reflect agency and institute priorities, scientific opportunity, program balance, workforce needs, and other core principles that will be consistently applied across the agency. By transparently establishing priorities and aligning our goals, we aim to demonstrate to the American public that we take this commitment seriously—and that we are doing all we can to honor their trust.

3. NIH has established an appeals process for grants and other awards that have been terminated in 2025.
    a. How many grants have been successfully appealed through this process?

Response:
Nearly 400 appeals sent to the NIH Office of the Director to date have resulted in NIH grants being either reinstated or renegotiated.

4. Many NIH grants have been terminated for their diversity-specific components without the opportunity for investigators to rescope their work to be more in line with the goals of the current administration. In your appearance before the committee, you committed to abiding by court orders requiring NIH reinstate canceled grants.
    a. Please share NIH's expected timeline and planned processes for reinstating grants.
    b. Has your department provided guidance to grantees whose funding you canceled? Please provide copies of all emails, notices, or other communications.
    c. Will NIH provide grant awardees the opportunity to update or to rescope their research to more closely reflect the priorities of the current administration - and maintain previously, competitively awarded funding?

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. NIH is advancing policies to maximize the impact of every federal taxpayer dollar and ensure proper oversight of its funding. For example, we have cancelled grants that funded research on, "adolescent health at the intersections of sexual, gender, racial/ethnic, immigrant identities, and native language", "COVID-19 Misinformation in low-income Latinx communities", and "effects of exogenous testosterone therapy on communication in gender diverse speakers". NIH is complying with all court orders. Furthermore, NIH permitted recipients to appeal terminations for nonalignment with agency priorities by submitting a request for such review no later than 30 days after the written notification of the determination is received. NIH is reviewing these appeal requests as expeditiously as possible. NIH welcomes scientists to continue submitting proposals for meritorious research that supports our goal of making all Americans healthier.

5. Congressionally-appropriated FY 2025 funding remains stalled, which will have an effect on the patients from around the country who come to NCI-designated Comprehensive Cancer Centers, academic medical centers, and independent research institutions for treatment or to enroll in clinical trials.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. What is your plan to ensure the appropriated funds are spent by the end of the fiscal year?
b. How will NIH obligate FY2025 funds if it indeed fails to obligate the appropriated amount by the end of the fiscal year?

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. NIH is seeking approaches to streamline and efficiently spend funds in order to advance NIH's mission to support scientific endeavors that advance the health and longevity of all Americans. To tackle these persistent and complex problems, NIH-funded research must be rigorous, reproducible, and generalizable. NIH will continue to support cancer research and ensure it is continuing to fund gold standard science in this space. NIH is doing everything in its power to increase the pace of funding to make these funds available for rigorous biomedical research. NIH has streamlined processes to fund awards as expeditiously as possible.

6. The National Institute of Environmental Health Sciences has been instrumental in our understanding of environmental contributors to chronic disease and as part of the National Institutes of Health, it has been able to integrate environmental health research into cross-NIH programs such as the All of Us research program.
    a. Describe how the proposed restructuring of NIH will preserve NIEHS' functions.
    b. Describe how NIH will integrate environmental health sciences expertise under the restructuring.

Response:
Under my leadership, the Department is considering a number of proposals to streamline and reduce inefficiencies. While there is an extensive and systematic process in place before NIH can enact restructuring, the key principle is to empower collaboration across scientific disciplines to increase knowledge. We must continue to share ideas and data, regardless of any specific reorganization NIH undertakes. NIH supports a multifaceted approach to understanding the most effective prevention and treatment efforts related to chronic illness and disease, including environmental risk factors. HHS is committed to ensuring that NIH delivers gold standard science to the public and continues to drive the discovery of life-changing treatments.

7. Supporting a robust biotechnology ecosystem in the United States is imperative for the country's public health and leadership in science and innovation. However, China is poised to outpace the United Stated and is eager to emerge as the global leader in medical product development and innovation.
    a. How will you ensure that the NIH is able to fulfill its important health and scientific mission and support our country's biotech research and development

pipeline so that we are not surpassed by China or other nations seeking to take over as the global leader in biotech?

b. What prospectively set, objective metrics will you use to evaluate how NIH and the American biotechnology sector are performing in relation to China?

Response:
The United States is the world leader in biomedical research and biotechnology. As the largest public funder of that research, NIH sets the standard for innovation and scientific discovery that aims to advance the health of the nation. At the heart of the NIH mission are the principles of gold standard science and NIH remains steadfast in that commitment. NIH has long supported programs, policies, and initiatives grounded in robust and rigorous science that are foundational to success. Public input and accountability are embedded throughout NIH processes, reinforcing the credibility and impact of our science and findings. These efforts foster an environment that advances the highest quality science to improve the health of all Americans. In his May 23, 2025, Executive Order on Restoring Gold Standard Science, President Trump articulated how his Administration is committed to promoting a gold standard for science to ensure that federally funded research is transparent, rigorous, and producing tangible benefits for the American public. As set forth in that order, NIH will spur innovation, translate discovery to success, and ensure continued American strength and global leadership in biotechnology.

8. What criteria did NIH use to determine which Institutes and Centers should be eliminated or consolidated as described in the Fiscal Year 2026 Budget?
    a. How does NIH plan to ensure that research priorities currently advanced by these standalone institutes—including those focused on vision, hearing, and rare neurological disorders—are not diluted or deprioritized under the umbrella of a broader neuroscience structure?
        i. What specific safeguards, funding mechanisms, or leadership structures will NIH put in place to guarantee that these areas do not lose visibility, advocacy, or budgetary protection?
    b. Stakeholders have expressed alarm that the proposed changes were developed behind closed doors with minimal external input from the research community, patients, or Congress.
        i. Please describe the engagement—if any—NIH undertook with scientific, clinical, and patient communities in advance of unveiling this plan?
        ii. Will NIH commit to pausing any implementation until a transparent, public process that includes congressional oversight can occur?

Response:
Under my leadership, the Department is considering a number of proposals to streamline and reduce inefficiencies. While there is an extensive and systematic process in place before

the agency can enact restructuring, the key principle is to empower collaboration across scientific disciplines to increase knowledge. We must continue to share ideas and data, regardless of the reorganization HHS undertakes. HHS is committed to delivering gold standard science to the public and continuing to drive the discovery of life-changing treatments. NIH will continue to support important meritorious research.

9. Type 1 diabetes (T1D) is an autoimmune disease for which there is no cure. My colleague, Representative Gus Bilirakis, and I have championed funding for the Special Diabetes Program, which is accelerating research to bring us to cures for T1D. This program supplements appropriated NIH funds.
    a. Will you ensure the Special Diabetes Program funding remains a supplement and does not supplant annual appropriations NIH receives for research on type 1 diabetes?

Response:
I remain committed to supporting the Special Diabetes Program and ensuring funds are used to support cutting edge gold standard science that supplements NIH's existing diabetes portfolio.

10. As a result of NIH-funded research, more children are surviving pediatric cancers, and we better understand the underlying causes of other childhood diseases and chronic health conditions. I am concerned about the proposed reorganization of the agency and impacts on pediatric research.
    a. How will you maintain the momentum of American-driven innovative research and the development of curative and life-enhancing therapies for children with chronic and life- threatening illnesses amidst the restructuring and substantial cuts at the NIH?

Response:
Under my leadership, the Department is considering a number of proposals to streamline and reduce inefficiencies. While there is an extensive and systematic process in place before the agency can enact restructuring, the key principle is to empower collaboration across scientific disciplines to increase knowledge. The National Cancer Institute (NCI) supports a broad range of research to better understand the causes, biology, and patterns of childhood cancers and to identify the best ways to successfully treat children with cancer. Recent advances have been made in a variety of pediatric cancers such as brain cancer, leukemia, and sarcoma, each of which has benefited from NIH-developed technologies that help identify and treat these cancers. The NIH will continue to do this critical work.

11. The National Institute of Child Health and Human Development (NICHD) is the only institute at NIH focused on maternal and child health. The NICHD supports critical research to promote healthy pregnancies, reduce infant deaths, and examine the

challenges associated with birth defects, intellectual and developmental disabilities, and chronic illness.

a. How will you protect and strengthen this vital work given the proposed restructuring and consolidations of institutes at the NIH?

Response:
NICHD provides leadership for scientific research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. Specifically, NICHD supports research on gynecological health conditions, fertility and infertility, contraception, and reproductive health. NICHD leads the scientific exploration of typical child development, as well as primary and specialty care for children with acute and chronic conditions.

All NIH institutes and centers support pediatric research. NICHD funds the largest portion of pediatric research among the NIH institutes, centers, and offices (ICOs), taking a leadership role in many pediatric research efforts that involve NIH-wide collaborations such as the Pediatric Research Consortium, which was established to coordinate pediatric research programs, best practices, and training opportunities across all NIH ICOs. Additionally, NIH's Clinical Center is the world's largest research hospital and serves as the primary location for pediatric clinical trials conducted by various NIH institutes and centers, including NCI's Pediatric Oncology Branch.

With respect to restructuring at NIH, the Administration continues to consider proposals to streamline and reduce inefficiencies and looks forward to working with Congress. The key principle for restructuring is to empower collaboration across scientific disciplines to increase knowledge. NIH will continue to support research on maternal and child health across the agency regardless of the structure of NIH.

12. What consideration has been given to the potential significant INCREASE in government spending (i.e., increased SSI/SSDI enrollment and costs, increased Medicaid enrollment and costs, reduced tax income from reduced personal income) that will occur for the ~20% of US citizens with disabilities if NIH/National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) grants are reduced?
    a. Given the focus of NIDILRR model systems on improving the outcomes of people with the most severe disabilities and ultimately reducing significant associated costs (e.g., SSDI, Medicaid, general government programs), is there a plan to address these major societal concerns through other programs?

Response:
NIDILRR Model Systems' (SCI, TBI, Burn) longitudinal data reveal the chronic nature and lifelong implications for living with these disabling conditions. Model systems data show positive outcomes tied to public and private spending with respect to

rehospitalizations after injury (TBI) over 10 years, and employment after injury (SCI), where better function and sustained employment are associated with fewer hospital days and greater earnings. The Budget provides $100 million to NIDILRR for them to continue existing grants.

13. What is the total spending (as a percent of total research funding) from NIDILRR and NIH that is devoted to SCI research and/or TBI research?
    a. What percent of the funded research coming from NIDLRR and NIH is focused on neuro- recovery and cure, and what percentage will be maintained under the reorganized NIH?

Response:
NIH supports research into spinal cord injury (SCI) and traumatic brain injury (TBI) in a variety of ways. While NIH does not officially track SCI research, the NIH Funding for Various Research, Condition, and Disease Categories (RCDC) does track TBI. NIH funding is largely driven by investigator-initiated research projects and these funding levels are very dependent on the meritorious research proposals received. With respect to restructuring at NIH, the Administration continues to consider proposals to streamline and reduce inefficiencies and looks forward to working with Congress. The key principle for restructuring is to empower collaboration across scientific disciplines to increase knowledge. NIH will continue to support meritorious research proposals for TBI and SCI in the future.

14. 80% of CDC's domestic budget goes out to state, local, tribal, and territorial partners, nongovernmental organizations, healthcare, universities, and other entities. As part of the reduction in force and reorganization, entire CDC programs have been eliminated, and in some cases all the staff administering certain programs have been eliminated.
    a. Because Congress has appropriated money for these programs, what are the Administration's plans for the FY2025 funding that has not yet been sent to the field?

Response:
My Department and CDC are committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

    b. How will HHS disburse and ensure effective use of grants if there are few, if any, staff remaining to administer them?

Response:
My Department and CDC are committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program

implementation that supports good stewardship of resources and the Administration's priorities.

15. The Congressional justification for the new Administration for a Healthy America (AHA) detailed how many existing chronic disease prevention programs currently housed at CDC would not be moved to AHA but rather completely eliminated.
    a. How will you address the diseases covered by prevention programs that are being eliminated? For instance, the budget proposes to eliminate the National Diabetes Prevention Program, which is proven to reduce type 1 diabetes risk.

Response:
The FY 2026 President's Budget request for the proposed Administration for a Healthy America (AHA) includes $14 billion as a part of the Make America Healthy Again initiative to address the chronic disease epidemic. HHS fully supports diabetes research and will continue to fund gold standard science in this space. HHS is working to bolster chronic disease prevention activities across the Department to better serve Americans.

    b. Under the proposed Administration for Healthy America, would these services move to a new division or be eliminated completely?
        i. If they are going to be moved, how will public health officials carry out these critical prevention programs with a significantly decreased budget?

Response:
The Administration is committed to reducing government inefficiencies. The Budget includes the reorganization to establish the Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans, including by addressing the root causes of chronic disease. Any proposed eliminations are part of broader efforts and to reduce duplication across HHS, and improve service delivery for the American people. HHS is working to enhance chronic disease prevention activities across the Department to better serve Americans.

16. When you dismissed 17 Advisory Committee on Immunization Practices (ACIP) members, you alleged the committee was "plagued with persistent conflicts of interest."
    a. What evidence do you have that these 17 former members have conflicts of interest that influenced their work at ACIP?
    b. Will the new members be held to the same standards for conflicts of interest, including, with regards to financial interests in treatments or supplements that are marketed as alternatives to vaccines for certain conditions?
    c. What application and review process did you use when naming the eight new ACIP members?
        i. Why was this process done secretly, despite your calls for a more transparent ACIP and greater transparency generally?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

d. Some of the new ACIP members have no experience in vaccinology or related public health issues. How can the American people and public health professionals be reassured that the new members are capable of undertaking ACIP's crucial responsibilities?
    i. How will you and your new ACIP members gain the trust of medical professionals who expect recommendations to be based upon sound scientific evidence?
e. Once confirmed, will you allow the new CDC Director to carry out her ACIP-related duties without interference?

Response:
The Advisory Committee on Immunization Practices (ACIP) serves as a body of external experts who advise the CDC on the use of vaccines for the control of diseases. Established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended, the ACIP is a federal advisory committee charged with providing advice and guidance to the CDC Director regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. It is comprised of outside advisors appointed by the HHS Secretary, who develop recommendations for U.S. immunizations for consideration by the CDC Director, including the ages at which vaccines should be given, dosing regimens, and precautions and contraindications for individual vaccines.

Current information regarding ACIP and its activities may be found at the ACIP website, located at https://www.cdc.gov/acip/index.html.

17. You have called for all new vaccines to undergo placebo trials.
    a. Is this HHS' official stance?
    b. If so, why is HHS' official stance contrary to accepted ethical principles?
    c. Do you accept there are circumstances when placebo groups are neither ethical nor practical?

Response:
FDA's guidance document for including a placebo control arm as part of clinical testing considers many advantages and disadvantages of placebo-controlled trials (e.g., see E 10 Choice of Control Group and Related Issues in Clinical Trials Section II.A.6 and 7), including, but not limited to ethical and practical issues. We note that on July 1, 2025, FDA approved the 2025-2026 seasonal influenza vaccines of all manufacturers with FDA-approved seasonal influenza vaccines. FDA did not require new placebo-controlled clinical trials to support the approvals of the 2025-2026 formulations.

18. Do you unequivocally support the administration of the MMR (measles-mumps-rubella) vaccine to children and adults?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
The most effective way to prevent the spread of measles is the MMR vaccine.

19. CDC's National Center for Injury Prevention and Control (Injury Center) has served as a leader in preventing Adverse Childhood Experiences (ACEs) since the 1990s, supporting states and local communities through research and initiatives including Preventing ACEs Training Modules. CDC research finds that preventing ACEs could reduce suicide attempts among high school students by nearly 90% and mitigate persistent feelings of sadness and hopelessness.
    a. Have you previously indicated a commitment to addressing the youth mental health crisis?
        i. If this is your commitment, why has the CDC's ACEs program been slated for elimination through President Trump's FY 2026 Budget Request?

Response:
The FY26 President's Budget proposes transferring activities of the CDC National Center for Injury Prevention and Control to AHA to streamline operations, enhance coordination across public health programs, and better align efforts to improve health outcomes nationwide. The Administration for a Healthy America will be the primary federal agency committed to transforming the health of all Americans.

20. CDC research finds that as the number of Adverse Childhood Experiences (ACEs) an individual experiences increases, the risk for chronic illnesses (such as asthma, diabetes, childhood and adult obesity, and cancer) across the lifespan also increases.
    a. Given your focus on addressing chronic disease, do you believe preventing ACEs is an important part of reducing long-term chronic disease risk?

Response:
The FY 2026 President's Budget proposes transferring activities of the CDC National Center for Injury Prevention and Control to AHA, which will be the primary federal agency committed to transforming the health of all Americans. Any proposed eliminations are part of broader efforts and to reduce duplication across HHS, and improve service delivery for the American people. Additionally, the budget request for AHA includes $14 billion as a part of the Make America Healthy Again initiative to address the chronic disease epidemic.

    b. What is your justification for eliminating the CDC's ACEs program and terminating state and local efforts to address one of the key drivers of chronic disease in this country, as proposed in the FY2026 budget?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The FY 2026 President's Budget proposes to reform the CDC to focus the agency on its core mission. The CDC supports infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. HHS/CDC is committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

21. The Administration for Community Living (ACL) successfully brought together aging and disability programs from across the federal government to help older adults and those with disabilities age in place and be active members of their communities.
    a. What is the rationale behind combining ACL with the Administration on Children and Families?
    b. Why were key ACL programs cut in the FY26 budget that older adults depend on such as falls prevention, chronic disease self-management, and Alzheimer's prevention?
22. As part of the recent reorganization, CDC's healthy aging branch, which includes programs to increase early detection and diagnosis of dementia, has been eliminated.
    a. How will the Administration for a Healthy America address older adult health?
    b. Which functions within AHA will be responsible for the work currently done by CDC's healthy aging branch?

Response (21-22):
The health and well-being of many Americans has long been in decline and the Trump Administration is taking bold steps to better fulfill our promises and make Americans healthy again. The Department of Health and Human Services is seeking to centralize shared services across the Department, such as human resources, procurement, and technology. While changes at ACL are still underway, please be assured that these changes are designed to minimize waste, fraud, and abuse, and ensure that HHS critical mission services and benefits, like those in ACL, are reaching key constituents. Facilitating collaborative workstreams between ACL and ACF constituencies will allow the Department to improve its focus of better addressing the needs of older adults and people with disabilities. The Budget does provide $2.5 million in discretionary funding for falls prevention and $16.8 million in discretionary funding for Alzheimer's Disease Program Initiative.

CDC works with state public health partners to quantify the burden of Alzheimer's disease and other dementias (ADRD) and assist public health agencies and partners to provide strategies to address these conditions and take action. These programs are creating a strong public health backbone to support and promote dementia risk reduction, early detection and diagnosis, prevention of avoidable hospitalizations, and dementia caregiving. HHS will continue the fight against diseases such as Alzheimer's with a particular focus to help

communities better understand the burden, while identifying the causes and remedies for combatting this affliction.

23. What is the goal of eliminating programs at CDC's National Center for Environmental Health such as the National Asthma Control Program, National Environmental Public Health Tracking Network and Trevor's Law (which tracks cancer clusters), as proposed in the FY2026 budget?
    a. How will HHS address these issues if these programs are eliminated?

Response:
Creation of the Administration for a Healthy America (AHA), which will combine multiple agencies — the Office of the Assistant Secretary for Health (OASH), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Toxic Substances and Disease Registry (ATSDR), and National Institute for Occupational Safety and Health (NIOSH) — into a new, unified entity. This centralization will improve coordination of health resources for low-income Americans and will focus on areas including, Primary Care, Maternal and Child Health, Mental Health, Environmental Health, HIV/AIDS, and workforce development.

The Administration is committed to reducing government expenditures and difficult decisions had to be made. HHS continues discussions on how to support environmental health programs across the department.

24. There is an ongoing lead poisoning crisis in schools in Wisconsin, but CNN reports that all of CDC's lead experts had been dismissed.
    a. Have all the staff been rehired, and if so, how will staff be able to quickly respond to the crisis?

Response:
On June 11, 2025, staff of CDC's Childhood Lead Poisoning Prevention were reinstated. Since this time the Childhood Lead Poisoning Prevention program has resumed regular meetings with the Milwaukee Health Department (MHD) to assess current needs and determine how CDC can provide essential assistance. CDC is actively collaborating with the MHD to develop a screening questionnaire to facilitate additional blood lead testing in the field, while also reviewing data from the health department's lead screening clinics and historical blood lead levels to identify patterns and trends. CDC, in conjunction with the Agency for Toxic Substances and Disease Registry (ATSDR), is also working to develop a webinar for area healthcare providers.

    b. With the Childhood Lead Poisoning Program slated to move to AHA, will these employees be transferred to the new agency?
        i. How will their expertise be incorporated into the new lead poisoning prevention efforts?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
The proposed reorganization will refocus CDC's core mission on infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. The proposed Administration for a Healthy America (AHA) will lead on chronic disease and maternal and child health activities for HHS. As part of the reorganization of HHS, all critical functions will be maintained and the department's capacity to best serve the American people will be increased through efficiencies and better organizational structure.

25. The Administration has stated that the reorganization will enable CDC to protect Americans from health threats and epidemics. Yet some of the reported programs that have been severely cut or eliminated are critical to community readiness for outbreaks emergencies, such as laboratories focused on viral hepatitis, immunization outreach, staff for the Strategic National Stockpile, and HIV and TB elimination. In addition, during local emergencies, state and local partners often request assistance from CDC, and CDC convenes a multidisciplinary team to provide technical assistance or deploy to the field.
    a. How is the Administration determining which infectious diseases are a threat and which are not?

Response:
The President's Budget streamlines and prioritizes activities to reduce waste and support efficiency. The renewed focus of CDC will better focus the agency on its core mission to protect Americans from health threats. This work is in close partnership with partners at the state, tribal, local, and territorial (STLT) level who are able to best identify how resources can help their local communities.

Further, CDC uses the Threat and Hazard Identification and Risk Assessment (THIRA) process as one tool to help determine which public health emergencies pose the greatest risk. CDC's process is modeled after the Federal Emergency Management Agency's more general THIRA but modified to be a collaborative, public health-focused risk assessment. Through the THIRA, CDC is able to effectively identify, assess, and prioritize threats and hazards, develop deliberate plans to respond, and assess agency capabilities. More general THIRAs are conducted every three years, and results are based on a 10-year history of CDC Emergency Operations Center-supported events and a hazard impact assessment conducted by CDC subject matter experts.

Additionally, at the state, tribal, local and territorial level and as part of CDC's Public Health Emergency Preparedness (PHEP) program requirements, recipients must complete and submit a risk assessment during the five-year period of performance. The information from the risk assessment helps CDC understand the unique risks of each jurisdiction, while also enabling the jurisdiction to focus their preparedness efforts on the public health threats of greatest consequence to their jurisdiction.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

What is the plan when – as we have seen numerous times – an emergency response requires experts in environmental health (such as East Palestine and wildfires), maternal and child health (such as Zika) or chronic disease (such as flu and COVID)?

Response:
During an emergency response, CDC relies on subject-matter specific expertise from across the agency, including staff who have expertise in non-infectious diseases. CDC will continue to utilize subject-matter experts from across CDC – now more easily identified since the introduction of CDC's ReadyResponder program, which catalogs the availability and skillsets of CDC staff for use in emergency responses. CDC also historically works closely with other HHS and federal agencies to respond to large-scale emergencies. In the event of a reorganization, CDC will need to continue to work closely with any new agencies to ensure that necessary staff from across the federal government can be rapidly utilized in any public health response, as needed.

26. The President's budget eliminates all funding for state and local public health emergency preparedness.
    a. What is the plan if there is an emergency that crosses state lines, such as a natural disaster or outbreak?

Response:
The FY 2026 President's Budget will continue to support and maintain a readiness standard to aid communities in need by acting as backstop for our State, Local, Tribal, and Territorial (SLTT) partners in times of crisis. As proposed in the Budget, the new CDC Center for Preparedness and Response, comprised of the Administration for Strategic Preparedness and Response (ASPR) programs such as the National Disaster Medical System, will continue to support and provide access to existing platforms and tools focused on preparedness and response.

Additionally, CDC remains a critical partner in the nation's public health system and CDC's capacity for surveillance, technical assistance, and rapid deployment remains robust. Additionally, CDC continues to support state and local health departments through investments in longstanding programs like the Public Health Emergency Preparedness (PHEP) cooperative agreement. Recognizing that public health threats cross jurisdictions, the PHEP cooperative agreement encourages cooperation, coordination, and collaboration between recipients, preparedness partners, and the federal government.

HHS is committed to ensuring that state, tribal, local and territorial jurisdictions are prepared for the next public health threat.

    b. What if one state invests in preparedness but the next one doesn't?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

When developing the PHEP cooperative agreement, CDC identified 15 preparedness capabilities that are the foundation of a strong preparedness program. Through years of PHEP investments, jurisdictions have built, and are now maintaining, these necessary preparedness capabilities. Although this investment has established a baseline preparedness network across the nation, the jurisdictional cost of maintaining a robust preparedness program is significant. Public health threats require a robust, coordinated response, which will be weakened if jurisdictions do not continue to invest in their preparedness capabilities.

27. Given the Administration's intent to eliminate nearly $800 million in HIV prevention and surveillance programs as proposed in the FY2026 budget:
    a. How will CDC increase access to PrEP medication, which prevents HIV transmission?

Response:
CDC has made great strides in advancing PrEP access, between 2017 and 2022, the number of people that have been prescribed PrEP has increased by 181%. In 2023, state and local health departments used CDC Ending the HIV Epidemic (EHE) funding to screen more than 113,000 persons without HIV for PrEP and of those, 77% were eligible for PrEP. Additionally, more than 43,000 people were referred to a PrEP provider, over 24,000 people were linked to a PrEP provider, and nearly 19,000 people were prescribed PrEP. CDC investments in STI clinics also identified more than 21,000 patients as PrEP eligible, and of those, nearly 3,000 people were prescribed PrEP.

The Administration is committed to reducing government inefficiencies. HHS continues to support HIV prevention through proposed consolidation of these efforts in AHA. AHA's FY26 budget request includes $220 million for Ending the HIV Epidemic (EHE) activities formerly carried out at CDC, such as HIV surveillance and laboratory services, including outbreak response as well as $165 million for Ryan White EHE activities and $157 million for Health Center EHE activities.

    b. How will CDC address viral hepatitis surveillance, prevention, and linkage to care within the proposed budget framework?

Response:
CDC prioritizes cost-effective, burden based, and scalable programs to efficiently and effectively reduce incidence of viral hepatitis, STIs, TB, and opioid- related infections. CDC is committed to advancing viral hepatitis prevention, diagnosis, and treatment in the United States. We continuously identify opportunities to integrate the delivery of services to address related infections and recognize the commonalities across these infections and develop streamlined capacities that can be shared across programs. CDC provides state

and local health departments with the flexibility to design and implement interventions that address the local needs of their communities.

State and local health department capacity to conduct viral hepatitis surveillance and detect and respond to viral hepatitis outbreaks is limited. Viral hepatitis funding is vital to reducing incidence of viral hepatitis in the United States and achieving national goals to eliminate viral hepatitis as a public health threat by 2030. The Administration is committed to reducing government expenditures, which is why the Budget proposes a consolidated block grant that will provide States with more flexibilities as they tackle viral hepatitis, STIs, and TB.. CDC will continue to support state, local, and territorial health departments to implement proven public health interventions, conduct infectious disease surveillance to track and respond to outbreaks, and address the dynamic consequences these diseases present.

28. During your confirmation process, you promised to maintain the CDC ACIP. Yet earlier this month, you dismissed every single voting member of ACIP. Typically, ACIP members serve out their terms, which often span more than one Administration, and then the public was given the opportunity to nominate new ACIP members through an open process. You appointed new ACIP members without any open nomination process, and ACIP is now filled with vaccine skeptics whose stated views are in conflict with the overwhelming evidence and widely accepted science in support of the tremendous benefits and safety of vaccines.
    a. Is this an example of the "radical transparency" you promised?
    b. Are you aware that if ACIP removes recommendations for vaccines, insurers will no longer be required to cover those vaccines?

Response:
The Advisory Committee on Immunization Practices (ACIP) serves as a body of external experts who advise the CDC on the use of vaccines for the control of diseases. Established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended, the ACIP is a federal advisory committee charged with providing advice and guidance to the CDC Director regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. It is comprised of outside advisors appointed by the HHS Secretary, who develop recommendations for U.S. immunizations for consideration by the CDC Director, including the ages at which vaccines should be given, dosing regimens, and precautions and contraindications for individual vaccines.

Current information regarding ACIP and its activities may be found at the ACIP website, located at https://www.cdc.gov/acip/index.html.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

29. State and county health departments throughout the U.S. have not received funding from CDC's flagship $480 million HIV prevention grant, which should have been awarded by June 1. Many are issuing stop work orders to their local grantees who provide critical services like HIV testing, linkage to treatment or prevention services, and surveillance and tracking, which impedes our progress in reducing new HIV transmissions, increases healthcare costs, and erases the progress we have made in reducing HIV infection rates throughout the U.S.
    a. Can you confirm that Year 2 funding for this essential HIV prevention grant will be continued?
    b. If so, when will the funds be disbursed?
    c. If not, how will this information be communicated to grantees?
    d. What is the expected timeline for a decision on Year 2 funding?

Response:
CDC's Office of Grant Services began making awards for Year 2 funding of PS-24-0047: High-Impact HIV Prevention and Surveillance Programs for Health Departments starting on 6/24/25.

30. The CDC Division of HIV Prevention was heavily impacted by the Administration's Reductions in Force, which has led to some HIV grants being cancelled or delayed due to a lack of a project officer to oversee them. I understand CDC has rescinded some of those RIFs and re-instated some CDC staff.
    a. Was the staff that oversees this funding reinstated?
    b. Does the CDC Division of HIV Prevention have adequate staff to administer this funding without disruption or delay?

Response:
As of June 10, 2025, all branches in CDC's Division of HIV Prevention were reinstated, except for the Prevention Communications Branch. All critical functions of the Division of HIV Prevention remain operational.

31. More than 90 percent of federal funding for HIV Prevention (more than $1 billion per year) is administered by CDC. The HHS FY26 budget proposes a reorganization of HIV programs under AHA. This $1 billion for HIV prevention is missing under the current proposal.
    a. How does HHS plan to prevent the transmission of HIV without funding HIV prevention services through state departments of health?

Response:
To better address the health of all Americans, the Budget reflects the planned establishment Administration for a Healthy America (AHA). As part of this proposal, the Budget reflects the consolidation of HIV/AIDS funding within AHA. AHA's FY26 budget

request includes $220 million for Ending the HIV Epidemic (EHE) activities formerly carried out at CDC, such as HIV surveillance and laboratory services, including outbreak response as well as $165 million for Ryan White EHE activities and $157 million for Health Center EHE activities.

32. Tobacco use cost our nation nearly $241 billion each year and remains the leading cause of preventable death in our nation. You repeatedly highlight the need to address chronic disease and protect children's health, yet your elimination of CDC's Office on Smoking and Health and mass reductions in force for FDA's Real Cost youth tobacco prevention campaign tell a very different story about your department's true priorities. Multiple news reports indicate states have yet to receive CDC tobacco grants that were supposed to go out in April to support tobacco quitlines, youth prevention programs, and tobacco cessation campaigns, and some are already ceasing programs and laying off employees.
    a. Will you commit to restoring funding for CDC's Office on Smoking and Health to ensure that vital grants to support cost-effective tobacco cessation programs continue?

Response:
My Department and CDC are committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

    b. How does eliminating the Office of Smoking and Health advance America's health?

Response:
The FY 2026 President's Budget proposes to reform the CDC to focus the agency on its core mission. The CDC supports infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. HHS/CDC is committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

    c. How does this administration's views on tobacco use and smoking cessation align or differ with those of the previous administration?

Response:
The FY 2026 President's Budget proposes to reform the CDC to focus the agency on its core mission. The CDC supports infectious disease surveillance, outbreak investigations, preparedness and response, and maintaining the Nation's public health infrastructure. HHS/CDC is committed to ensuring that funds are used efficiently.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

d. Is it the position of HHS that you do not have to spend funds that Congress appropriated for FY2025, or will the full Fiscal Year 2024 $246.5 million funding level for CDC's Office on Smoking and Health be expended in Fiscal Year 2025?

Response:
We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

33. CDC's Office on Smoking and Health saves the government money by spending a mere $246.5 million to cost-effectively address a preventable healthcare problem costing our nation $241 billion, the majority of whose costs are paid for by government.
    a. What is the projected increase in costs to Medicare, Medicaid, and private insurers due to the elimination of CDC's Office on Smoking and Health?

Response:
My Department is committed to chronic disease prevention work, including tobacco cessation efforts.

34. Secretary Kennedy, you have talked about the need to protect kids from toxic substances and addiction. According to FDA's and CDC's 2024 National Youth Tobacco Survey, 42.1% of youth e- cigarette users report vaping on 20 or more days a month, and roughly 70% of youth e-cigarette users say they use e-cigarettes because they come in flavors they like.
    a. What actions do you plan to take to protect kids from flavored tobacco products?
    b. How has your administration's elimination of CDC's Office on Smoking and Health and FDA's Real Cost youth tobacco prevention campaign impacted these efforts?

Response:
Under the proposed budget, tobacco cessation programs at HHS will continue, including $19.6 million in funding for the Assistant Secretary for Health and Surgeon General. This funding will allow the PHR journal to lead gold standard science with a focus on emerging public health concerns and topics, such as disease surveillance, chronic disease prevention, substance use disorders, mental health, and tobacco use in support of enhancing the health and well-being of all Americans.

The 2024 National Youth Tobacco Survey results showed that tobacco product use among U.S. middle and high school students has dropped to the lowest recorded level in 25 years. More recently, that decline has been driven by reductions in e-cigarette use, which has declined by more than 70% over the past five years. That includes half a million fewer kids using these products within the past year alone. See https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey-nyts.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

HHS and FDA remain focused on the mission to protect the public health of the U.S. population from tobacco-related death and disease. One of the main goals of this mission is to prevent people from starting to use tobacco products, and this includes youth.

35. You fired employees at FDA's Real Cost campaign just weeks after your agency announced that the campaign had prevented an estimated 444,252 youth from starting to use e-cigarettes between 2023 and 2024.
    a. Will you commit to ensuring this highly effective campaign continues?

Response:
FDA remains committed to educating youth about the health effects of tobacco product use.

36. FDA to date has denied applications for nearly all flavored e-cigarettes.
    a. Do you agree that flavored e-cigarettes pose an unacceptable risk to youth?

Response:
In accordance with the law, FDA continues to evaluate the impact of flavors in e-cigarettes through our premarket review of tobacco product applications, which ensures that each new product that is introduced to the U.S. market is appropriate for the protection of the public health ("APPH"). FDA reviews each individual premarket tobacco application (PMTA). FDA conducts a multidisciplinary review of multiple factors based on available information when assessing if a new tobacco product is APPH. It is the responsibility of the applicant to provide evidence to demonstrate that the marketing of their product meets the statutory requirements.

    b. What steps do you plan to take to clear the market of unauthorized, flavored e-cigarettes?

Response:
FDA's Center for Tobacco Products (CTP) actively monitors industry compliance with the law through surveillance, inspections, and investigations, and continues to harness market intelligence and other data to inform our enforcement strategies. To date, FDA has issued over 780 warning letters to firms for manufacturing, selling, or distributing unauthorized new tobacco products, as well as more than 860 warning letters to retailers for selling these products. In addition, FDA has filed Civil Money Penalty (CMP) complaints against 87 manufacturers and over 175 retailers for violations of the FD&C Act related to unauthorized tobacco products.

37. President Trump's budget proposal included the elimination of CDC's National Center for Chronic Disease Prevention and Health Promotion. This Center manages several chronic disease prevention divisions such as the Division on Diabetes Translation (DDT), which conducts critical diabetes surveillance and translational work.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. If the National Center for Chronic Disease Prevention and Health Promotion is eliminated, what will happen to divisions such as DDT?
b. Does the administration plan to absorb these workstreams into another agency or will these programs be eliminated entirely?

Response (a-b):
Under the proposed reorganization, the programs within the National Center for Chronic Diseases Prevention and Health Promotion will be moved to the Administration for a Healthy America. The President's Budget invests in funding to support the goals of the Administration to Make America Healthy Again (MAHA) initiative by addressing the root causes of America's escalating health crises, chronic conditions that lead to poorer health outcomes. The Prevention Innovation (PI) program provides communities with new and practical ways to support the goals of the MAHA initiative by addressing the root causes of America's escalating health crises, focusing on chronic conditions that lead to poorer health outcomes in rural areas. The Budget increased access to chronic disease prevention and management by funding approximately 1,400 Health Centers operating more than 15,000 service sites nationwide, each working with communities to improve the health and well-being of patients through the prevention and management of chronic diseases, such as diabetes and hypertension. This Budget Request will support services and capacity-building activities for rural communities in improving rural community health by focusing on chronic disease management.

38. President Trump's budget eliminates CDC's cancer prevention programs, including programs that provide cancer screenings to under-resourced communities like the National Breast and Cervical Cancer Early Detection Program, and programs that raise awareness of deadly, disfiguring, and largely preventable cancers like the National Skin Cancer Prevention Program. Unfortunately, it appears that these programs are not going to be part of AHA.
    a. How will you support the continuation of important Cancer Prevention and Early Detection programs?

Response:
The FY 2026 President's Budget proposes to reform the CDC to focus the agency on its core mission of detecting and preventing infectious diseases. Under the proposed reorganization, the programs within the National Center for Chronic Diseases Prevention and Health Promotion will be moved to the Administration for a Healthy America. The President's Budget invests in funding to support the goals of the Administration to Make America Healthy Again (MAHA) initiative by addressing the root causes of America's escalating health crises, chronic conditions that lead to poorer health outcomes. The Prevention Innovation (PI) program provides communities with new and practical ways to support the goals of the MAHA initiative by addressing the root causes of America's escalating health crises, focusing on chronic conditions that lead to poorer health outcomes in rural areas. The Budget increased access to chronic disease prevention and management by funding approximately 1,400 Health Centers operating more than 15,000 service sites nationwide, each working with communities to improve the health and well-being of

patients through the prevention and management of chronic diseases, such as diabetes and hypertension. This Budget Request will support services and capacity-building activities for rural communities in improving rural community health by focusing on chronic disease management.

39. You disbanded the existing ACIP committee and replaced it with outspoken anti-vaccine activists and skeptics — including Robert Malone, Vicky Pebsworth, and Martin Kulldorff.
    a. What objective criteria, other than ideological alignment, qualified these individuals to oversee vaccine policy for 330 million Americans?

Response:
The Advisory Committee on Immunization Practices (ACIP) serves as a body of external experts who advise the CDC on the use of vaccines for the control of diseases. Established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended, the ACIP is a federal advisory committee charged with providing advice and guidance to the CDC Director regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. It is comprised of outside advisors appointed by the HHS Secretary, who develop recommendations for U.S. immunizations for consideration by the CDC Director, including the ages at which vaccines should be given, dosing regimens, and precautions and contraindications for individual vaccines.

Current information regarding ACIP and its activities may be found at the ACIP website, located at https://www.cdc.gov/acip/index.html.

40. You called the prior ACIP committee "a rubber stamp for industry profit-taking agendas", but you have put on multiple new appointees whose profits appear to rise as vaccine confidence falls. Several new appointees earn income from speaking fees, social media revenue (i.e., Tweets), Substack newsletters, or consultancy work premised on vaccine doubts.
    a. Did HHS ethics officials clear these financial ties before their selection? Please provide the written determinations. ("Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC.")
    b. Please provide justification for your recent revision of ACIP's COVID-19 vaccine recommendations for children and pregnant women.
    c. What transparent and evidence-based process was utilized when you rescinded the recommendation for COVID-19 vaccine in certain populations?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

ACIP members are appointed as SGEs. All SGEs have a fiduciary responsibility to the federal government and must follow comprehensive federal ethics laws, including the criminal conflicts of interest and financial disclosure reporting laws, and the Standards of Ethical Conduct for Employees of the Executive Branch. All SGEs must comply with the financial disclosure requirements found in the OGE regulations.

HHS ethics officials ensured the financial interests and affiliations reported by ACIP members complied with applicable conflicts of interest statutes, regulations issued by OGE, additional agency requirements, and other applicable Federal ethics rules.

41. Why do unvaccinated kids die at a higher rate from flu than vaccinated kids?

Response:
On July 22, 2025, I adopted the ACIP committee's recommendation for routine annual influenza vaccination of all persons 6 months and older who do not have contraindications for the 2025-2026 season.

42. Why do unvaccinated kids die at a higher rate from measles than vaccinated kids?

Response:
As I have stated before, I support the measles vaccines. The most effective way to prevent the spread of measles is the MMR vaccine. I will do nothing as Secretary of the Department of Health and Human Services that makes it difficult or discourages people from taking the measles vaccines.

43. How will CDC comply with Freedom Of Information Act (FOIA) requests given the FOIA office has been given reduction in force notices and are on administrative leave?
    a. When will staff in CDC's FOIA office be returned to their duties?

Response:
My Department will continue to meet all statutorily required obligations. CDC is working with HHS to ensure that legal mandates under the Freedom of Information Act are fulfilled without interruption. Strategic workforce planning and resource realignment efforts are being implemented to support the Department's continued compliance with its statutory responsibilities.

44. What is the current status of the U.S. measles outbreak?
    a. How are you supporting CDC's measles response?
    b. What more should HHS and CDC be doing to maintain the United States' measles elimination status?
    c. Why isn't CDC providing regular public updates on the measles outbreak?
    d. What guidance, support, and resources is CDC/HHS offering to state and local health departments that are managing outbreaks in their jurisdictions?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
As of Thursday, July 24th, 1,325 measles cases have been reported, of which 87% are outbreak-associated, linked to 29 outbreaks so far this year. CDC's measles response consists of four objectives: monitor, mitigate, inform, and engage. CDC informs by providing up-to-date public-facing information regarding the current state of measles in the United States and share actionable information to prevent or treat disease. Since the start of the outbreak, CDC has posted weekly data updates on the Outbreak webpage. Additionally, CDC has held a series of bi-weekly calls with partners, clinicians, and affected jurisdictions to share information, receive feedback and address emerging issues.

CDC is actively engaged in responding to measles outbreaks. CDC is supporting states that request assistance with measles cases or outbreaks and helping states prepare for measles outbreaks. Three CDC teams traveled to Texas to support measles case investigations and public health follow-up at the request of the Texas Department of State Health Services (DSHS). Additionally, CDC has also provided on-the-ground support to the New Mexico Department of Health (NMDOH) and more recently, CDC provided similar support to the Kansas Department of Health & Environment (KDHE). CDC provided virtual support to other states with measles cases and outbreaks, as has been standard practice even in non-outbreak situations. CDC's efforts included offering technical assistance, laboratory support, and vaccine supply, at the request of the jurisdictions.

In response to the Southwest outbreak (Texas, New Mexico, and Oklahoma), CDC made 7,000 MMR vaccine doses available to the Texas DSHS, 2,900 doses to the NMDOH, and 2,000 doses to the Oklahoma State Department of Health, at the request of the jurisdictions.

In addition to working directly with jurisdictions, who are the lead authority in responding to disease outbreaks within their states, CDC posted the Be Ready for Measles Toolkit to understand the potential impact of isolation, quarantine, and vaccination on the size of a measles outbreak and created a CDC Measles Outbreak Simulator to provide outbreak response tools and communication materials.

CDC continues to provide epidemiological support, laboratory guidance for quality assurance, and technical assistance to any jurisdiction requesting it. Additionally, CDC has expanded and standardized testing for wastewater surveillance for measles with the National Wastewater Surveillance System (NWSS) and Center of Excellence in Texas and an additional 200 sites around the US.

In July, CDC awarded 66 state, territorial, and local jurisdictions with funding that provides critical resources for jurisdictions to prevent and control outbreaks of vaccine-preventable diseases (VPDs), like measles.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

45. Food and Drug Administration (FDA) Commissioner Dr. Martin Makary and Center for Biologics Evaluation and Research (CBER) Director Dr. Vinay Prasad recently published an article in the Journal of the American Medical Association laying out priorities the FDA seeks to accomplish, including a creating full inventory of concerning additive ingredients for food and over-the-counter drugs in the US that are not allowed in other developed countries.
    a. How will your Department review the existing scientific literature on this topic?

Response:
In 2024, FDA announced its plan to create a more systematic and risk-based approach to reassessing the safety of additives and ingredients in our food supply. FDA issued a discussion paper, held a public meeting, solicited public comment, and intend to finalize our process for this systematic post-market assessment program later this year.

    b. Will the evidence base and FDA's findings be made public?

Response:
FDA intends to publish our assessments of individual chemicals in foods that are being assessed as part of our systematic post-market review process. These assessments will describe the science upon which we may base any regulatory decisions.

    c. What threshold will FDA measure additive ingredients against to appropriately balance the benefits and harms of each ingredient?

Response:
The safety of food additives is evaluated using robust risk assessment approaches that take into consideration scientific information on the nature of the substance, its use levels, and safety and toxicity data. All ingredients and additives used in food must be supported by science that demonstrates its use meets the FDA's safety standard for additives and ingredients in food– a reasonable certainty of no harm. The reasonable certainty of no harm safety standard does not include a risk-benefit analysis; all substances added to food must be safe at their level of use.

46. What criteria will HHS use to determine which pharmaceutical companies or products qualify for the national priority review program?

Response:
Under the Commissioner's National Priority Voucher Pilot Program (CNPV), eligibility will be based on criteria of national priority including, but not limited to:

- **Addressing a health crisis in the U.S.**
- **Bringing potential innovative therapies to the American people.**
- **Addressing a large unmet medical need.**
- **Increasing affordability.**

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

47. FDA currently maintains an Essential Medicines List that has not been updated since May 2022.
    a. What steps would you take to ensure this list is regularly updated with supply chain vulnerabilities in mind—particularly for products heavily reliant on foreign adversaries like China for active pharmaceutical ingredients (APIs) and key starting materials (KSMs)?

Response:
Pursuant to Executive Order 13944, FDA created a list of Essential Medicines, Medical Countermeasures, and Critical Inputs in 2020 based on the EO's policy of protecting our citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. In follow up to this work, in 2022 the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) (now the Administration for Strategic Preparedness and Response) identified and developed a list of 86 of the most critical medicines needed for acute patient care from FDA's 2020 list through further consultation with experts and by review of the public comments submitted to the docket for the FDA Essential Medicines List.

48. Would you support directing HHS to map the full supply chains of essential medicines to identify vulnerabilities, including indirect dependencies on China for antibiotic APIs and KSM's?

Response:
Understanding gaps and vulnerabilities in the domestic supply chain is critical to enhance preparedness and eventual response to public health and medical emergencies and disasters. HHS is working on this effort and will support development of processes and tools to better understand manufacturing dependencies and challenges that predicate impacts to the supply chain.

49. Are there any critical gaps in data or information that HHS currently lacks or is unable to collect, which may prevent the Department from obtaining a comprehensive understanding of the full supply chains for essential medicines?

Response:
The United States has historically relied on overseas suppliers for many essential medicines—creating strategic vulnerabilities in the health care supply chain. HHS continues to work with industry and government partners to identify innovative and agile manufacturing models and increase visibility of supply chain vulnerabilities and dependencies, including any data gaps, and ways to minimize those challenges.

50. On April 22, 2025, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) announced a series of measures to eliminate synthetic

dyes from products marketed in the United States. However, the measures did not include mandatory steps for companies to phase out the use of synthetic dyes and is instead a request that companies voluntarily comply.

a. How will HHS and FDA work with manufacturers who do not agree to voluntarily comply?

Response:
Across the country, companies are stepping up and reformulating their products with alternative colors derived from natural sources and setting ambitious timelines to complete the transition. We will continue to work with industry to encourage the phase out of the use of these petroleum-based synthetic color additives. As always, we are committed to exploring the full range of our authorities as necessary and appropriate to protect public health.

b. Will HHS and FDA consider incentives for manufacturers and companies that choose to remove synthetic dyes and other additive ingredients from their products?
    i. What incentives would be feasible and within HHS' and FDA's regulatory flexibilities?

Response:
HHS and FDA announced its intent to work with industry to phase out petroleum-based synthetic dyes just 4 months ago, and we have been pleased by industry's response thus far. We will continue to monitor industry's pledges and actions and will consider taking further action if needed. See: Tracking Food Industry Pledges to Remove Petroleum Based Food Dyes | FDA

c. Given that compliance with HHS' and FDA's request is currently voluntary, is there consideration being given to revoking the authorization for synthetic dyes and other additive ingredients?
    i. If yes, how will FDA ensure there is a phased timeline for withdrawing additive ingredients from products marketed in the U.S.?
    ii. What does HHS envision an appropriate transition timeline would look like?

Response:
Currently, FDA is working to revoke the authorizations for Orange B and Citrus Red No. 2, though we do not anticipate the revocations will have any meaningful impact on industry since we believe industry has largely abandoned their use. If we deem similar action necessary for other petroleum-based synthetic color additives, we will consider a phased approach to allow industry to reformulate products. Regarding other additives, please see List of Select Chemicals in the Food Supply Under FDA Review.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

51. FDA appears to be losing key leadership each week. Just recently, the departure of the two most senior officials at FDA overseeing the review of gene and stem cell therapies was reported. Now there is the imminent departure of the Acting Director of the Center for Drug Evaluation and Research.
    a. How will you and FDA ensure these positions are filled in a timely manner and with qualified candidates who have the necessary training and expertise to lead these important offices?

Response:
FDA has a strong track record of recruiting senior leaders and each FDA center is currently being led by highly qualified senior leaders. FDA anticipated the retirement of the Acting Director, Center for Drug Evaluation and Research. FDA will continue to build on its strong track record to find the qualified candidates to advance the MAHA agenda.

52. Has FDA conducted an analysis to determine whether it has sufficient numbers of staff with the necessary experience to negotiate the next round of medical product user fee agreements? If so, please provide that analysis.
    a. How many staff who contributed to the previous round of medical product user fee agreements have left FDA since January 20, 2025?
    b. How does FDA plan to ensure that it has sufficient staff for the next round of medical product user fee agreements?

Response:
I am confident that FDA has sufficient staff for the next round of medical product user fee agreements.

53. Last year, FDA Center for Drug Evaluation and Research (CDER) approved 50 new drugs never before approved or marketed in the U.S., known as "novel" drugs. In addition, the Center for Biologics Evaluation and Research approved more than a dozen of new biological products, including life-saving cell and gene therapies.
    a. How will you ensure that the reductions in FDA staff at CDER and CBER do not delay key drug and biologic development and review activities, such as meetings with sponsors and review timelines?

Response:
FDA has continued to meet the majority of user fee goals across Centers. Performance data and user fee performance reports can be found at: Performance Data | FDA. FDA will continue to prioritize timely review of products in accordance with user fee commitments.

54. Please detail the following:
    a. Food and color additives under current FDA review

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The list of select chemicals in the food supply under post-market review is available here: List of Select Chemicals in the Food Supply Under FDA Review | FDA. FDA's Office of Premarket Additive Safety also reviews the safety of new and expanded uses of additives and ingredients used in food through various pre-market programs. FDA reviews submissions for these pre-market review programs as they are received and maintains public databases for all completed submissions. A list of food additives and color additives under pre-market review can be found here: Food Additive and Color Additive Petitions Under Review or Held in Abeyance. Through our food contact notification program, FDA performs pre-market safety evaluations of chemicals and ingredients included in submissions received from industry for uses of food contact substances. We also perform safety evaluations of other food substances through our voluntary generally recognized as safe (GRAS) notification program. We maintain inventories of our reviews of food contact notifications and GRAS notices on our website.

b. Food and color additives that FDA is otherwise prioritizing for future review

Response:
FDA recently released its proposed method for ranking chemicals in the food supply for post-market assessments. Once finalized, this method will provide a transparent, systematic, and science-based approach to determine which chemicals the Agency will prioritize for post-market assessments through the Agency's post-market chemical review program in the future.

c. The basis of potential safety concerns for food and color additives under current or future FDA review

Response:
FDA is made aware of potential safety concerns for approved food and color additives through many different means, including through regular monitoring of the scientific literature, through petitions, and through working with federal partners on new studies on the safety of a particular substance. As such, the basis for any potential safety concerns vary widely across additives. As part of our systematic post-market assessment process, we intend to be transparent in outlining the rationale for any regulatory action taken (or not taken) on a chemical as a result of a safety assessment.

d. The current status of the FDA review of food and color additives

Response:
The List of Select Chemicals in the Food Supply Under FDA Review | FDA contains a column listing the status of each chemical under review.

e. A timeline of review for each food and color additive

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

We are currently developing timelines for the review of each of the chemicals currently under review.

f. Additive ingredients are also used in over-the-counter (OTC) ingested drug products.
    i. Will the FDA's review processes include additive ingredients used in OTC, ingested drug products?

Response:
An inactive ingredient is any component of a drug product other than the active ingredient. For drugs subject to pre-market review and approval, FDA reviews inactive ingredients prior to marketing. Manufacturers of drugs marketed under section 505G of the FD&C Act (i.e. OTC monograph drugs), which are not subject to pre-market review and approval of individual products, are responsible for ensuring that the inactive ingredients in their products are safe and suitable for the intended use as a drug product component.[1]

g. While the appropriations process and FDA's plan to complete a comprehensive review of food and color additives move forward, what steps can HHS and FDA take in the interim to enhance transparency in how OTC products that include additive ingredients are labelled?

Response:
All nonprescription drug products are required to list inactive ingredients as part of the Drug Facts Label. In addition, the Inactive Ingredient Database provides information on inactive ingredients in FDA-approved drug products. This database is available to the public.

55. Four Prescription Drug User Fee Act (PDUFA) dates have been missed so far this year. Why?

Response:
Historically, FDA meets approximately 90% of UFA goals. FDA has continued to meet the majority of user fee goals across Centers and expects to meet over 90% of PDUFA goals this year. Performance data and user fee performance reports can be found at: Performance Data | FDA. FDA will continue to prioritize timely review of products in accordance with user fee commitments.

56. Major changes in FDA policy have been announced in the Journal of the American Medical Association since the beginning of this administration.
    a. Will FDA issue guidance relating to these policies?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The framework outlined in the NEJM represents a commitment to an evidence-based approach, and FDA will follow its standard practices with respect to engaging with sponsors about their specific applications in the context of scientific review.

b. Will FDA commit to announcing future policy changes through official agency communication and not through third parties?

Response:
FDA intends to follow applicable legal requirements.

57. Will CDER align its approach to smoking cessation products with those for treating other forms of addiction (i.e., a focus on harm reduction rather than total abstinence)?

Response:
Nicotine use disorder and other substance use disorders (e.g., opioid use disorder) are very different, even though they fall into the same general category of addictive disorders. In general, different substance use disorders have different mechanisms of action and clinical effects that may lead to differences in clinical presentation and responses to treatment. As a result, study designs, patient populations, and endpoints may differ across therapeutic areas targeting different forms of addiction.

58. How will you ensure the Department, and specifically CDER at FDA, approaches the risk-benefit considerations for nicotine replacement therapies in a manner that better reflects common sense and the real-world realities of how hard it is to quit and the sustained unmet need for patients who continue to fail in their quit attempts?

Response:
Nicotine is a highly addictive substance, making nicotine dependence a very challenging condition to treat. The reasons for low success quit rates include multiple factors unrelated to availability of safe and effective smoking cessation products, such as weight gain, lack of access to effective therapies due to financial hardship, exposure to other smokers and secondhand smoke, loss of an ability to manage stress, and comorbid alcohol and other substance use disorders. Fewer than one-third of smokers who try to quit use counseling and FDA-approved smoking cessation drug products, which is one potential area for intervention.

FDA's 2023 Nicotine Replacement Therapy (NRT) Guidance provides recommendations regarding development of novel therapies that go directly in the hands of consumers in the nonprescription setting, without going through development as a prescription product first. As such, it outlines the review pathways available to get approval direct to over-the-counter (OTC), which reduces potential hurdles for access, and provides recommendations for manufacturers to get novel products over the goal line for approval. It also outlines the abbreviated review pathways available for NRT products, including how to use FDA's

previous findings of safety and how already approved NRT products and published literature can be leveraged. Finally, the NRT Guidance encourages sponsors to consider expedited development and review pathways and provides details on how to qualify for this review.

59. Recent reporting has highlighted declining morale at the FDA, along with leadership departures and staff seeking employment elsewhere.
    a. What specific steps is HHS taking to prevent further brain drain and retain experienced scientific and regulatory staff at the FDA?

Response:
My Department remains firmly committed to preserving and advancing scientific excellence and leadership across all its components. As we undertake strategic workforce planning efforts, HHS will continue to prioritize mission-critical positions – including top-tier scientific and public health professionals – that directly support our mission and enhance the Department's ability to meet global evolving health needs.

60. Has the FDA experienced any measurable delays in new drug applications (NDA), biologics license applications (BLA), or device review timelines due to staffing or budget constraints?

Response:
FDA has continued to meet the majority of user fee agreement goals across Centers. Performance data and user fee performance reports can be found at: Performance Data | FDA. FDA will continue to prioritize timely review of products in accordance with user fee commitments.

    a. What steps is the agency taking to mitigate any backlogs?

Response:
FDA has continued to meet the majority of user fee agreement goals across Centers. Performance data and user fee performance reports can be found at: Performance Data | FDA. FDA will continue to prioritize timely review of products in accordance with user fee commitments.

61. Does HHS have any plans to modernize or revamp FDA's advisory committees, particularly those focused on vaccines and biologics?
    a. If so, what changes are under consideration?
62. How does HHS plan to increase transparency and public trust in the advisory committee process, particularly in areas that have become highly politicized?

Response (61-62):

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

We need to do all we can to get the right expertise and minimize conflicts of interest and give FDA the flexibility it needs to structure advisory committees in a manner that most appropriately meet the needs of patients by adhering to gold standard science.

63. The FY2026 budget proposes consolidating three key Substance Abuse and Mental Health Services Administration (SAMHSA) formula grant programs into a new Behavioral Health Innovation Block Grant.
    a. How will HHS ensure that this new structure maintains or enhances states' ability to fund overdose prevention efforts, especially those that also rely on targeted programs like First Responder Training that the President's Budget is proposing to eliminate?

Response:
Behavioral health encompasses preventing substance use and providing treatment to people with a substance use disorder. Overdose prevention is an important tool for addressing substance use as it saves lives and provides linkages to services whether for substance use prevention or treatment. AHA will continue to support the full behavioral health continuum of care. It is noted that the new Behavioral Health Innovation Block Grant will allow for state flexibility to provide overdose prevention efforts.

64. Many states have used federal funding, including from the State Opioid Response (SOR) program and the Substance Use Prevention, Treatment, and Recovery Services (SUPTRS) block grant, to fill gaps in their state Medicaid programs to address overdoses.
    a. How does the proposed budget protect or expand this vital role for federal discretionary dollars in overdose prevention to maximize treatment access, particularly in states with high rates of opioid-related deaths?

Response:
As overdose prevention and maximizing treatment access is an extremely high priority for the Trump administration, it is anticipated that grantees will aggressively target the use of federal discretionary Behavioral Health Innovation Block Grant dollars for lifesaving overdose prevention, intervention, and treatment interventions. Strategies include partnering with a broad array of vital community partners for the coordination and delivery of widespread prevention and education activities related to overdose, reducing barriers to treatment engagement and retention, and actively supporting community recovery activities for individuals and their families. These strategies specifically target states and communities with high rates of opioid-related deaths with services and approaches that are specific to the needs of these grantees.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

b. How does the FY 2026 budget ensure that prevention efforts evolve to meet the changing nature of drug use, including through investments in research, harm reduction, and community outreach?

Response:
Substance use prevention includes primary prevention, where evidence-based programs focus on preventing drug use in their communities. Drug Free Communities and Behavioral Health Innovation Block Grant grantees will utilize the Strategic Prevention Framework in their communities to assess what type of prevention interventions are needed and whether those interventions are effective.

65. Your Department eliminated the 'press 3 option' for LGBTQ+ youth on the 988 Suicide and Crisis Lifeline, which has served roughly 1.3 million callers since its pilot program in 2022.
    a. What criteria did you use to identify this option for elimination, as opposed to other options including the 'press 1 option' for veterans seeking similarly specialized support?

Response:
As of June 2025, more than $33 million in FY24 funds had been spent to support the Press 3 subnetwork. Continuing to fund the Press 3 option would have drawn funds away from broader 988 Lifeline services, most notably the national backup crisis contact centers for calls, chats and texts. These backup contact centers provide coverage for all Americans when local centers are not able to respond to people in crisis within an acceptable time range. An important distinction between the Veterans "Press 1" and "Press 3" is that SAMHSA does not provide funding for the calls that go to the Veterans Crisis Line, as that service is entirely funded by the Veterans Administration.

    b. What additional training, if any, did your Department offer to crisis counselors?
        i. Please provide all emails or other communications disseminated to crisis counselors and administrators of the 988 Lifeline regarding the elimination of the 'press 3 option.'

Response:
The Lifeline Administrator provided 30 days notice to all impacted centers in June of 2025. As most of the impacted centers provide additional services through the 988 Lifeline network and/or other crisis care, many counselors were able to transfer to other available service lines during this time. Communication was also provided to all centers in the broader Lifeline network to ensure access to training materials in working with all populations at higher risk of suicide, as well as information to states on Press 3 volume originating from within their jurisdictions to optimize preparation for any shifts in local volume. As mentioned above, the communication to all 988 crisis centers prior to the

closure of Press 3 included but was not limited to guidance documents, training corners, and basic awareness/educational training on areas for specific consideration in supporting individuals at higher risk.

66. You touted the promising potential of Journavx, a non-opioid pain relief treatment recently approved by FDA, during your appearance before the committee.
    a. Did your Department conduct an analysis of the impacts to patient access to such alternatives to opioids prior to planning elimination of the Emergency Department Alternatives to Opioids Program in your Department's FY26 Budget?
    b. Did your Department conduct a similar cost-benefit analysis in eliminating State Opioid Response Grants?
        i. If so, how will this elimination impact state ability to respond to the opioid crisis?

Response:
As overdose prevention and maximizing treatment access is an extremely high priority for the Trump administration, it is anticipated that grantees will aggressively target the use of federal discretionary Behavioral Health Innovation Block Grant dollars for lifesaving overdose prevention, intervention, and treatment interventions.

67. The FY2026 budget request proposes moving components of CDC, such as Overdose Data to Action (OD2A) program, to the Administration for a Healthy America.
    a. Are you proposing that the CDC experts would also transfer? If not, who would staff these programs?

Response:
There was a 17.1% decline in overdose deaths in the 12 months ending in October 2025, demonstrating the success of the Trump Administration's efforts to end the influx of illegal fentanyl into the United States that proliferated under the Biden Administration's open border policies. Substance use disorder and overdose prevention remain a top priority for the entire department. The Opioid Overdose Prevention and Surveillance program request in the Fiscal Year 2026 Congressional Justification for the Administration for a Healthy America will continue to support overdose prevention of suspected nonfatal opioid-involved overdose ED visits in June 2025 remained 6.5% lower than in June 2024.

    b. CDC staff play a unique role in overdose prevention by providing world-class expertise to track emerging data patterns, develop prevention strategies, and deliver actionable guidance to state and local jurisdictions. The FY26 President's Budget proposes this work move into AHA. Would existing programs, such as OD2A, which have helped contribute to a significant decline in overdose deaths in the past year, look different under AHA?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The FY 2026 AHA Congressional Justification requests $475.6 million for the Opioid Overdose Prevention and Surveillance program, which will fund overdose prevention and support for 49 states, the District of Columbia, and 40 localities through the Overdose Data to Action in States (OD2A-S) and Overdose Data to Action: LOCAL (OD2A: LOCAL) initiatives. Continued progress on the overdose crisis requires maintaining connections to existing CDC's data infrastructure, laboratory capabilities, and response capabilities. The Administration is actively discussing this transition, and HHS will keep Congress informed.

c. How would AHA programs interact with CDC laboratories, which help states identify contaminants and emerging threats in the drug supply?

Response:
The OD2A program relies upon CDC's laboratory expertise to help jurisdictions track and respond to emerging drug threats. OD2A's innovative surveillance strategies, which are at the cutting edge of identifying emerging drug trends, are inextricably linked to the critical laboratory expertise housed in CDC's National Center for Environmental Health. The Administration is actively discussing how to maintain the critical data and laboratory infrastructure between programs proposed to move to AHA and capabilities expected to remain at CDC. HHS is happy to keep Congress informed as decisions are made.

68. What is the desired outcome of HHS' reductions in force (RIF)?
    a. What performance targets using to determine whether there are sufficient staff in HHS' OpDivs?
    b. What prospectively set, objective metrics is HHS using to determine whether the goals of the RIFs have been met?
69. What prospectively set, objective metrics is HHS using to determine whether the proposed reorganization is successful?

Response (68-69):
The Department's reduction in force was administered in compliance with President Trump's Executive Order issued on February 11, 2025, "Department of Government Efficiency Workforce Optimization Initiative."

All of HHS's actions adhered to applicable statutes, regulations, and guidance.

70. How many HHS employees have received RIF notices since you were sworn in?
    a. Did you approve the layoff decisions?
    b. On April 3, you stated that 20 percent of workers laid off through the RIF would be reinstated and that was "always the plan." Have 20 percent of the workers who received RIF notices been reinstated?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

I was briefed and approved the high-level overall plan for the Department, as I announced in my public address in March. Any employees who were reinstated were done so at the request of their agency/Operating Division leaders.

71. Community Health Centers (CHC) have had level funding for the last ten years, even though the CHC program has grown over the last decade. The administration, in its proposed budget for the Department of Health and Human Services for Fiscal Year 2026, highlights the importance of Community Health Centers, by writing: "For nearly 60 years, health centers have delivered affordable, accessible, high-quality, and cost-effective primary health care to patients regardless of their ability to pay…. Health centers have become an essential primary care provider for millions of medically underserved, low-income people across the country."
    a. Does Congress provide sufficient funding for CHCs?
    b. Are CHCs able to meet demand given current funding?

Response:
The FY 2026 President's Budget request will enable health centers to continue to provide high quality, cost-effective primary care services to over 32 million patients.

72. At the same time that you propose level funding for Community Health Centers in your Fiscal Year 2026 budget, you propose to cut critical workforce programs, particularly the Area Health Education Centers (AHEC), which support future generations of health care workers to Community Health Centers.
    a. Do you agree that there are health workforce shortages across the country?

Response:
The FY 2026 President's Budget provides $948 million in mandatory and discretionary funding for health workforce programs. It focuses on strengthening the workforce in rural and underserved areas through scholarship and loan repayment programs with a service requirement and supporting behavioral health training. This includes $473.6 million for the National Health Service Corps to support an estimated 6,600 new scholarship and loan repayment awards, and an anticipated field strength of nearly 12,800 primary care, behavioral health, and oral health providers serving in communities of greatest need. These investments help expand access to care and improve health outcomes nationwide.

Funding requested for health workforce priorities in FY 2026 also includes $175 million in mandatory funding for the Teaching Health Center Graduate Medical Education Program. It expands the medical workforce by supporting graduate education in medicine, dentistry, and behavioral health in teaching health centers. These health centers will provide hands-on training to residents in community-based settings. In FY 2026, the program will support over 1,200 resident full-time equivalent slots. The Budget also includes funding for the

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

NURSE Corps, the Pediatric Subspecialty Loan Repayment Program, and Centers of Excellence, all of which also help address clinician shortages nationwide.

b. How does eliminating AHECs serve to mitigate such shortages?

Response:
My Department addresses health workforce shortages through a variety of programs that provide funding for training and development of health workers. The FY 2026 President's Budget requests funding to support the National Health Service Corps, Teaching Health Center Graduate Medical Education program, Nurse Corps, Pediatric Specialty Loan Repayment Program, and Centers of Excellence, which work to mitigate health workforce shortages across the country.

73. Did Elon Musk consult with you on the new approval process requiring budget justifications for routine drawdowns implemented within your Department?
    a. Who is responsible for approving drawdowns?

Response:
In accordance with President Trump's Executive Order 14222, "Implementing the President's "Department of Government Efficiency," my Department is utilizing the "Defend the Spend" system. This system was created to enhance transparency and accountability on federal grant spending to the American public. The system requires grant recipients to submit a brief, written justification for each payment request, then requires HHS staff to promptly review and submit a brief written justification for the payment prior to approval.

74. Over a decade ago, the National Alzheimer's Project Act (NAPA) was signed into law. This landmark law has led the way for policy advances, including the first National Plan to Address Alzheimer's Disease, the implementation of which is overseen by the Advisory Council on Alzheimer's Research, Care, and Services. Congress has just renewed its commitment to all Americans affected by the disease by reauthorizing NAPA. The Advisory Council has not met since January, and this delay could result in a delay in the progress of the plan.
    a. When will the Advisory Council meet next?

Response:
The ongoing work of the Advisory Council on Alzheimer's Research, Care and Services will continue as planned and in accordance with the intent of the NAPA. Any updates pertaining to the Council and upcoming meetings will be posted here.

75. Will you prioritize responses to inquiries from members of the Committee on Energy & Commerce, given its jurisdiction over your agency?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Department will continue to prioritize Congressional inquiries, including from those on committees of jurisdiction.

76. Recommendations of the US Preventive Services Task Force (USPSTF) play an important role in supporting evidence-based decisions for coverage of clinical laboratory and other health care services by Medicare, Medicaid, and other third-party payers. The President's FY 2026 Budget proposes a $129 million cut to the Agency for Healthcare Research and Quality (AHRQ), which provides funding for USPSTF's work, and moves AHRQ's functions to the new HHS Office of Strategy. USPSTF was already struggling to update its recommendations to match rapid advancements in science, and the President's budget proposal coupled with your HHS reorganization announcement make it unclear whether USPSTF will be provided with the resources it needs to update its recommendations in a timely manner. This doesn't feel like these policies will help Make America Healthy Again.
    a. How will the work of USPSTF be supported under the proposed reorganization?

Response:
Support for the USPSTF is included under the proposed reorganization in the Office of Strategy's Healthcare Research Budget.

    b. Will you maintain the current membership of USPSTF?

Response:
The membership of the USPSTF is under review.

    c. Will you commit to ensuring that HHS will provide USPSTF with the support necessary to help expedite evidence-based third-party payer coverage decisions for health care services?

Response:
The very important mission of the USPSTF has become distorted by misguided members in their pursuit of DEI initiatives and implementing radical gender ideology into our healthcare system. The bedrock to Make America Healthy Again is prevention and under the leadership of this Administration, the USPSTF will be restored to its intended purpose – to develop recommendations for the health care community and update previous clinical preventive recommendations.

77. Children's Health Defense (CHD) continues to promote and fundraise off of their relationship with you. When the measles outbreak in Texas worsened in March, they promoted "The Measles Book," with a foreword by Kennedy. Subtitle: Thirty-Five Secrets the Government and the Media Aren't Telling You About Measles and the Measles Vaccine.
    a. Does CHD have any outstanding lawsuits against any agencies you now run?

b. Have you fully divested from CHD?
c. Please share any communications between yourself and CHD officials since your confirmation

Response:
I am not part of the CHD. I resigned from the board on December 4, 2024, and I have no legal ties to the organization.

78. You were previously on the payroll of Morgan & Morgan, the nation's largest personal injury firm, from 2016 to 2022 and you remain co-counsel on contingency fee cases. Late last year, Morgan & Morgan filed a first-of-its-kind lawsuit alleging companies designed and marketed "ultra-processed foods" in a way that is addictive to children, leading to the rise in chronic diseases in children. There is concern that the MAHA report will be a boon for Morgan and Morgan, which is a potential conflict of interest concern.
    a. What is your plan for cutting ties with his law firm?

Response:
I have filed all required ethics paperwork for the position of Secretary of HHS and the Office of Government Ethics determined that I have complied completely with all applicable laws and regulations governing conflicts of interest.

79. Have you been in touch with the Lanier law firm or Wisner-Baum regarding Gardasil litigation in any capacity or way?
    a. Is your son—to whom you divested your share—involved in those cases?

Response:
As stated above, I am in compliance with all applicable laws and regulations set forth by the Office of Government Ethics. I will continue to comply with all federal laws and regulations pertaining to my position as Secretary.

80. Are Americans healthier now than they were 4 months ago?
    a. Why not?
    b. When can we start to see results?

Response:
Under this Administration, my Department has already made substantial strides to radically transform our food supply, implement the MAHA agenda, and improve the health of Americans. For example, the FDA is working with industry to phase out all petroleum-based synthetic dyes from the nation's food supply, I directed the FDA to close the GRAS loophole that has allowed ingredients and chemicals to be introduced into the food supply without notification to the FDA or public, and we are working with our colleagues at USDA to update the Dietary Guidelines for all Americans.

81. Do food dyes kill more Americans each year than tobacco use and firearms?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Why is HHS focusing on food dyes, while ignoring smoking and guns?

Response:
To fully address the growing health crisis in America, we must re-direct our national focus, toward understanding the sources of and combatting chronic disease. Chronic disease accounts for the overwhelming percentage of preventable deaths and disabilities in the United States and around the world. HHS remains committed to promoting public health and combating all preventable deaths.

82. Certain funding mechanisms within the NIH and other OpDivs have been terminated if they were determined to have violated executive orders and other administration priorities, even if some research or prevention activities funded under the mechanisms are unrelated to those topics or violations.
    a. How and when will HHS examine each specific project funded via terminated mechanisms and execute projects that have no violation and warrant continued support?

Response:
I directed my Department to review all wasteful grants and terminate them. Accordingly, individuals at HHS and within each specific Operating Division conducted an evaluation of all grants and terminated specific grants in accordance with independent agency authorities and priorities. I will continue to prioritize medical research on diseases that affect the health and wellbeing of all Americans.

83. How many fewer employees are currently employed at each of the following agencies—NIH, FDA, CMS, and CDC—compared to the same time last year?

Response:
Please see table above as reference.

84. What is the current status of the federal hiring freeze impacting HHS agencies, and when do you anticipate it being lifted?

Response:
On April 17, 2025, President Trump issued a presidential memorandum, "Extension of Hiring Freeze," that prohibits federal departments and agencies from filling Federal civilian positions that are presently vacant, and requires that no new position be created, except as otherwise provided for in President Trump's memorandum or required by applicable law. My Department is in compliance with the President's hiring freeze. A date on when it might be lifted has not been communicated to HHS.

85. Please provide the total number of staff who have left each agency over the past 12 months, disaggregated by voluntary departures, terminations of probationary employees, and RIFs.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
Please see table above as reference.

86. What is HHS doing to attract and retain early-career scientists and public health professionals to ensure long-term agency sustainability?

Response:
HHS remains firmly committed to preserving and advancing scientific excellence across all its components and will continue to prioritize mission-critical positions – including top-tier scientific and public health professionals – that directly support our mission and enhance the Department's ability to meet global evolving health needs.

87. What is the anticipated reduction in personnel budgets at each agency (NIH, FDA, CMS, CDC) due to staffing reductions, including both voluntary departures and reductions in force (RIFs)?

Response:
Each agency is currently working on their Fiscal Year 2027 budgets, including their requested personnel budgets, in consultation with HHS leadership and OMB. Those budgets will be made public on the timeline that OMB has discussed with Congress.

88. Will HHS commit to fully obligating and expending the funds appropriated by Congress for FY25, particularly for staffing and programmatic support at NIH, FDA, CMS, and CDC?

Response:
My Department will continue to comply with the law.

89. There is growing concern within the scientific and investment communities that the administration's perceived skepticism of mRNA vaccines could undermine investor confidence and slow innovation.
    a. How do you respond to these concerns, and what message are you sending to researchers and developers working on mRNA-based technologies?

Response:
BARDA is terminating 22 mRNA vaccine development investments because the data show these specific vaccines fail to protect effectively against upper respiratory infections like COVID and flu. HHS is shifting that funding toward broader vaccine platforms that remain effective even as viruses mutate. This decision is based on scientific data specific to effectiveness in protecting against upper respiratory infections and should not be perceived as skepticism of all mRNA-based technologies.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

90. How is HHS ensuring that scientific decisions – particularly those related to drug approvals, public health guidance, and vaccine oversight – remain insulated from political interference?

Response:
HHS is committed to gold standard science throughout all its work.

91. The scientific process requires regular exchange of ideas and information. Nationwide health promotion and disease prevention activities also necessitate robust communication channels and multi-level engagement of various partner organizations, including health systems, academic researchers, community-based organizations, and state and local governmental officials.
    a. Do you agree there is value in HHS employees' ability to communicate publicly, attend meetings with other researchers and health officials, engage in scientific exchange, and publish manuscripts in journals that have broad reach?
    b. Do you believe these activities contribute to effective research, public health, and program implementation?
    c. Do you believe these activities are important to the job satisfaction of researchers, public health professionals, and program administrators?
92. Newly instituted policies and burdensome approval procedures limit HHS employees' ability to communicate publicly, attend meetings and conferences, publish manuscripts, and engage in scientific exchange. These practices have undermined your agency's effectiveness and contributed to driving away federal workers with irreplaceable expertise.
    a. What steps are you actively taking to modify these practices and resume normal interactions with partners and the scientific community?
    b. What steps are you actively taking to retain scientific experts within HHS?

Response (91-92):
I am committed to improving healthcare quality and outcomes for all Americans and doing so with radical transparency. Individuals, communities, and members of the public are essential and equal partners in the scientific research and decision-making. As I've mentioned above, HHS remains firmly committed to preserving and advancing scientific excellence across all its components and will continue to prioritize mission-critical positions.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Debbie Dingell (D-MI)

1. More than 80 people were sickened by a recent e coli outbreak linked to Romane lettuce. A child almost died. FDA failed to provide timely communications to the public or identify the origins of the outbreak.
    a. Please explain what factors led to the FDA failing to warn consumers about this outbreak?
        i. How did recent layoffs and cuts at FDA that resulted in communications failures?
    b. Do you agree that the public has a right to know as soon as possible when FDA identifies outbreaks?
        i. And do you agree that the federal government plays an essential role in monitoring foodborne illnesses?

Response:
The federal government plays a critical role in monitoring foodborne illnesses. The 2024 E. coli outbreak was listed on FDA's CORE Investigation Table webpage; however, by the time investigators had confirmed the likely source, the outbreak had already ended and there was no actionable advice for consumers, so FDA did not issue an advisory. Additionally, FDA must follow the Trade Secrets Act, which limits the Agency's ability to disclose trade secrets and confidential commercial information, particularly when there is not an active recall to effectuate. Information covered by the Trade Secrets Act may include supply chain information.

FDA's Human Foods Program is dedicated to and continues to provide critical communications to consumers associated with foodborne outbreaks to the extent possible. Overall coordination of outbreak identification and response has not been affected by the reduction in force. For example, foodborne outbreak communications, recall communications, and the Outbreak Investigation Table continue to be published in order to provide relevant, timely, actionable information to consumers and stakeholders.

2. The SIREN grant program, which supports EMS agencies in rural areas, was previously housed at SAMHSA and moved into AHA; but there has been no mention of the SIREN program or its functions in the reorganization of your Department. Communities around the nation rely on these resources to help keep their doors open.
    a. Could you tell the Committee if the SIREN program will still be operational and where it will be housed?

Response:
The SIREN Reauthorization Act reauthorized funding for the Rural EMS Training and Equipment Assistance (REMSTEA) program which provides grants directly to rural fire and non-profit EMS organizations. The REMSTEA remains at SAMHSA and continuation

applications were recently reviewed with 61 grant continuations funded through September 29, 2026.

3. Could you explain the thinking behind the decision in the President's budget to eliminate the Geriatrics Workforce Enhancement Program and the Geriatric Academic Career Award program, two small but essential programs that support the training of the primary care and caregiver workforce in the geriatrics expertise they need to care for older adults?

Response:
My Department supports efforts to train the primary care workforce, including geriatricians who play a crucial role in the care of older adults and the diagnosis and management of Alzheimer's disease. Through the Teaching Health Center Graduate Medical Education program, HHS supports residency training in community-based settings with a focus on family medicine and geriatrics. The FY 2026 President's Budget requests $175 million for the THCGME, which will fund up to 1,273 resident full-time equivalent slots.

Overall, the budget provides $948 million in mandatory and discretionary funding for health workforce programs, including approximately $474 million for the National Health Service Corps. National Health Service Corps participants can serve at more than 20,600 eligible health care sites and provide care to more than 18 million patients regardless of their ability to pay. The Budget also includes funding for the NURSE Corps the Pediatric Subspecialty Loan Repayment Program, and Centers of Excellence.

4. The Center for Occupational Health and Safety Engineering at the University of Michigan -- one of the National Institute for Occupational Safety and Health's Education and Research Centers -- supports workers by identifying solutions to dangerous work environments and has trained more than 2,000 full-time health and safety professionals over its history.
    a. What are the plans to ensure that programs like the one at the University of Michigan remain operational in order to assist industry and workers with solutions to ensure safe and healthy workplaces?

Response:
The National Institute for Occupational Safety and Health (NIOSH)'s network of Education and Research Centers (ERCs) are academic institutions that provide high-quality interdisciplinary graduate and post-graduate training, research training, continuing education, and outreach in the core Occupational Safety and Health (OSH) disciplines. Under the Occupational Safety and Health Act of 1970, NIOSH is statutorily mandated to ensure that a sufficient supply of OSH professionals are available to meet national needs, and ERCs are the primary mechanism for meeting this requirement. HHS is working to consider how and where this work will continue.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

5. The University of Michigan's CDC Injury Control Research Center has worked to develop, test, and disseminate novel programs to prevent youth violence, opioid overdoses, teen driving crashes, and suicides occurring within our National Guard and rural populations.
    a. Can you explain how the void in injury prevention research would be filled if this critical CDC program is eliminated?

Response:
The Administration is committed to reducing government inefficiencies and streamlines activities across the Department into the newly established Administration for a Healthy America (AHA) . HHS continues to be supportive of injury prevention efforts and shifts CDC's National Center for Injury Control and Prevention to AHA.

6. CDC currently provides my state of Michigan with $3.7 million to address antimicrobial resistance (AMR). But funding clawbacks and expiration of supplemental funding mean that this year Michigan is set to lose 64% of our AMR funding.
    a. How will you ensure that our state health departments and health care facilities have the resources they need to protect patients from resistant infections?

Response:
CDC leads the U.S. public health fight against antimicrobial resistance (AR) in support of the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria. CDC's investments through the AR Solutions Initiative strengthen our ability to prevent infections, rapidly detect antimicrobial resistance threats, and respond to control their spread, preserve the effectiveness of antibiotics through increasing appropriate use, and innovate new strategies and products. CDC continues to work closely with other federal departments and agencies, jurisdictional public health departments, and academia and other partners to address antimicrobial resistance, including through multisectoral coordination, detection and surveillance, infection prevention and control, and antimicrobial stewardship. Through investments in every state health department (as well as in some large cities and territories), the U.S. can better fight new and emerging antimicrobial resistance threats. CDC's current AR Investment Map provides transparency for AR funding across the U.S. states and is updated annually.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Robin Kelly (D-IL)

1. Did you consult with any scientific or professional organizations, such as those representing pediatricians, gynecologists, obstetricians, family physicians, infectious disease physicians, or immunologists in arriving at your COVID-19 vaccine decision?
    a. Who specifically did you consult and what data was provided to support your decision?

Response:
On May 27, 2025, HHS announced that the COVID vaccine for healthy children and healthy pregnant women had been removed from the CDC recommended routine immunization schedule. For healthy children ages 6 months to 17 years who are not moderately or severely immunocompromised, the CDC now advises shared clinical decision-making.

Shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. For pregnant women, the schedule no longer includes a recommendation for the COVID vaccine.

2. Secretary Kennedy, as you well know, the MAHA Commission's recent report – which was an extremely flawed document - has significant implications for producers and consumers in my district.
    a. Given the concerns raised about the lack of public input in the drafting of the report, will you commit to correcting the record by opening a formal comment period to allow stakeholders the opportunity to provide valuable feedback and ensure the kind of radical transparency you ensured us would be a part of this process?

Response:
The Make America Healthy Again Commission prioritizes collaboration with top experts across government and industry in order to provide Americans with the information necessary to make the best decision for their health. We must shift the focus of healthcare from disease management to disease prevention. The MAHA plan encourages healthy eating, regular exercise, and routine health screenings to reduce preventable chronic diseases like heart disease and diabetes.

3. Secretary Kennedy, you have repeatedly vowed to "radically transform" the US food system. What specific transformational changes do you intend to make?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

My Department has already made steps to radically transform our food supply and implement the MAHA agenda. The FDA is working with industry to phase out all petroleum-based synthetic dyes from the nation's food supply, I directed the FDA to close the GRAS loophole that has allowed ingredients and chemicals to be introduced into the food supply without notification to the FDA or public, and we are working with our colleagues at USDA to update the Dietary Guidelines for all Americans.

4. Poor nutrition is a primary driver of poor health and preventable healthcare spending in the United States, and its resulting toll of chronic disease has negative impacts on economic competitiveness, productivity, and military readiness. Chronic diseases affected by nutrition, including cardiovascular disease, stroke, and diabetes, account for most of our nation's $4.3 trillion in annual health care costs. Food is medicine (FIM) – defined as the provision of healthy food such as medically tailored meals, medically tailored groceries, and produce prescriptions to treat or manage specific clinical conditions in a way that is integrated with and paid for by the health care sector – has demonstrated tremendous potential to reduce the burden of diet-related chronic conditions in a cost-effective manner.
    a. The FY26 NIH budget identifies the Food is Medicine Centers of Excellence – for which NIH approved the concept in 2023 but has yet to receive funding – as responding to the need to bridge nutrition support and clinical practice to address diet-related chronic diseases.
        i. How will you support and prioritize comprehensive food is medicine research at NIH?

Response:
Approximately one million people die annually in this country from diet-related chronic diseases, and this number continues to rise. Diet-related chronic diseases also disproportionally affect underserved communities and exacerbate health conditions. Under my leadership, HHS is committed to integrating nutrition education and research in medicine. For example, in May 2025, NIH and FDA announced a joint Nutrition Regulatory Science Program (NRSP). Under NRSP, the agencies will implement and accelerate a comprehensive nutrition research agenda that will provide critical information to inform effective food and nutrition policy actions to help make Americans' food and diets healthier.

    b. The budget request for the proposed Administration for a Healthy America (AHA) includes $119 million for a new Prevention Innovation Program, with a track dedicated to addressing chronic conditions, including by promoting access to healthy foods and implementing nutrition-driven programs in partnership with community organizations.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

i. How do you plan to leverage the MAHA Initiative, and specifically the Prevention Innovation Program, to implement and scale food is medicine services?

Response:
The Prevention Innovation (PI) program provides communities with new and practical ways to support the goals of the Administration to Make America Healthy Again (MAHA). The PI program supports the goals of the MAHA initiative by addressing the root causes of America's escalating health crises, focusing on maternal health delivery gaps and chronic conditions that lead to poorer health outcomes in rural areas. This request supports three tracks: one for maternal health, one for chronic disease, and one for Tribes (where applicants could support programs in either maternal health or chronic disease). The intent of the PI program is to improve overall health, reduce dependence on medications and other treatments, and ensure that people have access to resources such as nutrition services, physical activity venues, and other clean and healthy environmental and lifestyle options.

c. The HHS food is medicine initiative has served as a critical resource to food is medicine researchers, practitioners, and other stakeholders since its launch in FY 2024 by publishing an online knowledge hub, coordinating food is medicine programs across federal agencies, and developing partnerships with community-level and national FIM leaders.
    i. How do you intend to support and expand HHS's food is medicine efforts through this initiative?

Response:
My Department will work with USDA, ED, VA, and Department of Defense to improve access to whole, healthy foods in government-funded nutrition programs and meals, including in school meals, prisons, and VA hospitals, and ensure the availability of nutritious whole food for populations in need. HHS and FDA will continue efforts with USDA to develop a uniform definition for "Ultra-processed Food" to support potential future research and policy activity.

HHS, the VA, and USDA will study the impact of programs that implement food and lifestyle interventions to improve health outcomes and decrease costs. The NIH Office of Nutrition will coordinate research initiatives to improve rigorous studies and maximize impact, including through largescale randomized control trials.

5. Vaccines are one of the greatest success stories in public health and are among the most cost- effective ways to prevent disease. Childhood immunizations between 1994 and 2023 prevented approximately 508 million illnesses, avoided more than 1 million deaths, and saved $540 billion in direct costs and nearly $2.7 trillion in societal costs. For each

dollar invested in the U.S. childhood immunization program, there are nearly $11 in societal savings and $3 in direct medical savings.

Your recent action to replace all 17 members of CDC's vaccine advisory panel (ACIP) with eight new members, many of whom have expressed skepticism about current vaccine policies, has raised great concerns from public health experts about potential shifts in federal vaccine recommendations that could lead to higher costs through a number of coverage programs including Medicare, Medicaid, TRICARE, and most private health insurance plans, and reduced access to life-saving vaccinations. ACIP-recommended vaccines are available without cost-sharing to eligible children through the Vaccines for Children program, which provides federally purchased vaccines to approximately 52% of all children in the United States.

a. Given the clear evidence from the CDC and public health experts that vaccines prevent millions of illnesses and thousands of deaths annually, and considering recent outbreaks of vaccine-preventable diseases such as measles and influenza that continue to threaten public health, how do you plan to ensure that all Americans, especially vulnerable populations like children and those with chronic conditions, have equitable access to and confidence in vaccines through programs such as the CDC's 317 Immunization Program, to effectively prevent these diseases?

Response:
In July 2025, CDC awarded 66 state, territorial, and local jurisdictions with funding that provides critical resources for jurisdictions to prevent and control outbreaks of vaccine-preventable diseases. This funding supports CDC's 317 Discretionary Immunization Program and the operationalization of the Vaccines for Children (VFC) program by supporting jurisdictional efforts to get vaccines purchased and administered to individuals and families in need. This funding supports the work jurisdictions do to improve vaccine access, like enrolling birthing hospitals into the VFC Program, educating clinicians, and supporting the jurisdiction immunization workforce.

6. According to a 2024 March of Dimes report, over 35% of counties are considered maternity care deserts. This means that in 1,104 US counties, there is not a single birthing facility or obstetric clinician. Areas with no access to maternal care effect over 2.3 million women of reproductive age and 150,000 births in 2022. This data confirms that women living in maternity care deserts and counties with low access to care have poorer health before pregnancy, receive less prenatal care, and experience higher rates of preterm birth. The analysis revealed an excess of over 10,000 preterm births among those living in maternity care deserts and limited access counties in 2020-2022.
    a. With the recent restructuring within HHS-including the reduction of staff and programs across the agency, and severe cuts to Medicaid under the now enacted

budget reconciliation bill (H.R. 1), how does HHS plan to ensure that pregnant women across the country, including in rural communities, do not lose access to essential health coverage and services?

b. Specifically, what strategies will HHS implement to maintain and strengthen healthcare access in rural areas facing hospital closures, workforce shortages, and reduced federal Medicaid support?

7. The proposed elimination of the CDC's National Center for Chronic Diseases Prevention and Health Promotion and all its programs threatens the wellbeing of American families as it will dismantle critical programs that safeguard maternal and infant health. In particular, HHS has eliminated the Division of Reproductive Health, which oversaw and supported maternal mortality review committees (MMRCs) among other key maternal and infant health initiatives. This division's closure has disrupted critical data collection and surveillance systems essential for identifying and addressing maternal mortality and morbidity. Additionally, the Department's RIF has included the entire CDC maternal health team and many other employees involved in maternal and infant health data collection and analysis. This has halted programs that provide vital data for MMRCs to function effectively and could have disastrous long-term consequences on maternal health, especially for women who face higher mortality rates.
    a. What will the Department do to continue the important work of maternal mortality review committees (MMRC) to ensure that our mothers and babies are protected, and the care they receive continues to be informed and improved by the findings of MMRCs?

Response (6-7):
The FY 2026 President's Budget invests in programs to improve maternal health outcomes, particularly in underserved and rural areas, prioritizing programs that provide states and communities the flexibility to address local maternal and child health needs. This includes a new Prevention Innovation Program funded at $119 million as part of the Make America Healthy Again initiative to address the root causes of America's escalating health crises, including a track specific to maternal health challenges.

The President's Budget also continues investments in the Maternal and Child Health Block Grant, the State Maternal Health Innovation program, the Alliance for Innovation on Maternal Health program, the Integrated Services for Pregnant and Postpartum Women program, the Screening and Treatment for Maternal Mental Health program, and the Maternal Mental Health Hotline to provide support and referrals to pregnant and postpartum women facing mental health challenges.

The Budget also continues investments in rural maternal health through the Rural Maternity and Obstetric Management Strategies program, which provides start-up funding to test out new approaches to supporting, enhancing, and expanding maternal and

obstetrics care in rural communities. The Delta Region Maternal Care Coordination Program is also continued to expand access to care for pregnant women and new mothers by addressing barriers through care coordination strategies for the delivery of perinatal services.

The FY 2026 President's Budget continues to grow the maternal health workforce through the National Health Service Corps (NHSC) and Nurse Corps loan repayment and scholarship programs that support health care providers and nurses dedicated to working in areas with maternity care shortages. The NHSC Students to Service Loan Repayment Program, offers a supplemental loan repayment award of up to $40,000 to NHSC-awarded maternity care health professionals providing health services in Maternity Care Target Areas.

Under my leadership, HHS is committed to addressing the drivers of maternal mortality and seeking to find real solutions to reduce the maternal mortality rate in this country. While the Department is considering a number of proposals to reduce inefficiencies and eliminate redundant programs within the Department, programs focused on this important topic will be addressed, regardless of any actions taken to reorganize HHS.

8. Prior to the massive RIF at HHS and related agencies, we already were seeing problems with programs not functioning properly and as intended by law, such as the abrupt shutdown of Pregnancy Risk Assessment Monitoring System (PRAMS) earlier this year. PRAMS, which was developed in 1987, was designed to identify groups of women and infants at high risk for health problems, to monitor changes in health status, and to measure progress towards goals in improving the health of mothers and infants. Since then, the program has collected essential data on maternal behaviors and experiences before, during, and shortly after pregnancy through a site-specific and population-based surveillance system. The data helps monitor maternal and child health trends, allowing state, territorial, or local public health officials to implement targeted interventions. Maternal care providers rely on the data collected by PRAMS, which does not come from any other data source, to enhance prenatal and postnatal care.
    a. Now, with the layoffs affecting thousands of career staff across HHS programs at CDC, NIH and HRSA – including the layoff of all PRAMS staff – what does the Department plan to do to continue research and data collection programs essential to addressing our nation's maternal and infant health crisis?

Response:
Pregnancy Risk Assessment Monitoring System (PRAMS) activities are currently ongoing at CDC, including funding for the 2025 data collection cycle. Under the proposed reorganization, CDC's National Center on Birth Defects and Developmental Disabilities and HRSA's Maternal and Child Health Bureau will be consolidated under the Administration for a Healthy America. This will improve data gathering and streamline the

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Department's maternal health programs to better serve Americans. All states use HRSA Maternal Child Health (MCH) Block Grant funds for women and maternal health activities such as promoting well-woman visits, increasing access to prenatal and postpartum care, supporting Maternal Mortality Review Committees (MMRCs), and enhancing systems of care for maternal mental health.

9. Newborn screening is one of our nation's most successful public health programs, serving nearly million infants each year and saving thousands of babies' lives. In April, it was announced that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) administered by HRSA was being terminated, effective immediately. This was especially troubling because this advisory committee of experts served a critical function in making recommendations to state newborn screening panels and providing a central place to advocate for the important issues impacting the newborn screening community. It helped to bring uniformity to newborn screenings in all states and the advisory committee's work is a serious loss that poses a detriment to newborn screening nationwide. Additionally, the budget proposal would eliminate the Heritable Disorders program at HRSA that has significantly improved the quality of newborn screening programs throughout the country.
    a. What does the Department plan to do to replace the critical work of the HRSA Heritable Disorders Program, and the ACHDNC in reviewing and evaluating the medical and scientific evidence for adding newborn screening conditions with the goal of complete Recommended Uniform Screening Panel (RUSP) implementation as soon as possible?

Response:
Newborn screening is primarily a state-based program, with each state's public health department maintaining its newborn screening panel. HHS provides the Recommended Uniform Screening Panel (RUSP) as a resource to help guide states in their development and management of their screening program. HHS is reviewing the overall process of reviewing conditions for newborn screening, and we look forward to working with Congress on ways to improve newborn screening and child health.

10. The President's FY2026 budget proposes a major NIH reorganization, reducing 27 Institutes and Centers to a much smaller number. One plan would merge the National Institute of Dental and Craniofacial Research (NIDCR) into a new "Institute on Neuroscience and Brain Research" alongside NIH's Neurological Disorders (NINDS) and Eye (NEI). This raises concern that oral health research could lose its distinct visibility and funding. For nearly its entire existence, NIDCR has been at the forefront of research linking oral health and systemic health – for example, uncovering how the oral microbiome and periodontal disease inflammation connect to chronic conditions. Much

of what we know about the role of chronic inflammation in overall health stems from NIDCR-supported studies.

a. Will HHS commit to preserving Congress's appropriated funding for NIDCR and maintaining its autonomy (along with other specialized institutes) until Congress can undertake a transparent, stakeholder-informed review of NIH's structure?
b. In other words, can you assure that critical oral-health research capacity won't be lost or diluted through an administrative merger done ahead of Congressional input?

Response:
HHS is considering a number of proposals to streamline and reduce inefficiencies. While there is an extensive and systematic process in place before the agency can enact restructuring, the key principle is to empower collaboration across scientific disciplines to increase knowledge. The Administration continues to consider proposals to streamline and reduce inefficiencies and looks forward to working with Congress. NIH will continue to share ideas and data, regardless of any reorganization HHS undertakes. HHS is committed to delivering gold standard science and innovations to the public and continuing to drive the discovery of life-changing treatments. NIH will continue to support important meritorious research on oral health.

11. The HHS reorganization proposes to consolidate the HHS agencies AHRQ and ASPE into the single Office of Strategy. In this proposal, OMB enumerated activities that will be prioritized along with those programs that will no longer be conducted by the newly stablished office and listed the various income streams that will support the Office of Strategy in FY26; among them is the Patient-Centered Outcomes Research Trust Fund (PCORTF), which is a statutory trust fund, and from which $0 is proposed to be transferred. The document itself acknowledged that these transfers are "mandatory" but did not explain how the statutory requirements around the PCORTF would be discharged. The President's Budget went on to propose Congress introduce legislation that would eliminate the PCORTF along with the Patient-Centered Outcomes Research Institute (PCORI) which is not a federal agency and is funded entirely by the PCORTF. The Budget again acknowledges that this funding is mandatory and directed by separate statute - a statute that currently authorizes the PCORTF (and PCORI) through 2029.
    a. Given that the PCORTF is not discretionary, but rather comprised of mandatory spending and a user fee (and therefore budget neutral) why is this proposal part of the President's Budget?
    b. Why does the HHS reorganization propose to illegally terminate transfers from the PCORTF to HHS and end statutorily-required activities at AHRQ?
    c. Why is the President's Budget proposing to eliminate PCORI, which is not an agency but rather a 501(c)(1) and whose funding was bipartisanly reauthorized

and signed by President Trump in his first term and which funds healthcare research in all 50 states and the District of Columbia?

Response:
The FY 2026 President's Budget reflects a number of proposals to streamline the Department of Health and Human Services. Ultimately, it is up to Congress to decide programs' appropriation level and I will comply with the law.

12. Chronic diseases affect 80 percent of people age 65 and over. Nearly 45 percent of Medicare beneficiaries have four or more chronic conditions and account for more than 75 percent of Medicare costs. As a pharmacist, I worked closely with geriatrics professionals and long-term care providers to ensure they can meet the unique needs of medically complex older adults and am concerned about the severe shortage of geriatrics professionals and geriatrics expertise. For a number of years now, HRSA has successfully administered the only two federal programs designed to address the shortage of geriatrics professionals by supporting the training of the primary care and caregiver workforce in the geriatrics expertise they need to care for older adults. I have supported these programs most of my career and was disappointed to see these two programs – the Geriatrics Workforce Enhancement Program, including an Illinois Grantee, The SHARE Network (https://sharenetworkchicago.org/) and the Geriatric Academic Career Award program (Andrea Landi, MD at the U. of Chicago)- proposed for elimination in the President's budget.
    a. Could you explain the thinking behind the decision to eliminate these two small but essential programs?

Response:
My Department supports efforts to train the primary care workforce, including geriatricians who play a crucial role in the care of older adults and the diagnosis and management of Alzheimer's disease. The FY 2026 President's Budget provides $948 million in mandatory and discretionary funding for health workforce programs. It focuses on strengthening the workforce in rural and underserved areas through scholarship and loan repayment programs with a service requirement and supporting behavioral health training. This includes approximately $474 million for the National Health Service Corps. It will support more than 6,600 new scholarship, loan repayment awards, and an anticipated field strength of nearly 12,800 primary care, behavioral health, and oral health providers serving in communities of greatest need. National Health Service Corps participants can serve at more than 20,600 eligible health care sites and provide care to more than 18 million patients regardless of their ability to pay. These investments help expand access to care and improve health outcomes nationwide. This also includes $175 million in mandatory funding for the Teaching Health Center Graduate Medical Education Program. It expands the medical workforce by supporting graduate education in medicine,

dentistry, and behavioral health in teaching health centers. These health centers will provide hands-on training to residents in community-based settings. In FY 2026, the program will support over 1,200 resident full-time equivalent slots. The Budget also includes funding for the NURSE Corps the Pediatric Subspecialty Loan Repayment Program, and Centers of Excellence.

13. Maternal Mortality Review Committees (MMRCs) are multidisciplinary groups that convene at the state or local level to review deaths that occur during pregnancy, childbirth or within a year postpartum. Their primary goal is to identify causes and contributing factors to maternal deaths and develop recommendations to prevent them in the future. MMRCs play a critical role in addressing the maternal health crisis, and Congress has historically provided funding for state-based MMRCs on a bipartisan basis.

    In the 119th Congress, Reps. Buddy Carter (R-GA-01), Diana DeGette (D-CO-01), Robin Kelly (D- IL-02), Kat Cammack (R-FL-03), Kathy Castor (D-FL-14) and Ryan Mackenzie (R-PA-07) have reintroduced H.R. 1909, the Preventing Maternal Deaths Reauthorization Act of 2025, which would provide increased funding for MMRCs through FY2029. BCBSA has endorsed this bipartisan legislation.

    Despite maternal mortality rates decreasing slightly in recent years, the U.S. continues to have the highest maternal mortality rate among developed countries. Worse, Black women in America are three times more likely than white women to die from pregnancy-related complications. Maternal Mortality Review Committees (MMRCs) play a critical role in understanding why maternal deaths occur and how policymakers can take steps to prevent them. Congress, on a bipartisan basis, recognizes the importance of reauthorizing funding for MMRCs.

    a. Do you support increased funding for MMRCs to reduce maternal mortality rates and address the maternal health crisis?

Response:
My Department is committed to addressing the drivers of maternal mortality and seeking to find real solutions to reduce the maternal mortality rate in this country. This commitment includes working to improve maternal health outcomes for mothers across all demographics. While the Department is considering a number of proposals to reduce inefficiencies and eliminate redundant programs within the Department, programs focused on this important topic will be addressed, regardless of any actions taken to reorganize HHS.

Under the proposed reorganization, CDC's National Center on Birth Defects and Developmental Disabilities and HRSA's Maternal and Child Health Bureau will be consolidated under the Administration for a Healthy America. This will improve data

gathering and streamline the Department's maternal health programs to better serve Americans. All states use HRSA Maternal Child Health (MCH) Block Grant funds for women and maternal health activities such as promoting well-woman visits, increasing access to prenatal and postpartum care, supporting Maternal Mortality Review Committees (MMRCs), and enhancing systems of care for maternal mental health.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Lori Trahan (D-MA)

1. At a time when children and young people are struggling with unmet mental health needs, and 20% of youth report having seriously contemplated suicide in the last year, how will you ensure the continuation of vital SAMHSA programs, amid the proposed cuts and restructuring?

Response:
I recognize, as a national priority, continuation of accessible, evidence-based, and developmentally appropriate care for young people who experience serious emotional distress, including suicidal ideation. AHA will continue to leverage its core programs, including the Children's Mental Health Initiative (CMHI) and the network of Certified Community Behavioral Health Clinics (CCBHCs) to ensure that communities have the capacity to deliver trauma-informed, confidential, and youth-centered services. In addition, AHA will support crisis response systems, such as the 988 Suicide and Crisis Lifeline, and access to prevention, early intervention, and recovery supports. Working closely with states, tribal nations, local partners, and families, AHA will prioritize continuity of care, minimize disruption, and ensure that federal investments remain focused on reaching those most in need.

2. How will HRSA's programs that support the pediatric behavioral health workforce continue to be administered under your budget proposal?

Response:
The FY 2026 President's Budget request provides $129.3 million for Behavioral Health Workforce Development Programs to support the training of mental health and substance use disorder providers, as well as physicians specializing in the prevention, evaluation, and treatment of substance use disorder. Among these programs, the Behavioral Health Workforce Education and Training Program for Professionals aims to increase the supply, distribution, and quality of behavioral health professionals such as psychologists, psychiatrists, social workers, counselors, marriage and family therapists, and other mental health and addiction counselors. The Addiction Medicine Fellowship Program provides grants to organizations to expand the number of fellows at accredited addiction medicine and addiction psychiatry fellowship programs who are trained as addiction medicine specialists to work in community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services, including settings that serve pediatric populations.

The Budget also requests $10 million to continue the Pediatric Specialty Loan Repayment Program (PS LRP) in FY 2026. In exchange for a three-year, full-time service commitment, the PS LRP provides loan repayment assistance to a range of clinicians in pediatric primary and subspecialty care who work in a Health Professional Shortage Area, Medically Underserved Area, or who serve a Medically Underserved Population. The request will

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

support approximately 85 new PS LRP awards to bolster the pediatric health care workforce, including pediatric medical specialists, pediatric surgical specialists, and child and adolescent behavioral health care providers

The Budget request also continues funding for the Pediatric Mental Health Care Access (PMHCA) program. PMHCA funds tele-consultation and training programs to support pediatric primary care providers to diagnose, treat, and refer children with behavioral health conditions.

3. How will you ensure that NIH's programs – including those at NICHD – are not left behind, given the important insights they provide to childhood development, mental health in adolescence, and more?
    a. Please provide specific information on how these programs will continue when the court order on discussions about the reorganization is lifted.

Response:
HHS is considering a number of proposals to streamline and reduce inefficiencies. While there is an extensive and systematic process in place before the agency can enact restructuring, the key principle is to empower collaboration across scientific disciplines to increase knowledge. We must continue to share ideas and data, regardless of the reorganization HHS undertakes. HHS is committed to delivering gold standard science and innovations to the public and continuing to drive the discovery of life-changing treatments. NIH will continue to support important meritorious research on child health, maternal health, disabilities, and chronic disease.

4. With significant reductions in NIH funding extending to the elimination of mission-critical contracts, what metrics or measures are you using to determine whether contracts meet the strategic priorities of HHS?

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. NIH is advancing policies to maximize the impact of every federal taxpayer dollar and ensure proper oversight of funding. Individuals at HHS conducted an evaluation of contracts to maximize cost-savings. Contracts were terminated in accordance with Administration priorities.

5. The infectious diseases (ID) workforce shortage threatens patient outcomes and healthcare costs, yet many training programs remain unfilled, including at Boston Children's Hospital. Simultaneously, proposed cuts to NIAID undermine our pandemic preparedness by weakening research, training, and response capabilities.
    a. How will you address the ID workforce crisis and how do you justify dismantling critical infrastructure that protects Americans from future outbreaks?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. We are looking hard at how we can streamline and be efficient to spend smarter in order to advance NIH's mission to support scientific endeavors that advance the health and longevity of Americans. To tackle these persistent and complex problems, we need to ensure our research is rigorous, reproducible, and generalizable. HHS will continue to support gold standard science on infectious diseases.

6. Would you support executive action directing federal agencies to prioritize domestic API and finished dosage form (FDF) manufacturing—particularly for essential medicines like antibiotics and generic medicines (such as cardiology / oncology) that are consistently in shortage?

Response:
The United States has a significant dependency on global suppliers for generic drugs. We must focus on domestic production of supportive care fluids, drug substances and drug products to ensure we no longer are subject to shortages. This includes the need to develop agile and distributed platforms that will reduce supply chain constraints for key starting materials, APIs, finished dose form drugs and supportive care fluids. We need to increase domestic pharmaceutical manufacturing surge capacity, and more broadly commercialize novel manufacturing capacities that can lead to the manufacturing of drug substances, drug products and supportive care fluids.

   a. If so, what agencies would you expect to lead and implement this effort?

Response:
HHS, in consultation with the Department of Defense and the Department of Veterans Affairs should lead and implement this effort. Specifically, HHS ASPR will lead reshoring efforts for essential medicines, including their Key Starting Materials and APIs. HHS ASPR will coordinate with other HHS entities, as appropriate, to address needs in oncology and cardiology.

7. HHS currently maintains an Essential Medicines List that has not been updated since May 2022. What steps would you take to ensure this list is regularly updated with supply chain vulnerabilities in mind—particularly for products heavily reliant on foreign nations like China for APIs and key starting materials?

Response:
Pursuant to Executive Order 13944 signed by President Trump in his first term, FDA created a list of Essential Medicines, Medical Countermeasures, and Critical Inputs in 2020 based on the EO's policy of protecting our citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. In follow up to this work, in 2022 the HHS

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Office of the Assistant Secretary for Preparedness and Response (ASPR) (now the Administration for Strategic Preparedness and Response) identified and developed a list of 86 of the most critical medicines needed for acute patient care from FDA's 2020 list through further consultation with experts and by review of the public comments submitted to the docket for the FDA Essential Medicines List.

8. Would you support prioritizing the U.S.-made medicines in federal procurement programs like the Strategic National Stockpile and the Department of Defense?

Response:
Purchasing critical medical countermeasures (MCMs) domestically reduces the risk of relying on international partners. A Strategic National Stockpile (SNS) that relies on foreign manufacturing and production of critical products is not the best choice or best course of action for national security. When and where possible, the SNS looks to domestic sourcing for products to include in the stockpile. All SNS procurements are made in compliance with federal acquisition regulations (the Buy American statute is implemented at FAR at 48 CFR part 25 and requires contracting and procurement, when possible, with domestic suppliers). For awareness, the SNS does hold some products that are not commercially available and for which there is limited or no domestic manufacturing capacity.

As part of the Administration's priority to Make America Healthy Again, we need to bolster domestic manufacturing capability. Offshoring of manufacturing has been a decades long process and it cannot be reversed immediately. My Department is committed to working with Congress to identify efficient ways to improve domestic manufacturing capabilities.

   a. Additionally, how can CMS work within existing authorities to reward domestic manufacturing through preferred formulary placement, enhanced reimbursement, or other incentives?

Response:
We are working across the Department to fulfill President Trump's goals of lowering drug prices and putting America first, within the confines of the law.

9. Would you consider empowering CMS to create a long-term contracting marketplace for the top 50 essential medicines? Such a model could stabilize pricing, incentivize domestic production, and create a more resilient supply chain.

Response:
CMS is committed to ensuring that Americans with Medicare have access to affordable, lifesaving medications. HHS will continue to build off the historic efforts of President

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Trump's first term to lower prescription drug prices and continues to deliver on his promise to put American patients first as outlined in his Executive Order "Lowering Drug Prices by Once Again Putting Americans First."

10. How would your administration utilize the FDA and work with EPA to reduce red tape in order to fast-track domestic manufacturing?

Response:
My Department is committed to taking steps that can help reduce America's reliance on foreign drug manufacturing and ensure that Americans have a resilient and strong domestic drug supply. The FDA PreCheck program aims to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability and facilitating the construction of manufacturing sites in the United States.

FDA is also developing the Quality Management Maturity (QMM) Program, which aims to encourage drug manufacturers to implement quality management practices that go beyond current good manufacturing practice (CGMP) requirements. FDA also has programs to actively support the adoption of Advanced Manufacturing Technologies, which can help domestic production be more efficient and flexible. Through its Emerging Technology Program, FDA works directly with industry to resolve regulatory uncertainties and accelerate adoption of innovative platforms. Additionally, the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative is intended to prepare a regulatory framework to support the adoption of advanced manufacturing technologies that could start to bring benefits to patients over the next 5-10 years.

In addition, the Commissioner's National Priority Voucher program will review and potentially select recipients who file applications for approval of certain drugs and biological products that are aligned with U.S. national health priorities, including those that onshore drug development and manufacturing.

FDA is committed to working with EPA and other Agencies to achieve these goals within the scope of its authorities.

11. Would you support directing HHS to map the full supply chains of essential medicines to identify vulnerabilities?

Response:
Understanding gaps and vulnerabilities in the domestic supply chain is critical to enhance preparedness and eventual response to public health and medical emergencies and disasters. HHS is working on this effort and will support development of processes and tools to better understand manufacturing dependencies and challenges that predicate impacts to the supply chain.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

12. Are there any critical gaps in data or information that HHS currently lacks or is unable to collect, which may prevent the Department from obtaining a comprehensive understanding of the full supply chains for essential medicines?

Response:
The following are several critical sources of data necessary to support such work, and challenges and/or gaps in collecting such data:

- **Reporting on drug manufacturing volume information: need information on each source of API and drug substance intermediate used in the reported amount of drugs manufactured, and the extent of reliance on each source.**
- **Registration and listing information: need more complete and accurate information in certain cases, e.g., on "upstream" foreign manufacturers of API and drug substance intermediates used in finished drug products entering the U.S. market .**
- **Data on distribution of prescription drugs and certain biological products; need more complete information.**
- **Additional information from manufacturers to FDA regarding an increase in demand.**
- **Information on the original manufacturers of API and finished product in labeling.**
- **Granularity & Standardization: Gaps aren't just about missing data—they are about data fragmentation across FDA, CMS, VA, DoD, and private distributors.**
- **Foreign Ownership & Concentration Data: In addition to manufacturing volumes, we need visibility into corporate ownership structures, geographic concentration risks, and single-source suppliers.**
- **Digital Stockpile Integration: Linking data collection efforts to the Digital Stockpile & Manufacturing Response Network (DS-MRN) so information gaps feed directly into preparedness planning.**

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Marc Veasey (D-TX)

1. Mr. Secretary, do you unequivocally support the administration of the MMR (measles-mumps- rubella) vaccine to children and adults?

Response:
The most effective way to prevent the spread of measles is the MMR vaccine.

2. Would you agree that as Secretary of HHS, the final decisions on how HHS and its operating divisions respond to the current measles outbreak lie with you?
3. As part of the February and April 2025 RIF notices from HHS, did any of the CDC staff terminated have active responsibilities assisting states with their measles response, particularly Texas?

Response (2-3):
State and local health departments, including the Texas Department of State Health Services and the New Mexico Department of Health, took lead of the responses to the measles outbreaks within their own jurisdictions. The role of HHS and its operating divisions is to provide assistance to state and local response efforts. CDC Epidemic Intelligence Service (EIS) officers supported state officials in making decisions to prevent further spread of measles. I am committed to restoring this Department and our agencies to the gold standard of science. Under our leadership, the CDC was able to act swiftly providing vaccines, therapeutics and resources to the epicenter to quickly end the measles outbreak. HHS will continue to streamline and centralize its workforce to maximize effectiveness and efficiency in delivering critical services.

4. Yes or no: Did you instruct CDC to amend treatment guidance to include the use of Vitamin A as a treatment for measles?

Response:
I have been clear that the best means to prevent measles is through vaccination, which is also made clear in the CDC's guidance.

5. Will you commit to reinstating the Partnership Branch so that we can better protect the American people from outbreaks and make the federal response to the measles outbreak more effective?

Response:
Under my leadership, the Department will continue to streamline and centralize its workforce to maximize effectiveness and efficiency in assisting outbreak response efforts.

6. Newborn screening is one of our nation's most successful public health programs, serving nearly million infants each year and saving thousands of babies' lives. In April, it was announced that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) administered by HRSA was being terminated, effective

immediately. This was especially troubling because this advisory committee of experts served a critical function in making recommendations to state newborn screening panels and providing a central place to advocate for the important issues impacting the newborn screening community. It helped to bring uniformity to newborn screenings in all states and the advisory committee's work is a serious loss that poses a detriment to newborn screening nationwide. Additionally, the budget proposal would eliminate the Heritable Disorders program at HRSA that has significantly improved the quality of newborn screening programs throughout the country.

a. What does the Department plan to do to replace the critical work of the HRSA Heritable Disorders Program, and the ACHDNC in reviewing and evaluating the medical and scientific evidence for adding newborn screening conditions with the goal of complete Recommended Uniform Screening Panel (RUSP) implementation as soon as possible?

Response:
Newborn screening is primarily a state-based program, with each state's public health department maintaining its newborn screening panel. HHS provides the Recommended Uniform Screening Panel (RUSP) as a resource to help guide states in their development and management of their screening program. HHS is reviewing the overall process of reviewing conditions for newborn screening, and we look forward to working with Congress on ways to improve newborn screening and child health.

7. Given HHS's healthcare mission, can you give us specific examples of how HHS has assessed artificial color additives to be unsafe?

Response:
The MAHA Report released in May 2025 notes that the scientific community has conducted a number of studies raising concerns about the association between petroleum-based synthetic dyes and health conditions such as attention deficit hyperactivity disorder, obesity, and diabetes.

a. Furthermore, have you quantified/assessed the impact this could have on consumers from a pricing and accessibility of products perspective?

Response:
While we have not conducted an economic analysis of industry members' voluntary decisions to remove petroleum-based synthetic color additives from their products, we are committed to authorizing safe alternatives to petroleum-based synthetic colors. FDA has already authorized four new color additives derived from natural sources this year while also accelerating the review and approval of others.

8. Doulas are non-clinical, trained professionals that provide emotional, physical and informational support to women before, during and after childbirth. Current evidence

suggests that pregnant women who receive doula care are more likely to have a healthy birth outcome and a positive birth experience.

Today, only 27 states and Washington, D.C. include Medicaid coverage for doula care. A key barrier to broader doula coverage is the lack of uniform standards around the licensing and training of doulas at the state level. Uniform standards would improve the quality of doula care for patients and make it easier for health plans to include doulas in their provider networks.

Doulas play a critical role in supporting mothers before, during and after childbirth. However, only 27 states and Washington, D.C. include Medicaid coverage for doula care. A key barrier to broader coverage is the lack of uniform standards around the licensing and training of doulas at the state level.

a. What role will your Department play in encouraging states to adopt uniform licensing and training standards for doulas?

Response:
HHS and CMS are working to promote a health care system that will improve health outcomes across the country and provide access to quality care, including maternal health services, while ensuring patients are able to make decisions that work best for them. The first Trump Administration provided early support to increase access to these services by approving state plan amendments or otherwise supporting state efforts in many states, including Oregon (2017), Florida, and Minnesota (2020). Currently, 43 states and Washington DC either provide Medicaid coverage for doula care, are in the process of implementing Medicaid coverage, or have proposed covering doula care in Medicaid.

I will continue to work with CMS and states to help them achieve their goals with as much flexibility as possible, consistent with Medicaid program requirements and objectives.

9. Despite the FDA's own acknowledgment in Docket No. FDA-2022-N-0165 of the effectiveness of in-home drug disposal solutions in reducing the dangers posed by unused and unsecured opioids, and the 2019 GAO Report confirming that no federal barriers exist to their inclusion, as well as the SUPPORT Act's clear mandate to expand patient disposal options, the FDA has still failed to formally recommend or include these proven, commercially available products in the 2024 OA REMS guidance. This omission is especially indefensible given that manufacturers are already obligated to fund opioid risk mitigation strategies. The continued delay by the FDA in endorsing widely accessible, cost-effective, and life-saving in-home disposal options is unacceptable and puts lives at risk.
    a. What is the FDA's justification for the FDA's October 2024 announcement of yet another assessment—this time conflating fundamentally different technologies

like registrant-based systems with in/at-home disposal products—when the agency has already acknowledged the safety, accessibility, and public health value of in/at-home solutions? This appears less like due diligence and more like a deliberate delay tactic on an issue that has already been settled by both scientific consensus and federal policy.

Response:
Unlike mail-back envelopes, commercially available in-home disposal systems are not currently regulated by any federal agency, and these systems require careful consideration. To further modify the OA REMS, FDA needs to better understand these products so that it can develop appropriate specifications for them.

To that end, in June 2024, FDA commissioned a study by the University of Maryland's Centers of Excellence in Regulatory Science and Innovation (CERSI) to gain an understanding of the mechanisms of action, ingredients, safety, usability, and capability of commercially available in-home disposal systems. Completion of this study is expected in 2026.

While this study progresses, we are also planning to engage the public on what specifications these products should meet in order to make them an appropriate disposal option for inclusion in the OA REMS.

b. Furthermore, how does the FDA justify continuing to recommend outdated disposal methods – such as flushing medications or mixing them with unpalatable substances – despite growing environmental concerns, overwhelming patient preference for safer in/at-home solutions, and the well documented public health benefits of timely disposal, as outlined in multiple federal studies and reports?

Response:
FDA has developed a comprehensive approach to enable patients to dispose of their unused medications, including opioid analgesics, safety and securely. This approach includes a range of options to meet patients' needs and preferences. FDA first recommends that patients use a take-back option, like a pharmacy kiosk, take-back event, or mail-back envelope, to dispose of unused or expired opioids and is actively exploring other options, including in-home disposal systems. If a take-back option is not readily available, FDA recommends most opioids be flushed (i.e., 11 opioids that are on FDA's "Flush List", available at https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-fdas-flush-list-certain-medicines). FDA does not recommend that any opioid on the Flush List be mixed with unpalatable substances and disposed of in household trash.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Lizzie Fletcher (D-TX)

1. It has now been more than 80 days since HHS notified 16 Title X grantees that their funding would be withheld pending groundless investigations. Together, these grantees provided birth control, STI testing and treatment, and cancer screenings, to roughly 842,000 people in approximately 865 health centers.
    a. When can these grantees expect a response and resolution?
    b. What is the timeline for completing HHS's review and releasing the funds for all remaining grantees?

Response:
Due to active litigation, my Department cannot comment on the status of the grant recipients whose funding remains paused. HHS is committed to Title X program's mission of providing high-quality family planning and related preventive health services to low-income and uninsured individuals.

2. In your testimony in late May before the House Labor HHS subcommittee, you said Title X funds were withheld specifically because recipient organizations wouldn't isolate abortion related activities from other family planning services. We know from multiple reports, however, that the HHS notices the 16 grantees received telling them that their funding was withheld made no mention of abortion. The notices said funding was being withheld "pending investigation over 'possible violations' of grant terms and conditions, specifically federal civil rights laws and executive orders." While some grants have been restored as of late June, however, the grants to many Planned Parenthood centers have not. Why is this?

Response:
Due to active litigation, my Department cannot comment on the status of the grant recipients whose funding remains paused. HHS is committed to Title X program's mission of providing high-quality family planning and related preventive health services to low-income and uninsured individuals.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Alexandria Ocasio-Cortez (D-NY)

1. In March 2025, the Trump administration announced plans to dissolve the Substance Abuse and Mental Health Services Administration (SAMHSA) and consolidate the agency into the newly proposed Administration for a Healthy America (AHA). The proposed Department of Health and Human Services (HHS) budget allocates $5.7 billion for mental and behavioral health activities previously overseen by SAMHSA, representing a $1 billion reduction from SAMHSA's 2025 budget. With the proposed 2026 budget including the consolidation of three major SAMHSA grants—Community Mental Health Services; Substance Use Prevention, Treatment, and Recovery Services; and State Opioid Response—into a single "Behavioral Health Innovation Block Grant," states would receive $470 million less in funding compared to 2025 levels.
    a. How do you intend to continue SAMHSA's critical work following its dissolution and consolidation into AHA, especially in light of the significant budget cuts for overdose prevention and addiction services?

Response:
Behavioral health encompasses preventing substance use and providing treatment to people with a substance use disorder. Overdose prevention is an important tool for addressing substance use as it saves lives and provides linkages to services whether for substance use prevention or treatment. AHA will continue to support the full behavioral health continuum of care. It is noted that the new Behavioral Health Innovation Block Grant will include overdose prevention and substance use disorder treatment services.

2. The administration also proposes terminating federal grants essential to state and community overdose responses, such as the $56 million first-responder naloxone distribution program. Additional cuts to the Centers for Disease Control and Prevention (CDC)'s opioid prevention and surveillance efforts in the HHS budget proposal will reduce naloxone access, threatening to undermine the progress made in reducing overdose deaths.
    a. Do you support widespread naloxone availability to reduce overdose deaths and if so, why are you proposing to cut funding for it?

Response:
Naloxone availability is part of HHS' strategy to address opioid addiction and will continue under AHA. The FY 2026 President's Budget request for Injury Prevention and Control is $550,079,000. The FY 2026 request supports the planned HHS realignment of these activities from CDC to AHA.

3. In January 2025, the administration paused grant disbursements for domestic HIV/AIDS programs under OMB memorandum M-25-13 until a federal court injunction halted the freeze. The proposed 2026 budget further dissolves the Health Resources and Services Administration (HRSA) and includes significant cuts to HIV/AIDS funding, including to

the Ryan White program, which supports vital services that help prevent overdoses and the spread of infectious diseases.

a. What analysis, if any, has been conducted on the potential consequences of cutting HIV/AIDS prevention and care funding, particularly programs that support people who use drugs and reduce disease transmission? If no analysis was conducted, please explain why.

Response:
HHS is committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

HHS will continue to support activities to prevent and treat HIV. The FY 2026 President's Budget requests $2.5 billion for the Ryan White HIV/AIDS Program, including $165 million for the Ending the HIV Epidemic in the United States Initiative (EHE). The Budget also includes $157 million to continue EHE activities in Health Centers and $220 million to continue EHE activities formerly carried out by CDC. AHA will administer these programs and lead the coordination of EHE and other HIV/AIDS related activities formerly carried out by CDC, HRSA, and OASH under one entity.

The creation of AHA is not eliminating priorities or functions, but instead, taking these functions that operated independently and improving them so they will work in concert to Make America Healthy Again.

4. The President's Budget Request includes a 40% cut to NIH funding and a consolidation of its institutes, including the elimination of the National Institute on Drug Abuse (NIDA). As of July 2025, over 2,100 NIH grants totaling $9.5 billion have been terminated. According to a May report, 40% of the canceled grants focused on mental health. In recent months, we've made important strides in reducing overdose deaths by expanding health and overdose prevention interventions. Many of these lifesaving strategies were developed or studied by federally funded researchers.
    a. Do you support evidence-based treatment for substance use disorder and overdose reversal medications like naloxone?
        i. How will you ensure new treatments are developed and evaluated while NIH grants are being eliminated?

Response:
There was a 17.1% decline in overdose deaths in the 12 months ending in October 2025, demonstrating the success of the Trump Administration's efforts to end the influx of illegal fentanyl into the United States that proliferated under the Biden Administration's open border policies. Substance use disorder and overdose prevention remain a top priority for

the entire department. The Opioid Overdose Prevention and Surveillance program request in the Fiscal Year 2026 Congressional Justification for the Administration for a Healthy America will continue to support overdose prevention.

HHS is considering a number of proposals to streamline and reduce inefficiencies. While there is an extensive and systematic process in place before NIH can enact restructuring, the key principle is to empower collaboration across scientific disciplines to increase knowledge. NIH will continue to share ideas and data, regardless of the number and organization of NIH's Institutes and Centers. HHS is committed to ensuring that NIH delivers gold standard science and innovations to the public and continues to drive the discovery of life-changing treatments.

5. In June 2025, a federal judge ruled that the termination of NIH grants—particularly those focused on health disparities and minority health—was unlawful and discriminatory. Meanwhile, overdose death rates among Black, Indigenous, and Latino communities continue to rise.
    a. How do you intend to address these widening health disparities without the research necessary to understand barriers and evaluate effective interventions in these communities?

Response:
NIH will prioritize research that goes beyond measuring health disparities to focusing on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative evidence-based interventions and treatments that address poor health outcomes for all Americans.

6. You have publicly endorsed mandatory Medicaid and SNAP work reporting requirements in recent budget and reconciliation proposals. According to the Government Accountability Office (GAO), implementing these work reporting requirements has proven costly; in pilot states like Arkansas, 18,000 people lost coverage before a federal court ruled the policy unlawful.
    a. How will you ensure that the millions of Americans who stand to lose health coverage under these work reporting requirements continue to have access to essential health care services?
7. Medicaid is the primary payer of substance use disorder (SUD) treatment, covering more than half of all national spending on SUD care. The work reporting requirements that were signed into law on July 4, 2025, are projected to cause an estimated 1.6 million people receiving SUD treatment to lose their coverage.
    a. How will you protect access to care for the individuals with SUD who rely on Medicaid for treatment, given that these new requirements are expected to result in a loss of coverage?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response (6-7):
Work requirements will empower able-bodied adults to take personal responsibility, build economic mobility, and preserve Medicaid for future enrollees. In implementing these requirements (if they are enacted), HHS and CMS would draw upon lessons learned from successful reforms made to programs like SNAP (food stamps) and Temporary Assistance for Needy Families (TANF). HHS and CMS look forward to working with states to implement this commonsense approach while at the same time working to ensure appropriate guardrails are in place for those who are exempt from these requirements, including those with substance use disorder.

8. In April 2025, HHS terminated staff at the Office of the Assistant Secretary for Planning and Evaluation—those responsible for maintaining the federal poverty guidelines used to determine eligibility for Medicaid and SNAP.
    a. With the personnel responsible for maintaining the federal poverty guidelines now terminated, how will your department ensure states receive accurate and consistent guidance on eligibility for critical safety net programs—and prevent errors or waste resulting from outdated or unclear standards?

Response:
This concerns the April 2025 RIF announcement that is currently subject to litigation in New York v Kennedy (D. R.I, 1:25 cv 00196).

9. SAMHSA provides grants to support treatment services in drug courts, diversion programs, and reentry initiatives. More than half of incarcerated individuals have a substance use disorder, and research shows that access to treatment—particularly for those who are incarcerated or reentering society—significantly reduces the risk of overdose deaths.
    a. Under the recently passed Medicaid work reporting requirements, individuals reentering after incarceration, who already have significant barriers to employment due to their records, seemingly will be required to work in order to maintain coverage, beginning within approximately 3 months of incarceration. How do you plan to support this population to ensure they can access lifesaving treatment and recovery services?

Response:
CMS has been engaged in implementing several Congressionally mandated actions aimed at improving care transitions for certain individuals who are soon-to-be former inmates of a public institution and who are otherwise eligible for Medicaid and CHIP. This year, CMS awarded 4-year planning grants to 29 state Medicaid and CHIP agencies to develop operational capabilities to promote continuity of care for individuals who are inmates of a public institution and are eligible for medical assistance under the state Medicaid program or are eligible for child health assistance or pregnancy-related assistance under CHIP.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Funds may be used for addressing operational barriers and improving systems for continuity of care following incarceration in state-operated prisons, local, tribal, and county jails, and youth correctional or detention facilities.

10. More than 1.5 million people in New York are projected to lose Medicaid coverage as a result of the Republican-led reconciliation bill, which was signed into law on July 4, 2025. Sixty-two percent of New York's 2.4 million community health center patients rely on Medicaid or CHIP, and a majority of patients are considered extremely low-income. One community health center serving my district, Sun River Health, has 20,000 patients who are projected to lose their Medicaid coverage based on data made available by the New York State Department of Health. Federally Qualified Health Centers are required by law to serve all patients regardless of their insurance coverage or their ability to pay, but this law will seriously challenge their ability to do just that, jeopardizing services, jobs, and access to care. The President's Budget Request also allocates flat mandatory and discretionary funding for community health centers in FY26, which will further strain community health center finances.
    a. How does your agency plan to address these massive Health Center funding shortfalls that will result from Republican cuts to Medicaid and continued flat funding?

Response:
The FY 2026 President's Budget request will enable health centers to continue to provide high quality, cost-effective primary care services to over 32 million patients. This Administration is committed to protecting Medicaid's long-term fiscal integrity. The House-passed H.R. 1 provides CMS with the tools to ensure Medicaid resources are directed appropriately to strengthen program integrity, protect patient care, prevent taxpayer dollars from waste and abuse.

Mass layoffs at HHS have the potential to deeply impact community health center operations. Layoffs and closures at CMS regional offices have left health centers without local staff to respond to questions and provide technical assistance. Layoffs at HRSA have left the health center program severely understaffed, and the administration proposes now to completely disband HRSA and move its functions into an entirely new agency.

    b. Please share the administration's plans to ensure uninterrupted support for community health center operations following regional office closures and reduction in forces (RIFs)?

Response:
The FY 2026 President's Budget request supports approximately 1,400 Health Centers operating more than 16,200 service sites nationwide, that provide comprehensive medical care and support services such as health education, transportation, and preventive health screenings to over 32 million people.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

My Department utilizes a variety of methods to administer the Health Center Program and to monitor Health Center Program grantees to identify potential issues, including non-compliance with program requirements and areas where technical assistance might be beneficial. HHS monitoring includes the review of health center data reports, independent annual financial audits reports, ongoing communication with grantees, and site visits.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Jake Auchincloss (D-MA)

1. Certain executive branch employees must sign financial disclosure forms – Executive Branch Personnel Public Financial Disclosure Report (OGE Form 278e) and/or a supplemental Periodic Transaction Report (OGE Form 278-T). These reports are used to identify and address potential conflicts of interest and to ensure transparency in government. Neither Mr. Brad Smith nor Mr. Calley Means signed them due to their roles as special government employees. However, in light of their great potential for conflicts of interest, the American people deserve transparency.
    a. How do you intend on making financial disclosure forms for Mr. Calley Means and Mr. Brad Smith publicly available?

Response:
Special government employees are required to submit a financial disclosure report within 30 days of assuming their position if they are paid above the rate paid to a GS-15 and expected to serve for more than 60 days. 5 CFR 2634.

2. The Republican reconciliation package that recently passed the House without bipartisan support (H.R. 1) contained many provisions to expand HSA use significantly, which seems to financially benefit TrueMed's business model. At the hearing, you publicly defended the legislation.
    a. Can you please explain the extent to which Mr. Calley Means was involved in the drafting, revising, reviewing, or provision of feedback regarding the One Big Beautiful Bill Act?
    b. What steps did you take to ensure he avoided business interests when crafting recommendations?

Response:
Any technical assistance remains confidential between the Operating Division, the Immediate Office of the Secretary, and the staff requesting the technical assistance. In Mr. Means role, he is not involved in the Departmental technical assistance process.

3. The Trump Administration issued an Executive Order on February 13, 2025, entitled, Establishing the President's Make America Healthy Again Commission. The EO itself and the related MAHA Commission's report include provisions that seem to financially benefit TrueMed's business model. Public reports find that Mr. Calley Means was heavily involved.
    a. Can you please explain to what extent Mr. Means was involved in the drafting, revising, reviewing, or otherwise providing feedback regarding the EO and the related MAHA report?
    b. What steps did you take to ensure he avoided business interests when crafting recommendations?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
The MAHA Commission Report was drafted in consultation with the White House, the Department of Agriculture, the Environmental Protection Agency, and the Department of Health and Human Services. Mr. Means work on the MAHA Commission Report has not directly dealt with issues impacting TrueMed.

4. A supplements company filed an official complaint with the Office of Special Counsel, HHS Office of Civil Rights, HHS Office of Inspector General, and the Federal Trade Commission, on May 12, 2025. This competing company alleged that you used your government position to threaten the involvement of National Institutes of Health (NIH) Director Jay Bhattacharya and Secretary Kennedy in order to pressure the company into transacting with TrueMed.
    a. What was the nature of your involvement with Mr. Means' transaction negotiations with The Wellness Company?

Response:
I have had no involvement with Mr. Means' transaction negotiations with The Wellness Company.

5. Reports and people familiar with Mr. Brad Smith's role have stated his unique position in executing the reduction in force (RIF) at HHS allowed him to work with CMS officials to minimize any staffing cuts at CMS. Only about 300 jobs were cut at CMS, in stark contrast to cuts at other agencies within HHS – which included 3,500 at the FDA, 2,400 at CDC, and 1,200 at NIH.
    a. Why did you approve Mr. Smith's unbalanced RIF plan?

Response:
HHS' reduction in force was administered in compliance with President Trump's Executive Order issued on February 11, 2025, "Department of Government Efficiency Workforce Optimization Initiative (Workforce Optimization)."

All of HHS's actions adhered to applicable statutes, regulations, and guidance.

6. The Trump Administration was charged with finalizing a Biden proposed rule entitled, Contract Year (CY) 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-P). You and CMS issued the final rule on April 4, 2025, which took out many requirements from the proposed rule that Medicare Advantage Organization (MAOs) were required to comply with and increased capitated rates for MAOs. The policies included in the final rule are projected to increase payments to MAOs in CY 2026 by $25 billion compared to CY 2025.
    a. Please provide clarification on the rationale you used to make these changes between the proposed rule and the final rule.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

b. In other words, why did CMS decide to omit expanded requirements for MAOs and increase their capitated payment rates under your authority?

Response:
Seniors and other individuals with Medicare deserve to have choices for accessible, high-quality care. Medicare Advantage provides an opportunity for individuals eligible for Medicare to access choice and additional benefits based on their individual needs. I am working to ensure that Medicare Advantage is well administered, effective, and available for eligible beneficiaries. That's why CMS recently announced policy changes that will ensure that Medicare Advantage continues to offer access to critical services in an efficient, accountable manner while cutting down on waste, fraud, and abuse in the program.

In May, CMS also announced a significant expansion of its auditing efforts for Medicare Advantage plans. Under these efforts, CMS will begin auditing all eligible Medicare Advantage contracts each payment year, and will increase efforts to complete the backlog of audits for plan years 2018-2024. While the Administration values the work that Medicare Advantage plans do, CMS will execute its duty to ensure they are billing the government accurately for the coverage they provide to Medicare patients.

7. On June 17, 2025, FDA Commissioner Makary announced a new regulatory framework for drugs entitled, the Commissioner's National Priority Voucher Program (CNPRV). The CNPRV will begin in 2025 and is designed to accelerate the review of drugs the Commissioner deems is necessary to address critical national health priorities. Unlike traditional 10- to 12-month review timelines, the CNPV pathway would dramatically shorten it to just a one- or two-month review after final drug application submission. The Commissioners themselves would select drugs that are eligible for the CNPRV.

   This has a very strong potential to further conflicts of interest and corruption within the Trump Administration. The FDA's approval pathways ensure the highest standards of safety and efficacy for pharmaceutical drugs and medical devices. There are existing accelerated approval pathways that provide timely reviews but have safeguards in place to ensure the products are still safe and effective by requiring companies to submit follow-up evidence, show clear advantage over available therapies in preliminary clinical evidence, and/or hold more follow-up meetings with FDA officials.

   a. What safeguards will you and the FDA implement to this new pathway to ensure there are no conflicts of interest between Dr. Makary/future Commissioners and their policies and decisions for the CNPRV program?

Response:
Under the Commissioner's National Priority Voucher Pilot Program (CNPV), eligibility will be based on criteria of national priority including, but not limited to:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

- **Addressing a health crisis in the U.S.**
- **Bringing potential innovative therapies to the American people.**
- **Addressing a large unmet medical need.**
- **Increasing affordability.**

All FDA employees have a fiduciary responsibility to the federal government and must follow comprehensive federal ethics laws, including the criminal conflicts of interest and financial disclosure reporting laws, the Standards of Ethical Conduct for Employees of the Executive Branch, and the HHS Supplemental Standards of Ethical Conduct, including a prohibited holdings rule for FDA employees. All FDA employees must comply with the financial disclosure requirements found in the OGE regulations. FDA employees also are provided with ethics training as required by statute, regulation, and HHS/FDA policies upon appointment and will continue to do so annually throughout their service at FDA.

8. On June 10th NIH staff delivered the Bethesda Declaration to you demanding the agency stay true to its mission. As of today, over 300 staff have signed it along with support from more than 30,000 concerned citizens including Nobel Laureates and members of state and federal legislative bodies.

   One of the demands in the Declaration was that the grant cuts be reinstated, a position upheld most recently by Judge Young, a federal judge appointed by Ronald Reagan.
   a. Do you intend to comply with Judge Young's ruling?

Response:
I will always comply with the law and any court rulings.

   b. Additionally, this ruling dealt with one of five demands in the Bethesda Declaration, how do you intend to address the other four?

Response:
As Secretary, I intend to restore the American people's trust in our health agencies and to Make America Healthy Again. As such, my Department is focused on prioritizing transparency and restoring the gold standard of science.

9. Independent research on the economic impact of the proposed NIH budget cuts finds that the cuts will result in economic losses exceeding $46 billion and the overnight loss of 202,000 jobs. The private sector does not have the capacity to support 200,000 jobs lost nor the incentive to invest in much of the high-risk and long-term research that NIH conducts. This is already resulting in a brain drain of scientists to other countries around the world, including Canada, France, and China.
   a. How do you rectify this with NIH's mission and your stated goal of keeping the US as a world leader of biomedical research?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
Under the FY2026 proposed budget, the United States will remain the global leader in biomedical research and innovation. HHS is committed to ensuring that NIH delivers gold standard science to the public and continues to drive the discovery of life-changing treatments. Further, my Department is considering a number of proposals to streamline and reduce inefficiencies to ensure that all taxpayer dollars appropriated to the NIH are going as far as possible to deliver medical breakthroughs for the American people.

10. While the threat of cuts in NIH funding are detrimental across the biomedical research ecosystem, pediatric cancers in particular may face a devastating blow. Even in the absence of these cuts, according to the National Cancer Institute, only 4% of all government-allocated cancer research funds go towards pediatric cancer research. About 1 in 285 children will be diagnosed with cancer by their 20th birthday and nearly 16,000 new cases of pediatric cancer will be diagnosed this year.
    a. Are you concerned the contraction in federal research funding through NIH cuts will threaten future progress against pediatric forms of cancer?

Response:
The National Cancer Institute (NCI) supports a broad range of research to better understand the causes, biology, and patterns of childhood cancers and to identify the best ways to successfully treat children with cancer. Recent advances have been made in a variety of pediatric cancers such as brain cancer, leukemia, and sarcoma, each of which has benefited from NIH-developed technologies that help identify and treat these cancers. The FY2026 budget allows NIH to continue this critical work.

11. The 340B program enables savings on medication purchases for safety-net primary care providers like Community Health Centers. The health centers in the MA-04 congressional district and across the nation are good stewards of these savings, reinvesting them into providing patients access to low- cost medication and essential health services. However, a recent executive order targeting health centers' access to the 340B program will limit health center patients' access to drugs and discourage innovative approaches to making drugs affordable.
    a. Will you commit to soliciting feedback from health centers before implementing the Executive Order to provide administrative clarity and ensure patients have access to affordable medications?

Response:
Nothing in Executive Order (14273) reduces health centers' access to the 340B program. Instead, the order simply directs HRSA to ensure federally-qualified health centers are providing low-income patients with discounted insulin and epinephrine to make sure those lifesaving products are never out of reach for Americans. The Administration will continue

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

to engage with health centers to ensure they are equipped to deliver on the President's goal of access to affordable medications.

12. Independent advisors at the Advisory Committee on Immunization Practices (ACIP) have already unanimously recommended several vaccines after the FDA approved them. However, there are two outstanding recommendations on RSV and meningitis vaccines that haven't been taken up.
    a. What is the timeline on when the recommendations will be considered?

Response:
Information regarding ACIP and its activities may be found at the ACIP website, located at https://www.cdc.gov/acip/index.html.

13. On June 9th, you announced that you were dismissing all 17 sitting members of the ACIP. This is not only unprecedented, but incredibly destabilizing to vaccine confidence, access, and future development. There are explicit and stringent requirements and policies governing ACIP members' disclosure of conflicts and recusal from related discussions/votes. Every year, ACIP members must file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC.
    a. What specific criteria was used in the selection of the eight new ACIP members?
    b. What additional disclosures did you seek in addition to what ACIP members were already required to submit?
14. It has been widely reported that two of these ACIP members have received tens of thousands of dollars of compensation from serving as "expert witnesses" in legal actions targeting Gardasil. Vaccine and public health experts have expressed concerns about the qualification of many of those candidates. There are many other conflicts of interest that exist outside of pertaining to vaccine manufacturers.
    a. Will you commit to holding new and future ACIP members accountable not only for conflicts of interest related to engagement with vaccine manufacturers, but also for other actions that can influence their decision-making – such as financial stakes in litigation against manufacturers or other means of profiting from antivax rhetoric?
15. The childhood vaccine schedule has been informed by clinical and real-world data collected over decades. Per CDC: "Among children born during 1994–2023, routine childhood vaccinations will have prevented approximately 508 million cases of illness, 32 million hospitalizations, and 1,129,000 deaths, resulting in direct savings of $540 billion and societal savings of $2.7 trillion." You have stated multiple times that you would like the new ACIP members to "reevaluate the current childhood immunization schedule".

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. What changes do you think are necessary and what recommendations are under consideration?

16. The most recent ACIP meeting in April resulted in several recommendations for new and existing vaccines. The law requires ACIP recommendations to be reviewed by HHS prior to being finalized and historically, this has been delegated by the HHS Secretary to the CDC Director. However, you have indicated that you would be reviewing these recommendations yourself.
    a. What is your experience in vaccine policy-making and public health tracking?
    b. Will you commit to working with CDC health care officials to solidify recommendations for the upcoming respiratory season?

Response (13-16):
The Advisory Committee on Immunization Practices (ACIP) serves as a body of external experts who advise the CDC on the use of vaccines for the control of diseases. Established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended, the ACIP is a federal advisory committee charged with providing advice and guidance to the CDC Director regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. It is comprised of outside advisors appointed by the HHS Secretary, who develop recommendations for U.S. immunizations for consideration by the CDC Director, including the ages at which vaccines should be given, dosing regimens, and precautions and contraindications for individual vaccines.

17. The National Childhood Cancer Data Initiative was developed to pool data for every American child, adolescent and young adult with cancer, using cancer registry data to create the largest, strongest possible dataset for research. For this to succeed, a cancer registry is needed in every state, pooling and contributing data to the National Childhood Cancer Registry. For more than half of the state cancer registries, the major source of funding is from the CDC's National Program of Cancer Registries that would be cut under the proposed White House budget.
    a. Will you commit to funding a cancer registry in every state through the National program of Cancer Registries?

Response:
Gathering, harnessing, and sharing data from individuals with cancer has the potential to speed research and discovery. Specific to childhood cancers, the National Cancer Institute (NCI) developed the Childhood Cancer Data Initiative (CCDI), which includes the CCDI Data Ecosystem. This ecosystem provides infrastructure to expand comprehensive data collection and enhance data sharing from resources such as the National Childhood Cancer Registry and the CCDI Molecular Characterization Initiative (MCI).

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Administration is committed to reducing government inefficiencies and streamlines chronic disease activities through AHA. HHS continues to be supportive of cancer prevention efforts. The Budget includes the reorganization to establish the Administration for a Healthy America, which will be the primary federal agency committed to transforming the health of all Americans, including by addressing the root causes of chronic disease.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Greg Landsman (D-OH)

1. Millions of American workers in a wide range of industries depend on the work NIOSH employees do to safeguard their health. This should be a key part of HHS' stated goal to Make America Healthy Again. The proposed FY26 President's budget seeks to reduce NIOSH's funding by 80 percent, allocating just $73.2 million to coal miners and firefighters beginning on October 1st, 2025, a severe cut from the FY25 budget of $362.8 million.
    a. How does HHS plan to prioritize the health of nurses, construction workers, military personnel, and every other American worker with such a tight budget?

Response:
My Department will continue to meet all statutorily required obligations. NIOSH prioritizes resources that support statutory mandates and congressional directives, such as the Coal Workers Health Surveillance Program and the National Firefighter Cancer Registry. NIOSH would also seek opportunities to continue research and develop guidance that supports the health and safety of the broader US workforce.

    b. We have been told by employees who are on administrative leave pending separation from a RIF that they have been asked to resume work or train another employee on their duties while on administrative leave.
        i. If these NIOSH employees were given RIF notices because their duties were identified "as either unnecessary or virtually identical to duties performed elsewhere in the agency," then why does NIOSH leadership feel it is necessary, in order to carry out NIOSH's congressionally mandated functions, to ask those same employees to continue working?

Response:
My Department's Reduction in Force (RIF) is currently paused due to litigation, leaving certain NIOSH employees on administrative leave. Some employees on administrative leave have voluntarily assisted with critical functions or shared information with colleagues to ensure continuity of operations and avoid disruption to congressionally mandated programs.

    c. Employees still being RIFed have been paid to not work since either April 1 or May 2. Congress has already budgeted for these employees' salaries for FY '25.
        i. Why is HHS wasting taxpayers' money paying NIOSH employees to stay home and not work instead of completing their work that prevents workplace illnesses and injuries and saves worker lives?
        ii. What is HHS doing with this funding?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Under my leadership, HHS has made changes to the workforce to improve efficiency and reduce redundancy. We are no longer in a pandemic, and staffing levels needed to be adjusted accordingly to most efficiently meet the needs of the moment.

On July 8, 2025, the U.S. Supreme Court granted the Government's Application to stay the preliminary injunction, issued on May 22, 2025, by Judge Susan Illston of the U.S. District Court for the Northern District of California (Case No. 25-Cv-03698-Sl), which, at that time, prohibited HHS from further action on any existing RIF notices, including final separation of employees.

Following the Supreme Court's stay of the preliminary injunction, HHS administered a portion of its RIF. Accordingly, 4,623 employees were notified that they were officially separated from HHS at the close of business on July 14, 2025.

d. Title 42 employees are part of the excepted service employment category within the federal civil service and provide essential expertise in areas such as epidemiology, environmental health, occupational safety and health, emergency preparedness, and other critical public health fields. Since February, Title 42 employees' terms have not been extended, and one by one, they are being let go. Secretary Kennedy said: "As far as I know, we have not fired any working scientists, the working scientists, the people who are actually doing science." However, Title 42 employees represent a vital segment of the scientific workforce.
    i. Can HHS clarify why their terms are not being extended?
    ii. We have heard reports that some NIH Title 42s are getting renewed, but no CDC or NIOSH Title 42s are being renewed. Why is CDC/NIOSH being treated differently in this regard?

Response:
For the most recent RIF, HHS competitive areas were identified by organizational unit and geographic location, consistent with 5 CFR 351.402.

***Service Fellows* retained under 42 U.S.C §209(g) must be time-limited, as indefinite appointments are not permitted. Initial appointments may be made for varying periods not in excess of 5 years. Such appointments may be extended or renewed for varying periods not to exceed 5 years for each period. Extensions or renewals of appointments are not automatic and are based upon satisfactory performance.**

2. As I mentioned during the Energy and Commerce hearing with Secretary Kennedy, Head Start is incredibly important to me and paves the way for so many children in our country.
    a. What is the Secretary's plan to strengthen Head Start?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
I want to ensure appropriate resources are provided for our country's most vulnerable, including our children. The Head Start program provides comprehensive early childhood education, health, and nutrition services to low-income families, supporting families to gain self-sufficiency while promoting school readiness for children. Some examples of strengthening Head Start include enhanced nutrition guidance and Head Start 2.0.

Nutrition guidance: Currently, grantees provide up to two meals and one snack, or two snacks and one meal per day, through USDA/FNS Child and Adult Care Food Program, depending on the length of the program day. Secretary Rollins and I are committed to improving nutritional services and will update the Dietary Guidelines for America to ensure balanced meals are encouraged and promoted, consistent with this Administration's effort to Make America Healthy Again. This includes improving the quality of food offered to participants, as well as enhancing the nutrition supports to families so they can improve nutrition at home, as well.

Head Start 2.0: The FY 2026 President's Budget proposes a set of reform principles to modernize the Head Start program for the 21st century. Head Start 2.0 will refocus the program on the goals established 60 years ago, fulfilling its promise to help American families out of poverty by increasing efficiency of the funding, promoting parental choice and engagement, and improving health, education, and employment outcomes. ACFC is identifying the reforms that can be made through deregulation and operational changes and will identify changes needed from legislation to codify these improvements.

b. I've heard from local Head Start programs that the closures of the region 5 Head Start Office has resulted in confusion and no plan forward. The closure and cuts of federal workers has resulted in impacts to local programs and grant management.
    i. What is HHS doing to ensure local Head Start programs are not impacted by changes at the federal level?

Response:
HHS and OHS staff remain fully committed to supporting grant recipients and the important work they do to serve children, families, and childcare providers across the nation. All Head Start grant recipients have been notified of and are in direct communication with their current, regional office points of contact.

ii. I would also like to invite Secretary Kennedy to Cincinnati to take a tour of a Head Start facility to see firsthand the importance of the program and also to tour our NIOSH facility where life changing work is being done.

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Thank you for the invitation to visit programs in your district. My team will contact your office should we make a future visit to the Cincinnati area.

3. One of my constituents, Shane has a severe case of a rare disease called Epidermolysis Bullosa where the skin blisters and is incredibly painful and difficult to treat. Cincinnati Children's has one of the few EB centers in the country that provides comprehensive care for this condition and does great work in the rare diseases space. Shane is on Medicaid and spends millions of dollars a year on bandages alone just to manage his condition.

   I would like to see the Secretary commit to reinstating the Rare Pediatric Disease Priority Review Voucher Program and to see more funding go toward advancing treatments for rare diseases.

Response:
My Department supports the development of more drug and biologic products to address rare diseases and will continue to utilize all existing mechanisms to expedite development. We look forward to working with Congress in the reauthorization the Rare Pediatric Disease Priority Review Voucher program.

   a. How are FDA and CMS currently coordinating to ensure access to new treatments for those with Medicare and/or Medicaid coverage?
      i. Are there plans in place to speed up the process?

Response:
It is important that patients with rare diseases have access to high quality healthcare that improves health outcomes, and innovation is key to achieving that goal. As Secretary, I am working across the Department to explore the latest technological advances in improving our health system, as well as to ensure that innovators do not face unnecessary regulatory barriers in bringing these innovations to patients.

   b. Are there plans to create an FDA Center of Excellence for Rare Disease? How can we make that possible? Cincinnati Children's has one of the few EB centers in the country that provides comprehensive care for this condition and does great work in the rare diseases space.

Response:
FDA's Rare Disease Innovation Hub was created in 2024 to promote collaboration across FDA and advance a shared vision and comprehensive approach to address common challenges such as identifying and utilizing innovative scientific approaches to drug development and to streamline communications with the rare disease community. The Hub serves as a point of collaboration and connectivity between Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) with the goal of ultimately improving outcomes for patients. Although the Hub will work across rare

diseases, it will particularly focus on products intended for smaller populations or for diseases where the natural history is variable and not fully understood. You can learn more about the Hub including its recent strategic agenda here: FDA Rare Disease Innovation Hub | FDA.

c. What steps is CMS taking to ensure access to wound care supplies, including bandages, to promote equitable access to care for individuals living with EB and similar chronic conditions?

Response:
As stated above, I agree it is important that patients have access to high quality healthcare that improves health outcomes, and innovation is key to achieving that goal. As Secretary, I am working across the Department to explore the latest technological advances in improving our health system, as well as to ensure that innovators do not face unnecessary regulatory barriers in bringing these innovations to patients.

4. How does HHS plan to address the gap across race in maternal mortality that Secretary Kennedy mentioned during his testimony at the Energy and Commerce hearing?

Response:
I am committed to addressing the maternal mortality rate in this country and its underlying causes, including access to maternal health care for women throughout pregnancy. HHS programs recognize the importance of tailoring approaches to care to best serve communities. The State Maternal Health Innovation Program funds public health organizations, universities, community-based organizations and other groups to implement state specific innovation action plans to improve maternal health. The program establishes state-focused Maternal Health Task Forces, improves state-level data surveillance on maternal mortality and severe maternal morbidity, and promotes and executes innovations in maternal health service delivery.

Through the Alliance for Innovation on Maternal Health Program (AIM), HHS is supporting best practices across birth settings that make birth safer, improve the quality of maternal health care and outcomes, and save lives by supporting the expanded implementation of patient safety bundles. As of April 2025, the AIM program has been implemented in 49 states, the District of Columbia and Puerto Rico, with more than 2,000 birthing facilities implementing the AIM patient safety bundles. This represents 75% of all birthing facilities.

The Delta Region Maternal Care Coordination Program and the Rural Maternity and Obstetrics Management Strategies Program ensure geographically tailored delivery of maternal health services and incorporate feedback from mothers into the program.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

HHS is also supporting engagement with community health centers through the Health Center Program which funds 52 Primary Care Associations representing all U.S. States, Territories and Freely Associated States to provide training and technical assistance to improve maternal health outcomes for health center patients.

5. What is your plan to continue the essential work of the programs within the Safe Motherhood/Infant Health program that are vital to improved health outcomes for moms and babies, and ensure the continuation of successful maternal and infant health programs across HHS, now that the program is eliminated in the FY26 President's budget?

Response:
The FY 2026 President's Budget invests in programs to improve maternal health outcomes, particularly in underserved and rural areas, prioritizing programs that provide states and communities the flexibility to address local maternal and child health needs. This includes a new Prevention Innovation Program funded at $119 million as part of the Make America Healthy Again initiative to address the root causes of America's escalating health crises, including a track specific to maternal health challenges.

The President's Budget also continues investments in the Maternal and Child Health Block Grant, the State Maternal Health Innovation program, the Alliance for Innovation on Maternal Health program, the Integrated Services for Pregnant and Postpartum Women program, the Screening and Treatment for Maternal Mental Health program, and the Maternal Mental Health Hotline to provide support and referrals to pregnant and postpartum women facing mental health challenges.

The Budget also continues investments in rural maternal health through the Rural Maternity and Obstetric Management Strategies program, which provides start-up funding to test out new approaches to supporting, enhancing, and expanding maternal and obstetrics care in rural communities. The Delta Region Maternal Care Coordination Program is also continued to expand access to care for pregnant women and new mothers by addressing barriers through care coordination strategies for the delivery of perinatal services.

6. I recently visited the FDA National Forensic Chemistry Center in my district, FDA's only forensic laboratory specializing in the testing of adulteration/contamination, counterfeiting, and tampering of FDA-regulated products. The center mentioned that they need additional funding for scientists, laboratory support staff, and instruments. The FY26 President's budget for FDA is $6.8 billion, a 3.9 percent reduction from this year's fiscal budget.
    a. How does this reduction impact laboratories such as this one?
    b. Does this budget reduction impact the United States ability to ensure that FDA regulated products are safe from human consumption?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

c. Does this budget reduction impact the ability of this laboratory to conduct work in the opioid space, which has significantly reduced the number of overdose deaths we see in our country?

Response:
This budget is consistent with the personnel and organization changes that have already been made to make the Agency into a more efficient and effective organization. In fact, this budget would also allow us to redouble our efforts on critical priorities, such as dealing with America's chronic health crisis by providing an additional $65 million to support efforts in areas such as nutrition, infant formula, and food safety. This request will make FDA a much better steward of taxpayer funds by increasing our efficiency without losing any of our core functions.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Doris Matsui (D-CA)

1. Drug shortages are a serous public health threat. In April 2025, the Government Accountability Office (GAO) released a report on trends in drug shortages and the federal government's response capability, and made recommendations to improve HHS's readiness and response for drug shortages.
    a. Will you commit to implementing GAO's recommendations to (1) identify and implement a mechanism to formally coordinate its drug shortage activities and collaborate with other federal stakeholders, and (2) ensure this mechanism takes GAO leading practices for collaboration into consideration.

Response:
My Department takes seriously the issue of drug shortages and will continue our close review of the report and will implement the recommendations as appropriate.

2. The Make America Healthy Again (MAHA) Report cites the "aggregation of environmental chemicals" as a key driver of chronic disease in children. In fact, page 38 lists several key environmental exposures that are known disease-causing agents, and notes that regulation and government action have contributed to significantly reducing the exposures to these chemicals, like mercury. Yet the Environmental Protection Agency (EPA) has announced the "biggest deregulatory action in U.S. history," rolling back key regulations on particulate matter, arsenic, ethylene oxide, mercury, and more.
    a. Was the Department of Health and Human Services, specifically HHS Secretary and MAHA Commission Chair Robert F. Kennedy, consulted on any of these regulations?
    b. How do you explain the conflict between these regulations and the MAHA Report's stated goals?

Response:
EPA Administrator Zeldin is an integral Member of the Make America Healthy Again (MAHA) Commission. Administrator Zeldin is committed to ending America's childhood chronic disease crisis through safe and responsible regulation of chemicals. I look forward to continue collaborating on efforts to Make America Healthy Again.

3. Recent reporting (CBS News, June 6, 2025) has indicated early retirements, resignations, and the hiring freeze have led to an increasing gap in FDA's food safety inspection workforce —
    a. Can FDA confirm whether 1 in 5 food safety inspection positions are currently vacant?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

FDA's Food Inspectorate currently has approximately 470 investigators on board and approximately 100 vacancies. The number of investigators currently on board is similar to recent fiscal years (i.e., FY23 and 24).

b. How many inspectors does FDA need to hire to meet the inspection mandates set by Congress in the Food Safety Modernization Act?

Response:
To achieve full FSMA compliance, FDA estimates it needs an additional 1,062 (264 domestic and 798 foreign) full time investigators. Meanwhile, FDA is taking steps to usher in a new paradigm that leverages partnerships and data to be more targeted and integrated in how we meet our food safety responsibilities. We are working to further enhance the integrated Federal-State food safety system to rely more heavily on states to conduct domestic oversight activities, including routine inspections and sampling. We are also leaning into the power of data and new AI tools to further complement and inform our inspectional approach. Along with the data FDA collects through inspections and sampling, we are beginning to leverage third- party audit data, data sharing partnerships with industry, and arrangements with foreign regulatory counterparts to help us detect signals and trends that can help us better target our limited resources. We believe this paradigm shift will allow us to work smarter together toward building a fully integrated, risk-based oversight model. We envision this model will promote efficiency and reduce redundancy, expand inspection coverage, increase surveillance capacity and, ultimately, strengthen public health protection.

c. What steps is FDA taking to fill open inspection positions?

Response:
FDA was able to obtain exemptions under "Public Safety" to backfill for a variety of mission critical roles while FDA remains under a government hiring freeze. This includes food safety investigators. Job announcements for Investigator positions in the Human Food Inspectorate were posted via USAJOBS starting June 6, 2025, and as recently as July 14, 2025. Applicants for these announcements are in various stages of the hiring process.

4. Following the reduction-in-force at FDA, Congress and the public were repeatedly told that RIFs would not impact drug approvals. Yet multiple PDUFA dates have already been delayed, including KalVista Therapeutics'. That company was told the PDUFA date would not be met due to "heavy workload and limited resources" at FDA.
    a. How many drug and device reviewer positions are currently vacant?
    b. Was Commissioner Makary incorrect when he stated the RIFs would not impact drug approvals?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

c. How is FDA tracking other impacts of the RIF, such as delays in key decisions during drug development, but preceding the final PDUFA decision? (E.g, approval for changing a trial design, receiving a certain designation for a NDA)
d. Will FDA commit to rehiring the workforce if it becomes clear that the reduced workforce is having a measurable impact on mission-critical activities?
e. At what point will FDA commit to rehiring the workforce?
    i. Once FDA has missed key deadlines, PDUFA or otherwise, for 20% of applications? 50%? 100%?

Response:
FDA has continued to meet the majority of user fee agreement goals across Centers. Performance data and user fee performance reports can be found at: Performance Data | FDA. FDA will continue to prioritize timely review of products in accordance with user fee commitments.

The Agency continues to prioritize maintaining, training and, if needed, hiring more reviewers to maintain our mission in terms of ensuring the safety, efficacy, and security of medical products for American consumers.

5. On July 17, 2024, the FDA announced the creation of a Rare Disease Innovation Hub to serve as a point of collaboration and connectivity between the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) with the goal of ultimately improving outcomes for patients. Following public input, the Hub in January 2025 released its strategic agenda, which included three major goals and several strategic priories in order to complete those goals.
    a. Will FDA commit to continuing the activities of the Innovation Hub on the timeline laid out in the January 2025 strategic agenda? This includes:
        i. Sponsoring up to three multi-partner Rare disease Innovation, Science, and Exploration (RISE) workshops in the year 2025 to explore challenges that are common to multiple diseases or a class of diseases and for which evolving science offers innovative solutions.
        ii. Working with members of the rare disease community in 2025 to discuss ways that FDA might build on engagement efforts and to envision strategies to better engage the rare disease community in regulatory processes, as allowed by law.
        iii. Maintaining the Rare Disease Policy and Portfolio Council (RDPPC), which is a senior level forum to promote cross-Center dialogue on challenging and complex rare disease drug development program-related issues; and building on these meetings to put in place additional practices and policies to regularize cross-Center communication regarding the same or related diseases or issues, particularly regarding innovative approaches

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

in rare disease, to ensure that drug review within the Centers have common approaches when approaching similar populations or issues.

iv. In 2025, conducting an assessment of options to meet the need for a "one-stop shop" for FDA rare disease programs and information.

v. In 2025, working with members of the rare disease community, including patient organizations and drug developers, to serve on an informal educational materials committee that will assess FDA-wide rare disease educational materials and define gaps and redundancies in those materials.

Response:
Yes, the Hub is committed to meeting the goals in the Strategic Agenda.

The Rare Disease Innovation Hub plans to build upon the public comments it received through its 2024 public workshop, which, broadly, call for enhanced intra-agency and external communications and innovation.[1] On June 13, 2025, the Hub opened a public docket to solicit input on topics for future Rare Disease Innovation, Science, and Exploration (RISE) workshops, including a fall 2025 meeting. The purpose of the public workshops is to focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. Priority will be given to submissions that are germane to multiple disease states and/or that are submitted jointly by two or more entities. The Hub will hold its first RISE Workshop, "On the RISE: Controls in Rare Disease Clinical Trials for Small and Diminishing Populations," on September 3, 2025, and plans to host further RISE workshops in the near future.

b. Will FDA dedicate funding and resources to the Hub in order to ensure this mission is met?

Response:
Yes, the Hub has been able to use existing resources dedicated to rare disease activities to support the Hub activities.

6. On April 23, 2021, the FASTER Act was signed into law. This law required a report within 18 months of the bill's enactment that would describe ongoing Federal activities related to food allergy surveillance, diagnostics, and treatments; and recommend to Congress how to improve food allergen surveillance and safety. Specifically, Congress required FDA to share recommendations for the development and implementation of a regulatory process and framework that would allow for the timely, transparent, and evidence-based modification of the definition of "major food allergen"
    a. When will FDA provide this report to Congress?

[1] Advancing Rare Disease Therapies Through an FDA Rare Disease

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
FDA continues to provide updated resources to the public regarding sesame as a major food allergen, including final guidance for industry, on its website here: Food Allergies | FDA. We are aware that the FASTER Act required a Report to Congress to be submitted in 2022, and we are reviewing the statutory requirements.

7. On May 22, 2025, the first MAHA report was published. The report focuses on the increasing prevalence of chronic diseases and obesity, particularly among children. It identifies four potential drivers of the crisis, including aggregation of environmental chemicals. The report says, "The cumulative effect of multiple chemical exposures and impact on children over time is not fully understood."
    a. Does more research need to be done on the impact of environmental exposures on children and development?
    b. NIH terminated the following grants: Public drinking water contaminants and infant health; Pesticide exposure and child respiratory health; Exposure to metals and metal mixtures on late life cognitive health; And more.
        i. Can you tell us why these grants were cut when they seem to align with your priorities as outlined by the MAHA report?
    c. What was the process for determining which grants to revoke, and what was the basis of these determinations?

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. NIH is working to find better ways to prevent, treat, and cure chronic diseases. NIH-funded research has highlighted crucial roles of diet as it relates to chronic disease including obesity, type 2 diabetes, cardiovascular disease, and many cancers. Understanding the interactions among genetic, environmental, and health factors will improve the ability of scientists to prevent, diagnose, and treat chronic disease. To tackle these persistent and complex problems, NIH-funded research must be rigorous, reproducible, and generalizable. As an agency, we are dedicated to supporting and conducting gold-standard, evidence-based science. NIH has reviewed its portfolio of research funding with a key goal of addressing the chronic disease epidemic. Grants were evaluated and were terminated in accordance with independent authorities and agency priorities. NIH welcomes scientists to continue working with their organizations to submit meritorious research proposals that support our goal of making all Americans healthier.

8. Both you and the President have said addressing the opioid crisis and substance use disorders is a priority. Yet, the following NIH grants have been terminated: How to increase prescribing of naloxone; Virtual Reality treatments for chronic pain and opioid use disorder; Training the next generation of substance use and addiction researchers; And more.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Why would your administration cut research that's advancing our understanding of your priorities – and training the next generation of researchers?
b. We keep hearing that research "not advancing administration priorities," is being targeted, but these grants are directly within your stated priorities as outlined by the MAHA report.
    i. So, who was going through each NIH grant and making the decision to terminate certain ones?

Response:
President Trump is committed to ensuring that the United States remains the global leader in biomedical research. NIH is seeking approaches to streamline and efficiently spend funds in order to advance NIH's mission to support scientific endeavors that advance the health and longevity of the American people. To tackle these persistent and complex problems, NIH-funded research must be rigorous, reproducible, and generalizable. As an agency, we are dedicated to supporting and conducting gold-standard, evidence-based science. NIH has reviewed its portfolio of research funding with a key goal of addressing the chronic disease epidemic, which includes pain research. Grants were evaluated and were terminated in accordance with independent authorities and agency priorities. For example, we have cancelled grants that funded research on, "adolescent health at the intersections of sexual, gender, racial/ethnic, immigrant identities, and native language", "COVID-19 Misinformation in low-income Latinx communities", and "effects of exogenous testosterone therapy on communication in gender diverse speakers". NIH welcomes scientists to continue working with their organizations to meritorious research proposals that support our goal of making all Americans healthier by addressing chronic pain and reducing associated effects such as addiction to opioid pain medications.

9. In late May, NIH announced a new $50 million dollar autism research funding stream, known as the Autism Data Science Initiative. Autism researchers have expressed concerns that the initiative feels rushed and lacks transparency. They worry that their research could be misconstrued or manipulated to fulfill a certain agenda. Given the sensitive nature of this issue for so many families, this research needs to be well thought through and rigorously reviewed. It's especially critical to have safeguards in place to ensure transparency. But given the unusual process NIH used for this funding opportunity, researchers have no idea who will be reviewing their applications.
    a. Researchers were given a month to write and submit their study proposals. Can you explain why the Autism Data Science Initiative has such an accelerated application and approval timeline?
    b. Given this accelerated timeline, how will you ensure the quality of the applications received and reviewed?
    c. Who will be reviewing the grant applications?
    d. Will you commit to having an independent external advisory board of autism scientists and community members?
        i. Why or why not?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

e. What is the anticipated timeline for this research?
    i. When do you expect to start collecting and writing up the results?

Response:
NIH is committed to funding a research program that will produce valid and reliable information on the causes, prevalence, and treatment outcomes for Autism Spectrum Disorders. The shortened timeline will allow NIH to commit funds and support impactful science by the end of Fiscal Year 2025. The NIH received over 200 applications in response to the research opportunity announcement, and all but a handful were responsive.

Autism community members will inform each ADSI funded project. In addition to describing the proposed scientific approach, each applicant developed a Community Engagement Plan for describing community involvement in their project including identifying autism community partners. The plans also described how communities will be collaboratively engaged throughout the research project. NIH staff managing awards made through ADSI will track how well these plans are being implemented over the course of the project period.

Scientific proposals were subject to rigorous objective review by subject matter experts inside and outside the agency. This included experts in the etiology and treatment of autism and experts in data science. NIH scientific program staff developed funding recommendations informed by that objective review and subject to oversight by senior NIH scientific leaders with extensive subject matter expertise as well as agency leadership.

Projects will be funded for two to three years, including projects specifically directed at rigorous replication and validation of research results. Program researchers will be expected to submit their findings for publication per usual procedures and policies for NIH-supported research.

10. The Bipartisan Safer Communities Act required the Centers for Medicare & Medicaid Services to open an opportunity for an additional 10 states to join the CCBHC Demonstration every two years.
    a. Will CMS commit to opening an opportunity for 10 states to apply for the CCBHC demonstration this upcoming fall 2025, consistent with the statutory deadline of adding the additional states in 2026?

Response:
My Department plans to release the demonstration application with sufficient lead time to select up to 10 additional states before the July 1, 2026, statutory deadline.

11. Secretary Kennedy recently announced plans to re-examine a potential link between vaccination and autism spectrum disorder, even though dozens of scientific studies have failed to link the two.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. As part of this process, did HHS review the previously conducted research?
    i. What were the credentials and expertise of the review team?
b. What issues did HHS have with the previously conducted research?
c. If there are concerns with the methods used to conduct previous research, how does this new study's methodology differ?

Response:
I have been charged by the President to identify the underlying causes of autism. As part of the Administration's goal to return the Department to the Gold Standard of Science all previous studies and new research will continue to be reviewed in order to fully consider the science in any future recommendation.

12. This study is happening in the midst of massive terminations and drastic proposed restructuring of HHS.
    a. What is the budget for this study? Please share the breakdown of this budget and justification.
    b. How many staff will be hired to complete the study?

Response:
As previously mentioned, I have been charged by the President to identify the underlying causes of autism. As we undertake strategic workforce planning efforts, HHS will continue to prioritize this goal set forth by President Trump.

13. Given the sensitive nature of this topic, it's especially important that the methods of this study are sound to ensure the integrity of the results.
    a. Are there epidemiologists in charge of the study design, methods, statistical analysis plan?
    b. Who will be in charge of the actual data analysis and interpretation of results?
    c. Are you conducting primary data collection or doing secondary data analysis?
    d. If it is a secondary data analysis, who will determine which datasets to use?
    e. Will the study be peer reviewed? Why or why not? Who will be peer reviewing?

Response:
My top priority is to research the causes of chronic diseases, including autism spectrum disorders. As we work to study the possible causes of autism, our efforts will work with the top scientists and universities without a bias toward any cause. We will follow where the rigorously reviewed gold standard science takes us.

14. Secretary Kennedy claims that during his tenure as HHS Secretary, he is seeking to increase transparency and reduce bias in scientific research. This is seemingly contradicted by reports that David Geier was appointed to conduct the study.
    a. David Geier is a long-discredited researcher and vaccine skeptic. What will Geier's role in the research study be?

b. What parts of the research process will David Geier be involved in? Will he be involved in the data interpretation?
c. How do you plan to ensure that Geier's anti-vaccine sentiments won't be a conflict of interest?

Response:
David Geier is not conducting the study. David Geier has been hired on a contract that supports HHS with statistical survey design, implementation, data analysis, reporting, visual analytics, and quantitative decision support. In following with the gold-standard of science, any and all research will be rigorously reviewed without a bias toward any cause. We will continue to follow where the science takes us.

15. At the end of May Secretary Kennedy announced that COVID-19 vaccines for healthy children and healthy pregnant people had been removed from the CDC's recommended immunization schedule – without the input of the Advisory Committee for Immunization Practices (ACIP).
    a. Can you explain the process, research, and data used to come to this decision?
    b. Did you work with any groups or medical organizations to come to this decision?

Response:
On May 27, 2025, HHS announced that the COVID vaccine for healthy children and healthy pregnant women had been removed from the CDC recommended routine immunization schedule. For healthy children ages 6 months to 17 years who are not moderately or severely immunocompromised, the CDC now advises shared clinical decision-making.

Shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. For pregnant women, the schedule no longer includes a recommendation for the COVID vaccine.

16. Politico reported that HHS has been circulating a document justifying this decision to remove the vaccine recommendation for pregnant people.
    a. Who compiled and worked on the report that led the Secretary to make the decision to change the vaccine recommendation?
    b. Were epidemiologists involved in the literature review, synthesizing of the existing research, compilation of the report and findings and subsequent decision-making process?
        i. Why or why not?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The CDC and HHS encourage individuals to talk with their healthcare provider about any personal medical decision. ACIP and its activities may be found at the ACIP website, located at https://www.cdc.gov/acip/index.html.

17. This document includes a citation for a research paper on COVID-19 vaccination during pregnancy.
    a. The lead author of the study, Dr. Maria Velez told POLITICO that "the results of our manuscript were misrepresented." Additionally, some of the works cited in the document, just don't exist. How do you explain Dr. Velez's comments and the discrepancies?

Response:
HHS and the CDC encourage people to talk to their healthcare providers about any personal medical decision, including vaccines.

18. On April 13, 2025, California's Title X grantee, Essential Access Health, was notified that its funding would be withheld while HHS investigated Title X grantees' compliance with certain executive orders. Without Title X funding, 8% of California's Title X-funded agencies report that they will immediately or likely have layoffs, and 62% report there will be immediate reductions in sexual and reproductive health services. California's 350 Title X clinics served over 500,000 patients in 2024. Disruptions in their services, which include cancer screenings, sexually transmitted infection screening & treatment, and contraceptive care, can be life-threatening.
    a. Given the critical nature of this funding, especially in light of the Medicaid cuts to Title X clinics and the fact that several clinics will be excluded entirely from the Medicaid program, will HHS commit to maintaining the current funding structure for Title X clinics and avoiding any unnecessary risk by disrupting funding again?

Response:
I will follow the law and President Trump's policies regarding Title X funding for clinics across the country.

19. Secretary Kennedy, the President's budget request combines multiple agencies – including SAMHSA – into a new entity, called the Administration for a Healthy America (AHA).
    a. As the National Center of Excellence for Eating Disorders program is authorized through 2027, do you commit to ensuring programs that address eating disorders previously under the purview of SAMHSA will continue?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

There is currently no dedicated appropriation for eating disorders, and continued support will depend on future congressional funding decisions. States can leverage federal resources, including the Behavioral Health Innovation Block Grant, the Children's Mental Health Initiative (CMHI) for individuals with serious emotional disturbance (SED), , to address the needs of individuals with eating disorders.

b. Moving forward, how will HHS measure the cost-effectiveness of federal healthcare programs, including those designed to identify and treat health conditions early – including eating disorders – and implement strategies to streamline access to treatment?

Response:
Moving forward, HHS will measure the cost-effectiveness of federal healthcare programs by strengthening data collection, program evaluation, and access to care. The new Unified Performance Reporting Tools (SUPRT) will streamline reporting, reduce burden, and improve data consistency, enabling stronger outcome and cost-effectiveness analyses. HHS will continue evaluating existing programs to ensure resources are directed toward the most effective models. At the same time, we are expanding access through CCBHCs and strengthening coordination with the 988 Suicide & Crisis Lifeline and crisis systems of care. Together, these efforts will improve outcomes, reduce avoidable costs, and ensure individuals receive timely, effective treatment.

20. On June 17, the Substance Abuse and Mental Health Services Administration (SAMHSA) announced that on July 17 it was ceasing the operations of the "Press 3" call option to the 988 Lifeline, eliminating a critical service that connects LGBTQ+ youth to highly trained and culturally competent crisis support. At the same time, your Fiscal Year 2026 budget request touts the success of the entire 988 Lifeline – and rightfully so – which has included the LGBTQ+ youth specialized services since its inception. As you know, the 988 Lifeline has received approximately 15 million contacts, including more than 1.3 million contacts routed to the LGBTQ+ youth network. That means nearly one for every dozen person who contacts the 988 Lifeline has utilized the so-called Press 3 option. Having these options has saved young lives. Accordingly:
    a. What specific studies or analyses did your agency conduct that support eliminating the Press 3 option on the 988 Lifeline?

Response:
As of June 2025, more than $33 million in FY24 funds had been spent to support the Press 3 subnetwork. Continuing to fund the Press 3 option would have drawn funds away from broader 988 Lifeline services, most notably the national backup crisis contact centers for calls, chats and texts. These backup contact centers provide coverage for all Americans when local centers are not able to respond to people in crisis within an acceptable time range. An important distinction between the Veterans "Press 1" and "Press 3" is that

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

SAMHSA does not provide funding for the calls that go to the Veterans Crisis Line, as that service is entirely funded by the Veterans Administration.

b. Has your agency consulted with mental health professionals, public health experts, or other stakeholders while deciding to shut down the LGBTQ+ youth specialized services?
    i. Can you identify the names of reputable mental health organizations or professionals that support eliminating the Press 3 option?
c. Did you or your staff meet directly with any of the providers of youth LGBTQ+ youth specialized services prior to deciding to eliminate these services?
d. Please describe the training that 988 Lifeline counselors outside of the specialized services network receive to help them both serve the LGBTQ+ youth contacting the 988 Lifeline and respond to the significant volume of harassing contacts that are currently routed to the LGBTQ+ youth specialized services network.

Response (b-e):
Guidance documents, practice simulations, trainings, and webinars are available to all 988 counselors across the network. Help seekers within various high risk populations are represented in video examples as part of 988 counselor's initial required training. Counselors also receive additional training and support on working with abusive contacts.

21. The Mental Health a Mental Health Awareness Training (MHAT), also known as Mental Health First Aid (MHFA), is a critical program that provides training for individuals on the front lines of responding to mental health crises, such as adults who work with youth; emergency service personnel, including law enforcement and fire departments; veterans; and armed service members and their families. MHFA is an evidence-based program that has operated in the United States since 2008 and helps the public identify, understand and respond to signs of mental health and substance use disorder challenges. Since FY2014, the Substance Abuse and Mental Health Services Administration (SAMHSA) has funded state and local educational agencies to support the training of school personnel including classroom teachers, counselors, and principals. In 2016, the bipartisan *Mental Health First Aid Act* was passed as a provision of the bipartisan *21st Century Cures Act*. Since its passage, the program has trained more than four million Mental Health First Aiders, including Catholic Charities, YWCA, YMCA, Boy Scout and Girl Scout leaders, community colleges, veterans, and first responders, as well as over 500 law enforcement agencies, from all 50 states and U.S. territories, with the highest number of First Aiders in Florida and Texas. Given this proven track record, I was disappointed to see the program targeted for elimination in the President's FY26 Budget Request.
    a. Given HHS's interest in maintaining behavioral health programs, especially hose for individuals with serious mental illness, what is the Administration's rationale for eliminating the Mental Health Awareness Training program?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
AHA is committed to helping persons with serious mental illness live meaningful productive lives. This includes increasing awareness of mental illness in the behavioral health workforce, law enforcement and other professionals, as well as community members.

b. Is it no longer a priority for the Administration to ensure law enforcement officers are adequately trained to deal with individuals in mental health crises, to avoid putting themselves and the individuals with mental illness in danger?

Response:
I remain committed to reducing the use of law enforcement in behavioral health crises, utilizing alternatives such as mobile crisis teams except when law enforcement is needed for public safety. SAMHSA has recently published a range of materials to support diversion of crisis contacts from 911 and law enforcement where safe and possible and has published a range of guidance documents to help partners, including first responders, respond to behavioral health situations in the community.

22. California's Personal Responsibility Education Program (PREP) currently under review by HHS, which has given California 60 days to remove references to "gender ideology" from its curriculum or risk additional "enforcement action" that could include withholding or terminating federal awards.
    a. Governor Newsom's office stated that they were first made aware of the funding review via Fox News, not though HHS. Is this consistent with the agency's policy of being the most transparent HHS in history?

Response:
The Authorizing Official and Project Director of California's State Personal Responsibility Education Program (State PREP) at the California Department of Public Health (CDPH) was notified on June 20, 2025, that ACF identified content in the curricula and other program materials submitted by CA PREP that fall outside of the scope of PREP's authorizing statute (42 U.S.C. § 713). This communication to the Authorized Official and Project Director of CDPH occurred prior to an official HHS press release.

b. Reportedly, a "medical accuracy review" found that the curriculum and program materials in California's program went beyond scope of the statute authorizing the PREP program. Who conducted this medical accuracy review, and what were their credentials? Please share the sources they used to determine the curriculum information was not medically accurate.

Response:
As stated in the June 20, 2025, letter to CDPH, while preparing California's PREP content for medical accuracy review, HHS identified gender ideology content in the curricula and

other program materials that fall outside the scope of PREP's authorizing statute (42 U.S.C. § 713). In light of these findings, HHS changed the planned course of action and did not conduct the medical accuracy review because the content HHS was going to review for medical accuracy was outside of the content that is statutorily authorized in this program. HHS did not draw any conclusions about whether the curriculum content flagged as outside the scope of the authorizing statute was medically accurate.

c. This program provides over $6 million a year to California and reaches over 15,000 children annually.
    i. If California's funding is cut, what is HHS's plan to ensure youth and young adults are educated about sexual intercourse, protection from sexually transmitted infections, and contraception in a timely, age-appropriate, and scientifically accurate way?

Response:
HHS is committed to implementing PREP in accordance with its authorizing statute. Most states, including California, may reapply for PREP funding annually. 42 U.S.C. 713(a)(1)(C). If California does not choose to apply for PREP funds, the PREP statute (Sec. 513. [42 U.S.C. 713] (a)(4)(B)(i)(ii)) requires the HHS Secretary to make California's PREP funding available for competitive awards to local organizations, entities, and faith-based organizations or consortia to conduct PREP programs and activities.

    ii. Who will review the curriculum that HHS provides for scientific accuracy?

Response:
HHS has a vetted contractor that engages independent subject matter experts to review curricula and program materials for medical accuracy.

d. This program was also targeted for illumination in the President's FY26 budget request. California's PREP curriculum, and others, are evidence-based and have been shown to change behavior, including delaying sexual activity, increasing condom or contraceptive use for sexually active youth, or reducing number of sexual partners.
    i. What is HHS's suggested alternative curriculum if PREP is eliminated, and is that curriculum evidence-based and demonstrably shown to reduce teen pregnancy and sexually transmitted infection?

Response:
HHS does not endorse any one curriculum. However, PREP grant recipients must select curricula or programs that meet statutory requirements. The curricula or programs must be evidence-based and effective or must substantially incorporate elements of effective programs that have been proven on the basis of rigorous scientific research to change

behavior, which means delaying sexual activity, increasing condom or contraceptive use for sexually active youth, and reducing pregnancy among youth. Programs must be medically-accurate and complete and age-appropriate; include activities to educate youth who are sexually active regarding responsible sexual behavior with respect to both abstinence and the use of contraception; place substantial emphasis on both abstinence and contraception for the prevention of pregnancy among youth and sexually transmitted infections; and, the information and activities carried out under the program must be provided in the cultural context that is most appropriate for individuals in the particular population group to which they are directed, and programs must include three of six adulthood preparation subjects (i.e., healthy relationships, financial literacy, parent-child communication, adolescent development, health life skills, education and career success) articulated in the PREP authorizing statute at 42 U.S.C. 713(b)(2)(C).

23. I appreciate your commitment to addressing the chronic disease epidemic we face in the United States. Chronic diseases affect 80 percent of individuals aged 65 and older. Nearly 45 percent of Medicare beneficiaries have four or more chronic conditions, accounting for more than 75 percent of Medicare costs. Geriatric professionals and long-term care providers play a pivotal role in meeting the unique needs of medically complex older adults. I am deeply concerned about the severe shortage of geriatrics professionals and geriatric expertise.

    For several years, HRSA has successfully administered the only two federal programs specifically designed to address this shortage—by supporting the training of the primary care and caregiver workforce in the geriatric expertise needed to care for older adults. I have supported these programs throughout most of my career and was disappointed to see that the Geriatrics Workforce Enhancement Program and the Geriatric Academic Career Award program were proposed for elimination in the President's budget.

    a. What is the rationale behind the decision to eliminate these two small but essential programs?

Response:
Through the Teaching Health Center Graduate Medical Education (THCGME) program and the National Health Service Corps (NHSC) loan repayment and scholarship programs, HHS is supporting efforts to encourage primary care clinicians. The FY 2026 President's Budget requests $175 million in mandatory funding for THCGME to support up to 1,273 resident full-time equivalent slots in FY 2026. The FY 2026 President's Budget request for the NHSC includes $128.6 million in discretionary funding and $345 million in proposed mandatory resources to support clinician scholarship and loan repayment.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Budget also provides continued funding for the Rural Health Care Services Outreach Grants, which support collaborative models to deliver basic health care services to rural areas and are uniquely designed to meet rural needs.

b. What data or analysis informed the decision to target these specific programs for elimination, and was stakeholder input—including from clinicians, educators, and older adults—considered?

Response:
The FY 2026 President's Budget includes scholarship and loan repayment programs for primary care clinicians in rural and underserved communities and high need behavioral health workforce programs.

c. How does the Department plan to address the growing shortage of geriatric professionals if these programs are no longer funded?

Response:
HHS supports efforts to train the primary care workforce, including geriatricians who play a crucial role in the care of older adults and the diagnosis and management of Alzheimer's disease. Through the Teaching Health Center Graduate Medical Education program, HHS supports residency training in community-based settings with a focus on family medicine and geriatrics. The FY 2026 President's Budget requests $175 million for the THCGME, which will fund up to 1,273 resident full-time equivalent slots.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Kathy Castor (D-FL)

1. Florida families value and appreciate affordable health coverage—over 4.7 million Floridians selected an affordable plan in 2025, almost one-fifth of the 24.2 million enrollees nationally. Millions of families have seen the cost of their monthly insurance premiums go down, their financial security go up, and are saving hundreds or thousands of dollars each year. According to your Department's analysis, the policies included in the "ACA Marketplace Integrity Rule" would increase premiums for millions of consumers and result in approximately two million Americans losing coverage through the ACA Marketplace. These losses are expected to be concentrated in 9 states, including Florida, Georgia, Alabama, North Carolina, South Carolina, and Texas. In fact, your Department wrote in the proposed rule, "this range may underestimate the actual number of individuals impacted, as more eligible enrollees may lose coverage as a result of…..the provisions of this rule."

   In deciding to finalize the rule, are you aware that HHS' own analysis estimates:
   a. That it would cause approximately two million consumers to become uninsured?
   b. That it would cause eligible individuals who qualify for coverage to become uninsured?
   c. That it would increase consumer out-of-pocket costs and premiums by 4.4% and raise premiums by almost $3 billion?
   d. That individuals would be subject to more than 6 million hours of additional paperwork?
   e. That several policies related to verification would serve as barriers to enrollment and deter individuals from enrolling in coverage?
   f. That "an increase in the rate of uninsurance may impose greater burdens on the health care system through strain on emergency departments, additional costs to the Federal Government and to States and cause an overall reduction to labor productivity"?

Response:
On June 20, CMS finalized a rule that is projected to save taxpayers up to $12 billion in 2026 by lowering premiums, combating the surge of improper enrollments in the Affordable Care Act (ACA) Exchanges, reining in wasteful federal spending, and refocusing on making health insurance markets more affordable and sustainable for hardworking American families. The 2025 Marketplace Integrity and Affordability Final Rule restores oversight, strengthens accountability, and ensures taxpayer dollars are used only for those who are truly eligible. My Department will work to protect all Americans from being subject to waste, fraud, and abuse at the hands of malfeasant actors.

2. Public access to federal datasets and data-driven tools are essential to government accountability, public and private sector research, and the work of businesses and non-

profits. Those datasets have been created pursuant to Congressional direction and funded by American taxpayers. We therefore expect that data to remain publicly available, both out of duty to American taxpayers and out of economic common sense. Analyses have found that publicly-available federal health data alone adds more than $300 billion to the U.S. economy every year. Accurate, detailed and relevant data can help save lives, create jobs, and lower public and private sector costs. We are deeply concerned that those expectations are not being met.

a. What datasets and data-driven tools has the Administration removed from public-facing websites?

Response:
No data files or data tools managed by the Center for Financing, Access, and Cost trends (CFACT), including the Medical Expenditure Panel Survey (MEPS), Compendium of U.S. Health Systems, and the Community Level Health/Social Determinants of Health (SDOH) database have been removed from the AHRQ website. In addition, no Quality Indicators, Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, or Surveys on Patient Safety Culture (SOPS) have been removed.

The following information has been removed from AHRQ's Healthcare Cost and Utilization Project (HCUP-US) website:

- **Monthly tables showing state-specific counts of hospitalizations and ED visits related to COVID-19, Influenza, and other Acute or Viral Respiratory Infections.**
- **Graphs of inpatient Trends for COVID-19 and Other Conditions.**
- **A "Findings-At-A-Glance" report on Emergency Department Visits for Diagnoses Directly Indicating Heat Exposure.**

The National Quality and Disparities Report (NHQDR) Data Tools have been removed from the AHRQ Data Tools website following expiration of the vendor contract. Archived versions remain available.

b. Which, if any, does the Administration plan to restore public access to? Please provide a specific plan and timeline for restoring that access.
    i. Of those restored or planned to be restored, please identify which have had research parameters changed or data modified to comply with recent executive orders.
    ii. Of those restored or planned to be restored, has any metadata or functionality that researchers depend on to use the data been modified or eliminated?
c. Which, if any, does the Administration not plan to restore public access to?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

i. If any, please provide written explanations, specific to each dataset and data-driven tool, for why American taxpayers will be denied access going forward.

Response b-c:
My Department is committed to radical transparency in decision-making, to enhance the health and well-being of all Americans. This transparency includes public access to federal datasets and data-driven tools. HHS is committed to ensuring American have transparency from their public health institutions, from the foods Americans eat to the cost of drugs.

3. I am deeply concerned with the short-sighted decision to practically eliminate funding for the Affordable Care Act (ACA) Navigator program. ACA Navigators serve an indispensable role in assisting millions of Americans with access to health care and helping families lower their cost of living. A $90 million cut as families will struggle to determine which of the thousands of plans and options work best for them, particularly amid the myriad changes in the reconciliation legislation, could ultimately put health care out of reach for many. The value of Navigators to consumers is undeniable. Among consumers who worked with a Navigator in 2020, 40 percent thought it was unlikely they would have accessed a QHP without assistance. Navigators also help enroll hundreds of thousands of eligible consumers in Medicaid and CHIP coverage and can connect consumers to other local social services. Navigators help underserved, hard-to-reach populations, people who live in rural areas, and individuals with low literacy or who don't speak English as their primary language.

   In 2017, President Trump drastically cut the Navigator program, which resulted in staff layoffs, reduced outreach, and harm to the health, well-being, and pocketbooks of our local communities. Specifically, individuals with income between 150 and 250 percent of the Federal Poverty Level had lower Marketplace enrollment and higher rates of underinsurance following President Trump's cuts. Consumers under age 45, those who identified as Hispanic, and consumers who spoke a language other than English at home also experienced higher rates of uninsurance by 2019. President Biden worked to restore the Navigator program by dedicating appropriate funding and reinforcing the program's requirement that it focus on key underserved groups that have accounted for more than 20 percent of Marketplace enrollees in recent years.
   a. How will you ensure that Americans in need of free, unbiased assistance in choosing the health plan that is right for them will be able to find it?
   b. What sort of outreach will the Department do to fill the gaps from Navigator cuts, during Open Enrollment Period and throughout the year?

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

HHS and CMS are committed to promoting a health care system that will provide access to quality care while ensuring Americans across the country are equipped with the information they need to make healthcare decisions that work best for them and their families. Navigator performance data shows that Navigators were not enrolling nearly enough people to justify the substantial amount of federal dollars previously spent on the program. The Navigator program is funded by user fees, and because those fees directly contribute to the premium that health insurers charge consumers, the savings from decreasing Navigator program funding supports lower premiums for consumers in the individual health insurance market.

4. I am proud to represent a dynamic and growing state, with researchers and institutions performing cutting-edge medical research. In Fiscal Year 2024 alone, the NIH awarded $869 million in grants and contracts to the state of Florida, which had a $2.82 billion economic impact and supported over 14,600 jobs. NIH funding has allowed institutions across the state to study early detection of Alzheimer's disease, decode the human genome, utilize artificial intelligence for medical diagnoses, enhance preventive treatments to lower stroke risk and much more. Capping indirect costs at no more than 15% would curtail the groundbreaking and life-saving research being done across the state of Florida by colleges and universities, cancer centers, health systems and more. Such a drastic cut in federal support for biomedical research would diminish our nation's research capacity, slow scientific gains and harm access to patients and families across the country who benefit from NIH- funded research.

   Indirect costs' caps will have an outsized impact on small- and mid-sized research institutions who do not readily have access to means to cover lost facilities and administrative costs. With fewer dollars, laboratory space and equipment will quickly age and become obsolete and thorough compliance with federal regulations will become more difficult with insufficient administrative personnel. And if our research institutions begin to turn away, or not compete for, larger biomedical research awards because they lack the infrastructure to conduct the work, it will lead to fewer new drug therapies, medical technologies, clinical trials and jobs that support an ever-growing biomedical base in the state of Florida.
   a. Have you considered the impacts that would be put on small- and mid-sized research institutions from a uniform 15% cap?
   b. Will you commit to working together with a wide range of stakeholders, including academic medical centers and research institutions, to come to a consensus on a path forward on funding indirect costs for research grants?

Response:
President Trump believes the United States should have the best medical research in the world. To that end, we are advancing policies to maximize the impact of every federal

taxpayer dollar and ensure proper oversight of funding. NIH is required to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. The NIH mission is to "seek fundamental knowledge about the nature and behavior of living systems" to enhance health, lengthen life, and reduce illness and disability. In light of pending litigation concerning NIH's recent guidance setting the standard indirect rate, we are not able to comment on the matter at this time.

5. The Emergency Medical Services for Children (EMSC) program is the only federal program dedicated to improving emergency care for children and ensuring that hospitals and ambulances are properly equipped to treat pediatric emergencies. It was just reauthorized by Congress in a bipartisan, bicameral manner at the end of the 118th Congress in December. EMSC provides pediatric training to paramedics and first responders, and improves systems that allow for efficient, effective pediatric emergency medical care. I am very concerned about the proposed elimination of this vital program that has had measurable impacts on improving children's emergency care.
    a. Why did you decide to eliminate this program and how will you prioritize the unique emergency care needs of children without the EMSC?

Response:
The FY 2026 President's Budget proposes to eliminate several programs, including EMSC, for FY 2026 in an effort to streamline the bureaucracy, reset the proper balance between federal and state responsibilities, and save taxpayer funds. The Budget prioritizes programs that provide states and communities with the flexibility to target funding towards the services needed most, such as through the Title V Maternal and Child Health (MCH) Block Grant. Nationwide, the Title V MCH Block Grant reaches 61% of children and gives states the flexibility to meet their unique health needs.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Paul Tonko (D-NY)

1. Secretary Kennedy, your budget proposal eliminates dozens of mental and behavioral health programs, including eight that are included in the SUPPORT Act, which recently passed the House. These programs include First Responder Training, Residential Treatment for Pregnant and Postpartum Women, and Comprehensive Opioid Recovery Centers, among others. Republicans have repeatedly said that these programs are not in jeopardy, but your budget literally lists them out by names as ones it intends to eliminate.
    a. Assuming these SUPPORT act programs receive appropriations as they have in the past, do you commit to ensuring the programs included in the SUPPORT Act reauthorization be funded?
    b. Will you commit that these programs will be continued and funded at the congressionally appropriated level, and that you will not unilaterally impound or withhold funding for these programs even though they are listed for elimination in your budget proposal?
    c. Will you commit to this Committee that you will not unilaterally impound or withhold funding for any other programs on the eliminations list?
    d. If Congress reauthorizes the programs and appropriates money for them, will you commit to funding these programs?
    e. There are many programs listed for elimination that have not expired and have existing authorizations and appropriations, such as the Minority AIDS Initiative. Will these programs be funded?

Response:
I am committed to following appropriations law. I will comply with any legal orders around this matter but will also follow the broader Administration policy as required.

2. The HHS congressional justification includes a proposal to integrate the mental health block grant, the substance use block grant (SUPTRS), and the State Opioid Response (SOR) grant. In justifying this merger, it is stated that more flexibility will be given to states in administering this 4.1 billion grant program.
    a. Given recent staffing cuts, how will the new Administration for a Healthy America oversee these grants to make sure they are being spent on evidence-based care for people in need and that they are not wasted?

Response:
The consolidation of the MHBG, SUPTRS and SOR grant is designed to give states flexibility while strengthening accountability, ensuring funds are directed to evidence-based care by providing clear grant guidance and technical assistance. By bringing together staff from the three centers, HHS will enhance efficiency and deliver services in a more integrated and seamless fashion, ensuring comprehensive care for individuals and families in need.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

3. Secondly, the SUPTRS block grant pays for treatment for people who are uninsured, given the estimated millions of people who will lose insurance coverage due to the recent passage of the Great Big Beautiful bill, how will the needs of the uninsured be met when the budget proposal for these combined grants includes a $500 million funding cut? (SUPTRS, Mental health block grant, and SOR)

Response:
It is anticipated that grantees will be maximizing all avenues and resources for the enhancement of planned access to and use of all sources of available funding to address substance use disorder prevention, treatment, and recovery support services. Resources that will be maximized will include the use of regional, state, and local funding sources, the use of opioid settlement funds, coordination of benefits that are available through third party payment insurers, interfacing with private foundations and funding sources, and partnering with vital charitable, faith, health, education, social services, law enforcement and other community organizations that are pivotal to responding to these pressing needs.

4. The Administration says it supports prevention, yet it is cutting the Drug Free Communities program by nearly $29 million dollars, these programs don't cost $29 million to administer, what is the justification for this cut?

Response:
The FY 2026 President's Budget maintains significant funding for substance use prevention, including as part of the combined $4.1 billion behavioral health innovation block grant and $70 million for the Drug Free Communities (DFC) program. This request will fund approximately DFC 560 grant awards.

    a. At the same time, the Administration has put out an RFP for a $10 to 20 million ad campaign telling people to "just say no" to processed foods. Is drug prevention a lower priority?

Response:
Under my leadership, drug prevention will still remain a top priority. As part of our Take Your Health Back Campaign strategy, my Department will be leading a bold national advertising plan to inform Americans' about the benefits of integrating nutritional food into their diets.

5. While the President's proposed budget includes funds for the National Survey on Drug Use and Health, the only national survey of substance use and mental health in the US, the staff who interprets and administers the survey has been terminated.
    a. How will HHS make certain that the Survey is regularly updated and the information from the Survey will be interpreted and disseminated in order to drive public policy?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
The Center for Behavioral Health Statistics and Quality (CBHSQ) is a Recognized Statistical Agency or Unit under the federal statistical system, led by the Office of Management and Budget. Scientific integrity is safeguarded through adherence to technical best practices, including rigorous sampling designs, transparent methodologies, peer review (working with other internal and external statistical entities), and continual methodological innovation. CBHSQ always applies advanced scientific and statistical methods to produce data that are relevant, valid, reproducible, and protected in accordance with all confidentiality laws.

b. How does HHS intend to conduct this survey?

Response:
This survey will continue to be conducted through a contract, with oversight from federal staff.

c. More specifically, what staff will be overseeing the contractors and the survey as the comprehensive data it collects is vital to our understanding of the trends in substance use disorders?

Response:
Technical staff in CBHSQ continue to work with the NSDUH contractor to maintain uninterrupted data collection and to produce statistical reports using NSDUH data to inform policy and planning.

6. Given substance use disorders are pediatric onset diseases please explain how you intend to make America healthy again while proposing to cut almost all of the funding for the Center for Substance Abuse prevention in SAMHSA, whose programs such as the Sober Truth on Preventing (STOP) Underage Drinking Act programs and the Partnership for Success program have been key drivers of helping to dramatically reduce population levels of youth alcohol and drug use.
    a. Is prevention of underage drinking now a lower priority?

Response:
I will continue to focus on preventing the initiation and progression of substance use in individuals including underage drinking through the DFC Support Program and AHA's Behavioral Health Innovation Block Grant. Grantees will utilize the Strategic Prevention Framework in their communities to assess what type of prevention interventions are needed and whether those interventions are effective.

7. You have a stated goal of ending the poly drug epidemic facing out nation, please explain how you can possibly achieve this while gutting all of the program of regional and

national significance in SAMHSA's Centers for Substance Abuse Prevention and Treatment.

Response:
I remain deeply committed to addressing the poly drug epidemic and will continue to support and prioritize efforts that have the greatest impact on prevention, treatment, and recovery. AHA will ensure that critical programs, including those targeting poly drug use, remain supported through strategic investments, community partnerships, and evidence-based initiatives. Ending the poly drug crisis requires innovation and HHS is focused on sustaining and strengthening the programs that work.

8. The FY 26 HHS budget request proposes to combine the Community Mental Health Services Block Grant (MHBG), the Substance Use Prevention, Treatment, and Recovery Services Block Grant (SUPTRS BG) and the State Opioid Response (SOR) into a single grant, re-named the Behavioral Health Innovation Block Grant (BHIBG). Established by the first Trump Administration, the Opioid Response Network (ORN) provides no-cost Technical Assistance (TA) covering the prevention, treatment, and recovery of opioid use disorder, stimulant use disorders and co-occurring substance use and mental health conditions to SOR and Tribal Opioid Response (TOR) grantees.

   ORN includes over 45 national professional organization partners with many having state chapters that span prevention, treatment and recovery support services as well as organizations providing training/education for justice/corrections/legal professionals. Since the grant started, ORN has reached nearly a million people and delivered technical assistance in every state and 8 territories. Such technical assistance empowers communities across the country through evidence-based education, training and consultation; over 96 percent of Technical Assistant recipients indicate extreme satisfaction with the support they received.
   a. Should the block grants and SOR be combined as proposed, how would HHS ensure such vital technical assistance for states and local communities continue to be delivered?

Response:
HHS has an extremely sophisticated and robust array of technical assistance resources that will continue to be widely available to all grantees. These resources are individually tailored to the specific needs of grantees and involve the deployment of subject matter experts that can provide virtual or on-site consultation, education, guidance, and technical assistance. HHS also sponsors numerous TA opportunities throughout through the year, including educational forums, webinars, learning collaboratives, distance learning courses, policy academies, resource documents, and train the trainer course engagements. All of these activities are supplemental to the vital daily interface of grantees with State Project

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Officers and Government Project Officers in the dissemination of evidence-based policies and practices, and the delivery of guidance regarding the pivotal priorities of the administration.

9. How will HHS protect people in recovery from losing Medicaid coverage under new work or engagement requirements, especially those undergoing treatment, transitioning to the workforce, or rebuilding lives?
    a. Will there be tailored flexibility, transitional supports, or partnerships to ensure treatment continuity and prevent coverage loss?
    b. Research has shown that these individuals often face substantial barriers to consistent employment, including ongoing treatment needs, housing insecurity, and workplace discrimination.
        i. How do you respond to concerns that implementing work requirements for Medicaid could cut off treatment and increase overdose deaths for people with substance use disorders or those who have not yet been diagnosed?

Response:
Work requirements have the potential to empower able-bodied adults to take personal responsibility, build economic mobility, and preserve Medicaid for those in true need. In implementing these requirements, HHS and CMS would draw upon lessons learned from successful reforms made to programs like SNAP (food stamps) and Temporary Assistance for Needy Families (TANF). HHS and CMS look forward to working with states to implement this commonsense approach while at the same time working to ensure appropriate guardrails are in place for those who are exempt from these requirements, including those with substance use disorder.

10. Overdose is still the leading cause of death for Americans under 50—and yet substance use barely shows up in the Administration for a Healthy America.
    a. How can HHS claim to be modernizing health care while ignoring the deadliest public health crisis of our time?

Response:
Overdose prevention and substance use treatment are essential for saving lives and improving health outcomes. The new Behavioral Health Innovation Block Grant will address the overdose crisis by providing resources to states and territories and fund activities that prevent and treat substance use. Overdose prevention to maximize treatment access is an extremely high priority for the Administration. Through the Behavioral Health Innovation Block Grant, grantees will continue to use federal funds for lifesaving overdose prevention, intervention, and treatment interventions.

    b. What's the actual plan to align federal SUD policy across agencies and put it at the center of this agenda?"

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
Improving substance use disorder prevention and treatment is important to this Administration. AHA will continues to expand education, support, and services to prevent substance use and widen access to treatment, making recovery more attainable for many in our nation. The Administration for a Healthy America (AHA), will combine multiple agencies, including the Office of the Assistant Secretary for Health (OASH), Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), components of the Centers for Disease Control and Prevention (CDC), and others into a new, unified entity. This centralization will improve coordination, streamline services, and create synergy that will yield positive outcomes, leading to decreases in substance use disorder prevalence and incidence and overdose.

c. You have talked about cutting over $150 billion from the system rural communities rely on— and replacing it with what, exactly? These areas are already ground zero for the overdose crisis.
    i. What's the actual plan for deploying these so-called 'rural funds,' and how will HHS ensure they're not just left with less care and more deaths?"

Response:
The FY 2026 President's Budget provides funding to continue to build health care capacity and improve health outcomes for the estimated 62 million Americans who live in rural communities. The request includes $145 million for the Rural Communities Opioid Response program to maintain prevention, treatment, and recovery services for substance use disorder, and $101 million Rural Health Care Outreach program. The outreach program includes $12 million for the Rural Maternity and Obstetrics Management Strategies (RMOMS) program to increase access to maternal and obstetrics care in rural communities. In addition, the Budget provides $12.7 million for Rural Residency Planning and Development to expand the number of rural residency training programs with the goal of increasing the number of physicians choosing to practice in rural areas.

The FY 2026 President's Budget invests in primary care services with an emphasis on health promotion and disease prevention, particularly in medically underserved and rural areas where individuals may not otherwise have access to care. The Budget invests in the continued advancement of telehealth and provides grants to combat opioid use disorders and support the development of health providers in rural areas.

To address the needs of rural communities, the budget provides $284 million for grant programs and technical assistance. These investments help ensure that rural communities with limited access to care and providers receive the support they need to address pressing substance use challenges.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

11. States are being asked to build out major new Medicaid eligibility systems under H.R. 1—but $200 million spread across 50 states and the District of Columbia won't come close to covering the cost.
    a. How will HHS support states—especially rural ones—with real technical assistance, training, and tools?
    b. And how will you help providers manage the added administrative burden, without disrupting continuity of care?

Response:
HHS and CMS would look forward to implementing provisions that would give the Department more tools to ensure Medicaid benefits remain available for those who are eligible. CMS is actively working to strengthen the Medicaid IT infrastructure to support states' efforts to modernize their programs and implement the commonsense reforms in H.R. 1, which could help states combat these costs. Fighting true waste, fraud, and abuse will allow states to better focus their time and resources on those who truly need it.

12. With regard to merging the SUD and MH block grants together with the State Opioid Response grant, will you establish minimum amounts of funding to be made available for Substance Use Disorder and Mental Health or will you leave it states to make those determinations?
    a. Will you preserve the 10 percent set-aside form SUD prevention services?

Response:
I am committed to continue supporting substance prevention programs in communities. The Behavioral Health Innovation Block Grant will provide maximum flexibilities for use of the funding by states.

    b. What specific types of flexibility will you offer states in a merged federal BH grant?

Response:
The consolidation of the Community Mental Health Services Block Grant (MHBG), the Substance Use Prevention, Treatment, and Recovery Services Block Grant (SUPTRS BG), and the State Opioid Response (SOR) grants into a single grant aims to maximize states' flexibility in supporting mental health and substance use services to better address local needs. The BHIBG will support states in addressing critical gaps and unmet needs in their mental health and substance use disorder systems, collectively under the umbrella of behavioral health. In addition, the grant provides seed funding to pilot and expand evidence-based and promising practices. Grantees can use the funding to explore innovative solutions that improve access, engagement, and outcomes for individuals at-risk for or with behavioral health needs, fostering sustainable and transformative change across communities and systems. This flexible funding will allow states to fund various activities

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

that address the specific needs of their communities, including addressing mental illness, and substance use prevention, treatment and recovery services.

c. With regard to merging SAMHSA into the new larger office: Will you preserve CSAT especially given its regulatory role over Opioid Treatment Programs?

Response:
The FY 2026 President's Budget preserves funding for the Opioid Treatment Programs (OTP) and technical assistance. This investment includes OTP regulatory oversight and support of states and OTPs in the implementation of 42 CFR Part 8 and other regulations.

i. If no, what group of staff will oversee this discrete activity.

Response:
This aforementioned oversight requires specialized knowledge and skills related to the treatment of opioid use disorder.

d. Will you preserve the SUD recovery operational staffing?

Response:
The Office of Recovery continues to exist with the Office of the Assistant Secretary.

13. Please provide a full organizational chart including the number of staff who now work at each division of SAMHSA.
    a. Please include a breakdown of who was fired and how many staff remain broken down by division.

Response:

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Division	FY2019	FY2024	VERA / VSIP	Fork	Probationary	RIF Effectuated	Other Attrition	Current Number	% vs. FY2019
AHRQ	236	255	54	10	2	111	18	60	-75%
ACL	178	211	7	6	2	90	15	91	-49%
OS	2,517	3,388	248	103	69	332	154	2,482	-1%
OTHER	2,577	2,422	88	114	5	0	64	2,151	-17%
CDC	9,809	12,137	496	383	308	0	425	10,525	7%
ASPR	692	1,095	36	22	22	91	31	893	29%
CMS	6,047	6,515	168	164	228	316	282	5,357	-11%
NIH	13,267	16,126	803	350	608	1,055	693	12,617	-5%
FDA	15,733	18,903	708	476	438	1,605	576	15,100	-4%
ACF	1,036	1,627	115	53	83	397	88	891	-14%
IHS	14,880	14,731	96	61	0	0	662	13,912	-7%
HRSA	2,034	2,709	150	71	118	429	62	1,879	-8%
SAMHSA	487	876	40	16	31	197	41	551	13%
Total	**69,597**	**80,995**	**3,009**	**1,829**	**1,914**	**4,623**	**3,111**	**66,509**	-4%

Notes: *"Other" includes the Departmental Appeals Board, the Office of the Inspector General, and the Office of Medicare Hearings and Appeals; none of these entities were subject to RIF actions. CDC and ASPR are combined to illustrate the net effect for the future combined go-forward entity. ACF does not include ORR totals, given the unique changes in that office over the last five years. OS also includes PSC. Total staffing numbers in FY2019 and FY2024 reflect the HHS monthly "Workforce Highlights" Report, which has used consistent methodologies to calculate staffing levels for more than a decade, and therefore provides the best view of change over time. VERA/VSIP and Fork in the Road numbers are as most recently reported to the HHS CHCO by each Division; processing of individual actions is ongoing. The RIF numbers are predecisional and subject to change given ongoing litigation; *ASPR has effectuated their RIF, while all CDC RIF actions are pending litigation. Besides CDC, all ACF Head Start, ASPE, and FDA Center for Tobacco Products RIF actions have been stayed pending litigation.*

b. Please provide a list of employees who have been terminated since January 20, 2025, including a copy of SAMHSA and DOGE's charts and other documents reflecting staff reduction plans by program office and further disaggregated by field office and DC headquarters.

Response:
See chart above.

c. Please provide a specific line-item by line-item analysis of the impact of SAMHSA staffing reductions in the 50 percent range.

Response:
See chart above.

d. Please produce any written communications including texts, emails, memorandums, white papers and other documents indicating whether the intent of the proposed staffing reductions is to shut down SAMHSA programs by eliminating the staff needed to administer them.

Response:
SAMHSA abided by and remain compliant with all HHS, OMB, and OPM communications, as well as Executive Orders.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

14. Many rural communities do not have enough prescribers of buprenorphine to manage opioid use disorder. Several states have enabled pharmacists to prescribe buprenorphine to treat opioid use disorder.
    a. What will you do to make ensure all Americans struggling with opioid use disorder can access buprenorphine prescribed by the pharmacist in their community?

Response:
SAMHSA's Center for Substance Abuse Treatment is working with its federal partners, including NIH, ONDCP, FDA, and others to explore ways to increase access to Medications for Opioid Use Disorder (MOUD), including through pharmacists and other providers. This work will continue under AHA.

15. Recent reporting has highlighted that the CDC has not yet received its full FY2025 appropriation, and has been forced to operate on a 30-day funding cycle, resulting in delayed notices of award to state and local health departments and significant disruptions in services.
    a. Can you clarify whether HHS is currently impounding or withholding any congressionally appropriated funds for FY2025 across agencies like CDC, HRSA, or SAMHSA?
    b. What steps might the Department take to ensure timely disbursement of funds and to prevent these "pocket rescissions" from undermining public health efforts?

Response:
This Administration is committed to being good stewards of taxpayer funding. We're still in the process of reviewing some payments, but we have released many of the delayed funds and are continuing to work on resolving any issues.

16. The CDC and state public health officials have raised concerns that delayed or partial disbursement of funding has forced layoffs, paused grant programs, and jeopardized critical services (e.g., HIV prevention, overdose prevention, and cancer screening).
    a. Has HHS conducted or does it plan to conduct an impact assessment of these delays on state and local public health delivery?
    b. How does HHS plan to ensure transparency and accountability in future funding cycles to prevent these disruptions?

Response:
My Department and CDC are committed to ensuring that funds are used efficiently. We are following the law to execute these funds and are committed to effective program implementation that supports good stewardship of resources and the Administration's priorities.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

17. In 2024, Congress passed the Dr. Emmanuel Bilirakis and Honorable Jennifer Wexton National Plan to End Parkinson's Act with strong bipartisan support, calling for a whole-of-government effort to prevent, treat, and ultimately cure Parkinson's, which is the second most common and fastest- growing neurodegenerative disease. HHS has delegated responsibility for implementation to the NIH at a time of proposed deep budget cuts for the agency.
    a. As we now mark the 1-year anniversary of the legislation being signed into law, how will you ensure that the law's goals are not stalled by lack of resources or coordination?
    b. Scientific advances show that neurodegenerative diseases like Alzheimer's and Parkinson's share key biological mechanisms, yet research remains siloed across multiple NIH Institutes, limiting collaboration and efficiency. At the same time, the President's Budget Request proposes deep funding cuts that could severely hinder progress.
        i. As Secretary of HHS, how will you ensure NIH prioritizes coordinated, neurodegenerative disease research and protects funding to advance breakthroughs for these devastating conditions?

Response:
NIH remains committed to funding important breakthrough research on neurodegenerative diseases like Alzheimer's and Parkinson's. There are several collaborations that exist between Institutes that fund this research, and basic research on the brain often can provide insights into multiple neurodegenerative diseases.

NIH has been diligently working to implement the Dr. Emmanuel Bilirakis and Honorable Jennifer Wexton National Plan to End Parkinson's Act. HHS will continue to oversee the work of NIH as they collaborate with others to implement this law.

18. Please provide a full list of any staff at any agency you oversee that were fired who work on Alzheimer's or Parkinson's research, prevention, treatment or support.

Response:
NIH cannot provide a list of staff terminated for privacy reasons.

19. The President's budget calls for CDC to refocus its efforts on its work related to infectious disease, including outbreak investigations, preparedness and response, and maintaining public health infrastructure. A critical part of this is making certain NIOSH is evaluating and approving new, innovative respirators and their components. Respirators are a first line of defense for millions of workers, including health care workers, in case of a public health emergency or outbreak. The President's FY26 budget does not request funding for the Personal Protective Technology program within the National Institute for Occupational Safety and Health.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

a. Will you commit to working with Congress to make certain this critical program will be robustly funded in FY26?

Response:
The President's budget request focuses on streamlining services, programs, and capabilities to maximize efficiency of taxpayer dollars. My Department remains committed to working with Congress to prioritize programs that are essential to the Make America Healthy Agenda.

20. The president's proposed budget includes moving the National Center for Health Statistics from CDC to the Office of Strategy. To build trust in the federal government's data, it's imperative that any data from the National Center for Health Statistics not be politicized. In the first Trump Administration, political appointee approval was required for CDC MMWR releases.
    a. What precautions will you put in place to ensure that the data - including mortality data - released from this new HHS Office of Strategy is not politicized?

Response:
I am committed to improving healthcare quality and outcomes for all Americans and doing so with radical transparency. Our research and data collection efforts will be conducted without a bias toward any cause. Unlike under the previous Administration, HHS is committed to unbiased, politics free, transparent, evidence-based science in the public interest.

21. Under the Trump administration's Executive Order titled "Restoring Gold Standard Science," political appointees—yourself included—can now investigate, discipline, and even "correct" the work of federal scientists.
    a. Do you believe political staff at HHS or NIH should have the authority to alter or censor peer-reviewed, federally funded research?

Response:
I am committed to improving healthcare quality and outcomes for all Americans and doing so with radical transparency. Additionally, I am committed to carrying out President Trump's mission of returning the Department to the gold standard of science. Under my leadership, our research and data collection efforts will be conducted without a bias toward any cause.

22. The Biden-era OSTP released a robust scientific integrity framework developed by dozens of federal agencies, scientists, and watchdogs. Did anyone try to convince you not to throw out those best practices?
    a. Please include any agency communication or written documents that made a case for keeping the framework.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

Response:
I am returning HHS to the gold standard of science by building new models to treat complex diseases, working to eliminate conflicts of interest in science, and restoring the Department's focus on health, not bureaucracy.

23. Under your leadership, will you allow political officials to rewrite or suppress health guidance or suppress it behind closed doors?

Response:
As previously stated, I am committed to improving healthcare quality and outcomes for all Americans and doing so with radical transparency. Additionally, I am committed to carrying out President Trump's mission of returning the Department to the gold standard of science.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Darren Soto (D-FL)

1. One of the rules that Republicans aimed to repeal in H.R.1 relates to the Children's Health Insurance Program—known in Florida as KidCare. The rule under attack says that states can't lock a child out of coverage for missing a premium payment.
    a. Do you believe that states like my home state of Florida should be allowed to kick children off KidCare and lock them out of coverage for up to three months if their parents don't make that payment on time?
    b. Does the Trump Administration plan to maintain and enforce rules that prevent this from happening?
2. Do you support the rule that stops states from making children who are eligible for CHIP wait up to 90 days before enrolling in the program?
    a. Should children have to endure three months of forced uninsurance?
    b. Does the Trump Administration plan to maintain and enforce rules that prevent this from happening?
3. Do you agree with lifetime and annual limits on healthcare payments for children on KidCare?
    a. Should states should be able to tell children on KidCare that their health care needs cost too much and they've reached an arbitrary dollar threshold, at which point KidCare won't pay for their care?
    b. Does the Trump Administration plan to maintain and enforce rules that prevent this from happening?

Response (1-3):
Medicaid and CHIP can serve as a critical source of care for children from low-income households. Provisions included in the One Big Beautiful Bill Act (H.R. 1) would (if enacted) give HHS commonsense tools to preserve coverage for vulnerable populations while bolstering sustainability of the programs for current and future enrollees.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Rob Menendez (D-NJ)

1. Last month, I sent the Department of Health and Human Services ("HHS") a letter requesting a thorough evaluation and safety review of caffeine and urged the subsequent issuance of regulations and labeling requirements for food and dietary supplement containing caffeine. This evaluation and federal regulations are essential to protecting the health of our population, particularly children and teens. The United States is the world's largest consumer of caffeine, but it also has some of the loosest regulations on caffeine, resulting in confusion about if there is, and how much caffeine is present in energy drinks and other highly caffeinated beverages.

   Three years ago, the daughter of my constituents, Sarah Katz, tragically lost her life after consuming a highly caffeinated beverage from a national fast-food chain. When she was five years old, she was diagnosed with a heart condition known as Long QT syndrome, which was monitored by her cardiologist and well-managed by medication. She was diligent about avoiding energy drinks given their high amounts of sugar, caffeine, and other stimulants. She accidentally consumed a highly caffeinated beverage because it was marketed in a misleading way, and later that day she went into cardiac arrest. She was just 21 years old and a junior at the University of Pennsylvania.

   There have been numerous deaths and cardiac arrest incidents that have followed the consumption of highly caffeinated beverages. With their increasing popularity and prevalence in the market, it is well past time that HHS take serious action to regulate caffeine and ensure Americans have access to information about what they are putting into their bodies.
   a. Will HHS commit to conducting a thorough, evidence-based safety review of caffeine and subsequently issue updated regulations?
      i. Please provide a written outline detailing your plans to conduct this research.
   b. Will HHS commit to conducting a study on how caffeinated beverages are misleadingly marketed, including towards children and teens?
      i. Or will HHS commit to working with independent government agencies such as the Government Accountability Office to conduct such a study?
   c. And how will HHS plan to prioritize this review and study given the significant reductions in force recently implemented at the agency?
   d. And how does HHS plan to turn this review and study into necessary and long-overdue regulations given the significant reductions in force at the agency?

Response:
I am saddened by the passing of Sarah Katz and appreciate your continued interest in the regulation of caffeine in food products. I understand you are particularly interested in

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

evidence-based research to assess and establish safe limits for caffeine in drinks and federally mandating labels and warnings on energy drinks and in restaurants.

My Department will commit to working with independent government agencies such as the Government Accountability Office should they conduct a study on the marketing of caffeinated beverages. FDA routinely monitors the food supply and considers product labeling and the statements and representations made on product labels, including energy drinks, on a case-by-case basis. If FDA determines a product is misbranded, the Agency considers taking action as appropriate, consistent with the Agency's priorities and resources.

Under the Administration's priority to Make America Healthy Again, my Department has a renewed focus on promoting radical transparency to make sure that Americans know what is in their foods so they can make choices that are right for themselves and their families.

2. Mr. Secretary, I would like to discuss the World Trade Center Health Program and my deep concerns in the face of conflicting and concerning HHS actions including: firing, rehiring, firing again, rehiring, and moving of this program to an entirely new and uncertain home under your proposed AHA agency. In your testimony before the Senate HELP committee on May 14th in response to Senator Kim's questioning, you admitted that the firing of World Trade Center Health Program staff was a "mistake".
    a. Is that accurate?
3. I am concerned that this "mistake" caused enrollment in the program of 9/11 responders and survivors to stop for an entire month. It also resulted in cancer certifications under the program to cease to be processed for the month as well. Given your admission of this "mistake," I am left wondering how can the individuals who rely on this program be assured that the World Trade Center Health Program in will have the support and resources it needs under your proposed transition to the new Administration for a Healthy America. I am not confident the new Administration can and will provide medical care to over 140,000 9/11 responders and survivors who are in every state and 434 out of 435 Congressional Districts.
    a. What is HHS's plan to ensuring that the WTC Health Program receives the support that has been provided to the program by the CDC- for example, contract staff, grant staff, and program management staff? Please provide specifics.
4. I am shocked that, in your leadership capacity of HHS, you are unwilling to uphold a national commitment to the increasing numbers of first responders and survivors coming forward to ensure there are funds to cover all the care that is needed for those still suffering the physical and mental impact of 9/11. This includes the responders and survivors who will be newly diagnosed with 9/11- associated cancers caused by their toxic exposures in the coming years.

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

   a. Will you commit to work with Ranking Member Pallone and I to ensure that Congress deals with the impending funding shortfall facing the World Trade Center Health Program and make sure it is fully funded now and in the future?

5. When the Trump administration took over on January 21, the WTC Health Program had 93 staff. While the staff you fired did have their jobs restored, the program head count we understand is now down to around 80 staffers because of retirements and those that took the buyout, a 14% reduction in staff.
   a. Will you lift the hiring freeze for the program, understanding that this program is a mandatory spending program and had been authorized by OMB in the prior administration to increase staff levels to 138 to deal with the increased work load from new cases of 9/11 responders and survivors enrolling in the program, such as the 10,000 new enrollees that joined in 2024 and the expected additional 10,000 this year?

Response (2-5):
The 9/11 terrorist attack was a tragedy. The WTCHP provides critical services and treatment to individuals exposed to airborne toxins and other hazards. Under my leadership, and with gratitude for their service, I directed the CDC to restore 15 employees working on the WTCHP. While the Department is considering a number of proposals to reduce inefficiencies and eliminate redundant programs within the Department, programs focused on this important topic will be addressed, regardless of any actions taken to reorganize HHS.

Further, HHS is committed to carrying out appropriations in accordance with all applicable law and is committed to working with Congress to protect the health and well-being of every American.

###

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

The Honorable Jennifer McClellan (D-VA)

1. Plans for the new "Administration for a Healthy America" not only combine multiple agencies but also cut dozens of programs from those agencies—from provider pipeline to substance use treatment programs.
    a. What is the current status of the programs that Secretary Kennedy proposed to eliminate?
    b. Have agency staff already been instructed to hold on putting out Notices of Funding Opportunities?
    c. Why is Secretary Kennedy proposing to eliminate programs that are statutorily authorized and have received appropriations?
    d. Who specifically made the decision to propose the elimination of these programs?

Response:
The FY 2026 President's Budget request proposes The Administration for a Healthy America (AHA) in order to consolidate and streamline agency work that is currently duplicative and siloed.

2. Secretary Kennedy has said to Congress "If you appropriate the funds, I'm going to spend them." However, he has cancelled grants and entire programs with appropriated funding.
    a. Will the Secretary commit to spending all appropriated dollars for the purposes for which Congress intended them?

Response:
HHS is committed to carrying out appropriations in accordance with all applicable law.

3. Secretary Kennedy has said that as many as 20% of the staff fired by HHS could be brought back if they were deemed essential.
    a. Why weren't essential staff properly identified before the RIFs?

Response:
Some advance RIF notices were rescinded prior to actual separation as Department and priorities and requirements were continuously evaluated. These adjustments were made to ensure continuity of operations and mission accomplishment.

4. The "Defend the Spend" initiative requires government officials to manually review individual grant payments that agencies have already rigorously reviewed and approved. Grantees in VA-04 have reported that Defend the Spend has caused significant funding delays, jeopardizing their workforce retention and programming.
    a. Did HHS conduct an analysis of the cost and time burden for both the government and grantees prior to imposing Defend the Spend?
    b. Are political appointees within HHS involved in Defend the Spend reviews?
    c. Are external entities such as DOGE involved in this process?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

d. Is there an appeals process in place for drawdowns that are improperly denied or delayed due to this new process?

Response:
HHS is dedicated to restoring our agencies to their tradition of upholding gold-standard, evidence-based science. We have, therefore, worked with agency leaders to discontinue grants and contracts that are not meeting the needs of the Americans they serve or are not aligned with HHS's priorities.

In accordance with the Presidential Memo "Radical Transparency About Wasteful Spending," information on terminated grants may be accessed on Government Grants - Federal Funds Awarded | HHS TAGGS.

5. Since January 20, 2025, have any HHS personnel been instructed to withhold information about the status of grants or contracts, or to provide only vague or generic replies to recipients?
    a. Have all affected grant recipients been notified when their grants are under review or under consideration for cancellation?

Response:
HHS is dedicated to restoring our agencies to their tradition of upholding gold-standard, evidence-based science. We have, therefore, worked with agency leaders to discontinue grants and contracts that are not meeting the needs of the Americans they serve or are not aligned with HHS's priorities.

In accordance with the Presidential Memo "Radical Transparency About Wasteful Spending," information on terminated grants may be accessed on Government Grants - Federal Funds Awarded | HHS TAGGS.

6. Recently, HHS cancelled several training grants to VA-04 from the National Institute of General Medical Sciences. These are grants that would have supported biomedical sciences training for graduate and postdoctoral researchers. With respect to grants that have been cancelled since January 20, 2025:
    a. Please describe in detail the process used to make the determinations for cancellation.
    b. Were HHS subject matter experts involved in reviewing and deciding to cancel each grant that was cancelled?
    c. Was the Secretary personally involved in reviewing and deciding to cancel each grant that was cancelled?
    d. Which political appointees were involved in the review and decision-making process? Please provide names and titles/positions.
    e. What opportunities were grant recipients given to address any of HHS's concerns before their grant was canceled?

In keeping with past practice, the responses are dated as of June 24, 2025, unless otherwise specified.

f. What documentation exists to demonstrate the process used for review?

Response:
President Trump believes the United States should lead the world in biomedical research. To that end, we are advancing policies to maximize the impact of every federal taxpayer dollar and ensure proper oversight of this funding. NIH is required to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. The NIH mission is to "seek fundamental knowledge about the nature and behavior of living systems" to enhance health, lengthen life, and reduce illness and disability. NIH is dedicated to supporting and conducting gold-standard, evidence-based science. Grants were evaluated and terminated in accordance with independent authorities and agency priorities.

###