Documents for the Record

Subcommittee on Health Hearing
"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"
April 1, 2025

Majority:

- April 1, 2025 – Statement from Dan Bigman, a Small Business Owner
- April 1, 2025 – Document submitted by Rep. Joyce

Minority:

- March 28, 2025 – Document submitted by Rep. DeGette
- March 25, 2025, article from the Center for Science in the Public Interest
- LinkedIn post from Robert Califf
- March 31, 2025, letter from E. Cartier Esham, Ph.D., Executive Director, Alliance for a Stronger FDA
- March 28, 2025, press release by Friends of Cancer Research
- March 27, 2025, press release by Consumer Reports
- March 27, 2025, article from Endpoints News
- April 1, 2025, article from Endpoints News
- March 28, 2025, press release by Campaign for Tobacco-Free Kids
- March 27, 2025, article from InsideHealthPolicy
- March 4, 2025, article from MedPage Today
- March 28, 2025, article from Politico Prescription Pulse
- March 27, 2025, press release by Us Against Alzheimer's
- March 27, 2025, article from Reuters
- March 28, 2025, article from The Washington Post
- March 27, 2025, press release by the American Cancer Society, Cancer Action Network
- March 27, 2025, article from STAT News
- March 28, 2025, press release by Doctors for America

Written Statement of Dan Bigman – Small Business Owner – on FDA's OTC Monograph User Fee Burden

Chairman Guthrie, and Members of the Committee: Thank you for the opportunity to share my perspective as a small business owner on the FDA's regulation of Over-the-Counter (OTC) Monograph drugs. My name is Dan Bigman, and I own a company with 45 employees that manufactures OTC healthcare products. I urge Congress to support a small business discount for the Over-the-Counter Monograph User Fee Amendments (OMUFA) fees, which have climbed from roughly $25,000 in recent years to over $34,000 per facility today. This steep, one-size-fits-all fee is a heavy burden on small manufacturers like mine. A modest fee reduction would support U.S.-based small businesses, encourage the reshoring of healthcare product manufacturing, and strengthen our supply chains against shortages like those we experienced during the COVID-19 pandemic.

Background: OMUFA Fee Structure is One-Size-Fits-All

Under OMUFA (enacted as part of the CARES Act in 2020), the FDA charges annual fees to facilities that manufacture or process OTC monograph drugs. Every facility pays the same base fee, regardless of size or output, with only a distinction that contract manufacturing facilities (CMOs) pay two-thirds of the full fee. For Fiscal Year (FY) 2024, the standard MDF facility fee was $34,166, and the CMO fee (for facilities that only manufacture on contract) was $22,777. In FY 2025, those fees rose to $37,556 (MDF) and $25,037 (CMO) . These fees are applied uniformly – a small company with one or two OTC products pays the same $34k+ fee as a multinational firm with dozens of product lines. There is no small business tier or discount in the OMUFA statute or fee schedule. In other FDA user fee programs, it is common to have reduced rates or waivers for small businesses, but OMUFA currently provides no such relief. As a result, the fee burden on a small manufacturer is disproportionately high, effectively a regressive cost.

It is important to note that OMUFA fees have also increased sharply since the program's inception. The MDF facility fee in FY 2023 was about $26,153; just one year later, it jumped to over $34,000 – an increase of roughly 30% – and it continues to climb. This jump occurred because the total program costs are spread across a shrinking number of fee-paying facilities, with no adjustment for the ability to pay. FDA acknowledged that when certain facilities (such as small producers that made only pandemic-era hand sanitizers) were exempted from fees, "the facility fees for the remaining payors have increased" to compensate. In other words, as small companies drop out or are exempted, the fee on everyone else rises, further squeezing those who remain. This dynamic makes the fee especially punishing for small businesses and discourages new entrants.

Scope of the Issue: Many OMUFA Facilities are Small Businesses (and Many are Overseas)

It's important to understand the landscape of who is paying OMUFA fees. According to FDA data, roughly 1,102 facilities assessed OMUFA facility fees for FY 2024. These facilities include huge manufacturing sites owned by multinational pharmaceutical companies to tiny independent manufacturers. Although the FDA does not differentiate fees by company size, we can estimate how many of these facilities are "small businesses." Suppose we borrow the Prescription Drug

User Fee Act (PDUFA) definition of a small business (typically defined as a company with under 500 employees or under a certain revenue threshold). Over half of OTC monograph facilities might be considered small entities in that case. The Consumer Healthcare Products Association noted that if such a small business exemption were applied, "over half of facilities" would meet the criteria. That means hundreds of U.S. OTC drug facilities are likely small businesses like mine, all currently paying the full fee. These are precisely the companies that struggle most with the cost.

By contrast, many OMUFA fee-payers are larger firms, including many foreign manufacturers. The OTC drug supply chain is global. Many OTC products marketed in the U.S. (or their active ingredients) are produced overseas. Under OMUFA, foreign and domestic facilities are charged the same fee, with no additional surcharge for foreign facilities (unlike some other FDA programs). Thus, a large factory in India or China pays the same $37,556 fee as a U.S. facility. In practice, the flat fee structure inadvertently advantages foreign and larger manufacturers: A multinational can consolidate production in one large foreign plant and pay one fee, whereas a small U.S. business operating a single plant pays that same fee.

Contract manufacturers (CMOs), some very large companies that produce OTC drugs on behalf of brand owners, also pay a reduced rate (2/3 of the fee) by statute. For example, a huge contract manufacturing facility abroad might pay about $25k , while a small U.S. company with its own facility pays $37k. The policy rationale was to not "double charge" contract firms and marketers, but the outcome is that size or economic hardship doesn't factor in at all – some of the biggest players get the CMO discount by their business model, whereas a small U.S. manufacturer marketing its own product receives no discount.

Why does this matter? Because if we want to incentivize domestic manufacturing and support American small businesses, we must recognize that the current fee system is doing the opposite. Right now, a small U.S. firm faces higher labor and regulatory costs than some overseas competitors and an equal or greater user fee burden with no relief. It is easy to see how this could discourage a would-be entrepreneur from manufacturing an OTC drug domestically. Some might choose to outsource production to a foreign CMO (to at least take advantage of the lower fee category), and others might abandon their plans entirely. Neither of those outcomes helps American workers or consumers in the long run.

Financial Impact of a Small Business Discount: Feasible and Offset by Economic Gains

One understandable concern is how introducing a small business discount or tiered fee might affect the FDA's finances and the OMUFA program funding. After all, OMUFA was designed to collect a certain total revenue each year to fund OTC monograph reforms and oversight. If some companies pay less, would others have to pay more, or would FDA face a shortfall?

Let's estimate the scale of a potential discount. There are different ways to structure a small business fee reduction – for example, a percentage discount for companies below a certain size, a lower flat fee tier for small entities, or even a waiver of the first-year fee for new small entrants. For simplicity, consider a scenario where qualifying small businesses (defined by a revenue or employee threshold) pay 50% of the standard OMUFA fee. Using the FY 2025 rates, that would

be about $18,778 for a small business facility instead of $37,556. How many facilities might qualify? Assuming (conservatively) that perhaps 30% of the 1,100 fee-paying facilities are truly small under the definition, that's around 330 facilities. At a ~$18.8k discount each, the total fee revenue reduction would be $6.2 million. Even if half of the facilities qualified (≈550 facilities), at a 50% cut, the "lost" revenue would be about $10.3 million. For context, the total OMUFA facility fee revenue target for FY 2025 is about $36.5 million. So a 50% small business break for 30–50% of facilities might reduce the total collected by roughly 17–28%. This is a manageable gap to fill, especially given the alternatives available:

• Broaden the Base / Prevent Attrition: One of the best ways to offset the revenue impact is to keep more small businesses in the program (and attract new ones). If fees become more affordable, fewer facilities will deregister or exit the OTC market to avoid the fee. This means FDA would continue to collect fees from companies that might otherwise drop out. We've already seen the feedback loop where higher fees push some out, necessitating even higher fees on those remaining. A discount could reverse that cycle. For example, suppose a fee reduction allowed 50 small facilities to stay in business or join the market that would otherwise not pay. In that case, 50 extra fee payers contribute (even at a reduced rate). The additional payors would recoup some lost revenue. In economic terms, a lower price (fee) could increase the quantity of participants, thus maintaining or even boosting total revenue in the long run. This broader base also yields public health benefits (more manufacturers, more capacity), which is hard to quantify in dollars but extremely important.

Precedents and Models: Small Business Discounts in Other Federal Programs

Thankfully, we do not have to reinvent the wheel when it comes to providing small business relief in a user fee context. Many federal agencies and even FDA's own programs have successfully implemented small business discounts or waivers. These serve as useful models and counter any argument that "it can't be done." Below are a some notable examples:

• EPA's Toxic Substances Control Act (TSCA) Fees: The Environmental Protection Agency administers fees under TSCA for chemical reviews and testing. Under EPA's rules, a company that qualifies as a "small business concern" (defined by revenue thresholds) receives approximately an 80% reduction in the standard TSCA fee . This is a substantial discount intended to ensure that small firms can afford to comply with chemical reporting and testing requirements. EPA recognized that smaller companies might be priced out of compliance without such a reduction. The TSCA small business fee model shows that an agency can maintain its funding while giving a very large break to small entities – the lost revenue is made up by larger companies and by Congress as needed, in exchange for greater industry participation and fairness

• FDA's Medical Device User Fees (MDUFA): Within the FDA, there is precedent for small business discounts. Under the Medical Device User Fee Amendments, companies with under $100 million in gross receipts can apply for "small business" status. Once granted, they pay **significantly reduced fees for device submissions – often 25% of the standard fee. For example, in FY 2025 a standard 510(k) premarket notification for a medical device costs $24,335, but a small business pays only $6,084 . That is a 75% discount for small firms.

Likewise, a Premarket Approval (PMA) application fee is over $540k standard, but $135k for a small business (again, a 75% reduction). These differences are huge in absolute terms, yet the device program has thrived with this structure – FDA still meets its review goals and device innovation has flourished with participation from many small startups. It's also worth noting that while device firms get reduced submission fees, **they still must pay an annual establishment registration fee (which has no discount)】 , somewhat analogous to OMUFA's facility fee. Even so, Congress saw fit to give relief on the bigger ticket items so as not to choke off small innovators. For OTC monograph drugs, the facility fee is the big ticket item (since there are no individual applications), so that is where relief should be targeted.

For OMUFA, the most straightforward model would be to mirror something like the EPA or device program: establish a definition of "OMUFA small business" (for instance, an OTC drug company with under $X million in annual OTC drug sales or fewer than Y employees) and set its facility fee at a reduced rate (50% of standard, or perhaps a tiered scale such as 50% for the first facility, then 100% for additional facilities – there are many ways to structure it). We could also explore a graduated fee approach, where very small firms (e.g. <$1M revenue) pay a token fee, medium-small firms (next tier) pay half fee, and large firms pay full. The key point is that numerous precedents exist to guide us. There is no regulatory or legal barrier to implementing a small business fee – it is purely a matter of policy will. Congress can direct FDA to include such a structure in the next reauthorization or even as an amendment to the existing statute, just as it has for other user fee acts.

Conclusion: A Persuasive Case for a Small Business Fee Discount

In closing, I respectfully urge Congress and the FDA to institute a sensible small business discount for OMUFA facility fees. While well-intentioned to fund important FDA work, the current flat fee structure has placed a disproportionate burden on small U.S. businesses. It has already led to some negative outcomes – businesses closing or dropping OTC products – and, if left unchanged, will continue to favor large and foreign manufacturers at the expense of American entrepreneurs. We can achieve multiple policy goals by adopting a tiered fee system that lowers fees for qualifying small manufacturers.

My ask today is a practical one. I am not suggesting we eliminate OMUFA or reduce FDA's funding – only that we make the OMUFA fees more equitable by instituting a small business rate. Whether that's a half-fee for companies under a certain size, an incremental scale, or another mechanism, I defer to the lawmakers and experts to determine the exact method. The evidence and examples I've provided show that it is both necessary and feasible. Small businesses are the backbone of our economy, and in the OTC drug sector they have a vital role to play in keeping Americans healthy and safe. Let's not allow a blunt fee instrument to cut that backbone. With thoughtful adjustment, we can maintain the integrity of the OTC Monograph User Fee program and uplift the small manufacturers who want nothing more than to contribute to this industry and serve consumers.

The Public Access to SunScreens Coalition ("PASS" or "the Coalition") has worked with policy makers since 2012 to help prevent skin cancer and improve public health by ensuring Americans have access to safe and effective sunscreens and evidence-based education on sun-safe practices. This paper details activities, legislation, and regulation to achieve that goal. The PASS Coalition's efforts have resulted in improved coordination between Congress and the Executive Branch on these goals. However, no new sunscreens have been approved in the United States and, in fact, the Food and Drug Administration ("FDA") has taken actions that may make it more difficult for Americans to access existing sunscreen ingredients.

Consequently, more Congressional action is needed. Toward that end, the paper provides policy recommendations to Congress in advance of the consideration and reauthorization of over-the-counter monograph drug user fee program ("OMUFA").

Background

The last time the FDA approved a new over-the-counter monograph sunscreen active ingredient, or UV filter, was the 1990s. Since then, the rest of the world has moved one or two generations of sunscreen ahead of the United States. Since 2002, there have been 8 new sunscreen active ingredients approved around the rest of the globe that have been submitted to the FDA for consideration under the sunscreen monograph Time and Extent Application ("TEA") process that have been stalled and ultimately did not progress towards approval in the U.S.

In 2012, a multistakeholder group of public health organizations, health care providers, sunscreen manufacturers, and concerned citizens formed the the PASS Coalition. The Coalition came together to advocate for Americans to have access to the latest sunscreen technology and address the backlog of sunscreen ingredients pending before the FDA. The PASS Coalition's mission is to help prevent skin cancer and improve public health by ensuring Americans have access to safe and effective sunscreens and evidence-based education on sun-safe practices. Since inception, PASS has worked collaboratively with FDA, DHHS, Congress and other policymakers and stakeholders on public policy to advance the Coalition's mission.

In 2014, Congress enacted the bipartisan Sunscreen Innovation Act ("SIA"), which altered the review process for over-the-counter sunscreen active ingredients.[1] The SIA resulted in the establishment of timelines for consideration of both TEA and new sunscreen active ingredients, authorized the issuance of guidance for the criteria for a generally recognized as safe and effective ("GRASE") determination for nonprescription sunscreen products, and required the agency to finalize the sunscreen monograph within five years of enactment, or November 26, 2019. Despite the SIA, FDA approved no new sunscreen active ingredients. Moreover, in anticipation of the November 2019 deadline, the FDA published a proposed order that would, if finalized, lead to the market withdrawal of two sunscreen active ingredients and removal of an

[1] *FDA Reviewed Applications for Additional Active Ingredients and Determined More Data Needed*, United States Government Accountability Office (Nov. 17, 2017), available at: https://www.gao.gov/assets/gao-18-61.pdf.

additional 12 sunscreen active ingredients leaving only two UV filters as generally recognized as safe and effective, unless sunscreen manufacturers conducted additional scientific studies. The proposed order not only failed to achieve Congress' intended goal of approving new sunscreen active ingredients, it could result in the United States having only two sunscreen active ingredients available to consumers while the rest of the world continues to invest in new, broad spectrum sunscreen innovation. FDA's actions thwarted the intent and objectives of the SIA.

Public Health Risk of Skin Cancer

Skin cancer is the most common cancer in the U.S. The Surgeon General issued a Call to Action to Prevent Skin Cancer finding that over five million Americans each year are treated for skin cancer, and that such treatment costs over eight billion dollars per year. More people are diagnosed with skin cancer each year in the U.S. than all other cancers combined.

It's estimated that the number of new melanoma cases diagnosed in 2025 will increase by 5.9 percent. Skin cancer affects individuals of all ages, and melanoma is one of the most common cancers in young adults.

In the U.S., more than 9,500 people are diagnosed with skin cancer every day and more than two people die of the disease every hour. Tragically, according to the World Health Organization ("WHO"), four out of five cases of skin cancer can be prevented by adopting sun-safe practices.

According to the U.S. Environmental Protection Agency ("EPA"), the U.V. Index in the United States continues to rise, increasing the risk of melanoma and other skin cancers for Americans.[2] The EPA recommends Americans "Use a broad spectrum sunscreen with an Sun Protection Factor ("SPF") of at least 30" to protect against the risks of a rising U.V. Index.[3]

The Sunscreen Innovation Act/Interaction with FDA

In January 2002, FDA published a final rule establishing the TEA process to consider new applications for OTC active ingredients that were already approved in comparable jurisdictions, but were not covered by existing U.S. OTC monographs. A key element of the TEA process was that ingredients currently marketed overseas for at least five years could be eligible for marketing in the U.S. based on submission of that ex-U.S. data. Sunscreen active ingredients were placed in the category of products to be reviewed under this process. This was particularly important given that many sunscreens are safely used around the world, but are not available to Americans.

The final rulemaking stated that FDA "will strive to complete TEA evaluations in 90-180 days," and that the TEA process would follow the notice-and-comment rulemaking process. Despite the establishment of the TEA process, no final rule approving a TEA sunscreen active ingredient has been issued, leaving eight pending sunscreens, several of which have been used for over 20 years in other parts of the world, unapproved in the U.S.

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[2] "A Guide to the UV Index," U.S. Environmental Protection Agency, May 2004, *available at* https://www.epa.gov/sites/default/files/documents/uviguide.pdf

[3] "UV Index Overview," U.S. Environmental Protection Agency, available at https://www.epa.gov/enviro/uv-index-overview

The PASS Coalition has always worked collaboratively with FDA. Shortly after the Coalition's inception in 2012, PASS members met with senior FDA officials and noted that despite the TEA process, no new sunscreen active ingredients had been approved through the OTC monograph process since the late 1990s. Many of these sunscreen active ingredients had been in use in Europe and elsewhere in the world for many years with significant scientific data and real-life data validating their safety. Despite this record of safety, the FDA applications for sunscreen active ingredients had been under consideration by FDA for many years – some for over a decade – with no resolution or movement prior to the PASS Coalition engaging with the FDA and Congress.

FDA officials acknowledged that no sunscreens had been approved under the TEA process, which was a frustration for the FDA, and they said the existing notice and comment rule making process required updating the OTC monograph was cumbersome and time consuming. FDA indicated that delays would persist unless something could be done to address the inherent delays of notice and comment rulemaking.

Republicans and Democrats in Congress expressed concern about the growing rates of skin cancer and the public health impact that the lack of new sunscreen active ingredients was having. FDA's responses to congressional inquiries were insufficient to ease these concerns. Thus, a bipartisan and bicameral effort was launched to draft legislation to remedy the situation.

The SIA was drafted with FDA's input and was designed to remove the burden of notice and comment rulemaking and replace it with a proposed order process. FDA indicated this would speed approval of sunscreen ingredients without weakening safety requirements for new sunscreen active ingredients. The PASS Coalition strongly supported the enactment of the SIA, which Congress unanimously approved through the House and Senate in 2014. It was supported by the FDA because it responded to the concerns the Agency itself had raised with the TEA process and thereby enabled the FDA to ensure timely review of ingredients. During the legislative negotiations, FDA said that the agency expected that enactment of the SIA would lead to new sunscreen active ingredients available for the market in the U.S. within six months.

SIA's provisions resulted in the establishment of timelines for consideration of both TEA and new sunscreen ingredients, established an administrative order process for approval of sunscreen ingredients that replaced the notice and comment rule-making process, authorized the issuance of guidance for the criteria for a GRASE determination for sunscreen products, and required the Agency to finalize the sunscreen monograph within five years of enactment, or November 26, 2019.

Shortly after enactment of the SIA, FDA issued a guidance on sunscreen testing standards that strongly urged sponsors to perform a Maximum Usage Trial (MUsT Test) to test the safety of its product. This is a test FDA invented that had never been used for sunscreens and was described in only one published scientific journal article at the time of FDA's guidance. Meanwhile, there are numerous internationally-recognized absorption testing protocols that had been previously used on sunscreen active ingredients and the FDA could have adopted with robust experience and scientific evidence. Independent scientific analysis commissioned by the PASS Coalition determined the MUsT testing standards were inappropriate for sunscreens and virtually

impossible to meet. While FDA guidance does not have the force of law, by insisting sponsors of all sunscreen applications use a MUsT Test, the FDA slowed approval applications. Consequently, none of the pending TEA sunscreen ingredients – and no new applications – have been approved. Furthermore, FDA is now applying this same standard retroactively to the UV filters that have been used safely and effectively here in the U.S. for decades.

Provisions within the Coronavirus Aid, Relief, and Economic Security Act' ("CARES Act") enacted in 2020 that used the SIA as a basis for establishing an OTC monograph drug user fee system made important changes to how FDA considers new OTC products as well as sunscreen ingredients that have been held up under the outdated monograph process. In addition, the legislation offered a period of marketing exclusivity for new sunscreen ingredients approved under the new process and allowed companies to meet collaboratively with the FDA as their ingredient applications are considered. The legislation also provides new resources to the FDA to evaluate new OTC products through user fees, similar to those which have been used to bolster the FDA's funding in its consideration of other products, like prescription drugs and medical devices. Nonetheless, FDA has not approved any pending or new ingredients.

FDA's 2019 Proposed Order

Based on the additional testing FDA imposed after the passage of SIA, in February 2019, FDA then issued a proposed rule to update the regulatory requirements for non-prescription, OTC sunscreens to ensure their safety, efficacy, and other critical topics.

The proposed sunscreen rule indicated that additional safety and absorption testing (similar to the SIA testing) for 12 of the 16 currently FDA-approved sunscreen ingredients was needed, deeming these ingredients "Category III," which means the Agency does not believe it has sufficient data to make a GRASE determination. The rulemaking was essentially replaced with a proposed "order" under the monograph reform framework established in the CARES Act.

The FDA received over 20,000 comments from stakeholders. Additionally, the PASS Coalition raised concerns about the proposed order consistent with the Coalition's mission to reduce the incidence of skin cancer and ensure Americans have access to the latest sunscreen technology. PASS noted that if implemented, the order would greatly hinder Americans' access to the vast majority of sunscreen ingredients on the market today. Furthermore, should FDA decide that these 12 ingredients are not able to remain on the market, the impact on public health would be significant and would create the misimpression that currently marketed sunscreens are not safe. Given the high rates of skin cancer in the U.S., the PASS Coalition noted its strong interest in ensuring that Americans continue to have access to the broadest range of sunscreens possible to prevent skin cancer and that individuals have access to the sunscreen products they will use every day as part of comprehensive sun-safe behavior.

In addition, PASS pointed out that while FDA continues to develop a proposed order that calls into question the safety of currently marketed sunscreen ingredients, no new sunscreen ingredients have been approved for the U.S. market even if those ingredients are currently being sold elsewhere in the world.

PASS members also raised concerns that FDA's public statements, after the proposed rulemaking issuance, suggested that existing sunscreens might not be safe. Although FDA subsequently modified its statements, this led to public confusion about the safety and efficacy of sunscreen.

Consequently, due to the FDA's actions and messaging, the FDA's actions have been interpreted on traditional and social media as the inaccurate conclusion that sunscreens are unsafe, which could lead to reduced use of sunscreens and ultimately an increase in skin cancer. Furthermore, should access to currently marketed sunscreen ingredients be curbed without appropriate alternatives, Americans will have significantly-reduced access to a proven skin cancer prevention tool.

House and Senate Appropriations Report Language

Each year, starting in 2016, the Agriculture Subcommittees of the House and Senate Appropriations Committees have issued report language regarding the lack of new sunscreen approvals and the importance of the FDA working stakeholders to ensure sunscreen access. Over the years, Members have voiced concerns that FDA has not approved any new sunscreens and urged FDA to develop an administrative order process based on internationally recognized scientific standards with input from stakeholders. These concerns have been supported by both Republicans and Democrats. Examples of appropriations report language is below:

Here is the Senate Fiscal Year 2025 appropriations report language:

> Sunscreen.—The Committee is concerned that Americans are falling behind the rest of the world when it comes to access to sunscreen even though skin cancer is the most common cancer in the U.S. According to the Surgeon General, more than five million Americans each year are treated for skin cancer at a cost of over eight billion dollars per year. As a result, the Committee directs FDA to work with stakeholders to harmonize its approach with international testing standards to ensure Americans have access to as many sunscreen active ingredients as possible recognizing that safe and effective sunscreen products are a proven preventative tool against skin cancer. In addition, the Committee urges FDA to utilize its authorities provided under the CARES Act to evaluate new sunscreen ingredients already approved for use around the world and to educate stakeholders about the administrative order process to encourage research and development of new sunscreen technology.

Here is the House Fiscal Year 2025 appropriations report language:

> Sunscreen Regulation.—The Committee is concerned that Americans are falling behind the rest of the world when it comes to access to sunscreen even though skin cancer is the most common cancer in the U.S. According to the Surgeon General, more than five million Americans each year are treated for skin cancer at a cost of over eight billion dollars per year. As a result, the Committee encourages the FDA to work with stakeholders to harmonize its approach with international testing standards to the extent possible and to ensure Americans have access to the broadest spectrum of sunscreens as possible recognizing the benefit of currently marketed sunscreens as a proven preventative tool against skin cancer when used as directed along with other sun protection measures. In addition, the Committee urges FDA to utilize its authorities provided under the CARES Act to evaluate new sunscreen ingredients already approved for use around the world and to educate stakeholders about the administrative order process to encourage research and

development of new sunscreen technology.

New Alternative Methods.—The Committee directs FDA to efficiently and expeditiously utilize existing funds to reduce animal testing and advance alternative methods in a measurable and impactful way. The Committee awaits the report requested in House Report 118–124 providing details on the status of forming the New Alternative Methods Program in the Commissioner's office.

Policy Recommendations to Ensure Americans Have Access to Sunscreens

The public health crisis caused by skin cancer is well known. Use of broad spectrum sunscreen is a proven and effective prevention tool against skin cancer. Nonetheless, FDA has still not approved a new sunscreen active ingredient into the OTC monograph since the 1990s. Compounding the problem, the Agency has called into question the safety of the majority of the currently marketed sunscreen ingredients. Congress passed the SIA to reduce the incidence of skin cancer and ensure Americans have access to the latest sunscreen technology, and FDA has fundamentally thwarted Congressional intent. Collectively, this resulted in confusion for consumers who seek to protect themselves from the risks of skin cancer, and Americans still do not have access to the latest sunscreen technology to fight skin cancer.

The ramifications are significant. From the enactment of the SIA in 2014 until 2022 (the most recent year data is available), there were approximately 775,000 new cases of skin cancer and 75,000 people have died.[4]

To ensure Americans get timely access to sunscreens, the PASS Coalition calls on Congress to take bold action and recommends the Following provisions be included in the upcoming Over-the-Counter Monograph User Fee program (OMUFA) reauthorization:

- **Establish flexible standards for evaluating the safety and efficacy of sunscreen active ingredients**. This includes allowing the use of real-world evidence, observational studies, and other scientifically valid approaches as alternatives or supplements to traditional clinical tests. This change aims to streamline the approval process by broadening the types of evidence that can be considered.

- **Streamline the regulatory framework for sunscreen active ingredients that are currently on the market globally**. OMUFA reauthorization should ensure access to safe and effective sunscreens, including sunscreens that have demonstrated safety in the marketplace for many years and are a proven skin cancer prevention tool.

- **Reduce FDA's reliance on animal testing for sunscreen ingredient testing**. The EU and other modern countries ban animal testing on sunscreens, however the FDA is requiring animal testing creating regulatory conflict that prevents harmonization. OMUFA reauthorization should require the FDA to allow non-animal safety testing protocols for sunscreen ingredients that are consistent with modern science, international testing standards, and consistent with New Approach Methods (NAMs) to gather toxicological information as an alternative to animal testing.

Ultimately, the PASS Coalition aims to:

- Collaborate with Congress and the FDA to ensure that the implementation of OTC monograph reform includes safety testing protocols for sunscreen ingredients that are consistent with modern science and international testing standards. Developing a path forward for New Approach Methods

(NAMs) to gather toxicological information is a critical step. This includes adopting a flexible approach to safety testing including reducing the use of animals.

- Ensure access to safe and effective sunscreens, especially those that have demonstrated safety in the marketplace for many years and are a proven skin cancer prevention tool. Engaging with advocates and subject matter experts to develop appropriate sunscreen ingredient testing requirements would help ensure that the regulated community can provide the data FDA needs to review sunscreen product applications. It will also help the Agency accomplish its goals and communicate with the public to ensure that Americans can continue to have access to these important skin cancer prevention tools.
- Support both Congress and the FDA in developing a regulatory framework that harmonizes testing requirements for globally marketed ingredients. We recommend the consideration of internationally accepted testing standards appropriate to sunscreens as a topical skin cancer prevention tool.

We believe that by working together, we can drive greater innovation in the sunscreen space to allow and nurture the new development of products for all Americans. The rest of the world has moved one or two generations of sunscreen ahead of the United States. These actions will help ensure that Americans can choose the best sunscreen to protect themselves from the risks of skin cancer. The PASS Coalition would be happy to provide additional information or answer any questions.

Michael Werner – [redacted]
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March 28, 2025

Sara Brenner, MD, MPH
Acting Commissioner of Food and Drugs
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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.

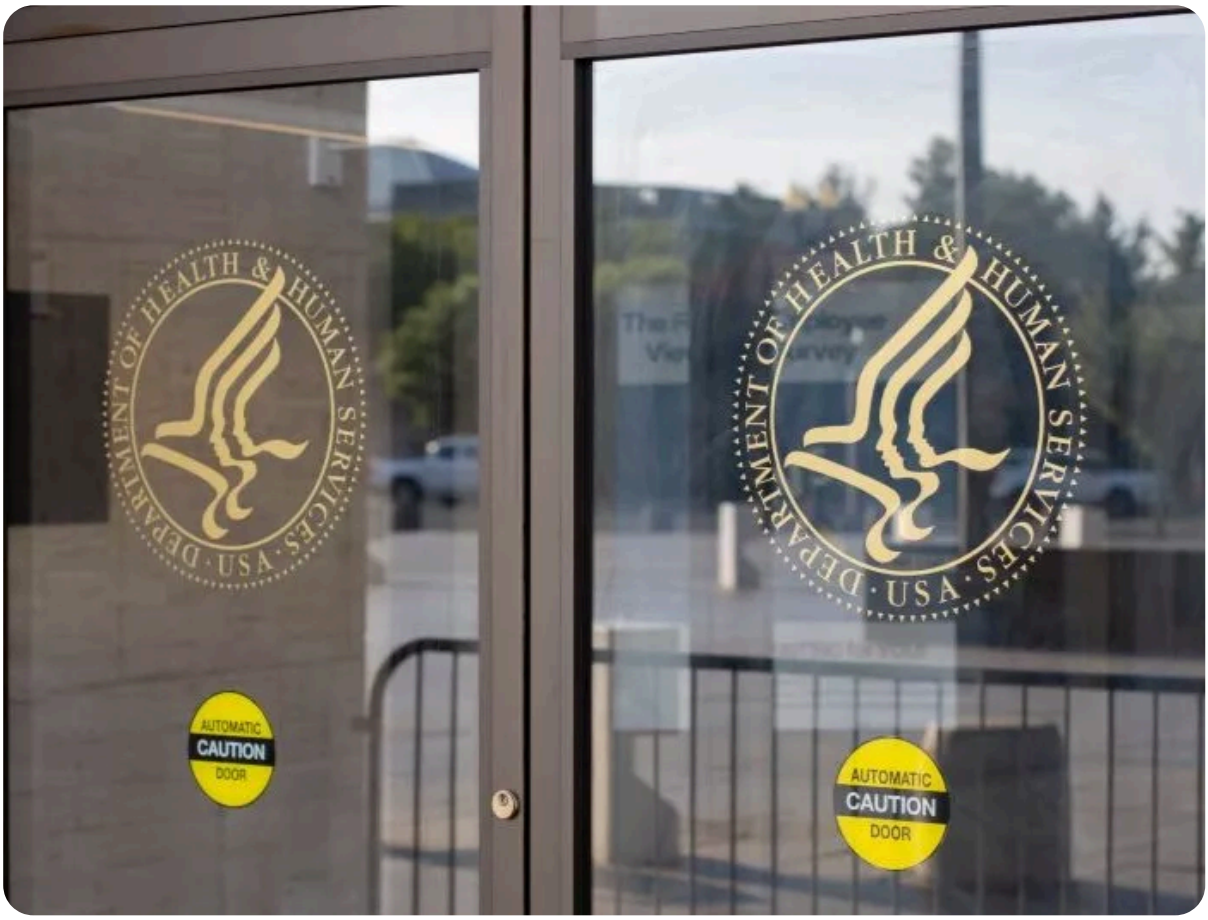
Sincerely,

Peter Marks, MD, PhD

CENTER FOR Science IN THE Public Interest

Closed-door debut of the MAHA Commission is a shaky start, scholars say

Updated: March 25, 2025



The Make America Healthy Again Commission, established by an executive order from President Donald Trump, is off to an inauspicious start with its closed-door inaugural meeting on March 11, according to the authors of a Viewpoint published today in JAMA Health Forum.

The invitation-only mix of officials and non-officials at the commission's debut is completely contrary to the emphasis on transparency described in the executive order creating the commission, chaired by Secretary of Health and Human Services Robert F. Kennedy, Jr. But, more broadly, the authors say that thus far the MAHA Commission seems focused on casting doubt on accepted scientific knowledge, promoting tangential issues or unscientific policies—all of which threaten to distract from the well-studied root causes of chronic disease.

The viewpoint is by Lawrence O. Gostin and Sarah A. Wetter, both of the O'Neill Institute for National and Global Health Law at Georgetown University, and Dr. Peter G. Lurie, president of the Center for Science in the Public Interest and a former Associate Commissioner of the Food and Drug Administration during the Obama administration.

Chronic diseases are the leading causes of death and disability in the US, and the need for a national strategy is urgent, according to the authors. Yet they say the idea of "making Americans healthy again" assumes HHS has neglected evidence-based policies—and that the commission can identify the neglected solutions in six months.

Moreover, the commission's stated priorities depart from the known causes of chronic disease,

public health experts on nutrition and physical activity. And it would not focus on Kennedy's pet peeves that have only marginal impacts on overweight and obesity in the United States.

The Center for Science in the Public Interest, for its part, was encouraged to see Secretary Kennedy recently directed the FDA to "explore" eliminating the loophole that enables food companies to self-certify that food additives are "generally recognized as safe," or GRAS. Lurie and his co-authors also recommend overhauling the agency's post-market review of already-approved food chemicals.

But the MAHA Commission is operating in the context of arbitrary and drastic cuts to all of the nation's health agencies, including the FDA and its newly revamped Human Foods Program. And just today, in a video posted on the social network X, Secretary Kennedy announced a new round of 10,000 layoffs at HHS. According to the Wall Street Journal, 3,500 positions at the FDA, or 19 percent of its workforce, will be eliminated.

"It beggars belief to suggest that this commission will discover long-ignored solutions that have been hiding in plain sight, and that it will do so on a vast array of social problems in a scant 180 days," Lurie said. "In fact, the scientific evidence on diet and disease has been accumulating for decades, including important research conducted by government scientists. You can either wage war on chronic disease or wage war on the federal workforce, but you can't do both at the same time."

# # #

Robert Califf • 2nd
Duke University
1h •

+ Follow ···

OK, i'm on a coast to coast flight, but i'm overwhelmed with messages about the firings. The FDA as we've known it is finished, with most of the leaders with institutional knowledge and a deep understanding of product development and safety no longer employed. I believe that history will see this a huge mistake. I will be glad if I'm proven wrong, but even then there is no good reason to treat people this way. It will be interesting to hear from the new leadership how they plan to put "Humpty Dumpty" back together again.

Kimberlee Trzeciak and 451 others 27 comments · 68 reposts

Like Comment Repost Send

ALLIANCE FOR A STRONGER FDA

March 31, 2025

The Honorable Brett Guthrie
Chairman
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Tom Cole
Chairman
House Appropriations Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Rosa De Lauro
Ranking Member
House Appropriations Committee
U.S. House of Representatives
Washington, DC 20515

Subject: Concern Regarding Impacts of Announced HHS Restructuring

Dear Chairman Guthrie, Chairman Cole, Ranking Member Pallone, and Ranking Member De Lauro:

As the Alliance for a Stronger FDA, we write with concern about the announced restructuring of the U.S. Department of Health and Human Services (HHS) on March 27, 2025, that will further reduce the Food and Drug Administration (FDA) workforce by about 3,500 employees, which constitutes nearly 20% of agency personnel, in addition to those who have left voluntarily. We recognize that Congress and the Administration share our goal of having an FDA that is adequately resourced and staffed to protect our food supply, keep pace with scientific advances, and ensure our country has first access to safe and effective next generation animal and human health medical interventions.

However, we are concerned that sudden sweeping changes may result in unintended consequences and encourage Congress and HHS to provide a more detailed plan and engage in a stakeholder dialogue prior to moving forward.

The responsibilities of the agency have increased dramatically in recent years and will continue to increase as a result of important new priorities that the new Administration has already announced. FDA staff are already struggling to fulfill the agency's mission and meet Congressional directives, especially in light of recent staffing reductions. Cutting another 3,500 personnel will reduce still further the agency's ability to meet Congressionally mandated deadlines. Despite statements that the March 27th announcement will not reduce the number of reviewers or inspectors, the review and inspection operations are carried out by teams and if critical team members are removed, these processes may be impaired or delayed. The American people need more details regarding the planned staffing cuts to better understand how this proposed workforce reduction will improve and streamline the agency's critical functions.

Additionally, Congress has recognized the need for skilled staff and resources at the FDA by passing legislation to improve recruitment and retention of top talent. We request that any changes to the current human resources structure acknowledge this longstanding Congressional intent and assist in the continued recruitment and retention of top talent at FDA. Moreover, any revisions to

communications, IT, or procurement policies should be tied to faster timelines for procuring and utilizing modern technologies and more timely communications on matters that are essential for improving public health. We look forward to understanding how the proposed restructuring will achieve those goals for the American taxpayer.

The Alliance is firm in its commitment to working with the Administration and Congress to achieve efficiencies in FDA operations, while ensuring Americans have timely access to safe food and safe and effective medications and medical devices and bolstering the agency as a global leader. However, we are concerned that sudden sweeping changes may result in unintended consequences. We urge both the Administration and Congress to work collaboratively on this plan before it is implemented. We stand ready as a resource to help in this effort.

Sincerely,

E. Cartier Esham, Ph.D.
Executive Director
Alliance for a Stronger FDA

The **Alliance for a Stronger FDA,** created in 2007, is a multi-stakeholder organization with 150+ members devoted to advocating for sufficient appropriations for the FDA and educating policymakers and the public about the FDA's mission and responsibilities. The Alliance's unique coalition of patient and consumer groups and industry mirrors FDA's unique role in public health, safety, and commerce.

A Weakened FDA and NIH Will Hurt Patients, Science, and the Economy

March 28, 2025

At Friends of Cancer Research, we have long been committed to increasing efficiency in the development of new medicines through advancing groundbreaking science and innovative policy. The recent announcement that 3,500 FDA staff will be let go underscores just how serious and immediate the consequences of these cuts have become. Alongside broader reductions at NIH and other key health agencies, these actions threaten to undermine the very foundation of American scientific leadership, innovation, and public health.

These agencies are not static bureaucratic institutions—they are the engines of discovery, safety, and progress that fuel the development of life-saving treatments for patients, protect public health, and drive economic growth. They are an integral part of our world-leading biomedical enterprise.

Maintaining a robust and expert workforce at these agencies is critical to ensure the U.S. remains the global leader in biomedical research, pharmaceutical development, regulatory science, and timely patient access. Slashing thousands of jobs without understanding the true needs of these agencies will have serious, long-term consequences for patients and the entire healthcare ecosystem.

The Consequences of Drastic Cuts

- **Delays in Life-Saving Treatments** – With severely reduced staff, longer wait times for new drug reviews and approvals are inevitable, slowing progress for cancer, rare diseases, and other life-threatening conditions.
- **Increased Public Health Risks** – The FDA ensures the safety of food, medicines, and medical devices. Weakening this capacity puts American lives at greater risk.
- **Economic & Job Losses** – The U.S. biomedical and pharmaceutical sectors contribute hundreds of billions to the economy and employ millions. Undermining regulatory infrastructure weakens innovation, competitiveness, and investor confidence.
- **Loss of Global Leadership** – The U.S. has long set the global standard in medical research and regulatory excellence. These cuts open the door for other nations to surpass us in discovery and development.

We cannot afford to dismantle the institutions that protect American patients and advance the future of medicine. **Smart, sustained investment—not indiscriminate cuts—is what's needed to preserve our leadership in science and ensure patients continue to receive the safest, most effective treatments.**

FRIENDS of CANCER RESEARCH

1800 M Street NW, Suite 1050 South,
Washington, DC 20036
Phone: (202) 944-6700

PRESS RELEASE

Consumer Reports statement on mass layoffs at Department of Health & Human Services

March 27, 2025

Staff cuts endanger public health and undermine administration's MAHA goals

WASHINGTON DC – Brian Ronholm, director of food policy at Consumer Reports, issued the following statement today in response to the announcement of mass layoffs (https://www.hhs.gov/about/news/hhs-restructuring-doge.html) at the Department of Health and Human Services:

"These staff cuts endanger public health and food safety, and they raise serious concerns that the administration's pledge to make Americans healthy again could become nothing more than an empty promise. Despite recent encouraging statements about addressing infant formula safety and harmful food chemicals, mass layoffs will undermine these initiatives and hinder the FDA's ability to ensure our food is safe to eat."

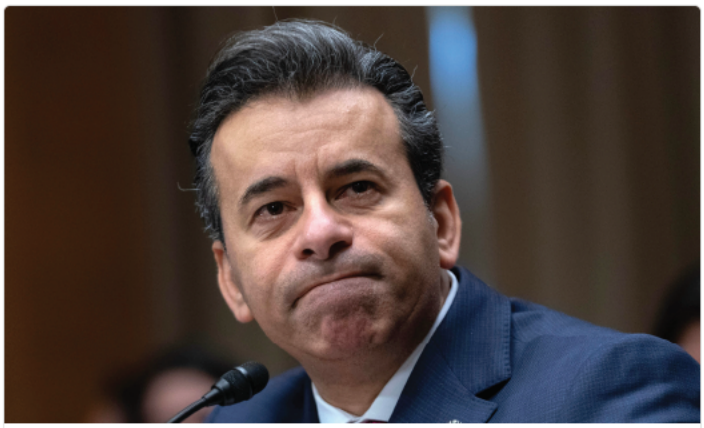
Media contact: Michael McCauley, [redacted]

ISSUES

Food (/issue/food)

EXPERT

Brian Ronholm
Director of Food Policy



Mar y Makary, FDA commissioner (AP Pho o/Jose Luis Magana)

March 27, 2025 02 55 PM EDT
Updated 04:12 PM
FDA , Law

FDA's policy, communications staff likely to be among agency's 3,500 staff cuts

Zachary Brennan
Senior Edi or

HHS' plans to eliminate almost 20% of the FDA's staff will likely take a major toll on policy, communications and other administrative staff at the agency, according to agency veterans and other sources.

While HHS has exempted the FDA's industry user fee-funded employees from the broad cuts announced Thursday, it hasn't made public more details on which departments at the agency will be affected, when the cuts might take place or what legal authority it will use to make the reductions.

But sources inside and outside the FDA told *Endpoints News* that the staff reductions will severely impact the agency's ability to conduct research, track ongoing biopharma developments and communicate with the public.

"I have not heard the details that would be needed to have an informed opinion, but it's hard for me to see how the service level at FDA can be sustained with an additional 3,500-person" reduction in staff, former FDA commissioner Robert Califf told Endpoints.

A current senior FDA employee said that if user-fee funded staff are excluded, a 3,500-person cut would amount to a very sharp reduction in personnel. The person spoke to Endpoints on condition of anonymity.

Many of the people likely to lose their jobs work on advancing regulatory science and new ways for the agency to adapt to the available medical evidence, Peter Pitts, former associate commissioner at the FDA, told Endpoints.

"Riffing these people away would be a mistake," Pitts said. He expects a lawsuit will be filed over the cuts, as has happened with other of the Trump administration's attempts to slash the government workforce.

Steven Grossman, an FDA consultant and former executive director of the Alliance for a Stronger FDA, said in a statement that "Logically, the policy, compliance, data collection, and regulatory staff are most at risk, as well as those whose jobs might be centralized at HHS."

While newly confirmed FDA Commissioner Marty Makary has told Congress that he would review any cuts, he also noted during his Senate hearing this month that the agency has grown substantially in recent years.

Sara Brenner, a career FDA staffer who has been serving as acting commissioner, wrote to employees Thursday in a message seen by Endpoints, telling them that the cuts would "be challenging for some employees" while emphasizing that they would "Make America Healthy Again" — invoking Kennedy's mission statement encompassing everything from a focus on chronic disease to a skepticism of vaccines and the FDA's relationships with the drug industry. According to Brenner's email signature, she appears to now be serving as principal deputy commissioner — the second-highest role at the agency.

An FDA spokesperson referred Endpoints to HHS for comment, and HHS didn't respond on Thursday.

Dire mood as cuts near

According to the letter, the wider HHS cuts are "primarily aimed at administrative positions including human resources, information technology, procurement, and finance. The [reduction in force] will also target roles in high-cost regions and employees in programmatic areas that have been determined to be redundant or duplicative with other functions in HHS or across the federal government."

Another employee at the FDA, who spoke on condition of anonymity, told Endpoints on Thursday that the mood at the FDA's White Oak campus was dire.

"The administration's claims that such deep cuts to the Food and Drug Administration and other critical HHS offices won't be harmful are preposterous," National Treasury Employees Union president Doreen Greenwald said in a statement. The union represents more than 11,000 FDA employees around the country.

And the main lobbying group for the biotech industry raised concerns Thursday that the cuts could lead to a loss of talent at the agency.

"It is critical to retain top-tier talent across government agencies, that safety monitoring and reviews continue without disruption, and that we continue to uphold the scientific rigor that makes American institutions the gold standard that is emulated around the world," a BIO spokesperson told Endpoints.

The House Energy and Commerce Committee is set to hold a hearing next week on user fees for over-the-counter drugs. Democratic Reps. Frank Pallone (NJ) and Diana DeGette (CO) called on committee Chair Brett Guthrie (R-KY) to "hold a hearing on these cuts immediately. There is zero sense in having a routine hearing on user fees next week before understanding the Trump administration's plan to gut the FDA by cutting 3,500 public servants."

Updated to note that the National Treasury Employees Union represents about 11,000 FDA employees.

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ENDPOINTS NEWS

April 1, 2025 08 00 AM EDT
Updated 08:12 AM
People, FDA

Breaking: Firings sweep across FDA, gutting leadership and whole offices

Zachary Brennan
Senior Edi or

Mass firings and forced resignations swept through the FDA on Tuesday, as part of thousands of planned job cuts at federal health agencies being implemented by the Trump administration.

Some employees who showed up to work at the FDA's main White Oak campus on Tuesday found out they had been fired when they attempted to check in at security, only to find out that their badges no longer worked and their jobs were gone. They were then escorted by security to collect their belongings. The scenes were described to *Endpoints News* by several people who witnessed them, and requested anonymity.

Others, such as CDER Office of New Drugs Director Peter Stein, were offered a new, hastily created role in a different department — or the choice to quit.

"I was offered a reassignment' in 'patient affairs' (as they were required to do) or termination (after admin leave). I declined the offer (as ridiculous) so am on administrative leave," Stein said in an email to Endpoints.

The moves are part of a sweeping and sudden transformation of an agency that will see 3,500 FDA staffers — 19% of the agency — depart. Already, HHS Secretary Robert F. Kennedy Jr. has pushed out one of the agency's highest profile leaders, biologics center chief Peter Marks. Other senior staff working in cancer drugs and biologics have left or been forced out, as well, Endpoints reported Monday.

That includes whole offices at the regulator, multiple FDA sources told Endpoints, including leadership and administrative staff in several departments.

This is a developing story and will be updated throughout the day...

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PRESS RELEASE

HHS Job Cuts and Weakening of Health Agencies Put Americans' Health and Safety at Risk

Statement of Yolonda C. Richardson, President and CEO, Campaign for Tobacco-Free Kids and Global Health Advocacy Incubator

March 28, 2025

WASHINGTON, D.C. – As an organization committed to improving public health, we are deeply concerned about the massive job cuts and other changes announced this week by the U.S. Department of Health and Human Services. These actions greatly undermine the nation's public health infrastructure and put the health and safety of Americans at risk. They weaken front-line agencies like the FDA, the CDC and SAMHSA that are critical to protecting Americans from preventable health threats including tobacco use, chronic diseases like cancer and heart disease, drug overdose, infectious disease outbreaks and much more.

President Trump and Secretary Kennedy have repeatedly stressed the need to reduce chronic disease and protect children's health. While we await more details about how particular agencies and programs will be impacted, we fear the proposed changes will leave HHS less equipped to address these challenges. In particular, cuts to the FDA and the CDC could undermine efforts to protect kids and save lives from tobacco use, which is the nation's leading cause of preventable death and a primary driver of chronic disease. Smoking is the top cause of cancer deaths in the U.S., responsible for about 30% of all cancer deaths, and is also a major cause of other chronic diseases including heart disease, stroke, COPD and diabetes. In addition, e-cigarettes continue to expose kids to massive doses of highly addictive nicotine, which can harm developing brains, and can also expose kids to other harmful chemicals such as formaldehyde, lead and benzene. The fight against tobacco must remain a priority if our nation is to succeed in tackling the chronic disease epidemic and protecting the health of our kids.

We urge the Administration to reconsider these cuts and changes to HHS, which will not make America healthier, safer or stronger. We also urge Congress to exercise its oversight responsibility to review these actions and to ensure that the nation's public health infrastructure is properly funded and staffed.

InsideHealthPolicy
An Inside Washington news service

FDA Cuts Could Stall Biotech Deals, Shake Investor Confidence, Experts Warn

By Maaisha Osman / March 27, 2025 at 4:35 PM

HHS announced Thursday (March 27) plans to cut an additional 3,500 full-time FDA employees, a move that industry experts are already warning could disrupt the biotech sector by delaying critical approvals, inspections and policy decisions--and in turn potentially slowing mergers, acquisitions and investment.

The newly announced cuts, which amount to about 19% of the agency's workforce, come in addition to February layoffs of 1,000 FDA employees, though 234 of those were later reinstated.

"FDA will decrease its workforce by approximately 3,500 full-time employees, with a focus on streamlining operations and centralizing administrative functions," an HHS fact sheet on the department's broader reorganization plan says. "This reduction will not affect drug, medical device, or food reviewers, nor will it impact inspectors."

But lawmakers are raising alarms about how the cuts could impact FDA's ability to meet the deadlines set out in its user fee agreements with industry. With the negotiation cycle for the over-the-counter monograph drug user fee agreement underway, the House Energy & Commerce Committee plans to hold a hearing on the program Monday (April 1).

The lead Democrats on the committee, Reps. Frank Pallone (DJ) and Diana DeGette (CO), said the committee should first address FDA staff cuts. "There is no logic in holding a routine discussion on user fees before understanding the Trump administration's plan to slash the FDA's workforce by 3,500 public servants," they said.

FDA operations may already be seeing delays. *Reuters* reported Thursday that two of FDA's scientists revealed their workloads have nearly doubled since February layoffs and other work is falling by the wayside as the agency struggles to keep up with review deadlines.

Newly confirmed FDA Commissioner Marty Makary stated during his Senate confirmation hearing that he plans to assess the agency's staffing needs and emphasized that any staff reductions should be strategic. However, he did not commit to rehiring terminated employees or confirm whether he would have the final say on the cuts.

Steve Grossman, the former director of the Alliance for a Stronger Alliance and author of the blog FDA Matters, noted the newly announced FDA layoffs are in addition to the loss of staffers who accepted voluntary separation packages.

While reviewers and inspectors are exempt from cuts, Grossman warned that other critical staff -- including those handling policy, compliance and regulatory data -- could be at risk. "Logically, the policy, compliance, data collection, and regulatory staff are most at risk, as well as those whose jobs might be centralized at HHS," he said.

However, the full impact remains uncertain until HHS releases its staffing plan, Grossman said.

One industry group, the Association for Accessible Medicines (AAM), is raising concerns over the impact of FDA workforce reductions, emphasizing possible setbacks for timely reviews of generic and biosimilar drugs.

AAM stressed that a fully staffed FDA is essential to maintaining a science-based regulatory process that supports

innovation, prevents drug shortages, and ensures affordable medicines remain accessible to patients.

“We stand ready to work with Dr. Makary and Congress to ensure that the FDA has the resources and staffing needed to fulfill its mission,” the group said.

During his confirmation hearing, Makary pledged to accelerate the approval of biosimilars and generic drugs and allow over-the-counter access to certain prescription products.

Andrew Goodman, partner in corporate department Paul Hastings law firm, told *Inside Health Policy* FDA’s workforce reduction could delay critical approvals, inspections and policy decisions, potentially stifling mergers and acquisitions (M&A) and investment in biomedical sector.

"The personnel cuts and the funding cuts, along with potential shifts in policy focus, are all going to impact M&A timelines," Goodman said. "That, in turn, could affect how much capital smaller biotech firms need to sustain operations until their next catalyst."

These "catalysts" -- key milestones such as regulatory approvals, trial results or commercial launches -- often serve as critical inflection points that determine a biotech company’s ability to secure financing or attract acquisition interest. Any delay in reaching these milestones due to a strained FDA workforce could leave companies in a precarious financial position.

Among the hardest-hit areas could be manufacturing and drug production, as FDA cuts could slow facility inspections, product approvals and re-inspections. "Those are prerequisites for companies to continue operations," Goodman noted. "If those get delayed, it could impact their business and make them less attractive as investment or M&A candidates."

For biotech investors, the uncertainty surrounding FDA timelines could pose a major risk. "In biotech, you're essentially making a bet on a binary outcome--either a drug succeeds, or it doesn’t. Timing is critical because investors need to ensure companies are sufficiently funded to navigate clinical trials, testing, and commercialization," Goodman explained.

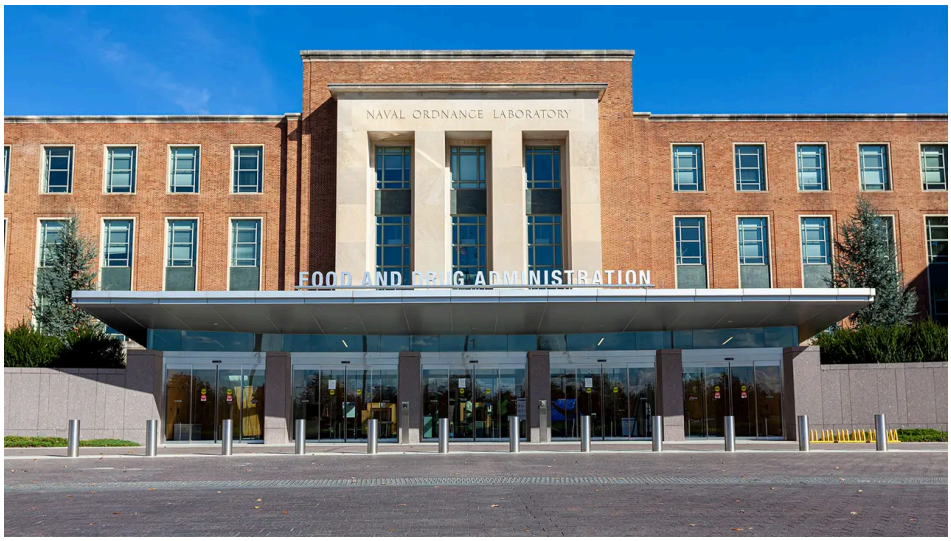
If FDA approval timelines lengthen, it could force biotech firms to raise more capital to sustain operations, potentially diluting their valuation and making them less appealing to investors. "The longer it takes to reach an inflection point, the more uncertainty and risk investors face," Goodman said. -- *Maaisha Osman* ([redacted])

147601

Gutting FDA Won't Make America Healthy

— The administration's deregulatory approach poses a threat to health and safety

by Reshma Ramachandran, MD, MPP, MHS, and Joseph S. Ross, MD, MHS
March 4, 2025



Ramachandran is a family physician and policy researcher. Ross is a general internist and health services researcher.

Shortly after Robert F. Kennedy Jr. was confirmed to be secretary of HHS, thousands of government scientists, technical advisors, and staff across federal public health agencies were dismissed. This was not without warning. Before being confirmed, Kennedy had ominously tweeted that FDA employees should "pack [their] bags" and voiced his intention to terminate 600 current NIH staff. When asked during the confirmation process if he would fire career staff who disagreed with him or the president on

scientific decision-making, he responded that he looked "forward to following the law, including relevant employment and labor relations laws."

The sudden mass loss of scientific and technical expertise across the government is only part of the first wave of gutting the federal public health workforce. Under an executive order, agency heads are to work with the Department of Government Efficiency (DOGE) to develop and institute plans "to initiate large-scale reductions in force" and identify components of agencies that could be "eliminated or consolidated." Such efforts are expected to result in the dismissal or resignation of thousands of employees.

The impact on the country will be disastrous, severely hampering our capacity to manage, much less improve, the health and healthcare of all Americans. Without immediate action by Congress or the courts, the future of HHS and the health of the nation are at risk.

FDA's Expansive and Essential Purview

FDA's role in protecting the health of all Americans cannot be underestimated. The agency regulates 20 cents of every dollar spent on consumer products in the U.S. Most of us think of drugs, vaccines, and medical devices when we think of FDA. But FDA also regulates most food, infant formula, cosmetics, pet food and veterinary drugs, laboratory tests, and tobacco products. FDA even regulates bottled water.

While the agency's annual budget of over $7 billion may seem large, nearly half the funds are paid by regulated industries (i.e. "users") as a fee to support adequate staffing, ensure timely approvals, and pay for other agency initiatives, such as surveillance efforts. Last year, Congress appropriated $3.5 billion to fund FDA, which

means that every American is paying an average of only $10 per year to live in a country where we can trust that the medicines we take work and the food we eat is safe.

As physicians and researchers, we are especially aware of the critical role FDA plays in overseeing the medical product industry. Before a drug, vaccine, or medical device is made available to the public (to be administered or prescribed), manufacturers must prove its safety and effectiveness. FDA staff with varied scientific, clinical, and technical expertise, including doctors, scientists, and engineers, review extensive patient-level data, oversee the clinical trials manufacturers conduct, and inspect production facilities in the U.S. and around the world. And FDA's regulatory role continues even after approval in monitoring safety to take timely action, including withdrawing the product from the market should significant harms be found, or warning physicians like us about serious side effects.

Necessary Growth at the FDA

FDA's remit in health innovation has only grown. Applications for new medical products to FDA have only increased over the past two decades, breakthroughs have yielded novel cell and gene therapies for diseases once

considered fatal, and medical devices leveraging artificial intelligence are now used routinely. Consequently, FDA has had to expand its regulatory capacity and its workforce. In 1990, FDA had just under 8,000 employees; as of last year, the agency comprised nearly 20,000.

With such growth, it is no surprise that the agency has been singled out with criticisms of bloat and inefficiency. But FDA has already taken steps to improve efficiencies and embrace public accountability. Over the past 5 years, the agency has undergone an extensive modernization effort for all of its core programs, improving data infrastructure and aligning initiatives within the agency. This culminated most recently in the creation of a Unified Human Foods Program with restructured field operations.

Moreover, perhaps uniquely among federal agencies, the "user fee" funding agreements include timelines for key agency actions, such as how much time the FDA is allowed to review a new drug application, and deadlines for issuing new guidance documents or implementing pilot programs, with opportunities for public comment to ensure accountability. And finally, the FDA is a leader in transparency efforts, making its reasoning and rationale behind all decisions public, convening public meetings with advisory committees to solicit expert advice, and publicly posting numerous data sources relevant to public health and safety.

Reform Is Good When Done Right

Nevertheless, as we have studied, written, and spoken about, further reforms at the FDA are indeed needed to win back public trust, both among physicians and patients. But firing or forcing the resignation of thousands of FDA employees will only be antithetical to Kennedy's goals of rigorously evaluating safety and enhancing transparency. Without sufficient staffing, these goals are

improbable, if not impossible. Among those that were fired are biostatisticians within drug and medical device review teams that ensure manufacturers' claims of efficacy are reflected within the data; pharmacologists who evaluate safety of drugs before and after approval; and scientific staff responsible for reviewing new medical devices, including software-based products leveraging artificial intelligence, to prevent patient harm.

These actions do, however, fit the administration's view that regulatory costs harm the economy, delay access to medicines, and thereby hurt patients. They have outlined aspirations for an agency that approves medical products only on the basis of safety, essentially letting the market decide which products to use. For an administration so focused on efficiency, this approach may seem penny-wise but it is actually pound-foolish. Most products are not miraculously effective, so clinical trials are needed to discern true benefits, and many safety issues are only appreciated after approval through use in large populations. This approach to regulation would lead to massive amounts of wasteful spending on ineffective, and potentially unsafe, products.

Cutting FDA staff as a cost-saving measure could also have a compound effect. In establishing the "user fee" approach, Congress stipulated that FDA must spend a specific amount of appropriated funds in order to accept, and spend, user fees from regulated industries. Because staffing is FDA's largest budget item by far, significant cuts may lead to an agency spending too little to accept the funding that makes up half its budget, further weakening FDA and possibly endangering patients and the public who rely on the agency's efforts.

A Threat to Health and Safety

Historically, the FDA has gained regulatory authority after officials became aware of pervasive risks posed to the public by health, medical, cosmetic, and food products. Corn and wheat being sold after adulteration with alum and clay. Unsanitary conditions in the meatpacking industry. More than a hundred deaths, including in children, from toxic Elixir Sulfanilamide. Thousands of birth defects from thalidomide.

It would be naïve to think that the same harms won't happen today as the current administration pursues a deregulatory agenda that decimates the federal public health workforce under the guise of government efficiency. At this week's confirmation hearing, Congress should ask the FDA commissioner nominee how he intends maintain the agency's critical mission of promoting public health and protecting public safety amid efforts to diminish its capacity to do so.

Reshma Ramachandran, MD, MPP, MHS, is an assistant professor at the Yale School of Medicine. Joseph S. Ross, MD, MHS, is a professor at the Yale Schools of Medicine and Public Health. Ramachandran and Ross co-direct the Collaboration for Regulatory Rigor, Integrity and Transparency (CRRIT) at Yale in New Haven, Connecticut.

Prescription Pulse

Delivered every Tuesday and Friday by 12 p.m., Prescription Pulse examines the latest pharmaceutical news and policy.

Wanted: More ‘details’ about FDA cuts

By **LAUREN GARDNER** and **DAVID LIM** | 03/28/2025 12:00 PM EDT

DRIVING THE DAY

REORG HITS FDA — HHS Secretary Robert F. Kennedy Jr.’s plan to slash an additional 10,000 jobs from the department raised more questions than answers among FDA employees and pharma sources Thursday as they wondered which agency functions would bear the brunt of the 3,500 layoffs expected.

One longtime industry advocate who promotes increased FDA appropriations said that number likely doesn’t include the hundreds of staffers who have already accepted voluntary buyouts — and that it’s unclear which positions have already been vacated.

“We are concerned by that number and exactly what positions and offices are being terminated,” said Cartier Esham, executive director of the Alliance for a Stronger FDA. “It’s really important that we start to see some more details.”

Whither reviews: An HHS fact sheet said the cuts aren’t supposed to impact FDA drug, medical device and food reviewers or inspectors. But one lobbyist focused on the FDA called the cuts a “disaster,” adding he didn’t know how the agency could cut so many positions without somehow affecting reviews of drug and device applications.

Kennedy “may also be looking at a lot of scientists, statisticians, and others who are critical to review programs and the agency but aren’t viewed by the administration as ‘reviewers,’” said the lobbyist, granted anonymity to speak freely about the cuts.

“Let’s face it, these guys just have no idea what they’re doing,” another pharmaceutical lobbyist said. “They are comfortable with the ‘fire everyone and try to rehire them if needed’ approach. They already had to [do that] once with devices.”

Esham said her group worries about the reorganization’s effects on the FDA’s ability to attract talent who could earn more money in the private sector.

“Congress, in a bipartisan manner, has continually supported legislation designed to ensure that the FDA is best able to recruit and retain world-class personnel,” Esham said. “We just want to make sure that continues.”

Remember: Dr. Marty Makary, who was confirmed to lead the FDA on Tuesday, repeatedly said he was not involved in earlier personnel decisions targeting probationary employees during his confirmation hearing earlier this month.

“If confirmed, you have my commitment that I will do an assessment within the agency of personnel, and it will be an ongoing assessment to ensure that the scientists and food inspectors have all the resources they need to do their job,” Makary told Sen. John Hickenlooper (D-Colo.) in response to questioning about agency staffing levels.

What’s next: Sen. Bill Cassidy, chair of the Senate Committee on Health, Education, Labor and Pensions, indicated to reporters that he wants more details on what positions will be eliminated.

“They’ve got their reorganization, but we’ll have more conversations, let me just put it that way,” Cassidy said.

IT'S FRIDAY. WELCOME BACK TO PRESCRIPTION PULSE. Are you affected by the HHS cuts? Reach out — we can keep you anonymous.

Send your tips to David Lim ([redacted], [redacted]) and Lauren Gardner ([redacted]).

EYE ON THE FDA

WHERE'S MAKARY? No one at the FDA seemed to know Thursday whether Makary had been — or when he would be — officially sworn in as the agency's commissioner. Some people inside the agency or who work closely with officials from the outside thought earlier this week he wouldn't start until Monday, but by Thursday, one former HHS official believed his ceremony was happening that day.

"When we have more information to share, we will reach out," the agency's press office said in an email when asked to confirm Makary's status.

AROUND THE AGENCIES

CMS CUTS HIT REGIONAL OFFICES — Other cuts at HHS are hitting CMS offices responsible for providing regional and minority health support.

Those cuts include people working on drug and health plan operations in an office that helps oversee health coverage for 60 million Medicare Advantage and marketplace beneficiaries, POLITICO's Ruth Reader, Kelly Hooper and Robert King report.

THE IMPACT ON AHRQ — POLITICO's Ruth Reader spoke with the former head of HHS' Agency for Healthcare Research and Quality, which focuses on improving real-world provider care, about the agency's work and what Trump administration-proposed cuts in the agency would mean for technological advancement.

Robert Otto Valdez, who stepped down as AHRQ director in January after three years, said the FDA often uses the agency's work to monitor how products perform in the real world after they're approved for market. Here's more of what they talked about.

The following has been edited for length and clarity.

Tell me how you work with the FDA on post-market surveillance.

The way FDA makes its decisions about safety and the ability of products, whether they're drugs or biologicals or devices, to go into the marketplace … is based on the kinds of studies, randomized clinical trials, that are based in experimental settings, which means that most experiments are designed to show some kind of positive effect.

But what works in an experimental setting may not work at all or may work much less well in the actual clinical setting. And so all of our health services research activities take place in real clinics and hospitals. FDA is constantly interested in knowing whether or not their decisions about the safety and efficacy of pharmaceuticals and devices actually are playing out in the real world, so that real-world experiences and surveillance is kind of what we do.

Former FDA Commissioner Robert Califf had complained that the FDA's existing authority to look at technology after it had been released to the market was inadequate for artificial intelligence. But AHRQ is better suited for that.

AHRQ had the role of making sure that AI was safe in its *actual* use and fed back into the FDA initial studies.

We're at the cusp of so many huge technological changes, both on the AI side, but also on the biotechnology side of things. For example, gene splicing and gene editing with CRISPR holds great promise for therapeutics and therapies, and while FDA will be able to make a decision based on the kinds of studies that the commercial people who are trying to get

their products out, provide them. We won't have that postmarketing capacity that AHRQ provided to respond and create that information loop back to FDA.

Potential Cuts to Health Agencies Could Upend Decades of Progress Toward a Cure for Alzheimer's Disease

Washington, DC (March 27, 2025) – Today, the United States Department of Health and Human Services announced "dramatic restructuring" that will eliminate an additional 10,000 people from its workforce, in addition to the 10,000 positions already eliminated this year. This injects further instability, uncertainty, and delays into the system that gives us disease prevention, cures, and safety monitoring.

People with degenerative diseases like Alzheimer's do not have time to waste. Alzheimer's disease is the only top 10 cause of death that has no cure and impacts over 50 percent of American families. The systemic disorder in our health care could delay or even prevent millions of people from receiving life-saving treatments and is already interrupting critical cure pathways.

UsAgainstAlzheimer's Chair and Co-Founder, George Vradenburg, released the following statement:

"Alzheimer's is a growing national crisis that impacts families across every community, and we cannot afford to take our foot off the gas in the pursuit of effective treatments and a cure. Hasty decisions made in secret that disrupt funding and remove experienced staff at key health agencies like the NIH, FDA, and CDC hinder the progress we have fought so hard to achieve.

"We have heard the Secretary say that his department will 'do more with less', and we hope he's right. But we have already seen disruption in research for a cure with the first round of cuts, and that disruption has meant that the government now is doing less with less. Another round of cuts made without any transparency is sure to mean even less. This cannot be the legacy the President wants to leave.

"With more than 6.9 million Americans currently living with Alzheimer's and millions more serving as caregivers, the disease remains one of the most significant health and economic challenges of our time.

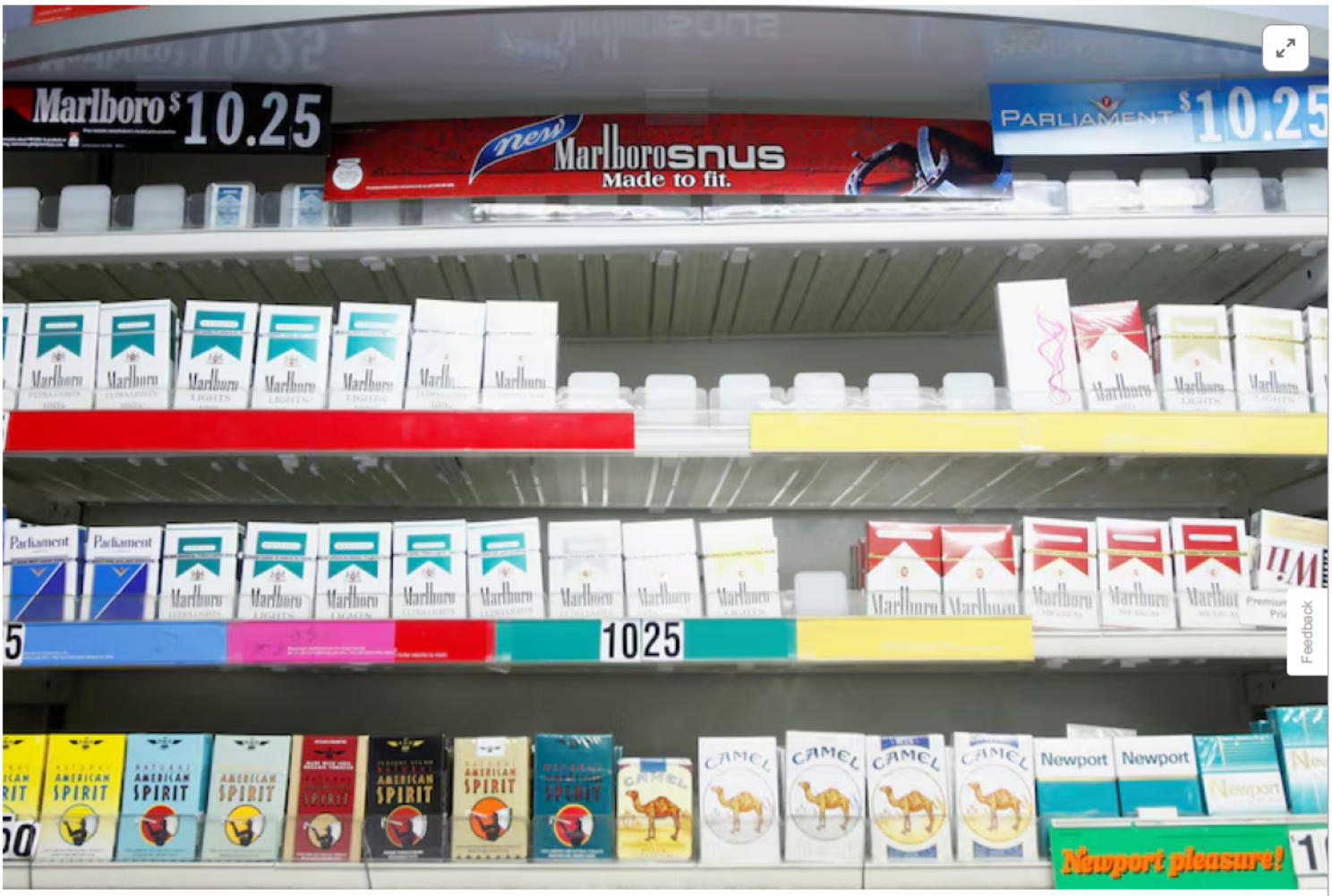
- Our Work

"We recognize the importance of increasing efficiency, and we support efforts to streamline progress toward a cure, but the recent restructuring decisions have been made without input from patients, and they appear to have been made without fully considering their impact on patients. So far, the funding cuts that have been implemented and are being proposed have slowed down our ability to find a cure. We urge the administration and Congress to act with greater transparency and collaboration. UsAgainstAlzheimer's remains committed to working alongside policymakers, researchers, and advocates to ensure that ending Alzheimer's stays a national priority."

Exclusive: FDA staff struggle to meet product review deadlines after DOGE layoffs

By **Patrick Wingrove**

March 27, 2025 2:31 PM EDT Updated 3 hours ago



[1/3] Cigarettes are displayed in a store in New York March 30, 2010. REUTERS/Lucas Jackson/File Photo Purchase Licensing Rights

Summary Companies

- Some scientists assigned double the number of new product applications for review
- Some deadlines for tobacco products will not be met and the start of new applications have been delayed, scientist says
- FDA staff told to shelve other work, including providing early feedback on planned product applications

March 27 (Reuters) - Some U.S. health regulators who review medical devices and tobacco products for safety and efficacy are struggling to meet deadlines mandated by Congress due to Trump administration layoffs, three scientists working on the projects told Reuters.

On Thursday, the government said it will cut jobs across health agencies, including 3,500 at the U.S. Food and Drug Administration, a follow-on to earlier layoffs.

Two of the scientists who work at the FDA said they had been assigned around double the number of new product applications for review since their colleagues were fired in February. They requested anonymity for fear of professional repercussions.

They said they were instructed to shelve other work, including oversight of other reviewers and providing early feedback on planned product applications before they are submitted for approval review.

One scientist at the FDA's Center for Tobacco Products said the center had delayed starting new applications while staff worked on existing submissions, some with reviews that must be completed within 180 days under U.S. law. Several tobacco-related research projects have also been canceled, he said.

"We have 180 days to complete those (existing) reviews, and we're not going to come anywhere close to that. It's just not going to happen," the scientist said.

The agency's tobacco center is currently reviewing high-profile projects including one from Philip Morris International (PM.N) that seeks approval for a new iteration of its heated tobacco device IQOS.

A Philip Morris spokesperson said the average wait time for a tobacco-product application is closer to 700 days than 180 days.

The FDA did not respond to a request for comment.

The U.S. Department of Government Efficiency - led by billionaire Elon Musk - fired around 1,000 probationary FDA employees last month, mostly from the agency's centers for tobacco, food and medical devices, before bringing some back.

Reuters could not confirm the final number of staff fired. The FDA had more than 20,000 workers earlier this year.

Ameet Sarpatwari, a professor at Harvard Medical School, said the FDA's loss of personnel and institutional experience could lead the agency to spend longer on reviews, resulting in products coming to market later, or spend less time on individual applications, increasing the risk of missing any red flags.

CANCELED MEETINGS

Eva Temkin, a lawyer at Arnold & Porter who advises clients on drug and medical device applications, said even if product reviewers are not terminated in the next round of layoffs, other FDA staff like policy experts and legal counsel are critical to product review work.

"If this plan goes forward, I do expect to see missed user fee goals and commitments," she said.

She said the FDA had already canceled some meetings with companies or reverted to providing written responses only.

A lawyer specializing in FDA regulation, who spoke on condition of anonymity, said her clients at large medical device companies were deeply concerned that the FDA would start missing deadlines following February's layoffs. Medical device industry group AdvaMed said the organization was hearing similar concerns, a spokesperson said.

The FDA last year approved more than 3,000 medical devices, around three-dozen of which were for original, high-risk devices like Medtronic's (MDT.N) Affera system to treat atrial fibrillation, and more than 250 applications for tobacco products, according to agency databases.

The administration had been offering $25,000 buyouts to FDA employees, excluding reviewers, investigators and security personnel, and early retirement ahead of that proposal, according to agency emails viewed by Reuters.

A second scientist in the tobacco division said he had been given more complicated applications to review, which require more in-depth study, after over a dozen people were fired in his office, while simpler submissions assigned to him had been put on pause.

He said he had also been given a regulatory memorandum to work on by himself that would normally be compiled by as many as six scientists.

Some of the probationary workers laid off from the FDA's tobacco center had been recruited last year for their understanding of emerging technologies, such as age verification software for electronic cigarettes, according to the first scientist.

"We needed a greater variety of expertise, and we lost that. And so that has left us scrambling quite a bit," he said.

Reporting by Patrick Wingrove; Editing by Caroline Humer, Michele Gershberg and Bill Berkrot

Democracy Dies in Darkness

RFK Jr. forces out Peter Marks, FDA's top vaccine scientist

In his resignation letter, Marks rebuked Kennedy for seeking "subservient confirmation of his misinformation and lies" about vaccines.

March 28, 2025

By Dan Diamond

The Trump administration on Friday pushed out Peter Marks, the nation's top vaccine regulator and an architect of the U.S. program to rapidly develop coronavirus vaccines, a move that comes as Health and Human Services Secretary Robert F. Kennedy Jr. continues his overhaul of the nation's health and science agencies amid a worsening U.S. outbreak of measles.

Marks, who joined the Food and Drug Administration in 2012 and had overseen its Center for Biologics Evaluation and Research since 2016, was offered the choice to resign or be fired, according to two people who spoke on the condition of anonymity to describe a sensitive situation.

He opted to resign, with an effective departure date of April 5.

Marks is leaving his post with a "heavy heart," he wrote in his resignation letter Friday, which was obtained by The Washington Post. The longtime regulator wrote that he was particularly worried about the measles outbreak in Texas, which "reminds us of what happens when confidence in well-established science underlying public health and well-being is undermined."

Reached Friday night, Marks confirmed that he was leaving the FDA but declined to comment on the circumstances of his departure.

Kennedy, who in his years as an anti-vaccine activist criticized measles shots and boosted vitamin A as a treatment, is now using his government position to tout the vitamin's accepted benefits. He has also said that receiving the measles vaccine should be a personal choice. Experts acknowledge that vitamin A can be beneficial after someone has become sickened, but they say it is not a replacement for vaccination to prevent measles.

"It is unconscionable with measles outbreaks to not have a full-throated endorsement of measles vaccinations," Marks told The Post.

The FDA did not immediately respond to a request for comment. A Department of Health and Human Services official, who spoke on the condition of anonymity to discuss personnel matters, said that Marks did not have a "place at FDA" if he did not buy into Kennedy's vision for the agency.

Two former FDA commissioners praised Marks on Friday night, highlighting his work at the agency. Marks helped conceive of Operation Warp Speed, the Trump administration's program to accelerate the development of coronavirus vaccines, which has been credited with helping end the threat of the covid-19 pandemic. A December 2022 study by the Commonwealth Fund, a health-care foundation, estimated that coronavirus vaccines prevented more than 18.5 million U.S. hospitalizations and 3.2 million deaths.

As head of the Center for Biologics Evaluation and Research, Marks led a team of experts who were charged with scrutinizing data on vaccines and other medical products before deciding whether to approve them.

"Peter has presided over an extraordinary period of medical progress, spearheading breakthroughs in cell and gene therapy that helped transform the treatment of pediatric leukemia, sickle cell disease, and certain forms of blindness," said Scott Gottlieb, who served as FDA commissioner during the first Trump administration.

"Peter's commitment to bringing the best science and data to the development and availability of lifesaving biomedical technologies, from gene and cell therapies to the Trump Administration's Operation Warp Speed, has saved countless lives," said Mark McClellan, who served as FDA commissioner during the George W. Bush administration. "His decade-long leadership at the FDA is a big reason why the FDA is the gold standard for advancing the most innovative breakthrough medicines."

In his resignation letter, Marks also said that he had been willing to work with Kennedy on the health secretary's planned efforts to review vaccine safety. Kennedy has repeatedly suggested that there could be a link between vaccines and autism — a claim that has been repeatedly debunked — and called for further study.

"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," Marks wrote.

HHS recently tapped a vaccine skeptic who has long promoted false claims about the connection between immunizations and autism to conduct a study of possible links between the two, according to current and former federal health officials.

Kennedy, who was grilled on his vaccine views by senators in his January confirmation hearings, had pledged to lawmakers that he would "restore trust" in public health and work to boost vaccine confidence if he was confirmed as the nation's top health official. While Sen. Bill Cassidy (R-Louisiana) and other Republicans questioned whether Kennedy would keep that commitment, they ultimately voted to confirm him.

Gottlieb lamented the departure of Marks and other top officials from the health department, warning that it would undermine future efforts to fight diseases and develop therapies.

“We’re failing to appreciate the people and institutions who’ve propelled these remarkable advances, undermining them without offering credible alternatives, and risking the loss of future breakthroughs that many patients are counting on,” Gottlieb said.

Lena H. Sun, Fenit Nirappil and Rachel Roubein contributed to this report.

What readers are saying

The comments express significant concern and outrage over the impact of Peter Marks's departure from the FDA, particularly in relation to vaccine development and public health efforts. Many commenters criticize the current administration, specifically RFK Jr., for undermining... Show more

This summary is AI-generated. AI can make mistakes and this summary is not a replacement for reading the comments.

Significant HHS Workforce Reduction and Restructuring Threaten the Nation's Fight Against Cancer

DRASTIC STAFF CUTS AND CHANGES IN KEY FEDERAL AGENCIES COULD DISRUPT OPERATIONS AND JEOPARDIZE PROGRAMS THAT TOUCH ALL POINTS OF THE CANCER CONTINUUM, FROM PREVENTION TO DETECTION, TO DRUG DEVELOPMENT, TREATMENT AND SURVIVORSHIP.

March 27, 2025

WASHINGTON, D.C. oday, the U S Department of Hea th and Human Serv ces (HHS) announced t w be cutt ng more than 10,000 jobs as part of a major restructur ng that w mpact operat ons at the U S Centers for D sease Contro and Prevent on (CDC), the Nat ona nst tutes of Hea th (N H), the Food and Drug Adm n strat on (FDA) and the Centers for Med care and Med ca d Serv ces (CMS), among other cr t ca agenc es hese changes cou d have d re and ong term consequences n the nat on's f ght aga nst cancer

he fo ow ng s a statement from Dr Wayne A Freder ck, nter m ch ef execut ve off cer of the Amer can Cancer Soc ety and the Amer can Cancer Soc ety Cancer Act on Network (ACS CAN) and pract c ng cancer surgeon

"ACS CAN acknow edges the adm n strat on's attempt to foster eff c ency However, any major changes to the federa nfrastructure, programs and serv ces must be mp emented n a thoughtfu way that ensures and protects progress n the f ght to manage chron c d seases, nc ud ng cancer he s gn f cant staff ng cuts and restructur ng of agenc es and operat ons at the U S Department of Hea th and Human Serv ces (HHS) announced today w touch a po nts of the cancer cont nuum, from prevent on to research, to treatment access and surv vorsh p care, and cou d d srupt our nat on's ab ty to deve op ear y detect on tests and treatments for the more than 200 d seases we know as cancer he abrupt and w despread reduct ons cou d a so resu t n future cancer breakthroughs angu sh ng n abs wh e pat ents suffer

"As a surg ca onco og st, have performed many surger es for pat ents suffer ng w th pancreat c cancer, a d sease that has seen an ncrease n both nc dence and morta ty, where the 5 year surv va rate for the most common pancreat c cancer s on y 8%, and ear y detect on rema ns cha eng ng And w th more than 2 m on peop e expected to be d agnosed w th cancer n the U S th s year a one, we can't afford to put n jeopardy the ev dence based programs and serv ces that have ong p ayed a cr t ca ro e n the cancer f ght

"W thout the workforce or nfrastructure necessary to execute the programs and serv ces at the CDC, the ead ng pub c hea th agency cou d ose the ab ty to run the cr t ca programs that have proven to prevent and f nd cancer ear y, when t s most treatab e and surv va rates are h gher, as we as support cancer surv vors CDC has deve oped an expert se n cancer contro and de vered programs that are not rep cated e sewhere n order to have the broadest reach across the U S to mpact the most peop e w th fact based nformat on and ntervent ons to he p peop e reduce the r r sk of cancer

"For the ast 50 years every major med ca breakthrough can be traced back to nvestments n the N H, wh ch houses the Nat ona Cancer nst tute (NC) Because of these nvestments, there are more than 18 m on cancer surv vors a ve n the U S today, and researchers stand on the cusp of numerous nnovat ve, new d agnost c too s and treatments W th these s gn f cant staff ng changes, new nnovat ons and cures may not see the ght of day, and pat ents cou d exper ence

d srupt on n access to serv ces and c n ca tr a s N H and NC deve opments save ves and spur econom c progress Reduc ng N H and NC 's workforce cou d jeopard ze the potent a to save more ves wh e s mu taneous y r sk ng our nat on's pos t on as the g oba eader n med ca research

"Pub c servants at CMS he p the a most 148 m on peop e who have hea th nsurance through Med ca d, nc ud ng rough y 1 n 3 ch dren w th cancer, and Med care nat onw de Reduc ng a workforce ded cated to prov d ng hea th nsurance coverage that makes t poss b e for nd v dua s to see a doctor regu ar y, get cancer screen ngs and access cancer treatment or surv vorsh p care cou d have fe threaten ng consequences

" he FDA p ays a cr t ca ro e n ensur ng that safe and effect ve drugs are ava ab e to mprove the hea th of the peop e n the U S E m nat ng pos t ons n th s agency, even non rev ew staff, cou d mpact the deve opment and approva of new drugs, ead ng the U S to ose ts pos t on as the country where cancer drugs are approved the fastest and made ava ab e f rst Loss of staff w a so undoubted y mpact the ab ty to respond to the drug shortages we are exper enc ng n add t on, the FDA's enforcement author ty on tobacco products cou d be underm ned, h nder ng the nat on's ab ty to decrease use and protect younger generat ons from start ng dead y tobacco products, the number one cause of preventab e cancer death

"Hea th s a nat ona secur ty ssue, and our nat on's hea th nfrastructure must be protected so that we cont nue to ach eve breakthroughs to ncrease prevent on and reduce death and suffer ng for peop e d agnosed w th cancer By ett ng thousands of hea th and human serv ces personne go, decades of nst tut ona know edge and expert se n the execut on of cancer serv ces and programs cou d be s gn f cant y mpeded he cumu at ve effect of cuts to federa hea th research fund ng and to staff at the HHS agenc es w put our g oba eadersh p and our hea th at r sk ACS CAN urges the adm n strat on to recons der the mpact of these reduct ons to cr t ca agenc es on the hea th and we be ng of peop e nat onw de and our co ect ve f ght aga nst cancer"

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MARCH 27, 2025

Significant HHS Workforce Reduction and Restructuring Threaten the Nation's Fight Against Cancer (/releases/significant-hhs-workforce-reduction-and-restructuring-threaten-nation%E2%80%99s-fight-against)

Today, the U.S. Department of Health and Human Services (HHS) announced it will be cutting more than 10,000 jobs as part of a major restructuring that will impact operations at the U.S. Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), among other critical agencies.

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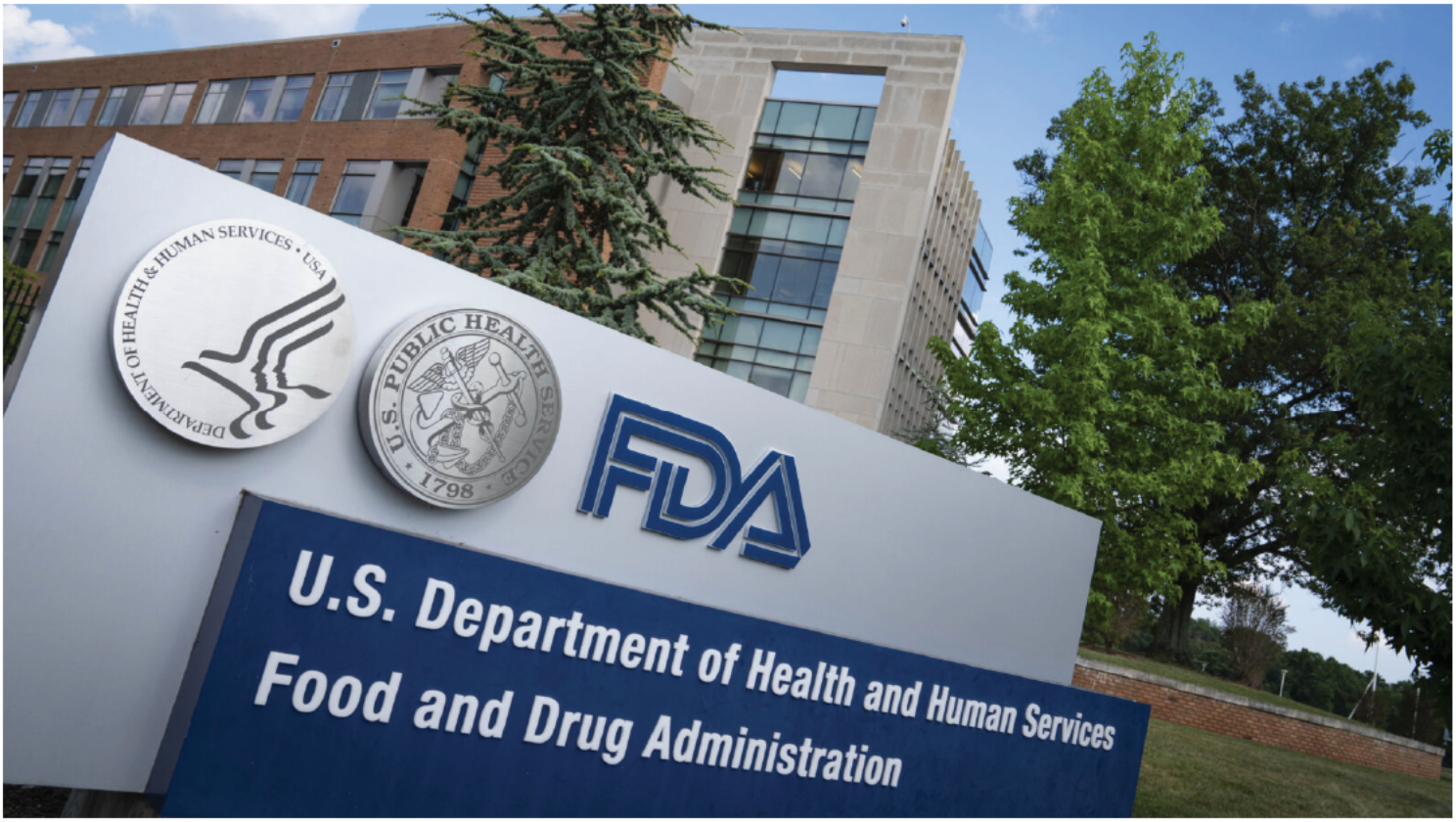
POLITICS

RFK Jr. brings FDA under tighter control with HHS workforce cuts

Current and former employees worry that the deep cuts will further erode morale and disrupt the agency's regulatory work



Sarah Silbiger/Getty Images

By Lizzy Lawrence, Sarah Todd, and Matthew Herper March 27, 2025

WASHINGTON — Around 3,500 employees are on the chopping block at the Food and Drug Administration, but they don't yet know who they are.

The Health and Human Services Department on Thursday announced a sweeping plan to cut 10,000 jobs and consolidate operations across its sub-agencies. FDA drug, medical device, or food reviewers and inspectors will not be among those fired, according to an HHS fact sheet. Instead, the cuts will target employees working on policy, human resources, information technology, procurement, and communications. The administration will start sending notices to employees on Friday, with the terminations coming into effect on May 27.

The sparing of FDA reviewers may put some industry leaders at ease, but other FDA experts are concerned that firing the thousands of employees supporting their work will make it more difficult for the agency to promote innovation and protect public health. The layoffs will shrink the FDA by almost 20%.

“Even though the intent is not to affect product reviews or or inspections, inevitably, by cutting back on services, there will be an impact,” said Wayne Pines, former associate commissioner for public affairs for the FDA.

The cuts align with Elon Musk and the U.S. DOGE Service’s mission to trim the workforce. But they also represent HHS Secretary Robert F. Kennedy Jr.’s goal to exert more control over the sub-agencies he oversees. Even high-level FDA officials appear not to have been briefed on the cuts, sources told STAT, indicating a tightening of command within HHS. The power shift is clear on the media side, as STAT’s media requests continue to be redirected from FDA to the HHS press team.

In a video message, Kennedy framed the cuts as a way to unite all the agencies and reduce bureaucracy so he can “make America healthy again.” He called out the agencies for “operating in silos,” as well as some civil servants for blocking his access to adverse event databases.

“In one case, defiant bureaucrats impeded the secretary’s office from accessing the closely guarded databases that might reveal the dangers of certain drugs and medical interventions,” Kennedy said.

This is not the administration’s first attempt to shrink HHS. In February, Musk laid off thousands of probationary workers, including people working on food safety, AI regulation, and preventing the spread of infectious diseases. After pushback from the

device industry, the administration rehired some FDA reviewers a week later. A federal judge has since paused all the probationary layoffs. The administration has also offered civil servants $25,000 to leave their posts, and instated a strict work-in-office work policy that has alienated some employees.

Several employees at FDA have told STAT that morale is extremely low, particularly given the agency's leadership vacuum. The Senate on Tuesday confirmed Marty Makary as FDA commissioner, but he hasn't yet been sworn into the role. Lawmakers pressed Makary at his confirmation hearing about the DOGE cuts at the FDA, urging him to personally assess personnel before any major culling of the agency.

"If confirmed as commissioner, you have my commitment that I will do an assessment of the staffing and personnel at the agency," Makary said. It is unclear if he will get the chance.

Acting FDA Commissioner Sara Brenner attempted to reassure staff during a device center town hall and over email, including a John F. Kennedy quote about the benefits of change in an agency-wide note.

"I recognize the changes for HHS and FDA may be challenging for some employees, who we value as both colleagues and friends," Brenner wrote. "As we chart our course into the future, I ask for your patience, grace, and sanguinity with both the process and with each other."

An FDA employee who listened to Brenner's town hall told STAT that the call kept freezing, lamenting the connection issues on the Silver Spring campus and the impending cuts to IT employees who might be able to address them.

Robert Califf, who headed the FDA during the Obama and Biden administrations, said he didn't have an issue with the HHS reorganization, but thought the way employees are being treated would be a barrier to success.

"If you do a reorganization with a demoralized workforce, which is being castigated and told it's lazy, it's unlikely to go as well," Califf said.

Pines noted that efforts to consolidate HHS and FDA are not new; as the former head of communications, he's witnessed several reorganizations. But he said the level of

consolidation is unprecedented, and could significantly impact the way FDA operates.

“The concept of consolidation, every secretary has had their point of view about that,” Pines said. “But there’s never been a change like this at FDA anywhere near this scale.”

The cuts seem “too big, too fast. I agree with RFK Jr., who says this is going to be painful, and I’m not sure what the rewards are going to be,” said Diana Zuckerman, a former congressional investigator for FDA approval standards and president of the nonprofit think tank National Center for Health Research. “These kinds of changes usually are extremely disruptive and not productive for at least a few years.”

Zuckerman wondered whether the cuts will ultimately impede Kennedy’s ambitions to reshape U.S. regulation of food. Kennedy has said he wants to focus on food labeling and fixing the “generally recognized as safe,” or GRAS, loophole in FDA review of food ingredients, as well as improving the quality and supply of infant formula.

“I think those are important,” Zuckerman said. “Who’s going to do that?” Even if the people working on those specific issues are not affected by the cuts, “usually you’d need more people working on those kinds of issues.”

Around 46% of the FDA’s total budget comes from “user fees” paid by industry to speed up product reviews. The FDA can use this money to fund employees who review medical product applications, conduct research to speed up regulatory decisions, inspect facilities, and evaluate products’ safety after they hit the market. The HHS reduction in force will likely spare most of these employees.

But the cuts won’t make their lives any easier. One FDA employee told STAT they are starting to lose access to medical journals they rely on for regulatory research. Gutting administrative personnel and cutting down on agency resources may slow down reviewers and worsen morale.

“Eliminating those people, it’s just going to be more difficult from a personnel perspective,” said Brian Ravitch, a regulatory consultant at Olsson Frank Weeda who worked for the FDA for 25 years.

STATEMENT RELEASE: DOCTORS FOR AMERICA CONDEMNS HHS CUTS

3 days ago

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March 28, 2025

Doctors for America Condemns HHS Cuts

WASHINGTON, D.C. – U.S. Department of Health and Human Services (HHS) Secretary Kennedy has announced that the agency will be drastically downsized, misleadingly characterizing this as a "transformation to make America healthy again." Doctors for America (DFA) strongly condemns this action and is deeply concerned about the impact this will have on all federal public health agencies, particularly the U.S. Food and Drug Administration (FDA) and U.S. Centers for Disease Control and Prevention (CDC), which will face an additional dissolution of nearly one-fifth of their scientific and technical capacity.

The plan announced today will reduce the overall HHS staff by roughly 20,000 overall–– adding 10,000 new layoffs to the 10,000 people who voluntarily left the agencies since the inauguration ––and further slashes the regional offices in half. Sweeping workforce cuts of this magnitude are unprecedented and threaten public health across the nation. We are particularly concerned about the impact on the FDA, which is anticipated to lose 3,500 of its critical staff members. The FDA regulates 20 cents of every dollar spent on consumer products in the U.S.––everything from medical products (e.g., drugs, medical devices, and vaccines) to food, tobacco, infant formula, and cosmetics. This extensive national footprint makes the agency one of the most critical federally funded public health institutions in the U.S.

“The dangerous announcement from Secretary Kennedy today will reduce critical oversight and public health infrastructure across the country. Americans should be worried–these cuts will weaken the nation’s ability to respond to public health emergencies, ensure safety standards, and safeguard medical research,” said Dr. Christine Petrin, Board President of Doctors for America.

The cuts announced today threaten to leave our patients and the American public at greater risk of exposure to treatments that are unsafe or not fully tested to prove efficacy. A fully staffed FDA is not only essential for the timely approval of safe and effective drugs and medical devices, but is also crucial for regulating the use of artificial intelligence (AI) in medical devices, overseeing and enforcing post-market studies, monitoring drug shortages, and providing guidance on emerging scientific issues. As the agency moves forward with a significantly diminished workforce, physicians who rely on the FDA to make treatment decisions will be left without clear, independent guidance on which medical products are truly effective and safe, ultimately putting patients at risk.

Moreover, mass layoffs at the CDC will only further destroy the nation’s public health infrastructure. While HHS states that this is intended to return the agency “to its core mission of preparing for and responding to epidemics and outbreaks”, these cuts will eliminate the agency’s work against the epidemic and leading cause of death among adolescents – gun violence. Additionally, using a shrunken CDC workforce to investigate the repeatedly discredited link between vaccines and autism diverts essential resources and tax-payer dollars from the necessary work to address infectious and chronic diseases, and runs counter to the administration’s claims that these cuts are meant to ensure “efficiency” or “workforce optimization.”

“The decision to proceed with large-scale cuts of the federal health agencies reflects an HHS Secretary who is dangerously misinformed. These cuts will hobble the ability of the FDA to comply with congressionally mandated duties of ensuring the safety and efficacy of medications and medical devices, leaving clinicians with too little information to make the right decisions for our patients,” said FDA Task Force Chair Dr. Jan Krommes. “Among FDA’s many important roles is its critical responsibility to foster the development of medical products to respond to public health threats. This cannot be accomplished without the manpower of trained experts. No manpower equates to no protection”

DFA believes the cuts announced today are antithetical to the administration’s stated goal of making America healthy again. While the rhetoric has been focused on “radical transparency” or “government efficiency,” no acceptable rationale has been given for the administration’s efforts to purge scientific and technical expertise amid ongoing and rising health threats. We strongly condemn these cuts and urge physicians as well as medical professional societies across the country to speak out about the negative impact this will have on patients and public health.

For press inquiries and to discuss this issue with members of Doctors for America, please contact Alli Everton with Continuum Health Group [redacted]

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About Doctors for America:

Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics to improve the health of our patients, communities, and nation. DFA is an organization of over 27,000 physician and medical student advocates in all 50 states, representing all areas of specialization. DFA teaches physicians and medical students advocacy skills and does advocacy at a state and federal level. Our impact areas focus on access to affordable care, community health and prevention, and health justice and equity. DFA focuses solely on what is best for our patients, not on the business side of medicine, and does not accept any funding from pharmaceutical or medical device companies, insurance companies or for-profit healthcare companies; which uniquely positions DFA as the organization that puts *patients over politics* and *patients over profits*. Find out more at doctorsforamerica.org and on Twitter drsforamerica or Bluesky drsforamerica.bsky.social.

DFA General, **FDA**