U.S. Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
"Aging Technology, Emerging Threats: Examining Cybersecurity Vulnerabilities in Legacy Medical Devices"
April 1, 2025
Documents for the Record

1. A letter addressed to the Honorable Robert F. Kennedy Jr., from Ranking Member Pallone, Ranking Member DeGette, and Ranking Member Clarke, submitted by the Minority.
2. A letter addressed to Sara Brenner, Acting Commissioner of Food and Drugs at the U.S. Food and Drug Administration, from Peter Marks, Director at the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration, submitted by the Minority.
3. A statement from AdvaMed entitled "AdvaMed Statement on Reports of Significant FDA Jobs Cuts," submitted by the Minority.

BRETT GUTHRIE, KENTUCKY
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-3641
Minority (202) 225-2927

April 1, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Kennedy:

We write to express our outrage at your reckless announcement terminating nearly 25 percent of the workforce at the Department of Health and Human Services (HHS) and to seek information about this decision, which you have not provided to Congress. Last week, you announced that HHS would be eliminating 10,000 jobs on top of the 10,000 public servants who have already been terminated, or who have taken the deferred resignation program. This is an alarming, irresponsible, DOGE-driven attempt to dismantle an entire department and its critical work in order to fund giant tax breaks for the wealthy. It is also a blatant effort to push out doctors and scientists whose work has been grounded in real science but that runs counter to your dangerous agenda of misinformation.

These layoffs and hastily concocted plans to restructure HHS will harm all Americans who rely on the expertise and efforts of staff across HHS for safe and effective medical products, for the delivery of essential healthcare services, and for the protection of public health and the advancement of biomedical research. To claim to want to make "America Healthy Again" and then dismiss 25percent of the people who work at HHS without regard to the impact these cuts will have on the American people is pure hypocrisy. Already, experts and organizations dedicated to public health have raised the alarm, calling the planned cuts "dangerous," "deeply misguided," and "preposterous."[1]

This announcement comes on the heels of a round of terminations of probationary employees in February that was not only illegal but also led to a substantial number of

[1] Doctors for America, *Doctors for America Condemns HHS Cuts* (March 28, 2025) (press release); Stat+, *Former HHS Secretary Donna Shalala on the Agency's 'Silly New Bureaucracy'* (Mar. 27, 2025) (https://www.statnews.com/2025/03/27/hhs-cuts-rfk-jr-kennedy-reorgnization-layoffs-donna-shalala-criticism/); *RFK Jr. Plans 10,000 Job Cuts in Major Restructuring of Health Department*, The Wall Street Journal (Mar. 27, 2025).

employees being asked to return once you and others at HHS realized they were indeed essential to HHS's mission.[2] Some HHS operating divisions are already struggling to maintain efficiency and quality after the February DOGE-led cuts. At the Food and Drug Administration (FDA), for example, scientists now have double the number of product applications to review as a result of those terminations, and the pace of review of new drug applications has slowed significantly.[3] The Department is also losing swaths of highly experienced leaders who resigned or refused to return to HHS even if their terminations were rescinded.[4] Appallingly, more experts are being forced to resign because they do not align with your misguided agenda, including your deeply misguided determination to set public health back a century by questioning the settled science regarding the safety and efficacy of vaccines.[5] We are concerned that your efforts will result in the resurgence of long eradicated diseases and the unnecessary deaths of many Americans to vaccine preventable diseases.

This is no time to carelessly eviscerate our health workforce. There is an ongoing risk of avian flu outbreaks and more cases of measles already this year than in the past five years.[6] Americans deserve the benefit of numerous treatments and cures that are being diligently researched and examined through clinical trials at NIH and elsewhere within HHS. They also deserve access to safe and effective medical products that are reviewed by FDA within the congressionally mandated timelines. Further, seniors and people with disabilities deserve the opportunity to live independently and participate in their communities—yet, you have carelessly cut the Administration for Community Living (ACL), which is the only federal agency specifically focused on this need.

Since you chose to provide only a six-minute video devoid of meaningful detail on this major announcement, Congress is left entirely without crucial information.[7] It is unacceptable that you refused to provide a briefing to the Committee or answer any questions regarding this proposed reorganization and layoffs – after all, Congress must approve many of the decisions

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[2] Fierce Healthcare, *Federal Union Draws Up Lawsuit Over Trump EO as RFK Jr. Readies 10,000 HHS Cuts* (https://www.fiercehealthcare.com/regulatory/rfk-jr-prepares-10000-job-cuts-across-hhs-new-wave-worker-reductions) (Mar. 28, 2025).

[3] Reuters, *Exclusive: FDA Staff Struggle to Meet Product Review Deadlines After DOGE Layoffs* (Mar. 27, 2025) (https://www.reuters.com/business/healthcare-pharmaceuticals/fda-staff-struggle-meet-product-review-deadlines-after-doge-layoffs-2025-03-27/).

[4] CBS News, *Top FDA Food Safety Official's Resignation Letter Warns Firings Will Backfire on RFK Jr.* (Feb. 20, 2025) (https://www.cbsnews.com/news/fda-food-safety-james-jones-resigns-warning-rfk-jr/).

[5] *Top F.D.A. Vaccine Official Resigns, Citing Kennedy's 'Misinformation and Lies',* The New York Times (Mar. 28, 2025).

[6] Centers for Disease Control and Prevention, *Measles Cases and Outbreaks* (Mar. 28, 2025) (https://www.cdc.gov/measles/data-research/index.html#cdc_data_surveillance_section_5-yearly-measles-cases); Centers for Disease Control and Prevention, *H5 Bird Flu: Current Situation* (Mar. 28, 2025) (https://www.cdc.gov/bird-flu/situation-summary/index.html).

[7] Secretary Kennedy (@SecKennedy), X (Mar. 27, 2025, 9:00 AM) (x.com/SecKennedy/status/1905243470366670926).

that you proposed. It is simply unclear what authority allows you to make these sweeping changes without congressional approval, and you have not provided that information.

As former Director of FDA's Center for Biologics Evaluation and Research Peter Marks wrote in his resignation letter last week, "[I]t has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies."[8] We demand truth and transparency, and we therefore require that you provide written answers to the following requests by April 15 and provide a briefing for Committee staff shortly thereafter.

1. Please provide a detailed list of the roles being eliminated across HHS. For each, provide:

    a. The title of the role;

    b. The operating division and office in which that role currently exists;

    c. A description of that role;

    d. How the work being performed by that role will be reassigned;

    e. Whether that role is currently occupied, and if so, whether the individual in that role will be terminated from or reassigned in HHS;

    f. What date that termination or reassignment will occur; and

    g. The statutory authority that provides the basis for these mass terminations, as well as the statutory authority that provides the basis for eliminating entire operating divisions of HHS, such as the Substance Abuse and Mental Health Services Administration (SAMHSA) and Health resources and Services Administration (HRSA), which have detailed and specific statutory responsibilities laid out in the Public Health Service Act.

2. Please describe in detail the process by which you determined what roles would be eliminated and produce all supporting documentation. Include in your answer:

    a. The individuals involved in deciding which roles would be eliminated, including their title and the agency for which they work;

    b. The criteria used to determine what roles could be eliminated;

[8] *Top Vaccine Official Resigns from FDA, Criticizes RFK Jr. for Promoting 'Misinformation and Lies',* Associated Press (Mar. 29, 2025).

c. The process for deciding whether the work conducted by a role would be reassigned or eliminated entirely;

d. Any risk assessments involved in determining whether a role was necessary for public health and safety and the individuals involved in conducting and reviewing those assessments;

e. What feedback, if any, was sought by leaders within operating divisions and offices as part of the process;

f. What feedback, if any, was provided by individuals outside of HHS;

g. What feedback, review, or consultation was provided by non-governmental organizations, contractors, consultants, or other non-federal entities or employees; and

h. Any impact analyses conducted by HHS of the impact these terminations will have on the ability of each operating division to meet its statutory responsibilities to the American people.

3. A fact sheet circulated by HHS states that the elimination of roles at FDA "will not affect drug, medical device, or food reviewers, nor will it impact inspectors."[9] Please specify what is meant by the elimination of 3,500 roles at FDA not "affect[ing] reviewers" or "impact[ing] reviewers."

4. The fact sheet circulated by HHS states that the reduction of 1,200 individuals at NIH will result from "centralizing procurement, human resources, and communications across its 27 institutes and centers."[10] Please confirm that this means that no other staff aside from those in purely procurement, human resources, or communications roles will be eliminated from NIH. To the extent that this is not accurate, please detail what other roles will be eliminated and why those were not described in the fact sheet.

5. The fact sheet circulated by HHS states that "programs within the Administration for Community Living (ACL) that support older adults and people of all ages with disabilities will be split across the Administration for Children and Families (ACF), Assistant Secretary for Planning and Evaluation (ASPE), and Centers for Medicare and Medicaid Services (CMS)." Please clarify specifically which programs will be transferred to which agencies and whether HHS is eliminating ACL employees, programs, and/or functions as part of this action.

[9] U.S. Department of Health and Human Services, *Fact Sheet: HHS' Transformation to Make America Healthy Again* (Mar. 27, 2025) (press release).

[10] *Id.*

6. Please specify which five regional offices will be closed and the process for determining why regional offices should be closed and which ones should be closed.

7. Please specify which operating divisions will be eliminated or consolidated. For each, please specify which new or existing operating division(s) will be responsible for carrying out the eliminated or consolidated operation division's work.

If you have any questions about this request, please contact the Committee Democratic staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Diana DeGette
Ranking Member
Subcommittee on Health

Yvette D. Clarke
Ranking Member
Subcommittee on Oversight
and Investigations

cc: The Honorable Brett Guthrie
Chairman

The Honorable Buddy Carter
Chairman
Subcommittee on Health

The Honorable Gary Palmer
Chairman
Subcommittee on Oversight and Investigations

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

March 28, 2025

Sara Brenner, MD, MPH
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Brenner:

It is with a heavy heart that I have decided to resign from FDA and retire from federal service as Director of the Center for Biologics Evaluation and Research effective April 5, 2025. I leave behind a staff of professionals who are undoubtedly the most devoted to protecting and promoting the public health of any group of people that I have encountered during my four decades working in the public and private sectors. I have always done my best to advocate for their well-being and I would ask that you do the same during this very difficult time during which their critical importance to the safety and security of our nation may be underappreciated.

Over the past years I have been involved in enhancing the safety of our nation's blood supply, in advancing the field of cell and gene therapy, and in responding to public health emergencies. In the last of these, during the COVID-19 pandemic I had the privilege of watching the vision that I conceived for Operation Warp Speed in March 2020 in collaboration with Dr. Robert Kadlec become a reality under the leadership of HHS Secretary Azar and President Trump due to the unwavering commitment of public servants at FDA and elsewhere across the government. At FDA, the tireless efforts of staff across the agency resulted in remarkably expediting the development of vaccines against the virus, meeting the standards for quality, safety, and effectiveness expected by the American public. The vaccines undoubtedly markedly reduced morbidity and mortality from COVID-19 in the United States and elsewhere. Many of these same individuals applied learnings from the pandemic during a flawless response helping to facilitate the rapid control of the mpox epidemic in the United States during 2022. Individuals who participated in these responses remain at the ready to address the infectious threats that undoubtedly will confront us in the coming years, including H5N1, which is now on our threshold.

Efforts currently being advanced by some on the adverse health effects of vaccination are concerning. The history of the potential individual and societal benefits of vaccination is as old as our great nation. George Washington considered protecting his troops in Cambridge, Massachusetts against smallpox early in the revolutionary war so that they would not be susceptible to infection by British troops infiltrating the ranks, and later in the war in February 1777 while encamped in Morristown, NJ, he went on to have the courage and foresight to sign an order requiring inoculation of his troops against smallpox. Subsequently, refinement of the smallpox vaccine combined with a widespread vaccination campaign resulted in the eradication of smallpox from the globe. The application of the remarkable scientific advances of Drs. Salk and Sabin's vaccines led to the elimination of polio in the United States. And these are just effects of two of the vaccines that have been associated with saving millions of lives.

The ongoing multistate measles outbreak that is particularly severe in Texas reminds us of what happens when confidence in well-established science underlying public health and well-being is undermined. Measles, which killed more than 100,000 unvaccinated children last year in Africa and Asia owing to pneumonitis and encephalitis caused by the virus, had been eliminated from our shores. The two-dose measles, mumps, rubella vaccine regimen (MMR) using over the past decades has a remarkably favorable benefit-risk profile. The MMR vaccine is 97% or more effective in preventing measles following the two-dose series, and its safety has been remarkably well studied. Though rarely followed by a single fever-related seizure, or very rarely by allergic reactions or blood clotting disorders, the vaccine very simply does not cause autism, nor is it associated with encephalitis or death. It does, however, protect against a potential devasting consequence of prior measles infection, subacute sclerosing panencephalitis (SSPE), which is an untreatable, relentlessly progressive neurologic disorder leading to death in about 1 in 10,000 individuals infected with measles. Undermining confidence in well-established vaccines that have met the high standards for quality, safety, and effectiveness that have been in place for decades at FDA is irresponsible, detrimental to public health, and a clear danger to our nation's health, safety. and security.

In the years following the pandemic, at the Center for Biologics Evaluation and Research we have applied the same unwavering commitment to public health priorities to the development of cell and gene therapies to address both hereditary and acquired rare diseases. During my tenure as Center Director we have approved 22 gene therapies, including the first gene therapy ever to be approved in the United States. However, we know that we must do better to expedite the development of treatments for those individual suffering from any one of the thousands of diseases potentially addressable by the advances in molecular medicine over the past decades. Drawing from learnings of the pandemic, the staff at the Center for Biologics Evaluation and Research are implementing best practices learned during the pandemic such as increased communication with product developers to further expedite bringing needed treatments to those in need. They have also been exploring the dramatic transformation of our regulatory approach to expedite the delivery of directly administered genome editing products. If thoughtfully approached and further developed and refined, these treatments have the potential to transform human health over the coming years.

Over the past 13 years I have done my best to ensure that we efficiently and effectively applied the best available science to benefit public health. As you are aware, I was willing to work to address the Secretary's concerns regarding vaccine safety and transparency by hearing from the public and implementing a variety of different public meetings and engagements with the National Academy of Sciences, Engineering, and Medicine. However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.

My hope is that during the coming years, the unprecedented assault on scientific truth that has adversely impacted public health in our nation comes to an end so that the citizens of our country can fully benefit from the breadth of advances in medical science. Though I will regret not being able to be part of future work at the FDA, I am truly grateful to have had the opportunity to work with such a remarkable group of individuals as the staff at FDA and will do my best to continue to advance public health in the future.

Sincerely,

Peter Marks, MD, PhD

AdvaMed® Statement on Reports of Significant FDA Job Cuts

February 18, 2025

Washington, D.C. – **AdvaMed®**, the Medtech Association, is the world's largest trade association representing medtech companies, ranging from multinational corporations to the smallest businesses and startups. The health care system relies on FDA regulation of medtech. The FDA determines whether a medtech device may be marketed to patients and providers. A user fee agreement between FDA and medtech companies, authorized by Congress, funds part of the regulatory setup. Scott Whitaker, AdvaMed® president and CEO, made the following **statement** on LinkedIn on news reports of significant FDA job cuts.

"Over the weekend, significant job cuts were made to FDA that could have a very negative impact on patient care in this country. Today, I sent a letter to HHS outlining our concerns.

"We understand and support the administration's overall goal to be more efficient with the taxpayer dollar. Our concern is that this round of cuts to FDA staff runs counter to that shared goal.

"Device review times were already too long, though they were improving as the result of our latest user-fee agreement. FDA was already struggling to keep pace with our industry's tens of thousands of new medical technology applications every year, all of which are intended to improve the lives of patients in this country. And in this regard FDA was improving as well (and also due to our latest user-fee agreement). That agreement, for the first time ever, created private sector-like incentives for FDA to be more efficient,

transparent, and predictable in its review process. And this was of tremendous benefit to the patients whose lives and health depend on access to America's leading-edge medical technologies and treatments.

"Unfortunately, as a result of these reductions, FDA will lose hundreds of new employees, the best and most innovative hires under our most recent agreement.

"But there remains time to change course. Working together, we can achieve a more efficient and effective FDA. But, on behalf of our members, I am concerned that the cuts made over the weekend not only will not accomplish that, I am also concerned that it puts at risk our nation's status as the top medtech market in the world—as the global leader in medtech innovation, manufacturing, and jobs.

"AI in health care is a clear, illustrative example. AI is driving earlier and more accurate diagnoses, which means earlier treatments and better outcomes for patients—which, in turn, translates into lower costs to patients and to our health care system overall. Eliminating FDA's recent critical new hires in the AI space will dramatically slow review times and require reassigning non-experts already at FDA to review these technologies who will inevitably make slower and potentially inappropriately conservative decisions.

"These cuts were planned before Secretary Kennedy was even sworn into office. I am sure this latest action would not align with his goal of making America healthy again.

"I hope we are able to work with Secretary Kennedy, his leadership team, and that of FDA to reverse these cuts, and then put our heads together on policies that will achieve the aims of President Trump and DOGE but without putting patients and America's leadership role in medtech at risk."

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