Documents for the Record

Subcommittee on Health Hearing
Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development.
Wednesday, July 15, 2026, at 10:15 a.m. (EST)

Majority:

1. July 15, 2026, letter to the Honorable H. Morgan Griffith and the Honorable Diana DeGette from the American Society of Health-System Pharmacists (ASHP).
2. July 15, 2026, statement for the record from the ERISA Industry Committee (ERIC) for the hearing on the U.S. Food and Drug Administration's role in advancing drug development in the United States.
3. July 15, 2026, statement for the record from the Alliance for Longevity Initiatives (A4LI).
4. July 15, 2026, statement for the record from Massachusetts Biotechnology (Mass Bio).
5. July 15, 2026, letter to the Honorable Brett Guthrie, the Honorable Morgan Griffith, the Honorable Frank Pallone, the Honorable Diana DeGette, and the Honorable Jake Auchincloss from the National Association of Community Health Centers.
6. July 15, 2026, statement for the record from Incubate.
7. July 15, 2026, letter to the Honorable H. Morgan Griffith and the Honorable Diana DeGette from Blood Cancer United.

Minority:

1. March 11, 2026, letter to the Honorable Martin Makary from the Honorable Diana DeGette.
2. March 11, 2026, letter to the Honorable Diana DeGette from the Honorable Martin Makary.
3. July 13, 2026, letter to the Honorable Russell Vought from E&C Democratic members.
4. July 15, 2026, statement for the record from the National Association of Community Health Centers.
5. July 8, 2026, *New York Times* article titled "Inside the Collapse of the F.D.A." submitted to the record by the Honorable Nanette Barragan.
6. June 30, 2026, letter to the Honorable Jamie Raskin from the Honorable Russell Vought.
7. July 13, 2026, statement for the record from United for Cures.
8. July 15, 2026, statement for the record from the Honorable Yvette Clarke.

July 15, 2026

The Honorable Chairman Morgan Griffith
The Energy and Commerce Committee
Health Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Ranking Member Diana DeGette
The Energy and Commerce Committee
Health Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

Re: Hearing on Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development

Dear Representatives Griffith and DeGette:

Thank you for holding this hearing on ensuring America's dominance in the biomedical field. The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing over 65,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. Our members rely on America's leadership in the biomedical field to ensure access to safe and affordable medications for their patients. To this end, we recommend the following recommendations that will ensure innovation of affordable medications as well as a strong pharmaceutical supply chain.

Expand Access to Biosimilars: Some payers and their PBMs cover only one preferred brand of a given biologic, excluding all other biosimilars. This contrasts with how some plans cover small-molecule generic drugs, where they may cover most commercially available versions. We recommend requiring that Medicaid, Medicare, group, and individual market plans, and PBMs in these markets, that already cover multiple small-molecule generic drugs in a formulary treat biosimilars similarly. Thus, if a plan and its PBM, cover a reference (brand name) biologic or any biosimilar, it must cover all biosimilars of that product. This would allow pharmacists to dispense the lowest cost version rather than only the products favored by payers and PBMs because of manufacturer rebates or other opaque incentives.

Eliminate Switching Studies: Despite a determination by the Food and Drug Administration (FDA) that a biosimilar has "no clinically meaningful differences" between the licensed biological product and the reference product in terms of safety, purity, and potency, federal law requires redundant switching studies to be performed for a product to be deemed interchangeable. These studies delay adoption of biosimilars and compromise patients' ability to access these lower-cost biosimilar products, despite FDA's previous determination that the products are safe and effective. The Biosimilar Red Tape Elimination Act would eliminate the requirement for switching studies, making a biosimilar interchangeable with its reference product upon FDA approval, thus allowing pharmacists to dispense these safe and effective products to patients at lower cost than their reference products. We recommend passage of the Biosimilar Red Tape Elimination Act (H.R. 5526) remove statutory limitations on interchangeability and eliminate the requirement for switching studies.

Provide Full Transparency of Pricing in DTC: Direct to consumer (DTC) advertisements are how a majority of consumers get their information on pharmaceuticals. With ever increasing pharmaceutical prices, consumers must also know how much the drugs cost so they can make an informed decisions on their care. We recommend passage of the Drug-Price Transparency for Consumers (DTC) Act (H.R. 3789) that would require drug manufacturers to disclose prices in DTC advertisements.

Prohibit Patent Thickets: Patent thickets, which consist of additional patents filed on a single existing product, undermine access to affordable, life-saving treatments. Prohibiting patent thickets would limit manufacturers' ability to unfairly stall generic and biosimilar drug development through abusive patent litigation practices. As a result, more generics and biologics could be approved and made available to patients in a timely manner, without being delayed by meritless litigation intended to stifle competition. We recommend passage of the Eliminating Thickets to Increase Competition Act (ETHIC) Act (H.R. 3269), prohibiting the use of patent thickets by drug manufacturers to delay generic competition.

Prohibit Product Hopping: Unfortunately, brand manufacturers can undermine clinicians' efforts to provide patients with access to more affordable medications through "product hopping." Product hopping occurs when a manufacturer of a brand pharmaceutical with an expiring patent moves patients to a new branded product that has modest to no therapeutic changes, in contrast to the original product. This practice offers patients little or no apparent medical benefit, yet burdens them with the costs of the new product's longer patent. We recommend passage of legislation that would prohibit product hopping by making this practice an antitrust violation.

Halt Abuse of Citizen Petitions: Some pharmaceutical manufacturers inappropriately and anti-competitively use the FDA's citizen's petition process to delay access to safe and effective biosimilar drugs. We recommend passage of legislation providing the Federal Trade Commission (FTC) statutory authority needed to halt the misuse of citizen petitions as well as the ability to institute civil penalties for such anti-competitive actions.

Protect the Efficient Skinny Label Application Process: The FDA's skinny label process for generics allows manufacturers to "carve out" a brand drug sponsor's patented methods of use from the generic manufacturer's approved labeling. Brand manufacturers have questioned this efficient way of ensuring rapid approval of lower cost generics. We recommend passage of the Skinny Labels, Big Savings Act (H.R. 6485), that would enshrine the skinny label pathway in statute.

Prohibit Pay-for-Delay and Other Anti-Competitive Agreements: Brand drug manufacturers sometimes enter into "pay-for-delay" agreements with other manufacturers where the manufacturer agrees to delay bringing its product to market, limiting access to affordable generic equivalents. This

anti-competitive practice keeps prices artificially high. We recommend passage of legislation providing the FTC with statutory authority to intervene in financial arrangements meant to halt competition from safe and effective generic medications.

Provide Transparency into the Patents that Manufacturers Assert: Biosimilar manufacturers typically find it difficult to launch a product due to multiple patents asserted by biologic manufacturers. Without knowing all the patents a manufacturer asserts, a biosimilar manufacturer may encounter multiple legal obstacles. We recommend passage of legislation requiring biologic developers disclose all patents to the Food and Drug Administration (FDA) for inclusion in the Purple Book, giving biosimilar manufacturers access to all patents the developer may later assert.

Limit the Number of Patents that Can be Litigated: Drug manufacturers stymie competition from generics through asserting multiple patent infringement suits under the Biologics Price Competition and Innovation Act. We recommend passage of the Affordable Prescriptions for Patents Act (H.R. 1768), which would limit the number of patents a biologic manufacturer can use to no more than 20.

Address the Economic Drivers of Generic Drug Shortages that Result in Shortages: Generic drug shortages affect Americans, whether they are seeking critical life-saving care in inpatient and outpatient facilities or simply trying to pick up medications at their community pharmacies. These shortages include common and reliable older drugs, including sterile fluids used for injection or irrigation, and critical oncology drugs, such as cisplatin, carboplatin, methotrexate, and vinblastine — medications commonly used by the population. While these drug shortages may be attributed to multiple factors, the root causes can be directly linked to economic factors that erode the resilience of the supply chain, including the race to the bottom for generic and multi-source drug prices. While reducing prices for single source drugs is critical to expanding patient access, generic drugs must be treated differently when it comes to pricing. We recommend passage of legislation increasing transparency into quality; providing low- or no-cost financing to encourage private sector maintenance of a buffer inventory of critical drugs; and giving the Centers for Medicare and Medicaid Services the authority to provide an add-on payment to certain providers for critical generic drugs determined by the Department of Health and Human Services to be at risk of experiencing a shortage.[1]

Require Consistency Between Representations to the FDA and USPTO: Manufacturers are currently able to unfairly secure extensions of their market exclusivity for medications by submitting potentially inconsistent information to FDA and U.S. Patent and Trademark Office (USPTO). We recommend Congress pass legislation that will require manufacturers to certify that they have not made inconsistent statements to the FDA and USPTO.

[1] Recommendations from ASHP and other healthcare providers in 2021 called for incentivizing the creation of private-sector reserves of essential medicines, medical devices, and supplies not adequately provided by the SNS. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

ASHP thanks you for holding this important hearing and considering our recommendations. We look forward to continuing to work with you to ensure seniors have access to care. If you have questions or if ASHP can assist your office in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus
American Society of Health-System Pharmacists

Statement for the Record by

The ERISA Industry Committee (ERIC)

To the U.S. House of Representatives
Committee on Energy and Commerce
Health Subcommittee
Washington, D.C.

"Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development"

July 15, 2026

Chairman Griffith, Ranking Member DeGette, and members of the Subcommittee, thank you for the opportunity to submit a statement for the record on behalf of The ERISA Industry Committee (ERIC) for the hearing on the U.S. Food and Drug Administration's role in advancing drug development in the United States.

ERIC is a national advocacy organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state, city, and congressional district.

Our member companies offer comprehensive health benefits, including prescription drug benefits, to employees, their families, and often retirees. On average, large employers pay approximately 80 percent of health care costs on behalf of their beneficiaries. More than 160 million people receive coverage through employer-sponsored insurance, including over 100 million through ERISA self-insured plans. These figures underscore the central role employers play in the nation's health care system—and the significant cost pressures they face in sustaining that coverage. Premium costs for employer-sponsored plans are now projected to grow by six to nine percent each year. For ERIC's member companies, some of which provide coverage to more than one million beneficiaries nationwide, these increases represent substantial costs that could otherwise be invested in wages, expanded benefits, or other support for workers and families.

For years, powerful interests have slowed biosimilar adoption by casting doubt on biosimilar safety, pressing for unnecessary phase III trials, advancing a misleading "interchangeability" designation, and preserving a patchwork of state substitution laws that restrict biosimilar dispensing. To counter this narrative, ERIC launched a groundbreaking initiative in 2020 with Johns Hopkins University to better understand the role biosimilars could play in reducing health care costs. Participating companies would have saved an average of $1.53 million on infliximab, an autoimmune drug, if they had used the biosimilar alternative.[1] Because these companies are self-insured, those savings would have returned to the benefit plan, lowered premiums, or supported improved and additional benefits. ERIC's data projected that all self-insured employer health benefit plans could have saved $1.4 billion on just two biologics in 2018 if appropriate biosimilar substitution had been used.[2] More than five years later, with many additional biosimilars now on the market, ERIC is updating this study and hopes to share new data when available.

ERIC urges Congress to take a holistic approach to lowering drug spending for employers and patients, one that addresses discovery, development, and delivery. Congress has before it a range of commonsense, bipartisan policy solutions designed to encourage lower-cost drug alternatives and restore competition in markets where it has been delayed or undermined. Many current challenges in the prescription drug market stem from departures from the balance established by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. The law rewards innovation with time-limited market exclusivity, followed by competition from generic products. Today, however, strategies that delay or avoid competition have contributed to high costs for plan sponsors and patients. ERIC strongly supports patent reforms that would promote investment in biosimilar and generic competition.

At the same time, there are several regulatory improvements squarely within the Committee's authority that deserve action this year. This Committee has long led on biosimilar policy: the Biologics Price Competition and Innovation Act (BPCIA), enacted nearly 16 years ago, originated here. Since then, experience has confirmed that biosimilars are safe and effective and can provide lower-cost alternatives for patients. Yet outdated regulatory standards continue to slow access.

[1] "Biosimilar Medications – Savings Opportunities for Large Employers" - Johns Hopkins Bloomberg School of Public Health, March 2020
[2] Ibid.

ERIC supports a broad set of reforms to address these challenges. Several bipartisan bills are ready for consideration and would speed biosimilar adoption and competition:

- Biosimilar Red Tape Elimination Act (H.R. 5526)
    - Led by Committee members Congressmen August Pfluger (R-TX) and Greg Landsman (D-OH), this bill removes certain requirements for biosimilars to receive an interchangeable designation. Specifically, it establishes a presumption that an approved biosimilar is interchangeable with the reference product without requiring additional manufacturer evidence and removes exclusivity periods for the first interchangeable biosimilar. ERIC believes the BPCIA's "interchangeability" designation, which does not exist in other countries, is an artificial barrier that delays market competition.

- STOP GAMES Act of 2026 (H.R. 8908)
    - Led by Congressman Eric Sorensen (D-IL) and Congresswoman Stephanie Bice (R-OK), this bill prevents brand-name pharmaceutical companies from abusing the FDA citizen petition process to delay approval of lower-cost generic and biosimilar applications. By curbing delay tactics that exploit regulatory processes, the legislation would help ensure patients and plan sponsors can benefit from competition as soon as lower-cost alternatives are ready for approval.

- Expedited Access to Biosimilars Act (H.R. 9661)
    - Led by Committee members Congressman Nick Langworthy (R-NY) and Congresswoman Kim Schrier (D-WA), this bill would streamline and accelerate biosimilar approvals by reducing unnecessary clinical trial requirements. Reducing duplicative or unnecessary studies would preserve FDA's rigorous safety and effectiveness standards while lowering development costs and bringing biosimilars to market more efficiently.

Conclusion

ERIC remains committed to working with the Subcommittee and Congress to advance policies that improve access, affordability, quality, transparency, and patient safety. The recommendations outlined above would address key drivers of rising costs while strengthening the employer-sponsored health system that serves more than 160 million American workers and their families. We look forward to working with the Committee to develop and enact meaningful reforms.

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS®

July 15, 2026

The Honorable Brett Guthrie
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Morgan Griffith
Chairman
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Jake Auchincloss
Member
Subcommittee on Health
House Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Guthrie, Ranking Member Pallone, Chairman Griffith, Ranking Member DeGette, and Representative Auchincloss:

America's 1,512 Community Health Centers (CHCs), also known as Federally Qualified Health Centers (FQHCs), form the nation's largest primary care network. They serve as the medical home for 52 million patients,[i] and employ 326,000 dedicated staff. CHCs deliver high-quality, affordable primary, preventive, dental, behavioral health, and pharmacy care at over 17,000 sites across the country. Notably, the Congressional Budget Office has found that CHCs also save taxpayers billions of dollars by reducing preventable ER visits, hospital admissions, and invasive procedures.[ii] In fact, research suggests every dollar invested in primary care yields a 13-to-1 return in health system savings — which can be invested back into CHCs to expand access to cutting-edge treatments for more Americans.[iii]

As the President and CEO of the National Association of Community Health Centers (NACHC), which has been the leading voice of CHCs for 55 years, I write to you today to thank you for holding this hearing on maintaining America's leadership in biomedical innovation. I want to ensure I convey that NACHC supports HHS's Operation Trialblazer roadmap and FDA's proposed Expedited IND Pilot Program, both aimed at cutting the time and cost of bringing new therapies to market and making these life-saving treatments accessible for more Americans. CHCs offer clinical trial sponsors and the FDA a ready-made, lower-cost complement to these reforms: a nationwide network of trusted providers who can accelerate enrollment, embed trials into routine clinical care, and get cutting-edge therapeutics into patients' hands faster.

Currently, clinical trials remain concentrated in a small number of academic medical centers, which slows recruitment, narrows the range of data that trial sponsors can generate, and leaves millions of patients — particularly those living in rural and underserved communities — without access to investigational drugs. Solving these challenges will require industry and government to collaborate with new research partners and new sites, such as CHCs.

As you consider reforms to strengthen the drug development pipeline, I urge the Committee to treat CHCs as a first-choice research partner alongside industry and academia. CHCs already reach patients in rural, tribal, frontier, island, and urban communities — meaning research embedded in CHCs can help trial sponsors recruit the patients that they most need and typically struggle to enroll. With modest investments, CHCs can help improve the quality and representativeness of trial data and ensure that innovation reaches patients faster and at lower cost per participant.

FDA's 2024 guidance on decentralized clinical trials recognizes local, community-based sites such as CHCs as a compliant, lower-cost way to conduct consent, follow-up, and data collection outside the four walls of an academic medical center.[iv] Other surveys show CHCs are among the most trusted sources of health information nationwide — unsurprising, as these organizations are governed by patient-majority boards, reflecting the local needs of each community. Notably, 89 percent of CHC patients believe clinical trials can improve their health.[v] Over half say they would consider enrolling in a clinical trial if their CHC provider invited them.[vi] Yet, 48 percent felt unfamiliar with clinical trials, and most had never participated in one (80 percent). A 2023 NACHC/Deloitte study found 42 percent of CHCs are already conducting research and 45 percent want to be involved.[vii] Among those not yet doing research, 35 percent specifically want to run clinical trials — untapped capacity sponsors can put to work today.[viii]

A major driver of these unmet needs is that CHCs have historically been treated as recruitment sites rather than research partners — a mismatch given their demonstrated capacity. The barrier is not a lack of interest — it is insufficient investment in infrastructure. CHCs need dedicated funding to ensure appropriate research space, staff training, and protected provider time are in place to expand trial participation at scale.[ix] The same 2023 survey found that 94 percent of CHCs cited time or workforce constraints as the top barrier to research, and 81 percent had no dedicated research staff at all.[x] Fifty-eight percent of individual CHC providers cited lack of time as their biggest obstacle.[xi] Thus, this is a resource problem, not a buy-in problem, and a comparatively affordable one to solve.[xii]

This is partly because encouraging research participation also helps with workforce retention. Amid a looming national primary care provider shortage, CHCs report research involvement is among the strongest tools they have for keeping staff engaged and growing professionally.[xiii] In a competitive labor market, offering providers a chance to do research work — not just providing clinical care— has measurably improved retention.[xiv]

Another point of note is that while CHCs serve 1 in 3 rural residents, rural sites are involved in clinical trials far less often than their urban counterparts,[xv] again largely due to a lack of staff and infrastructure. Reform that does not reach rural sites will leave rural patients further behind and leave trial sponsors without access to the patients they need for representative, FDA-ready data.

Therefore, I ask the Committee to ensure CHCs are not an afterthought as you consider biomedical innovation-friendly reforms in upcoming FDA reauthorization legislation. Specifically, I would respectfully ask the Committee to:

1. Direct FDA to clarify that CHCs and CHC-affiliated networks are eligible to participate as Qualified Research Institutions or partner sites under the proposed Expedited IND Pilot Program, which is currently open for public comment through July 22;
2. Support dedicated funding for CHC research infrastructure and staff so more sites can operate under FDA's 2024 decentralized clinical trials guidance; and
3. Encourage HHS to explicitly name CHCs in Operation Trialblazer's implementation plans, given the roadmap's recognition that community-based sites accelerate recruitment, consent, and evidence generation.
4. Incentivize industry, academia, and government to treat CHCs as research partners of choice, not just as recruitment vendors, so they are involved from the early stages of trial design and development.

Each action will help expand the trial-ready patient pool that trial sponsors are competing for and ensure that the quality of the data produced reflects the needs of American communities. CHC staff can help research partners troubleshoot problems locally, which keeps costs low and ensures a better return on investment.

Looking further ahead, CHCs are also well positioned to help pioneer the next wave of biomedical innovation that does not rely solely on expensive drug development projects, such as innovative Food for Health studies showing promising results. For instance, the Ceres Community Project's randomized controlled trial with Kaiser Permanente found that Medically Tailored Meals (MTM) measurably improved clinical outcomes and cut health care spending — the kind of low-cost, high-yield evidence base that complements pharmaceutical innovation rather than competing with it. CHCs, which already screen patients for food insecurity as part of routine care, are a natural network for scaling this research and generating the real-world evidence FDA and payers need to evaluate the efficacy and return on investment of Food for Health interventions.

Thank you for your leadership on this issue and for the opportunity to share CHCs' perspective. I look forward to working with the Committee to ensure CHCs, their staff and the patients they serve are full partners in America's biomedical innovation future. Please contact Joe Dunn, NACHC's Chief Policy Officer, should you have any questions.

Sincerely,

Kyu Rhee, MD, MPP
President and Chief Executive Officer

[i] Masselli, M., & Shin, P. (2025, August). *How many patients do Community Health Centers really care for? You'll be surprised!* Moses/Weitzman Health System & National Association of Community Health Centers. https://www.mwhs1.com/wp-content/uploads/2025/08/The-Real-CHC-Patient-Base_080525_final.pdf

[ii] Volerman A, Carlson B, Wan W, Murugesan M, Asfour N, Bolton J, Chin MH, Sripipatana A, Nocon RS. *Utilization, quality, and spending for pediatric Medicaid enrollees with primary care in CHCs vs non-CHCs.* BMC Pediatr. 2024 Feb 8;24(1):100. doi: 10.1186/s12887-024-04547-y. PMID: 38331758; PMCID: PMC10851548.

[iii] https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf

[iv] U.S. Food and Drug Administration. Conducting Clinical Trials With Decentralized Elements. September 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements

[v] North Carolina Community Health Center Association, *From Framework to Findings Improving Multicultural Engagement in Clinical Research Through Federally Qualified Health Centers and Community Health Worker Partnerships*, May 2026.

[vi] Ibid.

[vii] NACHC and Deloitte Center for Health Solutions, *Broadening research participation through community engagement*, November 2023. https://www.deloitte.com/us/en/insights/industry/health-care/community-based-inclusive-and-equitable-clinical-trials.html.

[viii] Ibid.

[ix] Ibid.

[x] Ibid.

[xi] North Carolina Community Health Center Association, *From Framework to Findings*.

[xii] NACHC and Deloitte, *Broadening research participation through community engagement*.

[xiii] Ibid.

[xiv] Ibid.

[xv] Ibid.

THE ALLIANCE FOR LONGEVITY INITIATIVES

Statement for the Record by The Alliance for Longevity Initiatives
U.S. House of Representatives
Committee on Energy and Commerce, Subcommittee on Health Hearing:
"Maintaining America's Leadership in Biomedical Innovation:
FDA's Role in Advancing U.S. Drug Development"
July 15, 2026

Introduction

The Alliance for Longevity Initiatives (A4LI) appreciates the opportunity to submit this statement in connection with the Subcommittee's July 15, 2026 hearing, *Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development.* A4LI is a nonpartisan advocacy organization dedicated to advancing the scientific and medical development of therapies that extend healthy human lifespan. We work with academic researchers, biotechnology companies, investors, and Members of both parties, including through the bipartisan Congressional Longevity Science Caucus, to align federal policy with the biology of aging.

We commend the Subcommittee for examining FDA's role in maintaining U.S. leadership in biomedical innovation. The United States remains the global leader in biotechnology, but that lead is eroding as other countries reduce the time and cost of drug development. We write to identify one structural gap in FDA's expedited-program architecture that bears directly on the Subcommittee's inquiry, and to recommend a targeted reform to close it: **The Multi-Disease Therapeutic Designation (MDTD)**.[1]

The reform we recommend requires no new appropriations, creates no new office or program, and does not lower FDA's standards for safety or efficacy. It fits cleanly within the PDUFA VIII reauthorization now moving toward the Committee. We respectfully urge its inclusion.

Addressing Modernization Through Greater Coordination

The hearing focuses on the efficiency of early-stage drug development and on the coordination failures that slow the U.S. clinical research enterprise. The Subcommittee's key questions ask how Congress and FDA can modernize regulatory requirements while upholding the agency's standard for safety and effectiveness, and how greater coordination across clinical development can reduce delay. MDTD is a direct answer to both.

FDA's existing expedited programs share a single assumption: one drug to treat one disease. That assumption no longer matches a growing class of investigational therapies. Over the past

[1] Full MDTD white paper available at https://a4li.org/wp-content/uploads/2026/06/MDTD_Whitepaper.pdf

two decades, geroscience, or the study of biological mechanisms of aging, has established that the major chronic diseases of aging share a common set of biological drivers. By developing treatments that respond to these common biological drivers, a single mechanism can produce benefit across multiple diseases at once.

While the science is progressing, current regulatory procedures are not keeping pace. For example, a sponsor developing such a therapy must today build a separate program for each indication, including separate pre-IND interactions, separate pivotal trials, separate endpoints, and submissions to review divisions that may not share a framework for interpreting the same mechanism of action. The consequences are the ones this Subcommittee is focused on examining, including duplicative cost, inconsistent endpoint expectations, and multi-year delay. Total clinical trial costs can reach more than $1 billion per drug, and pursuing two or three indications would multiply that figure add several more years. Where the regulatory pathway is unclear, capital flows to indications with cleaner economics, at the expense of the prevention-oriented programs that address the largest disease burden.

The Multi-Disease Therapeutic Designation

We propose adding a new Multi-Disease Therapeutic Designation as a means of addressing this issue. Under this designation, A drug would qualify if it were intended to address biological mechanisms common to two or more serious age-related chronic diseases, and preliminary clinical evidence indicates that it has the potential to address unmet medical needs for those diseases.

A designated therapy would receive development benefits modeled on tools that already work:

- Intensive FDA guidance on efficient development beginning as early as Phase 1;
- Senior FDA leadership engagement on novel trial design and endpoint questions; and
- Rolling review of application submissions as sections are completed.

Critically, on granting a designation FDA would constitute a **cross-divisional review team with a designated lead division**. This is the coordination reform the Subcommittee's third key question calls for, applied to the category of therapy where the coordination problem is most acute.

The designation does not lower FDA's approval standard. Sponsors must still demonstrate substantial evidence of effectiveness and an acceptable safety profile on the indications they pursue. MDTD changes how the agency coordinates during development, not what it must conclude before approval.

THE ALLIANCE FOR LONGEVITY INITIATIVES

PDUFA VIII as the Vehicle

MDTD follows a pattern Congress has used before. Breakthrough Therapy Designation was created in the 2012 PDUFA V reauthorization with no new appropriation and no new office; it has since become one of the most consequential drug-development reforms in three decades, with more than 600 designations granted and 374 designated products approved by March 2026.[2] Regenerative Medicine Advanced Therapy (RMAT) and Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) were added as separate pathways through the 21st Century Cures Act of 2016, each targeting a therapeutic category the existing architecture did not fit. MDTD is the next iteration of that pattern. The PDUFA VIII reauthorization is the natural vehicle to implement a procedural reform within FDA's existing authority and budget, within the Committee's jurisdiction, and with visible bipartisan support.

MDTD to Address Global Competition

The Subcommittee's fourth key question asks what is at stake if the United States loses its leadership in biopharmaceutical innovation. In geroscience, the answer is concrete. The United States currently leads in the early-stage firms pursuing such longevity-focused therapies, but that lead is not assured. China has invested heavily in geroscience infrastructure, including growing public research investment; Russia has announced multi-billion-dollar commitments to aging science; and regulators in the European Union have begun engaging multi-disease prevention frameworks through programs such as Priority Medicines (PRIME), designed to expedite drug approval. Regulatory clarity is one of the principal variables determining where the next generation of this development is anchored.

The fiscal case reinforces the strategic one. Chronic conditions drive roughly 90 percent of the nation's $4.9 trillion in annual healthcare spending.[3] 45 percent of Medicare beneficiaries live with four or more of them.[4] A therapy that reduces the incidence of several age-related conditions at once compounds federal savings in a way disease-by-disease development structurally cannot. Independent modeling estimates that a 20 percent slowing of biological aging would carry a fiscal value on the order of $7.1 trillion over fifty years.[5] The math is simple: A reform that improves the regulatory pathway for the therapies targeting that biology has significantly more economic value.

[2] https://friendsofcancerresearch.org/about-breakthrough-therapies/
[3] https://www.cdc.gov/chronic-disease/data-research/facts-stats/index html
[4] https://www.kff.org/medicare/health-policy-101-medicare/
[5] https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0052

THE ALLIANCE FOR LONGEVITY INITIATIVES

Recommendation

The chronic diseases of aging are the largest and fastest-growing source of medical cost, disability, and mortality in the United States. They share a common biological substrate that FDA's expedited-program architecture does not yet reflect, and a growing pipeline of investigational therapies is built around that substrate. Aligning the pathway with the biology is among the highest-leverage, lowest-cost interventions available in this reauthorization cycle.

A4LI respectfully urges the Subcommittee to include the Multi-Disease Therapeutic Designation in the PDUFA VIII reauthorization package. We welcome the opportunity to work with Committee staff on bill text, and we thank the Subcommittee for its attention to these issues.

LEUKEMIA & LYMPHOMA SOCIETY® is now

Blood Cancer United

July 15, 2026

The Honorable Morgan Griffith
Chair
Subcommittee on Health
Committee on Energy and Commerce

The Honorable Diana DeGette
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

Statement for the record Re: Energy and Commerce Health Subcommittee hearing on "Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development"

Dear Chair Griffith and Ranking Member DeGette:

On behalf of the more than 1.8 million Americans living with a blood cancer diagnosis, Blood Cancer United (previously The Leukemia & Lymphoma Society) appreciates the opportunity to provide this statement for the record regarding clinical trial modernization and the ability of the Food and Drug Administration (FDA) to continue to represent gold-standard regulatory oversight of the drug development and approval process, particularly as it relates to the upcoming reauthorization of several FDA User Fee Acts in 2027.

At Blood Cancer United, our mission is to cure blood cancer and improve the quality of life of all patients and their families. To achieve it, we unite a community of people—patients and their families, volunteers, healthcare providers, scientists, staff, partners, fundraisers, and philanthropists—who believe all blood cancer patients deserve longer, fuller lives. We fund innovative research, offer free resources and personalized support, and advocate at state and national levels for more accessible and affordable healthcare for all patients.

Since our founding, we have invested over $2 billion in cancer research, and Blood Cancer United-funded research has helped advance more than 70% of all blood cancer treatments approved by the FDA over the last two decades.

Well-designed clinical trials are critical to Blood Cancer United's mission. In 2016, we launched the Beat AML® Master Clinical Trial, the first collaborative precision medicine clinical trial in a blood cancer. The trial uses advanced technology to examine the genetic make-up of each patient's cancer and then matches patients to the most promising targeted treatment. In June 2022, we launched the PedAL Master Clinical Trial, the first integrated, global, acute leukemia master clinical trial to test new, safer therapies on children, who will be matched to treatments based on their unique tumor biology. We also run a Clinical Trial Support Center, with Nurse Navigators who have expertise in pediatric and adult blood cancers helping identify clinical trial options for each patient's unique needs and circumstances.

User fees are critical to the functioning of the FDA. Yet, as you know, user fees must be reauthorized by Congress every five years, including user fees for brand-name prescription drugs (PDUFA VIII), generic drugs (GDUFA IV), and biosimilars (BsUFA IV) that are up for reauthorization in 2027. User fee reauthorization legislation represents a significant opportunity for Congress to shape and improve

drug development, evaluation, and approval in the United States. As this Committee looks ahead to the reauthorizations coming up next year, Blood Cancer United appreciates the ability to share our priorities regarding the upcoming user fee negotiations in the interest of blood cancer patients and their families:

FDA advisory committees and the patient voice

Therapeutic and disease-specific advisory committees are integral to ensuring that the FDA is well-informed by scientific consensus and patient perspectives. In many formal drug and biologic advisory committee meetings, patient input remains intermittent, non-voting, or narrowly framed. Patients are experts in living with their conditions, and their insights are critical to contextualizing benefit-risk. PDUFA VIII should solidify patient participation as a standing component of advisory committee meetings rather than an ad-hoc addition.

The patient voice should also be integrated into the post-approval process via patient-reported outcomes and data. PDUFA VIII should commit the FDA to piloting continuous, structured patient-reported outcome collection in post-approval studies—linked where possible to CMS claims data—and to issuing clear, multilingual summaries of advisory committee outcomes, major safety updates, and annual performance reports, thereby sustaining patient engagement across the entire product life cycle.

Each therapeutically focused advisory committee should include at least one trained individual patient representative and one representative of a qualified patient organization as standing members with voting privileges. Standing advisory committees should be constituted to inform ongoing reviews in relevant therapeutic areas, and ad-hoc advisory committees should be convened to resolve disagreements between career review staff and senior leadership.

Consistency, transparency, scientific integrity, and agency accountability

Having a predictable regulatory environment, including a predictable fee and revenue approach for PDUFA, will enhance companies' ability to invest in innovation. Industry depends on a stable, well-resourced FDA, staffed by subject matter experts free from political influence, to conduct the regulatory oversight required to bring safe and effective therapeutics to patients.

We are concerned that, as early as fall 2025, without Congressional authorization or a regulatory notice-and-comment rulemaking period, the FDA established a process in which top agency officials, including at least one political appointee, conducted an around-the-table vote on whether to approve a new drug under the recently created Commissioner's National Priority Voucher program (CNPV) without providing a single vote to the career staff who had conducted the drug's regulatory review.[i]

This represents a dramatic shift away from the agency's traditional approach of vesting drug review decisions with its independent career professionals. It's precisely those career experts who have both specialized expertise relevant to the product and disease being addressed and the benefit of months spent personally engaging with the evidence submitted by the product sponsor.

This new process also raises concerns about whether the agency officials involved—several of whom had only months of experience at FDA prior to the vote in question—were casting their votes based on

political factors unrelated to the drug's safety and efficacy. For example, one of the appointees who voted in this new process has since resigned in the wake of an internal investigation[ii] into allegations he had leveraged his government position to retaliate against a former colleague in the private sector.

These concerns have been exacerbated by the FDA's own statements that appear to prejudge the approval decisions for drugs reviewed under this new pathway, saying[iii] that the pilot program intends to "expedite approval of applications" rather than simply accelerating the agency's final determination regarding approval, whatever the decision. Further, reports indicate that the program has been used as a bargaining chip[iv] in broader negotiations with drug manufacturers in order to advance Administration goals related to increasing domestic manufacturing or lowering the price of drugs. While voucher receipt does not guarantee product approval, decisions often align with the Administration's stated objectives.

As advocates for patients who need access to innovative therapies, we know that even the appearance of improper political influence may result in patients losing access to products approved through this new process. Payers with the power to determine whether new, costly drugs are truly accessible for patients have already demonstrated their skepticism of expedited approval pathways, including those pathways with more transparency and demonstrated rigor than the CNPV program. The drastically truncated review times associated with CNPV reviews, combined with the involvement of political appointees in CNPV approval decisions, create the exact uncertainty that payers cite in questioning whether they should cover a newly approved drug.

In the past several years, criticisms of political interference in the FDA's actions have tarnished the agency's public reputation, leading consumers and others to question whether significant[v] agency[vi] decisions[vii] were made based on scientific evidence. These concerns have been exacerbated by the announcement that the agency will forgo external expert input[viii] into drug reviews, recently leaked internal warnings about the safety risks[ix] inherent in the Commissioner's National Priority Voucher program's timetable, the unprecedented instability[x] in the agency's leadership, reports that political appointees are threatening[xi] career agency leaders with losing their jobs "if they did not play ball," the highly-publicized hurried rehiring[xii] of mistakenly fired experts, and FDA's decision to flout a statute[xiii] mandating new guidance on clinical trial requirements. It is clear to our organization that the last thing the FDA needs now is more political intervention.

Simply put, patients with serious health conditions have too much at stake to tolerate the FDA substituting the judgment of top officials and political appointees for that of the expert staff with both relevant expertise and time for a comprehensive review of the evidence. To rebuild trust with patients, we recommend that PDUFA VIII include language directing the FDA to ensure that each decision to approve or reject a product under review lies with the relevant review team, and to clarify that career staff involved in such decisions are squarely focused on a science-based determination of the product's safety and efficacy.

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FDA workforce

We recognize the need for additional FDA staff. The required knowledge and bandwidth to appropriately regulate the therapeutic development space, particularly in oncology, continue to expand. We are concerned about the impact the Reductions in Force are having on drug approval timeliness and the expertise needed to complete projects. For example, the FDA has lost many longtime career scientists and review teams within the Oncology Center of Excellence. Recruitment of additional expertise would help advance much-needed efforts to develop updated positions on functional and structural endpoints. Congress should exert oversight to understand the extent to which FDA is fully leveraging its existing enhanced hiring authorities and whether new authorities are necessary to ensure FDA maintains a workforce ready and able to review increasingly complex products.

Diversity Action Plan guidance

Despite racial and ethnic minority groups comprising nearly 40% of the U.S. population, about 75% of participants in trials for drugs approved by the FDA in 2020 were white.[xiv] This disparity persists: between 2017 and 2023, only 6% of pivotal trial enrollments matched the distribution of the four largest racial and ethnic groups in the U.S. population.[xv] Not only does this dynamic inhibit a full understanding of how effective new drugs might be across these populations, but it also exacerbates disparities in access to treatment when enrolling in a clinical trial may be the most effective treatment option for the individual patient.

Since 2022, Congress has directed the FDA to require drug sponsors to submit diversity action plans (DAPs) that must specify enrollment goals by race, ethnicity, sex, and age. As directed by the Food and Drug Omnibus Reform Act (FDORA), enacted in December 2022 as part of the Consolidated Appropriations Act of 2023, the FDA *must* publish a draft guidance and finalize it, after which the mandate takes effect. However, the FDA has chosen to flout this law, refusing to issue this final guidance.

Congress should use PDUFA VIII to reiterate in statute that FDA must quickly finalize the DAP guidance and that the agency should enforce the statutory DAP requirement. Moreover, we urge Congress to consider what accountability measures may be appropriate to build into the legislation to compel the agency's compliance.

Special protocol assessments

Put in place in 2018, special protocol assessments (SPAs) allow the FDA to pre-review and provide guidance on pivotal Phase III trials before a company invests significant time and money. A SPA acts as a binding agreement with the FDA that the protocol will be sufficient to support a regulatory submission. This ensures stability for the industry between political changes at the FDA.

However, SPAs have been largely hamstrung by long timeframes for the FDA to fully review protocols. Congress should consider ways to promote reforms that would evolve the SPA process into a shorter, more streamlined procedure in which the FDA reviews only core elements, including 1) the proposed primary endpoint and 2) the statistical model the trial will use. Such a process would provide critical certainty to product sponsors who have seen several recent examples of the FDA "moving the

goalposts" following significant time and resources devoted to implementing studies that reflected earlier agency feedback.

Continue and strengthen the Rare Disease Innovation Hub
The Rare Disease Innovation Hub, an existing PDUFA VII commitment, has been integral to fostering connections and community engagement across rare diseases. Congress should codify authority, funding, and duties for the Rare Disease Innovation Hub as part of PDUFA VIII.

Real-world evidence
Integrating real-world evidence (RWE) into clinical trial design should be done with caution. We recommend adopting support for regulatory use of externally controlled trials, including through RWE, where appropriate and scientifically justified. This includes issuing clear methodological guidance, expanding internal review capacity, and supporting sponsor engagement earlier in the trial design process. When methodologically rigorous and appropriately validated, these tools can enhance trial feasibility in small populations and rare conditions while maintaining the scientific standards and predictability essential for regulatory decision-making.

Trial decentralization
We support the effort to bring clinical trials to where patients live. In particular, we support legislative efforts to promote decentralized clinical trial designs, and Congress should use the user fee act reauthorizations to do so. Decentralizing aspects of clinical trials and bringing them to where patients live results in increased participation, particularly for underrepresented populations, and decreased attrition without compromising data quality.

Migrating care from a centralized trial site to a patient's community has the potential to reduce meaningful burdens on trial participants and their caregivers, including:

- reducing the time that participants must devote to travel, both to and from in-person clinical visits to investigational sites;
- reducing the money spent by participants on such travel;
- reducing exposure by potentially immunocompromised participants to other individuals on public transportation and in public spaces;
- reducing the time investment for caregivers providing transportation and support; and
- retaining clinical relationships between trial participants and their community providers.

Global regulatory harmonization
We broadly support efforts to align regulatory requirements with our international counterparts. The FDA should be directed to consider opportunities to deepen collaboration with international regulatory agencies such as the European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), Health Canada, and the Pharmaceuticals and Medical Devices Agency (PMDA). Reducing duplicative requirements and exploring mutual recognition agreements for certain aspects of product review could accelerate global patient access and ease regulatory burden without compromising safety or quality. Global harmonization is particularly needed with respect to rare disease clinical trials, for which data from multiple countries must be collected to generate

sufficient data. Indeed, harmonizing trial data requirements across jurisdictions lowers barriers to trial entry and has the potential to expedite trial timelines.

Support for clinical Trials Advancing Rare disease Therapeutics (START)
The START program provides enhanced communication between the FDA and selected sponsors for rare disease therapeutics. Created outside of PDUFA VII, its scope is limited, with only seven sponsors participating. Congress should evaluate the START program via PDUFA VIII to determine whether it has led to sound trial designs and smoother progression through the clinical development pipeline.

Biologics and biosimilars
Biosimilars were designed to be lower-cost alternatives, much like generics. But red tape, anti-competitive tactics, and flawed payment incentives have stood in the way.

Biosimilars have the potential to produce real, meaningful savings. When biosimilars became available for rituximab (RituxanTM) – a critical blood cancer treatment – prices dropped 63%, improving affordability for patients and generating significant systemwide savings.[xvi] With one in four cancer patients unable to afford to take their therapies as prescribed, such a dramatic reduction can be lifesaving.[xvii]

Yet only 10% of the biologics set to lose exclusivity in the next decade have a biosimilar in development. If policymakers don't act quickly to remove barriers to biosimilars, patients, employers, and taxpayers could lose $189 billion in potential savings.[xviii]

In 2010, Congress set up a special FDA approval process for biosimilars that included extra testing requirements that didn't apply to traditional generics. Since then, years of experience have shown that many of these extra steps aren't needed. In fact, the FDA itself no longer recommends them.[xix] Removing these costly requirements as part of the BsUFA reauthorization would speed up competition and help bring down drug prices for patients.

Today, anti-competitive practices too often delay biosimilars and extend monopoly prices. For example, some biologics manufacturers have set up what's known as "patent thickets," overlapping collections of patents on the same drug, which mire competitors in lawsuits and keep prices high for blockbuster drugs. This and other anticompetitive practices—from "pay to delay" agreements to abusing the FDA's citizen petition process—are hindering the savings biosimilars could bring to patients.

Congress should act to break down these barriers and speed access to biosimilars and generics alike. We urge lawmakers to consider the policies laid out in the following bipartisan bills and include them in any legislative package reauthorizing BsUFA:

- Biosimilars Red Tape Elimination Act *(HR 5526, S 1954)*
- Skinny Labels, Big Savings Act *(HR 6485, S 43)*
- Ensuring Access to Lower-Cost Medicines for Seniors Act *(HR 8143, S 4323)*

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- Affordable Prescriptions for Patients Act *(S 1041)*
- Interagency Patent Coordination & Improvement Act *(S 1097)*
- Preserve Access to Affordable Generics & Biosimilars Act *(S 1096)*
- Stop STALLING Act *(S 1095)*

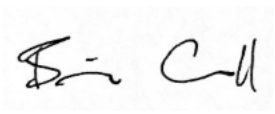
Additionally, BsUFA should establish a 505b(2) pathway for follow-on biologics. This pathway has helped lower costs and approval timelines for generic drugs, and such an option for follow-on biologics would be similarly useful.

Finally, we support biosimilar naming harmonization with the rest of the world. The U.S. is the only country in the world that adds suffixes to the nonproprietary name of biological drugs. This does not help prevent medication errors and is not consistently used in adverse event reporting. Instead, the suffix has led to confusion among patients and prescribers, undermining confidence in biosimilars and perpetuating unjustified concerns that biosimilars pose safety issues.

Conclusion

Blood Cancer United would welcome the opportunity to meet with you and your staff to discuss these concepts in the coming weeks. As you consider these and other issues of priority for blood cancer patients, please do not hesitate to contact Jessica Burnell, Director of Federal Government Affairs, at Jessica.Burnell@bloodcancerunited.org.

Sincerely,



Brian Connell
Vice President, Federal Affairs

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Statement for the Record: Incubate Coalition

Submitted to the U.S. House of Representatives
Committee on Energy and Commerce, Subcommittee on Health
"Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development"

July 15, 2026

Incubate appreciates the opportunity to submit this statement for the record. Incubate is a coalition of venture capital firms and early-stage life science organizations from the investment, corporate, and philanthropic communities focused on advocating for policies that support venture capital in moving promising science from the laboratory to patients. Our members fund companies at the earliest and riskiest stage of drug development, at the point where a discovery either advances toward a clinical trial or never leaves the bench.

We commend the Subcommittee for examining the FDA's role in maintaining U.S. leadership drug development. The FDA is the gold standard of the world but now requires modernization. The right response to rising competition is not to lower our standards or to retreat behind them. It is to have better ideas that enable a faster, more predictable, risk-proportionate FDA that produces more impact for patients and keeps discovery, capital, and manufacturing in the United States.

America still leads, but the early-stage lead is eroding.

Inefficiencies in the U.S. preclinical and early-clinical ecosystem are contributing to a measurable shift of preclinical, Phase 1, and Phase 2 research overseas, primarily to China, Australia, and parts of Europe.

The numbers are direct. The time between an initial meeting request and IND submission is an average of 380 days in the United States.[1] By comparison, many trials begin in fewer than 70 days in Australia and China has even exceeded that pace. These gaps are not accidents of geography. Australia relies on a Clinical Trial Notification pathway, and China has compressed its timelines through a streamlined IND process, a large contract research ecosystem, and regulatory capacity that grew from roughly 200 reviewers in 2017 to 1,300 in 2024.[2]

The volume gap follows the same pattern. China conducted more than 7,100 registered clinical trials in 2024, compared with roughly 6,000 in the United States.[3] Early-stage trials were an afterthought in Australia, representing just 9 percent of active trials in 2006. By 2020, they had

[1] https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf
[2]https://www reaganudall.org/sites/default/files/2026-06/Enhancing%20Early-Stage%20Drug%20Development%20in%20the%20US_1.pdf
[3] https://itif.org/publications/2025/06/09/china-surpassed-us-number-drug-clinical-trials-1-100-more/

risen to 40 percent, a clear indicator that its regulatory framework and incentives had proven effective and enticing for biotech companies.[4] And the trajectory compounds: China is projected to account for approximately 35 percent of U.S. FDA approvals by 2040.[5] On current trends, the United States is ceding the earliest and most formative stage of drug development.

This is a competition the United States can win, because our science base and our capital markets are still the best in the world. But capital is mobile, and it follows predictability. When the process to start a trial is several times longer here than abroad, capital moves abroad with it.

Investors Are Clear: Instability raises the cost of capital.

Earlier this year, Incubate and Manatt Health interviewed biotech investors spanning seed, venture, and private equity. Their conclusion was consistent: regulatory uncertainty is undermining trust in the FDA and diminishing the attractiveness of U.S. biopharmaceutical investment.[6]

This matters because of how drug development is financed. It takes 10 to 15 years and more than $2 billion to bring a medicine from discovery to approval and only about 12 percent of drugs that enter clinical trials are ultimately approved.[7] Investors underwrite the immense risk of failure by building probability-weighted models of success. When regulatory risk becomes unquantifiable, such as when a company cannot articulate a clear, durable path to approval, expected value falls and financing dries up. As one surveyed investor put it, a company *"becomes un-investable"* without a regulatory pathway it can articulate to its investors.

The impact is uneven. Investors reported the greatest reluctance in precisely the areas where regulatory uncertainty and shifting evidentiary standards are disproportionately being seen, including vaccines, cell and gene therapies, and oncology. First-in-class programs are penalized more than fast-follower programs. And instability beyond the FDA, including reduced and less predictable NIH support for the early-stage research that feeds the entire pipeline, compounds the effect over the longer term.

Critically, the capital does not disappear. It moves. Investors described redirecting capital toward later-stage, lower-risk assets and toward opportunities abroad, including China. This shift isn't necessarily out of strategic preference, but because the U.S. pathway had become too uncertain to underwrite. That is the central finding: instability is not merely slowing investment at home; it is changing where capital flows globally.

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[4] https://www.reaganudall.org/sites/default/files/2026-06/Enhancing%20Early-Stage%20Drug%20Development%20in%20the%20US_1.pdf
[5] https://www.biotech.senate.gov/wp-content/uploads/2025/12/NSCEB-Future-of-U.S.-China-Biotech-Competition-Dec-2025.pdf
[6] https://www.incubatecoalition.org/post/incubate-and-manatt-release-new-report-regulatory-instability-at-fda-is-reshaping-biotech-investmen
[7] https://pmc ncbi.nlm.nih.gov/articles/PMC8212735/

Biotech executives are asking for the same thing.

Incubate's recent surveys point in the same direction. Investors are pulling back from U.S. programs because they cannot price FDA risk: more than two-thirds of executives have had investors cite FDA instability as a reason to decline or delay an investment.[8] At the same time, executives are recognizing the advantages of China in clinical trial speed and cost. These facts are linked. Capital leaves an unpredictable system for a faster one. The reform respondents most wanted was not lower standards or new trade barriers, but a stable, predictable, and faster FDA.

Restricting where American capital can flow does not fix this. Outbound-investment restrictions treat the symptom rather than the cause; they do nothing to shorten the U.S. pathway, and a company still needs a credible route to approval to be fundable at all. The durable answer is to out-compete, not to wall off.

Pricing policy is the clearest test of whether policy moves capital.

The same logic applies to how the government sets prices. Investors underwrite a decade of risk against the expected value of a successful product. When policy compresses the years a medicine can earn a market return, expected value falls, and capital moves to where the math still works. This is not theoretical. Recent pricing policy has produced a clean natural experiment, and the result is consistent: policy moves capital, quickly and measurably.

Two provisions of the same law make the point. The Inflation Reduction Act exempted orphan drugs from Medicare price negotiation, but only when a drug treated a single rare disease. The moment a sponsor pursued a second rare-disease indication, the drug lost its exemption, penalizing precisely the additional research these patients need. Congress corrected this in 2025 with the ORPHAN Cures Act, extending the exemption to drugs with one or more orphan designations. The fix renewed investor interest in the rare-disease space, restoring the incentive to pursue follow-on indications for the smallest patient populations, and one year following enactment rare disease treatments have seen close to $4 Billion invested, more than double the year prior.[9] A targeted pricing correction pulled capital back toward one of the hardest and most valuable areas of drug development.

The same law's treatment of small molecules runs the other way. Small-molecule medicines, the pills that account for the overwhelming majority of prescriptions, become eligible for price setting nine years after approval. Biologics receive thirteen. That four-year gap falls on the most commercially important years of a product's life, and investors have responded. Research has found that aggregate small-molecule investment by companies valued under $2 billion, the early-stage innovators, fell 68 percent after the IRA, alongside a 35 percent decline in early-stage

[8] https://www.incubatecoalition.org/post/biotech-ceo-survey-the-future-of-biotech-leadership-demands-better-policy-at-home
[9] https://lifesciencetracker.com/rare/

Phase 1 and Phase 2 programs.[10] Incubate's own surveys are blunter: roughly 80 percent of venture investors report reduced interest in funding small molecules because of the policy.[11] The science is not the problem. Capital is retreating because of a pricing rule. The bipartisan EPIC Act would close the gap by aligning the two timelines.

This is the context for judging broader price-setting proposals. The Most-Favored-Nation framework would tie U.S. prices to those paid abroad across new launches in the commercial, Medicare, and Medicaid markets, and the administration is now working with Congress to codify it. Whatever its intent, investors have told us repeatedly that pricing instability of this scale reduces investment. It is why more than 400 public biotech companies have flagged MFN as a material risk to their business and operations since May 2025.[12] It is the same mechanism that drove capital out of small molecules, now applied economy-wide and to first launches, where early-stage risk is highest. Codifying a broad, internationally referenced price control would deepen the very retreat this Subcommittee is working to reverse. The lesson of the past two years is exact: fix a pricing disincentive and capital returns; impose an unpredictable one and it leaves.

Data and AI can shorten timelines and reduce costs

The Subcommittee has asked what opportunities exist to make clinical research more efficient. The opportunity is substantial. The United States holds an unmatched wealth of patient data across its health system. Used well, and paired with artificial intelligence, that data can compress timelines and cost at every stage of development: matching patients to trials, identifying and activating sites, refining eligibility criteria, strengthening endpoints, and generating real-world evidence to support and monitor approvals.

Barriers stand in the way, though fixes are available. First, health data remains fragmented and difficult to use at the scale AI requires; investment in interoperable, research-ready data infrastructure would change that. Second, regulatory pathways do not yet have clear standards for how AI-generated and real-world evidence will be weighed, and that uncertainty chills the very investment needed to build these tools. Clear, durable evidentiary standards would unlock it.

The payoff is most vivid in rare disease, where patients have the least time to wait and trials are the hardest to run. FDA has recognized the core problem directly: for many rare diseases, no single country has a large enough population to generate robust data. International data pooling is the way through. One such effort, the Alport Syndrome Surrogate Endpoint Network (ASSENT) Initiative, pools data from researchers across the world to enable Alport syndrome trials to run faster and with smaller patient populations.[13] Patient organizations can cross those

[10] https://vitaltransformation.com/wp-content/uploads/2025/04/New-Research-Reveals-the-Devastating-Impact-of-IRA-Pill-Penalty_Press-Release_041425_FINAL-updated.pdf
[11] https://www.incubatecoalition.org/post/2026-investor-survey-one-pager
[12] https://lifesciencetracker.com/mfn/
[13] https://alportsyndrome.org/assent-initiative/

borders in ways that sponsors and regulators cannot. Modernizing how FDA validates endpoints and accepts high-quality data, wherever it is generated, turns that patient-driven work into approvals.

Federal leadership on data infrastructure, evidentiary standards, and aligned incentives is the same principle applied to evidence itself: better ideas, more impact.

The path forward: better ideas, more impact.

The gold standard has always been about safe, effective medicines that patients, physicians, and investors can trust. Modernization can strengthen this gold standard by focusing the FDA's finite resources where the risk actually is.

We were encouraged by HHS's June 2026 announcement of Operation TrialBlazer and by the growing bipartisan consensus around concrete, achievable reforms. Incubate supports the following:

1. **Risk-proportionate IND requirements.** Calibrate submission requirements to the actual risk of the product and the proposed study, so that low-risk, early-phase trials are not held to the same documentary burden as high-risk ones.
2. **Rolling IND submissions.** Allow sponsors to submit IND components as they are completed, rather than requiring a single complete package, to compress the discovery-to-trial timeline without lowering the evidentiary bar.
3. **A Phase 1 clinical trial notification pathway.** Pilot a U.S. notification pathway for lower-risk first-in-human studies, drawing on Australia's CTN model while preserving FDA oversight and accredited IRB review, to close the timeline gap with competitors.
4. **Restored predictability and engagement.** Re-establish clear and durable evidentiary standards, timely and substantive FDA engagement, and visible, consistent scientific leadership. Investors have repeatedly told us these are precisely the conditions that would rebuild their confidence.
5. **Pricing predictability that rewards innovation.** Align Medicare negotiation timelines for small molecules and biologics through the EPIC Act, and resist broad, internationally referenced price-setting that discourages early-stage investment.
6. **Research-ready data infrastructure and standards for AI-generated evidence.** Invest in interoperable health data and set clear, durable standards for how AI and real-world evidence support IND, approval, and post-market decisions.
7. **Endpoint modernization and international data acceptance.** Expand validation and use of surrogate endpoints, and accept high-quality data wherever it is generated, so rare-disease and small-population trials can move faster.

Conclusion

The Subcommittee's final question asks what happens to patients, public health, and national biosecurity if the United States loses its lead. The answer is that all three erode together, because they rest on the same foundation.

For patients, it means fewer new medicines, discovered later and reaching the clinic slower. For those with rare or serious diseases, who have the least time to wait, it can mean treatments that never arrive at all. For public health, it means a country less able to develop and manufacture the medicines its people depend on, and less prepared to respond when the next threat emerges. And for national biosecurity, it means growing dependence on a strategic competitor for the clinical research, manufacturing, and research infrastructure that underpin the medicines of the future. When early-stage science migrates abroad, the capacity to make and secure our own medicines migrates with it.

The gap that exists today was built by deliberate policy choices, and it can be closed by better ones. The United States still has the best science and the deepest capital markets in the world; what it lacks is a regulatory pathway fast and predictable enough to keep both at home. That is within Congress's reach. The reforms above would shorten timelines, restore predictability, and keep discovery, capital, and manufacturing on American soil, all without lowering the standard that makes FDA approval mean something the world over. Incubate urges the Subcommittee to act this Congress, and stands ready to help.

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Statement for the Record: Massachusetts Biotechnology Council (MassBio)

U.S. House of Representatives
Committee on Energy and Commerce, Subcommittee on Health Hearing:
"Maintaining America's Leadership in Biomedical Innovation:
FDA's Role in Advancing U.S. Drug Development"
July 15, 2026

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to submit this statement. MassBio represents more than 1,700 member organizations spanning every stage of the biopharmaceutical lifecycle, from first-time founders to global manufacturers, all united by the mission of bringing breakthrough medicines to patients. We commend the Subcommittee for examining the single most consequential question facing our industry: whether the United States will remain the place where the world's most important and impactful medicines are discovered, developed, and brought to patients.

The United States remains the global leader in drug development, but that leadership is eroding. The cause is not a decline in our science. It is policy and regulatory unpredictability. Innovation is not leaving the United States because the FDA's standards are too high; it is leaving because the process has become too uncertain, too slow, and too costly to plan around. That is a solvable problem, and it is within the power of Congress and the FDA to solve it without lowering the gold standard for safety and effectiveness that patients depend on.

Massachusetts: The Nation's Leading Life Sciences Hub

Massachusetts is the center of gravity for global biopharmaceutical innovation. Our industry snapshot captures the breadth of our footprint.[1] Companies headquartered in Massachusetts account for 15.7% of the U.S. drug development pipeline and 6.4% of the entire global pipeline. Massachusetts is home to more than 700 active clinical trials and roughly 23% of the nation's biopharma research and development workforce. In 2024 alone, 23 companies with a Massachusetts presence secured FDA approvals for therapies spanning RSV, schizophrenia, leukemia, and advanced cancers.[2]

This concentration is precisely why Massachusetts is an early warning system for the health of the national ecosystem. For the first time in the history of our annual Industry Snapshot, Massachusetts recorded a decline in R&D employment, and venture capital investment fell to its lowest level since

[1] https://www.massbio.org/wp-content/uploads/2025/08/FINAL-2025_IndustrySnapshot.pdf
[2] https://www.massbio.org/news/recent-news/massbio-year-end-funding-report-released/

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2017. When the leading hub contracts, it signals stress that will be felt nationwide. The policy choices this Subcommittee examines will shape whether that stress reverses or deepens.

Early-Stage Research Is Moving Offshore

There is a clear trend across the ecosystem of research shifting abroad. China, Australia, and Europe have seen growing preclinical, Phase 1, and Phase 2 research, aided by faster and more predictable early-stage pathways abroad. MassBio's members are living this shift in real time. In a recent MassBio survey of biotech executives, the overwhelming majority representing small, early-stage companies that drive first-in-human innovation, the data is unambiguous.

- **On a level regulatory playing field, 78% of respondents rank the United States as their first choice for first-in-human (FIH) trials.** The American preference is overwhelming. Not a single respondent would choose China first if the regulatory environments were equivalent.
- **Under the current FDA environment, only 29% still rank the United States first.** The U.S. falls from an average rank of 1.5 to nearly 4 out of eight regions. Australia rises to the top choice, and China (chosen first by no one on a level field) draws first-place votes from five companies.
- **Half of all respondents say recent FDA changes make them less likely to run FIH trials in the United States.** 70% report they were already hesitant to run FIH trials here because of the regulatory framework.

The survey findings point to a clear result: American companies want to stay. Our science and our scientists remain the world's best, and no company is eager to move its most sensitive early work overseas. The variable pushing them abroad is the regulatory experience. Fortunately, this variable is fully within our control.

The Driver Is Cost and Uncertainty

It is essential to be precise about what is deterring domestic investment, because the answer refutes any suggestion that industry is seeking a weaker FDA. When asked to identify their top reasons for hesitancy in launching US-based trials, respondents pointed to economics and process, not scientific rigor. The cost of delay from a clinical hold was cited by 67% of respondents. The absence of clearly defined preclinical data requirements was cited by 42% of respondents. 37% of respondents cited Risk of not understanding/remediating pre-IND FDA feedback. Companies demand rigorous safety review. What deters them is the unpredictable financial consequences of a hold, especially when the preclinical data requirements aren't clearly defined upfront.

Not one respondent said they were free of hesitancy. As one executive put it in the survey's open-ended responses: *"Regulations that keep patients safe are good. Regulation that adds tens of millions of*

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dollars in cost for no safety reason is concerning." That distinction is the heart of the matter, and the root of regulatory flight abroad.

Much of that unpredictability traces to instability at the agency itself. Companies describe reaching agreement on a pivotal study protocol with the FDA only to have a new reviewer reverse course, stranding tens of millions of dollars at the most expensive stage of development. High turnover and unfilled senior vacancies compound the problem. The mode of engagement makes it worse: over the past five years, roughly 78% of respondents' FDA interactions were written responses only, and a majority of executives reported that written feedback was ambiguous or confusing. Less than a third involved face-to-face interaction with meeting minutes.

Recommendations for Congress and the FDA

The Subcommittee asked how Congress and the FDA can modernize early-stage regulation while upholding the gold standard. MassBio offers four priorities, each drawn directly from member experience and each designed to increase predictability and speed without touching the safety bar.

1. **Modernize IND requirements and fix the No Observed Adverse Effect Level (NOAEL) dosing standard.** Congress should press the FDA to adopt risk-proportionate IND submission requirements, enable rolling IND submissions, and issue clear guidance defining preclinical data package expectations, so companies know the requirements before they invest. A concrete, high-consensus starting point from our survey: 87% of surveyed companies support limiting the 1/10 NOAEL guidance to setting a maximum safe starting dose rather than capping the maximum clinical dose, with human safety data driving the dose ceiling.
2. **Harmonize U.S. nonclinical data expectations with international standards.** The clearest competitiveness lever is to align U.S. nonclinical data requirements with those of Australia, the EU, and the UK. Companies are not asking the FDA to lower its bar; they are asking it to stop maintaining a uniquely burdensome one relative to peer regulators, particularly for rare-disease indications where the benefit-risk calculus differs from typical Phase 1 populations.
3. **Restore stability and commit to real-time engagement.** Congress should support filling FDA vacancies, reducing reviewer turnover, and establishing a commitment to real-time, face-to-face meetings with documented minutes rather than written-only feedback, paired with predictable review timelines. Our members consistently rate live engagement as clearer and more actionable than written responses.
4. **Make Operation TrialBlazer durable.** MassBio has long pressed for exactly the kind of reform Operation TrialBlazer represents, and we commend HHS and the FDA for launching it. But a roadmap advanced under acting leadership only matters if it is built to last. Congress should ensure these reforms are implemented with sustained industry input, that pilot programs become permanent policy, and that the FDA stands up a dedicated emerging-biotech function empowered

to resolve misalignments before they become costly delays. When companies were asked whether they would pilot a substantively restructured IND pathway, 80% responded they were highly likely to do so.

NIH: The Foundation of the Innovation Pipeline

American biomedical leadership does not begin at the FDA. It begins with the federally funded basic and translational research on which the entire private pipeline is built. NIH-supported science is the foundation from which biotech companies form, raise capital, and advance therapies toward the clinic. That foundation came under significant strain over the past year and has exposed how vulnerable the research base is to sudden, unpredictable funding decisions.

That vulnerability threatens to be exacerbated by proposals now under consideration. MassBio has raised serious concerns about a proposed federal rule governing federal financial assistance that would expand agencies' authority to terminate grants mid-award, subject funding to pre-issuance review against shifting priorities rather than the statutorily grounded, merit-based peer review that has long governed NIH, and restrict the international collaboration and scientific exchange on which research depends. Peer review is the mechanism that ensures federal dollars follow the best science; layering political review on top of it undermines the very commitment to gold-standard science the government, and this Committee, has set for itself. Drug development runs 10 to 15 years, and research of that duration cannot survive funding that can be revoked at will or redirected mid-course. This instability falls hardest on the small, pre-revenue companies that form the backbone of the Massachusetts ecosystem, and, as with clinical development, it does not strengthen American competitiveness. When research teams lose funding, they are recruited by competing clusters abroad.

The principle that should guide FDA reform should guide the research base as well: stability, predictability, and decisions grounded in scientific merit. Congress should protect NIH funding that is stable and merit-based and preserve the foundational basic research that keeps the United States at the center of global research.

What Is at Stake

The consequences of losing global leadership in clinical research are severe and cascading. Early-stage research sits at the front of the value chain: where first-in-human trials go it is reasonable to assume that later-stage development, manufacturing, intellectual property, and high-wage jobs will follow. And the competition is not just about where trials are run, but where innovation originates. China has become one of the world's largest sources of early-stage assets, with a rising share of first-in-class and best-in-class molecules discovered there. Between mid-2024 and mid-2025, China's drug pipeline grew by

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nearly 17%, while Massachusetts grew 6.7%.[3] China is projected to account for roughly 35% of FDA approvals by 2040 and already runs more registered clinical trials each year than the United States.[4]

This shift is compounded by the financing environment facing the companies that matter most. Public markets have reopened selectively, rewarding firms with mature clinical data and lower development risk. Capital increasingly finances clinical execution rather than scientific risk. Yet the companies carrying that scientific risk, such as those with first-in-class therapeutics, gene editing, RNA technologies, cell therapies, synthetic biology, are precisely those with the greatest long-term potential, and precisely those most exposed to FDA unpredictability. When regulatory friction is layered on top of a financing gap, the most scientifically ambitious companies are the first to stall, fail, or relocate.

A durable pipeline depends on a continuous supply of new early-stage companies. If the earliest stage becomes too costly and too uncertain to sustain, the ecosystem loses its capacity to replenish itself, and patients feel the consequence years later, in medicines that are never developed.

Ceding the earliest and most formative stage of drug development is therefore not merely an economic loss. It is a national security and public health vulnerability, surrendering influence over which medicines are developed, where they are manufactured, and under what data-integrity and patient-safety standards, to systems that do not share our own. Disruptions at one end of the scientific pipeline are felt at the other.

Faced with this competition, there is understandable pressure to respond with defensive measures, chief among them proposals to restrict the flow of American capital and investment abroad. MassBio shares the concern that biotechnology has become a strategic technology deserving of serious federal attention but urges that proper attention be paid to the secondary impacts of such policies. Measures that reduce capital formation or cut off access to promising science, without building new domestic capacity in their place, risk producing fewer medicines for patients rather than greater security. The strongest and safest way to counter a rising competitor is to strengthen our own capabilities rather than simply constrain others.

Conclusion

The United States has not lost its scientific edge, and its companies are not eager to leave. The single largest force pushing early research offshore is a regulatory experience that has become unpredictable and costly, but it is a problem entirely within our power to fix. We encourage Congress and the FDA to focus on the speed, clarity, and engagement that peer nations already provide. Do that, and the strongest

[3] https://www.massbio.org/wp-content/uploads/2025/08/FINAL-2025_IndustrySnapshot.pdf
[4] https://www.biotech.senate.gov/wp-content/uploads/2025/12/NSCEB-Future-of-U.S.-China-Biotech-Competition-Dec-2025.pdf

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reason to develop anywhere but here disappears. Regulatory modernization is necessary, but it is not sufficient on its own. Sustaining American leadership will also depend on a healthy environment for early-stage financing and a strong federal research base to feed the pipeline the FDA then helps advance.

MassBio and our members stand ready to serve as a resource to the Subcommittee as it advances this work. We thank you for your leadership and for the opportunity to submit this statement for the record.

Respectfully,

Kendalle Burlin O'Connell
President & CEO
Massachusetts Biotechnology Council

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

June 30, 2026

The Honorable Jamie Raskin
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Raskin:

Thank you for your letter to the Office of Management and Budget (OMB) regarding your opposition to the Notice of Proposed Rulemaking (NPRM), *Regulation for Federal Financial Assistance*, issued jointly by OMB and 41 Federal agencies.

OMB remains committed to improving transparency and accountability in Federal grantmaking. The waste, fraud, and abuse in the distribution of taxpayer dollars, particularly by the last Administration, will no longer be tolerated. For too long, Federal grantmaking has operated as if discretionary grants — in which Congress has authorized executive agencies to exercise politically accountable judgment in selecting projects, recipients, and award amounts — were a permanent entitlement for various "woke" ideological projects, initiatives, and organizations that the American people never voted for and Congress never authorized.

The American people elected President Donald J. Trump to change the direction of the Federal Government. Ensuring accountability to the American people means that elections matter and are reflected in the administration of discretionary grant programs. It also means ensuring that Federal funds are only used for public purposes authorized by law, and not for unauthorized activities or ideological objectives beyond the approved scope of Federal awards. This administration is committed to restoring basic accountability to Federal grantmaking.

The NPRM would restore accountability by making clear that taxpayer dollars must serve the American people — not entrenched ideologies or unelected bureaucracies. Where executive agencies have authority to administer discretionary award programs, that authority should not be used to undermine the policies the American people voted for or advance radical and divisive ideological agendas not authorized by law. Grant recipients remain free to pursue their own views and activities with their own resources, but not with discretionary taxpayer-funded awards. This is about enforcing legal boundaries, not advancing political objectives.

Your letter specifically mentions the National Institutes of Health (NIH) and claims that this NPRM will politicize science. However, this NPRM is intended to prevent the politicization of taxpayer dollars at the NIH, including practices that occurred under the last Administration. NIH lost the trust of the American people through wasteful spending, misleading public information, risky research, and the promotion of contested ideologies that undermine sound

public health policy. Under the last Administration, the NIH pushed DEI related grants with little connection to core statutory purposes. Some examples of DEI related funding include:

- Studying how "structural racism" impacts social connectedness among "gender minority people of color" and comparing sexually transmitted infections in "transgender women";
- Surveying how Buddhism creates "HIV-stigma" in Thailand;
- Evaluating "Friendship Benches" for women who use methamphetamine in Vietnam;
- Researching "racial and ethnic disparities" in back pain therapies; and
- Studying "mindfulness-based intervention" on HIV risk and "mental and sexual health" among "young men who have sex with men."

The National Institute of Allergy and Infectious Diseases (NIAID) also funneled millions of dollars to EcoHealth Alliance, which funded the Wuhan Institute of Virology, the likely source of the COVID-19 pandemic, under Dr. Anthony Fauci. Dr. Fauci also commissioned "The Proximal Origin of SARS-CoV-2," a publication that was used to politicize science and discredit and dismiss any assertion that COVID-19 leaked from a lab, even though several intelligence agencies now assess that a lab-related origin is the likely explanation for COVID-19.

The proposed updates in the NPRM would ensure Federal financial assistance is administered consistent with current law, current agency priorities, including as reflected in Executive Orders, and the public purposes for which the funds were authorized. The proposed updates modernize outdated provisions, close gaps that have led to confusion or misuse, and reinforce accountability for taxpayer dollars. The timing reflects the need for a clear, government-wide framework aligned with current policy direction.

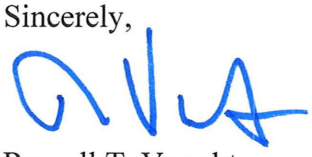
The changes target misuse of funds and improve consistency in the administration of Federal financial assistance. They also would seek to decrease administrative burden and maximize the effectiveness of limited taxpayer dollars so that they best serve the interests of the American people. OMB worked closely with grantmaking Federal agencies across the Federal Government in development of the NPRM, including the Department of Health and Human Services, and incorporated input from those agencies, prior requests for information, audits, and other sources. The notice and comment rulemaking process provides an opportunity for public comment and further stakeholder engagement. This process helps ensure that the final rule will reflect both practical experience, public input, and applicable legal requirements.

Your letter also suggests that the NPRM would grant OMB "unilateral authority over grant terminations" and "consolidate termination authority" within OMB. This is not reflected in the text of the NPRM. The NPRM proposes a common framework for administration of grants and other forms of financial assistance by Federal agencies. The authority for any specific termination decision, where consistent with applicable law and the terms and conditions of the award, would remain with the Federal agency that issued the grant. OMB does not directly issue or administer Federal grants. Discretionary termination authority is an accountability tool for

Federal agencies. It helps to ensure that Federal agencies tasked by Congress with carrying out Federal award programs are capable of exercising responsible stewardship of Federal funds in their administration of those programs. Federal financial assistance programs must remain accountable to the taxpayers who fund them.

If you have any additional questions or concerns, please have your staff contact the Office of Legislative Affairs at OMBLegislativeAffairs@omb.eop.gov.

Sincerely,



Russell T. Vought
Director

Cc:

The Honorable Lori Trahan
The Honorable Suzan K. DelBene
The Honorable Mark Pocan
The Honorable Debbie Wasserman Schultz
The Honorable Sharice L. Davids
The Honorable Adriano Espaillat
The Honorable Maxine Waters
The Honorable Suhas Subramanyam
The Honorable Nancy Pelosi
The Honorable Bennie G. Thompson
The Honorable Mike Quigley
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The Honorable Sylvia R. Garcia
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The Honorable Madeleine Dean
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The Honorable Shontel M. Brown
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The Honorable Christian D. Menefee
The Honorable Yassamin Ansari
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The Honorable Brad Sherman
The Honorable Ted W. Lieu
The Honorable Adelita S. Grijalva
The Honorable Andrea Salinas
The Honorable Maxine Dexter, M.D.
The Honorable Haley M. Stevens
The Honorable John B. Larson
The Honorable Valerie P. Foushee
The Honorable Donald S. Beyer Jr.
The Honorable Mike Levin
The Honorable Lateefah Simon
The Honorable Analilia Mejia
The Honorable Kathy Castor
The Honorable Jennifer L. McClellan
The Honorable Jan Schakowsky
The Honorable Paul D. Tonko
The Honorable Robin L. Kelly
The Honorable Eric Sorensen
The Honorable Judy Chu
The Honorable Johnny Olszewski, Jr.
The Honorable Greg Stanton
The Honorable Alexandria Ocasio-Cortez
The Honorable Ro Khanna
The Honorable Deborah K. Ross
The Honorable Emanuel Cleaver, II
The Honorable Glenn F. Ivey
The Honorable Nellie Pou
The Honorable Juan Vargas
The Honorable Joaquin Castro
The Honorable Frederica S. Wilson
The Honorable Chellie Pingree
The Honorable Gabe Amo
The Honorable Mark Takano
The Honorable Derek T. Tran
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The Honorable J. Luis Correa
The Honorable John Garamendi
The Honorable Angie Craig
The Honorable Kweisi Mfume
The Honorable Julia Brownley
The Honorable Zoe Lofgren
The Honorable Seth Magaziner

The Honorable Debbie Dingell
The Honorable Sarah McBride
The Honorable Sean Casten
The Honorable Grace Meng
The Honorable Raja Krishnamoorthi
The Honorable Ayanna Pressley
The Honorable Wesley Bell
The Honorable Jasmine Crockett
The Honorable Melanie Stansbury
The Honorable Sam T. Liccardo
The Honorable Kelly Morrison
The Honorable Jesús G. "Chuy" García
The Honorable Maggie Goodlander
The Honorable Salud Carbajal
The Honorable Chrissy Houlahan
The Honorable Troy A. Carter, Sr.
The Honorable Shomari Figures
The Honorable Dina Titus
The Honorable Rick Larsen
The Honorable Terri A. Sewell
The Honorable Bill Foster
The Honorable Julie Johnson
The Honorable Jake Auchincloss
The Honorable Mike Thompson
The Honorable Jared Huffman
The Honorable Delia C. Ramirez
The Honorable Lizzie Fletcher
The Honorable Rosa L. DeLauro
The Honorable Brittany Pettersen
The Honorable Bradley Scott Schneider
The Honorable Emily Randall
The Honorable Jim Himes
The Honorable Pramila Jayapal
The Honorable Jahana Hayes
The Honorable Lois Frankel
The Honorable Dwight Evans

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS®

July 15, 2026

The Honorable Brett Guthrie
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Morgan Griffith
Chairman
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Jake Auchincloss
Member
Subcommittee on Health
House Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Guthrie, Ranking Member Pallone, Chairman Griffith, Ranking Member DeGette, and Representative Auchincloss:

America's 1,512 Community Health Centers (CHCs), also known as Federally Qualified Health Centers (FQHCs), form the nation's largest primary care network. They serve as the medical home for 52 million patients,[i] and employ 326,000 dedicated staff. CHCs deliver high-quality, affordable primary, preventive, dental, behavioral health, and pharmacy care at over 17,000 sites across the country. Notably, the Congressional Budget Office has found that CHCs also save taxpayers billions of dollars by reducing preventable ER visits, hospital admissions, and invasive procedures.[ii] In fact, research suggests every dollar invested in primary care yields a 13-to-1 return in health system savings — which can be invested back into CHCs to expand access to cutting-edge treatments for more Americans.[iii]

As the President and CEO of the National Association of Community Health Centers (NACHC), which has been the leading voice of CHCs for 55 years, I write to you today to thank you for holding this hearing on maintaining America's leadership in biomedical innovation. I want to ensure I convey that NACHC supports HHS's Operation Trialblazer roadmap and FDA's proposed Expedited IND Pilot Program, both aimed at cutting the time and cost of bringing new therapies to market and making these life-saving treatments accessible for more Americans. CHCs offer clinical trial sponsors and the FDA a ready-made, lower-cost complement to these reforms: a nationwide network of trusted providers who can accelerate enrollment, embed trials into routine clinical care, and get cutting-edge therapeutics into patients' hands faster.

Currently, clinical trials remain concentrated in a small number of academic medical centers, which slows recruitment, narrows the range of data that trial sponsors can generate, and leaves millions of patients — particularly those living in rural and underserved communities — without access to investigational drugs. Solving these challenges will require industry and government to collaborate with new research partners and new sites, such as CHCs.

As you consider reforms to strengthen the drug development pipeline, I urge the Committee to treat CHCs as a first-choice research partner alongside industry and academia. CHCs already reach patients in rural, tribal, frontier, island, and urban communities — meaning research embedded in CHCs can help trial sponsors recruit the patients that they most need and typically struggle to enroll. With modest investments, CHCs can help improve the quality and representativeness of trial data and ensure that innovation reaches patients faster and at lower cost per participant.

FDA's 2024 guidance on decentralized clinical trials recognizes local, community-based sites such as CHCs as a compliant, lower-cost way to conduct consent, follow-up, and data collection outside the four walls of an academic medical center.[iv] Other surveys show CHCs are among the most trusted sources of health information nationwide — unsurprising, as these organizations are governed by patient-majority boards, reflecting the local needs of each community. Notably, 89 percent of CHC patients believe clinical trials can improve their health.[v] Over half say they would consider enrolling in a clinical trial if their CHC provider invited them.[vi] Yet, 48 percent felt unfamiliar with clinical trials, and most had never participated in one (80 percent). A 2023 NACHC/Deloitte study found 42 percent of CHCs are already conducting research and 45 percent want to be involved.[vii] Among those not yet doing research, 35 percent specifically want to run clinical trials — untapped capacity sponsors can put to work today.[viii]

A major driver of these unmet needs is that CHCs have historically been treated as recruitment sites rather than research partners — a mismatch given their demonstrated capacity. The barrier is not a lack of interest — it is insufficient investment in infrastructure. CHCs need dedicated funding to ensure appropriate research space, staff training, and protected provider time are in place to expand trial participation at scale.[ix] The same 2023 survey found that 94 percent of CHCs cited time or workforce constraints as the top barrier to research, and 81 percent had no dedicated research staff at all.[x] Fifty-eight percent of individual CHC providers cited lack of time as their biggest obstacle.[xi] Thus, this is a resource problem, not a buy-in problem, and a comparatively affordable one to solve.[xii]

This is partly because encouraging research participation also helps with workforce retention. Amid a looming national primary care provider shortage, CHCs report research involvement is among the strongest tools they have for keeping staff engaged and growing professionally.[xiii] In a competitive labor market, offering providers a chance to do research work — not just providing clinical care— has measurably improved retention.[xiv]

Another point of note is that while CHCs serve 1 in 3 rural residents, rural sites are involved in clinical trials far less often than their urban counterparts,[xv] again largely due to a lack of staff and infrastructure. Reform that does not reach rural sites will leave rural patients further behind and leave trial sponsors without access to the patients they need for representative, FDA-ready data.

Therefore, I ask the Committee to ensure CHCs are not an afterthought as you consider biomedical innovation-friendly reforms in upcoming FDA reauthorization legislation. Specifically, I would respectfully ask the Committee to:

1. Direct FDA to clarify that CHCs and CHC-affiliated networks are eligible to participate as Qualified Research Institutions or partner sites under the proposed Expedited IND Pilot Program, which is currently open for public comment through July 22;
2. Support dedicated funding for CHC research infrastructure and staff so more sites can operate under FDA's 2024 decentralized clinical trials guidance; and
3. Encourage HHS to explicitly name CHCs in Operation Trialblazer's implementation plans, given the roadmap's recognition that community-based sites accelerate recruitment, consent, and evidence generation.
4. Incentivize industry, academia, and government to treat CHCs as research partners of choice, not just as recruitment vendors, so they are involved from the early stages of trial design and development.

Each action will help expand the trial-ready patient pool that trial sponsors are competing for and ensure that the quality of the data produced reflects the needs of American communities. CHC staff can help research partners troubleshoot problems locally, which keeps costs low and ensures a better return on investment.

Looking further ahead, CHCs are also well positioned to help pioneer the next wave of biomedical innovation that does not rely solely on expensive drug development projects, such as innovative Food for Health studies showing promising results. For instance, the Ceres Community Project's randomized controlled trial with Kaiser Permanente found that Medically Tailored Meals (MTM) measurably improved clinical outcomes and cut health care spending — the kind of low-cost, high-yield evidence base that complements pharmaceutical innovation rather than competing with it. CHCs, which already screen patients for food insecurity as part of routine care, are a natural network for scaling this research and generating the real-world evidence FDA and payers need to evaluate the efficacy and return on investment of Food for Health interventions.

Thank you for your leadership on this issue and for the opportunity to share CHCs' perspective. I look forward to working with the Committee to ensure CHCs, their staff and the patients they serve are full partners in America's biomedical innovation future. Please contact Joe Dunn, NACHC's Chief Policy Officer, should you have any questions.

Sincerely,

Kyu Rhee, MD, MPP
President and Chief Executive Officer

[i] Masselli, M., & Shin, P. (2025, August). *How many patients do Community Health Centers really care for? You'll be surprised!* Moses/Weitzman Health System & National Association of Community Health Centers. https://www.mwhs1.com/wp-content/uploads/2025/08/The-Real-CHC-Patient-Base_080525_final.pdf

[ii] Volerman A, Carlson B, Wan W, Murugesan M, Asfour N, Bolton J, Chin MH, Sripipatana A, Nocon RS. *Utilization, quality, and spending for pediatric Medicaid enrollees with primary care in CHCs vs non-CHCs.* BMC Pediatr. 2024 Feb 8;24(1):100. doi: 10.1186/s12887-024-04547-y. PMID: 38331758; PMCID: PMC10851548.

[iii] https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf

[iv] U.S. Food and Drug Administration. Conducting Clinical Trials With Decentralized Elements. September 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements

[v] North Carolina Community Health Center Association, *From Framework to Findings Improving Multicultural Engagement in Clinical Research Through Federally Qualified Health Centers and Community Health Worker Partnerships*, May 2026.

[vi] Ibid.

[vii] NACHC and Deloitte Center for Health Solutions, *Broadening research participation through community engagement*, November 2023. https://www.deloitte.com/us/en/insights/industry/health-care/community-based-inclusive-and-equitable-clinical-trials.html.

[viii] Ibid.

[ix] Ibid.

[x] Ibid.

[xi] North Carolina Community Health Center Association, *From Framework to Findings*.

[xii] NACHC and Deloitte, *Broadening research participation through community engagement*.

[xiii] Ibid.

[xiv] Ibid.

[xv] Ibid.

July 2, 2026

The Honorable Diana DeGette
Ranking Member, Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Representative DeGette:

Thank you for your letter to the Food and Drug Administration (FDA or the Agency) regarding FDA's good guidance practices. We appreciate your interest in this topic.

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for regulated industry, FDA staff, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. Unlike statutes and regulations, guidance documents generally do not establish legally enforceable rights or responsibilities and are thus exempt from notice and comment requirements applicable to most rulemakings under the Administrative Procedure Act. Section 701(h) of the Federal Food, Drug, and Cosmetic Act and FDA's Good Guidance Practices (GGP) regulation[1] govern the issuance of guidance documents. The GGP regulation establishes two types of guidance documents (Level 1 and Level 2) and describes the procedures for issuing both types of guidance documents. Level 1 guidance documents include those that (1) set forth initial interpretations of statutory or regulatory requirements, (2) set forth changes in interpretation or policy that are of more than a minor nature, (3) include complex scientific issues, or (4) cover highly controversial issues.[2] In contrast, Level 2 guidance documents set forth existing practices or minor changes in interpretation or policy.[3] Typically, FDA solicits input on Level 1 guidances prior to implementation, and in preparing the final guidances, we review and consider all comments we receive.[4] Consistent with our statutory and regulatory requirements, FDA does not solicit public input prior to the issuance of final Level 1 guidances for which FDA determines that prior public participation is not feasible or appropriate, or prior to the issuance of Level 2 guidances.[5] However, FDA provides for comment on such guidances and takes these comments into account upon implementation.[6] FDA posts all guidance documents on its

[1] 21 CFR 10.115.
[2] 21 CFR 10.115(c)(1).
[3] 21 CFR 10.115(c)(2).
[4] 21 CFR 10.115(g)(1)(ii)(C) and (g)(1)(iv)(A).
[5] 21 CFR 10.115(g)(2), (g)(4).
[6] Federal Food Drug & Cosmetic Act § 701(h)(1)(C)(i) and (D).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

website[7] and interested parties may comment on them at any time after they have been issued.[8] FDA periodically reviews all comments and revises its guidance documents as appropriate.[9]

FDA guidance documents benefit the Agency, regulated industry, and the public by providing consistency, transparency, and valuable insight into approaches that may assist industry and other interested parties in complying with applicable statutes and regulations, ensuring consumer and patient safety, and developing new and innovative products to improve public health. FDA uses guidance documents to assist regulated industry, FDA staff, and the public in understanding the Agency's current thinking on policy, scientific, medical, and regulatory issues.

Please see additional responses to your questions below.

1. **What criteria does FDA consider when deciding whether to issue formal guidance?**

   The guidance development process is fluid and changes depending on public health needs and the Agency's resources and priorities. In contrast with regulations, guidances do not impose new regulatory requirements and do not create rights or obligations for any party. Guidances are also meant to be developed faster and updated more easily, so they can keep up with rapidly changing science and technology and reflect the latest scientific, medical, and public health recommendations. Centers and Offices evaluate whether guidance is the appropriate mechanism to convey information, as well as the appropriate guidance level (i.e., Level 1 or 2). Interested people also may provide input on topics for future guidance development. Such input may be provided to FDA in a variety of forums, including at advisory committee meetings, industry meetings, roundtables, and listening sessions; during user fee negotiations; or by contacting the applicable FDA Center or Office. Although not required by statute, FDA often publishes guidance agendas listing topics anticipated for upcoming guidance development or revision. These agendas provide the public with information on possible new topics for guidance documents or revisions to existing guidance documents that each Center or Office is currently intending to issue in the coming year. The Centers are not bound by these agendas; they are not required to issue every guidance on the agenda, nor are they precluded from issuing guidance documents on topics not on the agenda.

2. **Please list all announcements of policy on regulatory issues, or new interpretations of law, policy, or regulations, FDA has made since January 19, 2025, including the date, title, and forum of such announcement(s).**

   For statements of policy and interpretations of statutes and regulations, please see FDA guidance here.[10]

[7] "Search for FDA Guidance Documents," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.
[8] 21 CFR 10.115(g)(3), (g)(4).
[9] 21 CFR 10.115(g)(5).
[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents

CAR T-cell Therapy Superiority

1. **Is the article titled "Advancing CAR T-Cell Therapy: Evidence-Based Trial Design for Chimeric Antigen Receptor T-Cell Therapy in Oncology," published online in JAMA on December 8, 2025, or any component thereof, intended to communicate the agency's interpretation of or policy on a regulatory issue?**

No, the intent of the article was not to communicate FDA policy on, or interpretation of, a regulatory issue.

   a. **If not, what is its intended purpose?**

   The purpose was to provide a retrospective analysis of experience to date with Chimeric Antigen Receptor (CAR) T-cell therapies, and to describe possible considerations for future CAR T-cell products as the field continues to mature based on scientific and clinical experience.

2. **Does FDA consider this article to be guidance?**

No, FDA does not consider this article to be an FDA guidance document.

   a. **If not, will FDA publish draft and final guidance on this topic? Please provide a specific timeline for publication.**

   The Center for Biologics Evaluation and Research (CBER) has published a list of guidance topics the Center is considering for development during calendar year 2026.[11] Guidance on CAR T-cell Therapy in oncology is not on the list. However, as discussed on the guidance agenda website, CBER can publish guidance on topics not included on the list. CBER also typically updates the guidance agenda mid-year.

3. **Is regulated industry expected to adhere to the expectations outlined in the article referenced above?**

No, the article describes possible considerations for future CAR T-cell products; it does not set forth expectations for industry.

4. **Is FDA's policy regarding the applications for licensure of CAR T-cell products different than it was on January 19, 2025?**

No, FDA's policy specific to the licensure of CAR T-cell products for oncology indications are not different. However, FDA has published other guidance documents, e.g., more general guidance on oncology endpoints and trial design, that may apply to CAR T-cell products.

[11] https://www fda.gov/vaccines-blood-biologics/biologics-guidances/guidance-agenda-guidance-documents-cber-planning-publish-during-calendar-year-2026

a. If so, please describe each policy shift and how the shift was communicated to the public.

See response to question 4.

5. Please describe any stakeholder engagement that took place in developing the article and associated policy.

The authors of the article used their experience with CAR T-cell products for oncology as well as stakeholder feedback received during various meetings, including public workshops and advisory committee meetings and comments received in response to prior FDA guidance documents in developing the article.

6. Please describe any formal opportunity stakeholders have to raise concerns with the policy described in the article and how it may be implemented.

Stakeholders had an opportunity to provide comments on the draft version of the Considerations for the Development of Chimeric Antigen Receptor (CAR) T-cell Products guidance document, published in 2022, before FDA issued the final guidance of the same title in 2024. Members of the public may comment on the final version at any time, as with any FDA guidance document.

7. How have the policies discussed in the article been communicated to relevant FDA staff?

Although general concepts in the article (such as the need to establish substantial evidence of effectiveness for CAR T-cell products) are contained in existing guidance documents and have been communicated to FDA staff through standard training and guidance implementation processes, no change in policy as a result of the article has been communicated to FDA staff because there is no change in policy.

a. Please provide copies of all written communication of the policy to FDA staff.

See response to question 7.

8. Please list the title, role, and assigned organizational unit of each FDA and HHS staff member who participated in the development and/or review of this article.

The authors of the article include:

- Vinay Prasad, MD, MPH; former Director, CBER
- Upendra Mahat, MD; Supervisory Physician, Division of Clinical Evaluation Hematology, Office of Clinical Evaluation, CBER
- Asha Das, MD; Director, Office of Clinical Evaluation, CBER
- Vijay Kumar, MD; Acting Director, Office of Therapeutic Products, CBER

9. The article referenced above is behind a paywall. Can interested parties obtain a copy free of charge from FDA? If so, how?

We appreciate the concern, and in consultation with JAMA, will consider additional methods to ensure access. Individuals may reach out to the Office of Public Engagement at publicengagement@fda.hhs.gov, and congressional offices can reach out to legislation@fda.hhs.gov for copies.

Plausible Mechanism Pathway

1. Is FDA's policy regarding the applications for personalized therapeutic products, including investigational gene editing treatments, different than it was on January 19, 2025?

a. If so, please describe each policy shift and how the shift was communicated to the public.

FDA's policies regarding individualized therapies have been evolving as this field matures, and FDA has been working on a framework for how to streamline the development of individualized therapies, including genome editing therapies, intended for the treatment of rare, debilitating diseases. On February 23, 2026, concomitant with FDA's observance of Rare Disease Day 2026,[12] FDA issued the draft guidance Considerations for the use of the Plausible Mechanism Framework to Develop Individualized Therapies that Target Specific Genetic Conditions with Known Biological Cause.[13] This draft guidance describes considerations for generating substantial evidence of effectiveness and safety for individualized therapies based on a plausible mechanism framework. The draft guidance focuses on therapies that target a specific genetic, cellular, or molecular abnormality and are designed to correct or modify the underlying cause of disease. The draft guidance outlines a set of recommendations to help developers of individualized therapies generate sufficient clinical safety and efficacy data to demonstrate that a drug or biological product is safe and effective for the intended use. The draft guidance generally expands on FDA's current thinking regarding drug development and clinical trial design issues for individualized therapies for the treatment of rare genetic disorders in the final guidances for industry titled Rare Diseases, Considerations for the Development of Drugs and Biological Products (December 2023) and Human Gene Therapy Products Incorporating Human Genome Editing (January 2024), and the draft guidance for sponsor-investigators titled IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations (December 2021).

[12] *See Related Materials, HHS Press Event: Advancing Innovation on Rare Disease Therapies*, Public Meeting: FDA Rare Disease Day 2026 (Feb 23, 2026) (accessed at https://www fda.gov/news-events/fda-meetings-conferences-and-workshops/public-meeting-fda-rare-disease-day-2026-02232026).
[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-plausible-mechanism-framework-develop-individualized-therapies-target-specific

2. **Please describe any stakeholder engagement that took place in developing the article and associated policy.**

Based on Investigational New Drug (IND) submissions and formal meetings with sponsors (in both the Center for Drug Evaluation and Research (CDER) and CBER) over the last 5 years, FDA recognized the need for guidance on an approach to approval of individualized therapies. The Centers initially discussed plans to develop a white paper in the summer of 2025. The first step was the Rare Disease Innovation Hub's RISE workshop that occurred in November 2025,[14] with the intent that the discussions from that workshop would be informative for drafting a white paper. Given the interest in the field, following that workshop, the Centers met again and determined it would be preferable and feasible to write a draft guidance.

3. **Prior to the development and issuance of draft guidance, how were the policies discussed in the article been communicated to relevant FDA staff?**

    a. **Please provide copies of all written communication of the policy to FDA staff.**

    The article did not communicate FDA policy or interpretation of a regulatory issue.

    Please see response to question 2 regarding internal FDA discussions about guidance.

4. **Please list the title, role, and assigned organizational unit of each FDA and HHS staff member who participated in the development and/or review of this article.**

The authors of this article are:

- Vinay Prasad, M.D., M.P.H.; former Director, CBER
- Martin A. Makary, M.D., MPH; former Commissioner, Food and Drug Administration

5. **Please list the title, role, and assigned organizational unit of each FDA and HHS staff member who participated in the development and/or review of the February 23, 2026 draft guidance.**

This draft guidance went through the typical Agency development, review, and clearance process for guidance. It was a collaborative effort between many individuals in multiple offices in CDER and CBER.

6. **The New England Journal of Medicine requires a paid subscription or creation of an account to gain access to the article referenced above. Can interested parties obtain a copy free of charge from FDA? If so, how?**

We appreciate the concern, and in consultation with NEJM, will consider additional methods to ensure access. Individuals may reach out to the Office of Public Engagement at

[14] https://healthpolicy.duke.edu/events/individualized-therapies-rise

publicengagement@fda.hhs.gov, and congressional offices can reach out to legislation@fda.hhs.gov for copies.

Commissioner's National Priority Voucher (CNPV) Program

1. **How is FDA communicating its expectations and criteria for prospective participants in the Commissioner's National Priority Voucher program?**

    a. **Please provide copies of all outreach communications to prospective participants.**

    Expectations and criteria are all publicly available here.[15]

2. **Does FDA consider the FAQ document "FAQs: Commissioner's National Priority Voucher Pilot Program" initially published June 17, 2025 to be guidance?**

No, FDA does not consider the FAQ document to be an FDA guidance document.

3. **Does FDA plan to publish draft and final guidance on the CNPV program? Please provide a specific timeline.**

FDA recently held a public hearing on June 4, 2026.[16] FDA plans to evaluate the need for guidance following the hearing.

4. **What are the specific criteria for participation in the CNPV program, and how are different prospective participants evaluated against one another?**

The process of voucher selection, including selection criteria, has been delineated in a publicly available staff manual guide.[17] Criteria may be further updated or refined based upon feedback obtained through the Federal Register Notice (FRN) and the public meeting (as above).

Briefly, the CNPV program accepts potential voucher candidates through two pathways: FDA-initiated nominations and sponsor-submitted statements of interest.

Evaluations have been made on a case-by-case basis, consistent with the pilot's need for flexibility. Importantly, receiving a voucher does not indicate a higher likelihood of approval or any reduction in evidentiary standards. For the purposes of the pilot, FDA considered the following factors for selection:

[15] https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program
[16] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-06042026
[17] Please refer to Staff Manual Guide 2010.23, Commissioner's National Priority Review Council, available at https://www.fda.gov/media/190099/download?attachment.

- Alignment with national priority(ies) and potential public health impact;
- Readiness indicators (e.g., completeness of Chemistry, Manufacturing, and Controls (CMC), results of key studies or pivotal trials, labeling maturity);
- Resource and timing considerations raised by the relevant Center(s); and
- Known risks, uncertainties, or dependencies (e.g., safety issues, unconventional endpoints).

Through an iterative screening process involving discussion with relevant subject matter experts, review of the scientific literature and consensus-based selection, the final voucher selection decision rests with the Commissioner or a delegated official (e.g., Deputy Chief Medical Officer), who considers input from relevant FDA components, as well as the overall balance between national priority alignment and operational feasibility. The Commissioner or delegated official has three options: select a product for voucher issuance, defer the decision pending additional information, or decline selection without prejudice to future consideration. No applications are permanently rejected for future consideration.

5. **Have the criteria for participation in the CNPV program changed since it was first announced on June 17, 2025?**
   a. **If so, how were such changes communicated to the public?**

No, criteria for participation in the CNPV program have not changed since it was first announced.

6. **How has direction on implementation of the CNPV program been communicated to FDA staff?**
   a. **Please provide copies of all manuals, procedures, emailed instructions, and other documents describing how to administer the CNPV program that have been given to relevant FDA staff.**

   The staff manual guide can be found on FDA's website.[18]

Thank you again for contacting us regarding this matter. If you have questions, please contact FDA's Office of Legislation at legislation@fda.hhs.gov.

Sincerely,

Kyle Diamantas, J.D.
Acting Commissioner of Food and Drugs

[18] https://www.fda.gov/media/190099/download?attachment

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SUBCOMMITTEE ON COMMUNICATIONS AND TECHNOLOGY

Yvette D. Clarke
Congress of the United States
9th District of New York

July 15, 2026

Statement for the Record Prepared by Congresswoman Yvette D. Clarke (NY-09)
Submitted to the House Committee on Energy and Commerce
Health Subcommittee

First, I would like to thank Chairman Griffith and Ranking Member DeGette for convening this important hearing on maintaining America's leadership in biomedical innovation. Continued investment in biomedical research and innovation is essential to preserving our nation's global leadership, advancing scientific discovery, and improving health outcomes for patients across the country.

I am proud of the work the House Energy and Commerce Committee has done to explore and address various aspects of biomedical research and development. However, biomedical research faces a significant threat as the White House Office of Management and Budget (OMB) has proposed a sweeping overhaul of the Uniform Guidance governing federal grants, including all National Institutes of Health (NIH) funding. These vital grants play a critical role in supporting biomedical research and innovation, ensuring that the United States remains a global leader in advancing lifesaving discoveries.

As witnesses today highlighted the growing concerns about the United States' global competitiveness in early-stage biomedical development, I want to amplify bicameral legislation that Senator Elizabeth Warren (D-MA) and I have led in Congress that prioritizes biomedical research and innovation, *the National Biomedical Research Act*. This legislation would supplement annual appropriations to support basic research, disruptive innovation, research on burdensome diseases, early-career scientists, efforts to improve diversity in the biomedical workforce, regulatory science, and medical product surveillance. Furthermore, it would also provide researchers with the vital resources they need to continue diagnosing, treating, and preventing a wide range of diseases, many of which disproportionately affect communities of color. That is why sustained funding for institutions at the forefront of biomedical research and innovation is of the utmost importance.

As the OMB proposed changes to federal grants and NIH funding threaten the United States' ability to maintain its leadership in biomedical research and innovation, their impact will be particularly harmful when considering the longstanding underrepresentation of racial and ethnic minorities in both clinical trials and biomedical research. It is essential that we sustain the current grant-funding system and continue expanding investments to develop diverse biomedical datasets that identify how diseases and health conditions affect

different racial and ethnic populations. Without adequate representation, research findings remain disproportionately skewed, further exacerbating existing health disparities.

We must re-establish our commitment to supporting scientists and doctors, which dramatically improves their ability to safeguard our communities against the devastating effects of health care disparities. *The National Biomedical Research Act* is an opportunity to proactively protect American families, and it is incumbent upon us, as Members of Congress, to ensure this happens.

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COMMITTEE ON
ENERGY AND COMMERCE
HEALTH — RANKING MEMBER
ENERGY
OVERSIGHT AND INVESTIGATIONS

Congress of the United States
House of Representatives
Washington, DC 20515

March 11, 2026

The Honorable Martin A. Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Makary:

The Food and Drug Administration (FDA) is responsible for regulating medical products contributing to approximately one-fifth of the American economy. Stability, predictability, and consistency of agency procedures are of paramount importance for these highly regulated U.S. industries and the people who benefit from their products. FDA has historically recognized the need to follow deliberate and transparent processes for policy development. Recently, FDA has exhibited a pattern of circumventing proper processes and formal stakeholder input, announcing new policies through atypical channels, such as journal articles and podcasts. We are concerned this approach results in incautious policymaking, lessens predictability for industry, and undermines the public's trust in FDA.

The Food and Drug Administration Modernization Act of 1997 required FDA to codify its Good Guidance Practices (GGPs), which it did in a final rule dated September 19, 2000.[1] The GGPs outline the agency's procedures for development, issuance, and use of guidance documents. FDA is required to follow the GGPs when it releases guidance for industry.

The GGPs define guidance in part as "documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue." The GGPs go on to say that "The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGPs must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience." We note documents and other means of communication excluded from the definition of guidance documents include speeches, journal articles and editorials, media interviews, and press materials.

GGPs promote transparency, consistency, and scientifically up-to-date expectations for developers, ensuring patients benefit from safer, more effective medical products. Although guidance may evolve as regulatory science advances, the GGP process ensures a stable and durable understanding of FDA's current thinking. As a result, patients and providers can rely on well-vetted scientific information and developers gain a clear view of regulatory expectations.

[1] 21 CFR 10.115.

It is troubling that on numerous occasions over the past year, FDA has failed to follow GGPs, raising concerns about how FDA is approaching issues of critical importance. Below, we discuss three illustrative examples of information that has been communicated through inconsistent, unusual, and obscure means, leading to uncertainty for stakeholders.

CAR T-Cell Therapy Superiority:

On December 8, 2025, Director of the Center for Biologics Evaluation and Research (CBER) Vinay Prasad and FDA officials published an article in JAMA outlining plans to require developers of many CAR T-cell (short for chimeric antigen receptor T-cell) therapies to show superiority over existing treatments.[2] Single-group trials are currently the common standard in this field, which reflects the fact CAR T-cell therapies often target small, highly selected patient populations, including those with rare cancers or relapsed/refractory disease. For these patients, randomized controlled trials may be ethically or operationally infeasible.

Communicating through informal means an overhaul of clinical trial requirements for CAR T-cell therapy approval—what appears to be a significant change in FDA's regulatory expectations of sponsors—is expressly prohibited by FDA's GGPs. Publication of such information behind an academic journal's paywall, with no opportunity for public comment in an open docket, prevents meaningful public access and input. Further, the evidentiary standards for CAR T-cell therapies outlined in the article contradict those published through formal guidance and still available on FDA's website,[3] clouding and likely complicating the pathway to approval for therapies with high magnitude for impact.

Had FDA adhered to GGPs and the deliberative process it requires, the agency would have received important feedback from a variety of stakeholders, likely including the multiple developers currently or recently conducting trials of investigational CAR T-cell therapies, whose path to approval is now uncertain. Gilead and Arcellx, for instance, recently published results from a single-arm trial evaluating their anti-BCMA CAR T-cell therapy for multiple myeloma, which may offer a potentially safer alternative to approved CAR T-cell therapies. Because FDA did not follow GGPs in announcing new evidentiary standards, the agency has left unanswered whether it will accept this evidence or require additional clinical trials with a control arm, a time-intensive and expensive undertaking for such personalized therapies as CAR T-cells. Even drug developers already voluntarily conducting comparative trials, including Bristol Myers Squibb, Gilead, and Lyell Immunotherapy, now have an unpredictable path to approval due to FDA's failure to detail its standards for comparator group selection beyond a nebulous sentence in the JAMA article listing global considerations such as available standard treatments, ethical concerns, and the need to separate treatment effect from unrelated outcomes.

Regulatory certainty is a prerequisite for investment in drug development. Decisions about investment into clinical research and trial design are currently being made through a regulatory smokescreen, where researchers and industry must rely on vague statements that may have multiple interpretations. Such sparse detail on heightened evidentiary standards provided through non-binding, non-guidance documents risks companies delaying or abandoning clinical trials of

[2] JAMA. 2026 Jan 6;335(1):21-24.
[3] 89 FR 5910

CAR T-cell therapies due to the unpredictability of FDA accepting the evidence they generate, whether now or under a future administration that can easily change course in the absence of formal guidance.

Plausible Mechanism Pathway:

On April 17, 2025, you personally announced on the Megyn Kelly Show, a podcast and online talk show, that FDA will establish a new approval pathway for treatments of a rare or incurable condition that affects a small number of people, "on sort of a conditional basis."[4] On November 12, 2025, more than six months later, you and CBER Director Prasad published an article in the New England Journal of Medicine (NEJM) offering slightly more detail on the approval pathway, insinuating that though FDA is "always open to additional feedback or suggestions," the 'plausible mechanism pathway' has already been developed.[5] On February 23, 2026—more than 10 months after the pathway was first announced—FDA finally released draft guidance detailing how the plausible mechanism framework may work.

Communication of significant policy ideas through a talk show does not give industry the tools it needs to pursue new evidentiary standards, nor allow scientists to deliberate it. Your use of the term "conditional approval" and "plausible mechanism" on the Megyn Kelly Show raises questions about whether they were intended as general, non-technical descriptions viewers of the show would understand, or as deliberate signals of new approval criteria. Neither the NEJM article nor the Megyn Kelly Show announcements indicated FDA intended to clarify by releasing formal guidance. Industry had to wait more than six months, with no opportunity to comment on the new framework, for additional information that still came through informal methods of communication, and four additional months for draft guidance. The draft guidance ultimately did not even mention "conditional approval," nor describe the framework as a "pathway," contradictions that create avoidable confusion for industry and underscore the importance of clearly communicating FDA's current thinking through formal, GGP-adherent methods.

Commissioner's National Priority Voucher (CNPV) Program:

On June 17, 2025, you announced in a press release, frequently asked questions (FAQ) document, and video a priority review pathway available to U.S. companies awarded based not on criteria directly related to patient benefit, but a sponsor's general alignment with the administration's priorities.[6] FDA has so far granted 15 companies a voucher, but has yet to establish, or at least communicate, specific eligibility criteria for the program.

The failure to publish formal guidance for the Commissioner's National Priority Voucher (CNPV) program breeds uncertainty across industry and distrust among patients and providers.

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[4] Megyn Kelly, "Dr. Marty Makary Responds to Critiques From Former Top FDA Vaccine Official Over Direction of Agency," posted April 17, 2025, by Megyn Kelly, YouTube, 8 min., 15 sec., https://www.youtube.com/watch?app=desktop&v=-ZKkXlFR8FQ**.**

[5] Vinay Prasad and Martin Makary, "FDA's New Plausible Mechanism Pathway," *New England Journal of Medicine* 393, no. 23 (2025): 2365-2367, https://www nejm.org/doi/full/10.1056/NEJMsb2512695.

[6] U.S. Food and Drug Administration (FDA). 2025. "FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests." FDA Newsroom. https://www fda.gov/news-events/press-announcements/fda-issue-new-commissioners-nationalpriority-vouchers-companies-supporting-us-national-interests.

Announcement of a brand-new priority review pathway via FAQ document, rather than formal guidance, raises questions about the program's durability. Developers' time horizons for planning extend over many years; they cannot dramatically change direction in existing studies or investments without the assurances of consistency that typically accompany formal and deliberate guidance development. The improper method of communication also risks disparate treatment of industry and inconsistent application of the program across review divisions, given FDA's failure to provide agency staff precise guidance for implementing an amended review process. FAQ documents, press releases, and public videos achieve an entirely different objective than technical guidance documents do for division staff.

Beyond the lack of clarity for industry and FDA's own staff, FDA's violations of GGPs in crafting and announcing the CNPV Program should concern patients and providers using treatments sponsored by recipients of the voucher. GGPs are designed to preempt this distrust through transparency in both the formulation and communication of regulatory priorities. It is both a GGPs requirement and a public health imperative that FDA release details on how it plans to achieve 1-2 month review times without cutting important regulatory corners such as safety inspections. Similarly, the public should know the specifics of FDA's eligibility criteria for the voucher, as murky criteria lends itself to abuse and in turn, distrust among those intended to benefit from the program. Because FDA did not adhere to GGPs in this instance, the public cannot have confidence the agency contemplated and appropriately addressed concerns regarding safety and efficacy.

To shed light on FDA's adherence to its GGPs, please respond to the following questions no later than Monday, April 1, 2026:

Questions:

1. What criteria does FDA consider when deciding whether to issue formal guidance?
2. Please list all announcements of policy on regulatory issues, or new interpretations of law, policy, or regulations, FDA has made since January 19, 2025, including the date, title, and forum of such announcement(s).

CAR T-cell Therapy Superiority

1. Is the article titled "Advancing CAR T-Cell Therapy: Evidence-Based Trial Design for Chimeric Antigen Receptor T-Cell Therapy in Oncology," published online in JAMA on December 8, 2025, or any component thereof, intended to communicate the agency's interpretation of or policy on a regulatory issue?
    a. If not, what is its intended purpose?
2. Does FDA consider this article to be guidance?
    a. If not, will FDA publish draft and final guidance on this topic? Please provide a specific timeline for publication.
3. Is regulated industry expected to adhere to the expectations outlined in the article referenced above?

4. Is FDA's policy regarding the applications for licensure of CAR T-cell products different than it was on January 19, 2025?
    a. If so, please describe each policy shift and how the shift was communicated to the public.
5. Please describe any stakeholder engagement that took place in developing the article and associated policy.
6. Please describe any formal opportunity stakeholders have to raise concerns with the policy described in the article and how it may be implemented.
7. How have the policies discussed in the article been communicated to relevant FDA staff?
    a. Please provide copies of all written communication of the policy to FDA staff.
8. Please list the title, role, and assigned organizational unit of each FDA and HHS staff member who participated in the development and/or review of this article.
9. The article referenced above is behind a paywall. Can interested parties obtain a copy free of charge from FDA? If so, how?

Plausible Mechanism Pathway

1. Is FDA's policy regarding the applications for personalized therapeutic products, including investigational gene editing treatments, different than it was on January 19, 2025?
    a. If so, please describe each policy shift and how the shift was communicated to the public.
2. Please describe any stakeholder engagement that took place in developing the article and associated policy.
3. Prior to the development and issuance of draft guidance, how were the policies discussed in the article been communicated to relevant FDA staff?
    a. Please provide copies of all written communication of the policy to FDA staff.
4. Please list the title, role, and assigned organizational unit of each FDA and HHS staff member who participated in the development and/or review of this article.
5. Please list the title, role, and assigned organizational unit of each FDA and HHS staff member who participated in the development and/or review of the February 23, 2026 draft guidance.
6. The New England Journal of Medicine requires a paid subscription or creation of an account to gain access to the article referenced above. Can interested parties obtain a copy free of charge from FDA? If so, how?

Commissioner's National Priority Voucher (CNPV) Program

1. How is FDA communicating its expectations and criteria for prospective participants in the Commissioner's National Priority Voucher program?

   a. Please provide copies of all outreach communications to prospective participants.
2. Does FDA consider the FAQ document "FAQs: Commissioner's National Priority Voucher Pilot Program" initially published June 17, 2025 to be guidance?
3. Does FDA plan to publish draft and final guidance on the CNPV program? Please provide a specific timeline.
4. What are the specific criteria for participation in the CNPV program, and how are different prospective participants evaluated against one another?
5. Have the criteria for participation in the CNPV program changed since it was first announced on June 17, 2025?
   a. If so, how were such changes communicated to the public?
6. How has direction on implementation of the CNPV program been communicated to FDA staff?
   a. Please provide copies of all manuals, procedures, emailed instructions, and other documents describing how to administer the CNPV program that have been given to relevant FDA staff.

Sincerely,

Diana DeGette
Ranking Member, Subcommittee on Health
Committee on Energy & Commerce

Congress of the United States

Washington, DC 20515

July 13, 2026

The Honorable Russell Vought
Director
Office of Management and Budget
1650 Pennsylvania Ave N.W.
Washington, DC 20503

Re: OMB-2026-0034, Office of Management and Budget (OMB) Regulation for Federal Financial Assistance

Dear Director Vought:

We are writing to submit our comments in response to the proposed rule "Regulation for Federal Financial Assistance (OMB-2026-0034)" and raise serious concerns regarding the impact on U.S. biomedical research and public health. The proposed rule fails at its stated purpose of improving transparency, accountability, and oversight for federal awards. Instead, it usurps the ability of federal agencies to carry out their congressionally directed missions and injects the whims of political appointees into all federal agency grantmaking processes. If finalized, the rule would reduce transparency and accountability by holding recipient organizations to a set of political standards that are ill-defined and allow political appointments to police standards of scientific integrity. We strongly urge the proposed rule be withdrawn.

The proposed rule threatens a world-leading biomedical research enterprise that has taken decades to build. It adds unnecessary bureaucracy to a federal grantmaking process that has already slowed precipitously under the Trump Administration. New procedural hurdles will further damage federal grantmaking. Allowing agencies to unilaterally terminate grants at their discretion will disrupt research and programs and slow reviews and approvals, ultimately wasting taxpayer dollars. Furthermore, requiring that grants advance the President's policy priorities will introduce policy whiplash, diminishing the stability and predictability of federal grantmaking. By politicizing federal grantmaking, this rule will stifle scientific discovery and dismantle America's dominance in biomedical innovation at a critical moment for domestic research and global competition.

This rule threatens to upend federal funding for the external research institutions that conduct the majority of federal research in the United States. These research institutions make large up-front investments in the facilities, equipment, and administrative support necessary to conduct cutting-edge biomedical research. They are willing to take on these calculated risks because, for several decades, federal support for biomedical research has been stable and consistent, supported by strong bipartisan majorities in Congress and many successive Republican and Democratic administrations. This concept of stable funding of capable recipients forms the basis of multi-year federal grant and cooperative agreement funding mechanisms, which are designed to endure beyond transitions in presidential administrations. This stability also directly benefits patients—people enroll in clinical trials with the assumption that their care

through a trial will not be disrupted for any reason other than a legitimate clinical issue. That assumption would fail under this rule. The rule would disturb the predictability of funding institutions and patients rely on.

The proposed rule's changes to grantmaking procedures are explicitly designed to diminish the role of scientific judgment. It requires a new pre-issuance review process for grants that would be conducted by political appointees, with no regard as to whether they have training in the underlying subject of the grant. Peer review by experts in the field, which forms the core of merit review-based funding decisions, is explicitly relegated to an "advisory" function on which appointees may not rely. The risks of this change could be especially pronounced for grants involving climate change, pandemic disease, sexual and reproductive health, behavioral health intervention, and others. But it could also impact National Institutes of Health (NIH)-funded biomedical research, Administration for Strategic Preparedness and Response (ASPR)-funded hospital disaster preparedness grants, Centers for Disease Control and Prevention (CDC)-funded influenza tracking programs, Substance Abuse and Mental Health Services Administration (SAMHSA)-funded substance use disorder treatment centers, and Health Resources and Services Administration (HRSA)-funded health workforce training grants, among others. Layering on a requirement that grants advance the President's policy priorities further diminishes the role of scientific judgment and increases the importance of the views of political actors, which may change across or even within administrations.

Congress authorized NIH to award grants that support cures, vaccines, treatments, and scientific research based on scientific merit, which is affirmed throughout Title IV of the Public Health Service Act. Nowhere in NIH's statute does Congress provide OMB or the White House a role in adjudicating individual grants, to define criteria for grant selection, or to put its policy preferences ahead of Congress's directions. Congress has established scientific review processes to insulate grantmaking from political interference. That includes a statutory two-step peer review process to principally inform decision-making on grants and ensure projects are funded based on their scientific merits and in good stewardship of taxpayer funds. Throughout NIH's authorizing statute Congress expresses the purpose of the agency at large and its institutes and centers, and these purposes are understood to be driven by the best science. The proposed rule undermines these statutory requirements by injecting political preferences into a process Congress intentionally designed to be merit-based.

Section 492 of the Public Health Service Act mandates that the NIH Director require appropriate scientific peer review of grant applications and gives the NIH Director authority to design such procedures. The statute even goes so far as to prohibit the Secretary of Health and Human Services from approving or funding proposals that have not undergone such review in accordance with Section 492. Congress's recognition of the value of peer review and scientific expertise is reflected in other authorizing statutes. For example, section 504 of the Public Health Service Act requires that SAMHSA grants exceeding a certain dollar amount must be peer reviewed by "eminently qualified" individuals, specifically including those licensed and experienced in relevant fields with limits to even the Secretary's personal discretion. In contrast, the proposed rule states "senior appointees must conduct these reviews and apply specific principles when evaluating proposals." However, appointees selected on the basis of their

political alignment with an Administration often lack the expertise to evaluate the scientific merits of a proposal. Furthermore, industries with a political connection to senior Administration officials could influence a decision to fund research that benefits them or terminate a study of product-related harms. It is because of these risks of political favoritism that Congress authored NIH's grantmaking authorities to ensure science be left to the scientists—a principle this rule brazenly contradicts.

Requiring senior political appointees to conduct pre-award reviews of all proposals will enable any Administration in power to issue awards to politically aligned proposals of dubious scientific merit. For example, CDC's planned study of the hepatitis B vaccine birth dose among newborns in Guinea-Bissau was prioritized by political appointees, lacked scientific expert review, and was funded without open competition.[1] The study is now halted after Guinea-Bissau health officials, the World Health Organization, and Members of Congress raised serious ethical and procedural flaws about the project, including its potential to expose neonates to hepatitis B by depriving them of the birth dose.[2] Review by scientists with relevant scientific experience ensures projects are ethically and scientifically sound.

Basic scientific research, interventional trials, clinical care delivery, and implementation of public health programs require consistent support for infrastructure and staffing. When those supports are interrupted, the foundation for the entire research and public health enterprise is jeopardized beyond any one grant. Congress designed HHS' grantmaking programs to operate in a merit-based way and to provide that consistent support for research and public health activities. We strongly urge you to withdraw this proposed rule.

Sincerely,

Diana DeGette
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce

[1] Rolling Stone. New documents reveal a controversial vaccine study's unusual path to CDC approval. https://www.rollingstone.com/politics/politics-features/new-documents-vaccine-study-cdc-approval-1235518406/ (February 20, 2026)

[2] CIDRAP. Guinea-Bissau officials stop CDC-funded hepatitis B vaccine trial. https://www.cidrap.umn.edu/hepatitis/guinea-bissau-officials-stop-cdc-funded-hepatitis-b-vaccine-trial (February 24, 2026).

Raul Ruiz, M.D.
Member of Congress

Debbie Dingell
Member of Congress

Robin L. Kelly
Member of Congress

Nanette Diaz Barragán
Member of Congress

Kim Schrier, M.D.
Member of Congress

Lori Trahan
Member of Congress

Marc A. Veasey
Member of Congress

Lizzie Fletcher
Member of Congress

Alexandria Ocasio-Cortez
Member of Congress

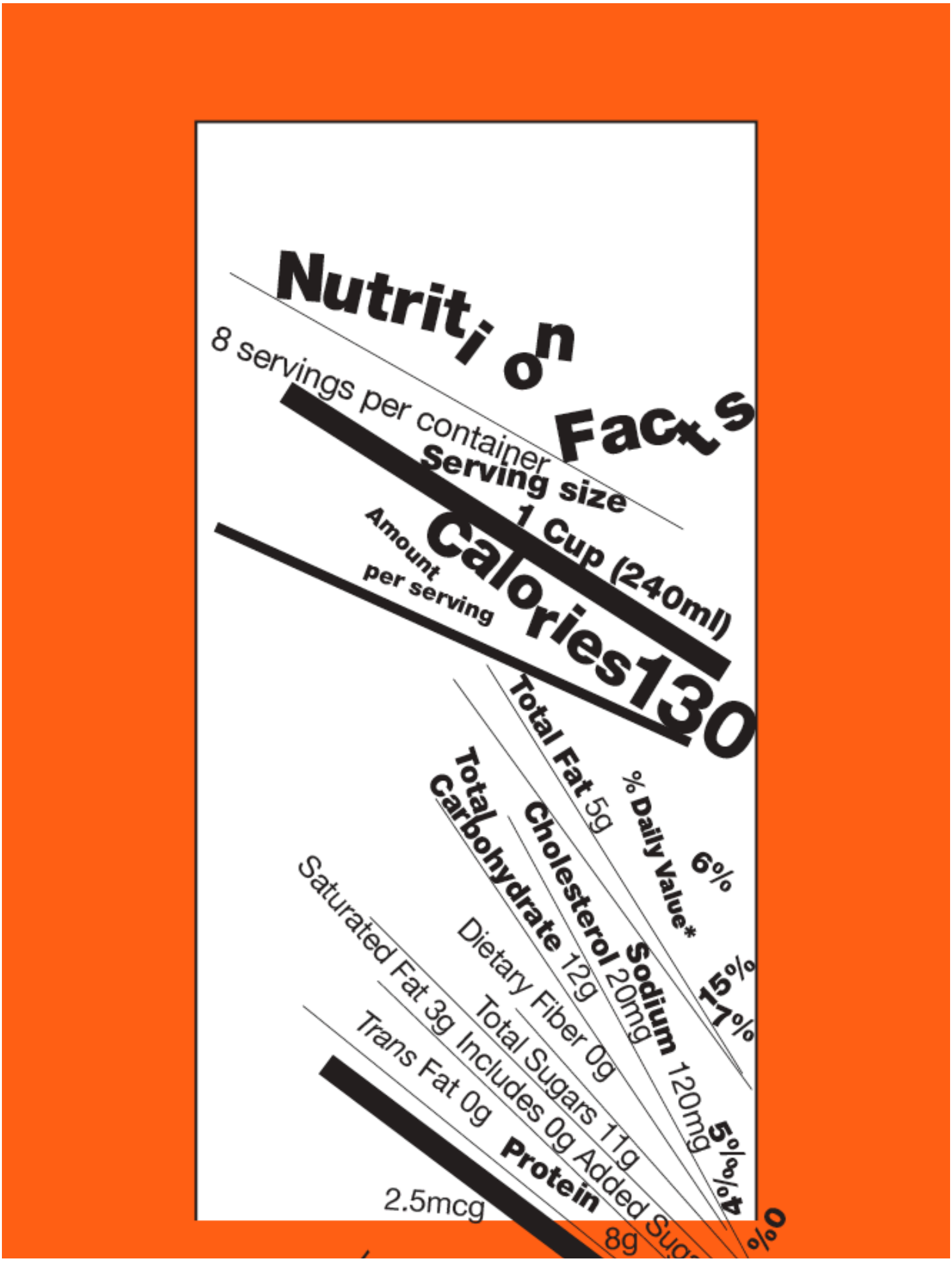
Jake Auchincloss
Member of Congress

Troy A. Carter, Sr.
Member of Congress

Greg Landsman
Member of Congress

The New York Times Magazine

https://www.nytimes.com/2025/07/08/magazine/fda-collapse-rfk-kennedy.html


Nutrition Facts
8 servings per container
Serving size
1 Cup (240ml)
Amount per serving
Calories130
% Daily Value*
Total Fat 5g
6%
Saturated Fat 3g
15%
Trans Fat 0g
Cholesterol 20mg
7%
Sodium 120mg
5%
Total Carbohydrate 12g
4%
Dietary Fiber 0g
0%
Total Sugars 11g
Includes 0g Added Sugars
Protein
2.5mcg
8g

Inside the Collapse of the F.D.A.

How the new health secretary, Robert F. Kennedy Jr., is dismantling the agency.

By Jeneen Interlandi

Jeneen Interlandi, a domestic correspondent for Opinion and a staff writer at the magazine, writes frequently about public health. For this article, she interviewed dozens of people who have worked with and for the F.D.A.

July 8, 2025

The reckoning that Robert Califf spent years warning about began, as so many things seem to these days, on social media. It was October 2024. His tenure as commissioner of the Food and Drug Administration was winding down, and he was starting to imagine a happy retirement surrounded by grandchildren when he noticed Robert F. Kennedy Jr. taking aim at his agency, and the 19,000 or so people who worked there, on X.

“FDA’s war on public health is about to end,” Kennedy wrote. “This includes its aggressive suppression of psychedelics, peptides, stem cells, raw milk, hyperbaric therapies, chelating compounds, ivermectin, hydroxychloroquine, vitamins, clean foods, sunshine, exercise, nutraceuticals and anything else that advances human health and can’t be patented by Pharma. If you work for the FDA and are part of this corrupt system, I have two messages for you. 1. Preserve your records, and 2. Pack your bags.”

It was a confused, almost comically pompous declaration, Califf recalls thinking, and it ought to have been the least of his concerns. Kennedy had not yet been tapped to serve as anything, let alone the highest health official in the land. Still, it struck a nerve. More and more, people seemed to clamor for things that were

unproven, to question things that were and to express not only mistrust but outright hostility toward the doctors, scientists and civil servants trying to separate one from the other. That hostility was being nourished by exactly the kind of mis- and disinformation Kennedy was espousing. It was easy to paint the F.D.A. as a supervillain (an aggressive suppressor of sunlight, vitamins and exercise, to borrow Kennedy's language), in part because the truth was so much more complex.

Americans have always been ambivalent about public health in general and the American regulatory project in particular. We want protection from bad food and bad medicine and other unsafe products, but we also want to draw the line between safe and unsafe for ourselves and to redraw it whenever we see fit. The F.D.A. has always reflected this tension. On the one hand, the agency's regulators have a truly enormous remit: Which drugs, medical devices, food, pet food, dietary supplements, tobacco products and cosmetics we can buy — one in every five dollars we spend, by official estimates — comes down to the decisions they make. On the other hand, the agency itself is profoundly under-resourced.

The F.D.A. receives less money from Congress than any of its sibling institutions, including the Centers for Disease Control and Prevention and the National Institutes of Health. In fact, its federal budget is roughly the size of the budget of the local school district in Montgomery County, Md., where it is based. Its infrastructure is wildly inadequate: fax machines, clunky computer systems, warehouses full of paper records that should long since have been digitized. And its staff members are poorly paid and frequently outgunned by the companies they are charged with regulating.

One perfect example of this dynamic involved the food and beverage industry, which Kennedy was so fond of calling out. Regulators had been working for years to get companies to reduce the salt content of their products and to add more and better "front of package" health warnings. Critics seemed to relish pointing out that other countries managed to implement both policies to great effect and with ease. But the United States was not like other countries. In the United States, corporations had the same rights as individuals and were likely to advance legal

challenges against just about any rule with which they were confronted. To prevail in court, the F.D.A. would need its own research, which it did not have the money to conduct, or industry data, which it did not have the authority to demand.

To mount a broader attack on ultraprocessed food, which Califf agreed was designed explicitly to addict young children, the agency would have to contend with how those products were being promoted. Manufacturers used carefully tailored ads that appealed to consumers on an emotional level; the agency was restricted, by law, to plain facts. Like almost all its biggest challenges, the trouble boiled down to two things: The F.D.A. needed more money, and the F.D.A. needed more authority. Both were on Congress to provide, but lawmakers had a habit of heaping mandates on the agency without addressing either issue — and then heaping blame on regulators for every failure that resulted.

But it was not just stingy congresspeople and litigious corporations that frustrated and worried Califf. He and his colleagues had also been engaged in a decades-long debate with a sprawling community of watchdogs — mostly doctors, lawyers and scientists from outside the agency — who were often broadly supportive of the agency's mission but who fought with officials like Califf, sometimes bitterly, over the specifics: How should the F.D.A. be financed? What kind of evidence should new drugs and medical devices require? How should regulators weigh the concerns of industry against the needs of doctors, patients and consumers?

Robert Califf, who served as commissioner of the Food and Drug Administration before retiring from the agency in January, has warned that the F.D.A. is being dismantled by the new administration. Nate Langston Palmer for The New York Times

In Califf's opinion, the watchdogs tended to amplify every disagreement and misstep, without acknowledging the vast areas of consensus — or the fact that most of the time things went exactly as they were supposed to. That was not to say that the agency was infallible or that it should not be scrutinized. But the way he saw it, their critiques were undermining public trust and providing ammunition to those less interested in improving the agency than in dismantling it altogether. "I think often the people that are doing the critiquing assume that the agency is going to be there in the future," he warned at a conference in 2023. Now it looked as if the crisis he had sensed coming for a long time was finally here.

When President-elect Trump tapped Kennedy to head the Department of Health and Human Services in mid-November, Califf reconsidered Kennedy's post. If "preserve your records" was meant as a threat, Califf interpreted it differently. "He's right," he told his staff as his tenure wound down. "We need to save every last record we have. Because one day, somebody will have to figure out how to put this all back together again."

In late January, the new cost-cutting initiative known as the Department of Government Efficiency (or DOGE) asked leaders across H.H.S. to verify lists of probationary staff (those hired or promoted within the past year). Jim Jones, a former administrator at the Environmental Protection Agency who took control of the F.D.A.'s food division in September 2023, was standing with his colleagues when the request came in. Their hearts seemed to sink in unison as they pored over the list together.

"We looked at each other and said, 'They're going to fire them all,'" he told me afterward. "That was quite a chilling moment." Jones was initially optimistic about Kennedy's appointment. The F.D.A.'s chronic disease and chemical-safety programs had long been among the agency's most poorly funded, and Kennedy was the only prospective secretary he could think of who had mentioned either, let alone vowed to prioritize both. Jones's team had just finished revamping the F.D.A.'s Human Foods Program, the largest reorganization in the agency's long history. And the changes they had implemented, and the ones they were still working on, were all in line with Kennedy's stated goals.

They had changed the food division's leadership structure to clarify chains of command. They had bolstered the nutrition department and created a new office to review the safety of chemicals used in food. They had revoked the agency's approval of Red Dye No. 3 and finalized a rule defining which foods can be labeled "healthy." They had also announced the next phase of their sodium-reduction initiative and proposed another rule that would require companies to put nutrition labels on the front of food packages.

They still had work to do. The food-safety division was grossly understaffed, and while inspection schedules had improved (once a year instead of once every three years for infant formula, for example), they were still inadequate. According to an investigation by ProPublica, some infant-formula plants continued to be plagued by leaky pipes and other contamination issues, and the F.D.A. was not doing nearly enough to punish companies for violations. But they were making progress, and with a leader who seemed focused on their normally neglected division (the "F" in "F.D.A.," as they liked to remind people), Jones was hopeful that they would stay the course even as the political winds shifted.

In mid-February, 89 people from his own team and several hundred more from across the agency were fired in a process that seemed to Jones needlessly cruel, astonishingly clumsy and potentially illegal. Managers had not been told who was going or staying, nor given a chance to weigh in about which cuts made the most sense. Most people found out via email that they had been terminated, but many did not know until they came to work and discovered that their badges had been deactivated.

In Jones's department, the people fired were the ones most needed for the things the health secretary had said he hoped to focus on. "There is nothing strategic about it," Jones told me at the time. Nobody seemed to have weighed DOGE's reductions against Kennedy's stated agenda. He hoped that Kennedy would push back against Musk's team or that somebody up top would call attention to the discrepancy between rhetoric and action and then change course. But it soon became clear that no such cavalry was coming.

Robert F. Kennedy Jr., secretary of health and human services, has vowed to loosen F.D.A. standards to allow consumers to access more — often unproven and even harmful — alternative therapies. Haiyun Jiang for The New York Times

Jones resigned the following week, in protest and defeat. “The only thing I’d be doing would be trying to scramble to plug all the holes being created by decision makers outside of H.H.S.,” he told me at the time. “There would be very limited opportunity to work on the secretary’s agenda.”

In the weeks that followed, the chaos only deepened. The new administration seemed to rule by social media post alone and to relish the confusion those missives caused. Rumors that DOGE operatives were patrolling the corridors of F.D.A. and H.H.S. with lie detectors drove a protective wedge between those who had been terminated and those who remained: There was a gag order in place, which meant that discussing agency business with anyone outside the agency was grounds for termination. The fired staff members I spoke with were worried that just calling their former colleagues might cost them their jobs.

‘We looked at each other and said, “They’re going to fire them all.”’

New return-to-office policies, meanwhile, were forcing thousands of F.D.A. employees into a headquarters that was never meant to accommodate them all. Those who had been working remotely now faced hourslong drives followed by hourslong waits to access the main campus, and then not enough parking spaces, office spaces, maintenance staff or I.T. support once they got there. Worst of all, a Legionella outbreak that had plagued the water supply for several weeks was not entirely resolved, according to Jeremy Faust, a physician at Brigham and Women’s Hospital in Boston, who reports on the F.D.A. for his Substack, Inside Medicine.

Neither Jones nor any of his colleagues or former colleagues could discern the purpose of any of the new measures, least of all the staff cuts. “You have to have a deep cynicism about what these workers are doing to believe that fewer of them is better,” Peter Lurie, a doctor who was an associate commissioner during the Obama administration, told me, as more layoffs were announced one early spring afternoon. Most offices were understaffed, almost as a rule, he said. The ones that weren’t tended to be paid for by user fees (money that drug and device makers give the agency to cover the cost of reviewing their products). But neither DOGE members who counted those layoffs as a cost-cutting win nor the health secretary himself seemed aware of this fact.

The principles governing Kennedy’s Make America Healthy Again movement are simple: Conventional medicine has largely failed us, as rising rates of autism, obesity and chronic disease clearly demonstrate. And the profit-driven industries that hold such sway over our health cannot be trusted. Those who feel betrayed by our corporate health care system should be free to turn to the vast array of alternatives — adult stem-cell injections, dietary supplements, raw milk and testosterone therapy for men, to name a few — at their disposal. It’s true that many of these alternatives have not been tested or proved beneficial in the

conventional, scientific way. But in a free society, personal choice should be paramount. “If you want to take an experimental drug — you can do that, you ought to be able to do that,” Kennedy said on one podcast. “And of course you’re going to get a lot of charlatans, and you’re going to get people who have bad results.” He went on, “Ultimately, you can’t prevent that either way.”

But that was exactly what the modern F.D.A. was created to do: prevent Americans from being swindled, or worse, by purveyors of ineffective medicine. In the early 1960s, when the agency was still restricted to vetting products for safety, Americans spent a billion dollars or so a year on a wide range of wholly untested elixirs, including pigskin extract, bottled seawater and shark oil. It was clear to health officials that many of these products did not work, and that the very ill were especially vulnerable to scammers.

Some lawmakers and consumer advocates wanted to establish standards for effectiveness. Ensuring that health products worked as advertised seemed like the least a government could do for its people, they argued. But Congress was sharply divided over whether to expand the F.D.A.’s authority. No other federal agency had that kind of power: to decide what counts as safe, what counts as effective, what counts as evidence and then to permit or prohibit sales based on those criteria. No other nation in the world had that kind of barrier around its pharmaceutical market. And as the historian and Harvard professor Daniel Carpenter notes in his epic 2010 history of the agency, “Reputation and Power,” the United States — home of big business, small government, free markets and free choice — was an odd place to set such a high bar.

It was in the shadows of this debate, in 1960, that an application for a new sedative called thalidomide landed on the desk of Frances Kelsey, a pediatrician and pharmacologist who had just joined the F.D.A.’s drug division. Thalidomide was Kelsey’s first assignment, and it was meant to be a softball (sedatives tended to be simple drugs, and this one was already on the market in Europe). But after noting several errors in the application, she asked the applicant for more data. The drug’s makers pressed Kelsey’s bosses to bypass her and approve their product quickly, but Kelsey’s bosses stood firm.

Eventually, it became clear that thalidomide caused serious birth defects, including missing and malformed limbs, when women took it during pregnancy. Thousands of babies around the world had already been affected. Thanks to Kelsey and her colleagues, most infants in the United States were spared. It was in the wake of those revelations that Congress finally granted the F.D.A. new authority to require that drugs be proved effective — with adequate, well-controlled clinical trials — before they could be sold to American consumers.

President John F. Kennedy signing the legislation that created the modern F.D.A. Second from the left is Dr. Frances Kelsey, whose work on thalidomide helped bring Congress and the public around to stricter regulation of food and drugs.
Bettmann/Getty Images

President John F. Kennedy signed those powers into law in 1962, with Kelsey standing behind him. The new statutes helped set a new global standard. They also touched off what experts now refer to as a golden age of clinical medicine, not only by clearing the market of junk medicine but also because consistency and rigor turned out to be great both for industry innovation and for consumer confidence.

Over the next three decades, the F.D.A.'s reputation soared. Even as mistrust in other federal institutions grew, Carpenter writes, a vast majority of Americans understood what the agency was doing — and approved. But that honeymoon came to an end in the late 1980s and early 1990s, when regulators faced an array of new challenges. Advances in technology were triggering an explosion in the number and types of drugs being developed. Highly vocal AIDS activists began demanding access to some of those new drugs as quickly as possible. And just as the F.D.A.'s workload was expanding, a rising anti-regulatory fervor shrank the agency's budget and diminished its sway over lawmakers.

In 1992, the agency implemented two new policies to address these issues. It created an accelerated pathway for approving certain drugs (those designed to treat deadly diseases for which there was no current treatment) with less evidence. It also began charging drug makers (and eventually, medical-device makers) for product reviews, through new "user fee" laws.

For a while, the fixes worked as intended. A yawning gap in the F.D.A.'s budget was finally plugged. Product reviews became faster and more efficient, and more of those products made it to market. But before long, critics were arguing that the fees gave industry far too much influence and that, as a result, exceptions to the nation's high drug-approval standards were becoming the rule. In the late 1990s, the agency began requiring fewer clinical trials for some drugs. In the 2000s, it modified the efficacy standards for others.

By then, a majority of new drugs were being routed through one expedited approval process or another. The United States had also become one of just two countries where drug makers could advertise their products directly to consumers.

And the F.D.A. was being excoriated for its role in exactly the kind of deadly mishaps it was created to prevent. The anti-inflammatory drug Vioxx was linked to heart attacks and strokes; the antidepressant Paxil increased the risk of suicide in teenagers; prescription opioids like OxyContin helped seed an overdose crisis that would go on to claim 100,000 lives a year. In "Doctored," a book about the quest to cure Alzheimer's, published this year, Charles Piller details how the agency failed to properly police clinical trials for safety or fraud.

Gardiner Harris, a former Times reporter, unpacks what he sees as a grim roster of additional failures in "No More Tears," his 2025 book about Johnson & Johnson: baby powder that contained asbestos, a cancer drug that increased tumor growth, medical devices that caused debilitating injuries. In case after case, Harris writes, the company knew its products were dangerous but withheld data from the F.D.A. Thousands of deaths and serious injuries may have resulted. Johnson & Johnson rarely received more than a slap on the wrist and sometimes not even that. (Johnson & Johnson disputes Harris's claims. "We stand behind the safety of our products and are focused on what we do best: delivering medical innovation for patients around the world," a spokeswoman said.)

'What you see over time is that industry's priorities become agency priorities.'

Holding drug makers to account for malfeasance has proved extremely difficult, Harris and others say. In many states, F.D.A.-approval offers protection against negligence claims or prevents juries from assessing punitive damages. In the case of Johnson & Johnson's baby powder, hundreds of millions of dollars in judgments against the company have been repeatedly overturned on appeal. But if the price paid by industry has been small, the cost to the F.D.A. has not: By 2025, according to data from the Kaiser Family Foundation, less than half of all Americans said they trusted the agency to carry out its core responsibilities.

Well before that mistrust mushroomed into the MAHA movement or propelled a vaccine skeptic to the highest health office in the nation, F.D.A. watchdogs were fighting to reverse the policies that had led to so many agency missteps.

Among other things, they were pressing for more judicious use of accelerated drug approvals; better safety monitoring of drugs that made it to market; far more rigorous follow-up studies for drugs approved with incomplete data; and, perhaps most important, an end to the user fees that now accounted for roughly half the agency's overall budget. "The F.D.A. meets with industry hundreds of times over the user-fee renewals, and only half a dozen or so times with the rest of us," Reshma Ramachandran, a physician and a co-director of the Yale Collaboration for Regulatory Rigor, Integrity and Transparency, or CRITT, told me. "Whether it's conscious or deliberate or not, what you see over time is that industry's priorities become agency priorities."

Reshma Ramachandran is co-director of a Yale watchdog group that has long advocated reforming the F.D.A. She now worries that calls for judicious reform are being replaced by a wholesale attack on the agency. Nate Langston Palmer for The New York Times

Along with her colleagues, Ramachandran submitted public comments to the agency, spoke at drug-approval hearings, met with lawmakers and conducted her own research on the effects of agency policies. What she most wanted regulators and their congressional overseers to understand was this: approving drugs quickly and with less evidence might give doctors and patients more options, but it also shifted a huge burden of uncertainty from the agency onto them.

She remembered feeling hopeful at the end of the Biden administration. Policymakers had expressed interest in their proposal for a publicly funded clinical-trial program, and at least some members of Congress had been receptive to their warnings about the dangers of ever-lower approval standards. But as a new administration took control of the agency, she and her colleagues sensed that their measured pleas for smart, scalpel-level reforms would now be drowned out by the sound of sledgehammers.

On March 27, a few days before the F.D.A.'s 27th commissioner, Martin Makary, was sworn in, Kennedy announced he would fire about 10,000 civil servants from the Department of Health and Human Services. The Food and Drug Administration would face heavy losses: 3,500 terminations in all, or 20 percent of its work force. Those layoffs were temporarily blocked by a federal judge on July 1, who said the mass firings exceeded the health secretary's authority and were most likely illegal. But the damage was done. The offices for medical devices, tobacco products and generic drugs were all but eviscerated. The agency's library was shuttered and subscriptions to key scientific journals canceled. Administrative staff across the agency was cut to the bone. "Dr. Makary was brought in to clean up an F.D.A. plagued by bloated bureaucracy, unaccountable leadership and regulatory capture," says Andrew Nixon, director of communications at H.H.S. "Under his watch, the agency is finally returning to evidence-based science, speed and public service."

A couple of weeks later, Kennedy made his first in-person visit to agency headquarters. In a speech broadcast from a private room to a large hall where the agency's staff had gathered, he doubled down on the sentiments expressed in his

October post. The Deep State was real, he said. And the F.D.A. was a mere industry "sock puppet."

At first blush, Kennedy's remarks appeared to dovetail with the critiques leveled by experts like Ramachandran. So many of the F.D.A.'s missteps seemed — to both agency watchdogs and the MAHA faithful — to come down to the undue influence of industry over the institution. But where Kennedy and his ilk saw conspiracy or corruption, Ramachandran and other watchdogs saw something far more complicated. For one thing, it was not just the agency that had been captured by industry. Congress, doctors, patient-advocacy groups and a regulation-wary public had all played a role in weakening the F.D.A. For another, those who had served on both sides of the watchdog-regulator divide knew firsthand how mission-driven most of the agency's rank and file were and how irrelevant political considerations were to their actual work.

'How can people have such divergent views of what the agency is trying to do?'

Lurie, a doctor who spent years challenging the agency from his perch at the nonprofit Public Citizen, remembers how his perception of the F.D.A. changed once he became a deputy commissioner under President Barack Obama. "I thought, Well, you know, this agency is just completely captured by industry, and I'm going to stand up for, you know, what's good and right in the world," he told me. "But that's a misunderstanding of the way that government actually works." Most of the meetings he attended, he says, involved smart people trying to achieve shared objectives. Political ideologies or feelings about industry never came up at all and would not have mattered if they did.

Mitch Zeller, who worked at the Center for Science in the Public Interest before leading the F.D.A.'s tobacco division, described a similar acclimation process for the dozen or so political appointees who joined the agency during the first Trump

administration. They quickly came around to the agency and its mission, he said. When there was pressure on Zeller to exempt premium cigars from a series of new regulations, something he considered both illegal and bad for public health, the appointees ran interference so that he could prevail.

The F.D.A.'s real problem, Lurie and others suggested, was not so much industry capture as a fundamental weakness at the heart of the agency. In theory, its authority was ironclad. In practice, the agency's position was like that of a federal judge who rules against a sitting president and is immediately confronted with a constitutional crisis. In the F.D.A.'s case, every interest group — from lawmakers to drug makers to doctors and patients — was president, and every judgment was a potential tipping point. This precariousness made agency officials deeply reluctant to admit mistakes or even to communicate openly. But that reluctance had costs of its own.

Multiple exposés of the F.D.A.'s role in the opioid crisis made the agency's own silence on it deafening. In the thick of the pandemic, when clinical trials testing Covid-19 vaccines in children faced repeated delays, the agency's failure to communicate left parents in a vacuum far more detrimental to public trust than any honest dialogue would have been. "They should have been briefing parents every week," Joshua M. Sharfstein, a professor at the Johns Hopkins Bloomberg School of Public Health, told me. "A golden rule of public health is that if you don't explain what you're doing and why, someone else will explain it for you."

This was brought home to Sharfstein when he led the Obama administration's F.D.A. transition team. He was meeting with interest group after interest group — a dizzying ritual, not unlike speed dating — when he realized two things: Everyone, regardless of whom they represented (industry, patients, doctors, consumers), hated the F.D.A. And different organizations often had the exact opposite idea of what regulators were doing wrong and why. If one group said that the agency was too slow or that people were dying for want of cures while bureaucrats dotted I's and crossed T's, the next would accuse them of rushing products to market without sufficient regard for safety or effectiveness.

“I thought, How can people have such wildly divergent views about what the agency is intending and trying to do?” he told me. “And then someone said that, ‘You know, it would really help a lot if the F.D.A. explained itself.’” Sharfstein and his team did their best to heed that advice. They published detailed explanations of their decisions, convened a task force and created an agencywide transparency initiative that included making key documents on drug approvals and rejections publicly available. The idea was well received. Venture capitalists said they would be more likely to invest in risky biotech innovations if they could hear directly from regulators, instead of being forced to take the word of industry executives. And watchdog groups said that releasing more information would help build trust — and dispel medical conspiracy theories.

Joshua M. Sharfstein, a professor at the Johns Hopkins Bloomberg School of Public Health, pushed for more transparency at the F.D.A., as a way to improve public trust in the agency. Nate Langston Palmer for The New York Times

When the pandemic hit, few of those proposals had been implemented. “You have these stories of people filing FOIA requests at the F.D.A. for vaccine data” — on Covid-19 vaccines — “and the F.D.A. telling them it would take 55 years to respond,” Christopher Morten, director of the Science, Health and Information Clinic at New York University School of Law, told me. “That becomes a story unto itself, that the F.D.A. is, quote unquote, hiding data from the public. Conspiracy theorists seize on that.”

Morten and other watchdogs view transparency as a key to the F.D.A.’s salvation. Janet Woodcock, who spent almost 40 years as one of the agency’s top drug regulators before retiring in 2024, is far less sanguine. Woodcock has been heavily criticized for her role in regulating several controversial drugs, including OxyContin, the now discontinued Alzheimer’s drug Aduhelm and Exondys 51, a treatment for Duchenne muscular dystrophy that the F.D.A.’s own reviewers urged the agency to reject. In June, a ProPublica investigation also faulted Woodcock for allowing factories in India and elsewhere to send generic drugs to the United States through a secretive exemption process, despite serious safety violations, including filthy laboratories and contaminated products.

She stood by all those decisions, she told me. It was easy to single out missteps, but the F.D.A. made hundreds of complex decisions every day, and each one came with benefits and trade-offs. The risk posed by a substandard factory, for example, had to be weighed against the prospect of major drug shortages, including of medications that treat cancer in children. And the downsides to approving a drug whose benefits appeared to be minimal had to be viewed in light of the patients who were facing certain death. Regulators like her did a pretty good job balancing those concerns, she insisted, especially relative to the resources at their disposal.

More transparency might improve trust, she went on. But it was much more likely to provide bad-faith actors with further ammunition for their attacks on the agency. “I’ve gotten emails saying that I was committing crimes against humanity for not approving certain products fast enough,” she said. “And then you know,

messages saying I'd be tried at Nuremberg once that same product was approved. We get blamed for everything, on all sides. Releasing more documents isn't going to fix that."

That defensive crouch might have insulated Woodcock and her colleagues from the vagaries of public opinion, but it also made them uniquely vulnerable to current attacks, which increasingly appeared to spell the agency's doom.

As the first 100 days of the new administration ticked along, watchdogs and institutionalists alike found themselves caught up in a vast retrenching. Rather than working to make the F.D.A. stronger, many were suddenly — strangely — defending things that they previously criticized and balking at things they previously argued for. Their positions hadn't changed. But the new administration's solutions to the agency's intractable problems were even worse than the problems themselves.

'What they appear poised to do is to pack the advisory committees with their cronies.'

Those who had opposed industry-paid user fees because they undermined the F.D.A.'s credibility or independence now found themselves praying that the system remained intact, because problematic funding was better than no funding at all. Those pushing transparency initiatives now cringed to hear the new health secretary talk about "radical transparency," because it seemed to mean something very different to him than it did to them: not an honest and impartial sharing of information but a scorched-earth search for something — anything — that would bolster dangerous and disproven theories. And those who for years complained that the F.D.A. was shutting out advisory committees (outside experts who consult with the agency on product approvals) were now worried that they would take their recommendations to heart.

“What they appear poised to do is to pack the advisory committees with their cronies and make the process even less credible than it stands right now,” Aaron Kesselheim, a professor at Harvard Medical School and a former advisory committee member, told me recently. Doctors and scientists who criticized the F.D.A. for ignoring advisory committees when it came to Alzheimer’s drugs would now be complaining about the exact opposite: abiding by the advisory committee when it came to, say, pulling polio vaccines off the market. They would be dismissed as hypocrites, he speculated. And the truth — that the committees themselves had been radically altered — would be lost in the noise.

In the meantime, Ramachandran and her colleagues were trying to hold the line wherever they could. When administration officials began removing troves of vital health information from various federal websites this winter, they filed a lawsuit and won a temporary restraining order. After mass firings all but eliminated public-information offices at the F.D.A., Ramachandran contemplated filing more lawsuits: Could they sue under the Freedom of Information Act, if their information requests were delayed for too long? What about the secretary’s plan to eliminate public comments in certain cases? Could they challenge that proposal in court?

It was impossible to say how much worse things would get — how many more people would be fired, policies rescinded or projects canceled — or what if anything would be preserved from the preceding era. David Kessler, who served as F.D.A. commissioner during both the George H. W. Bush and Clinton administrations, thought the core tenets of drug regulation would endure, in part because the success of American industry hinged on those tenets. “There were debates decades ago about removing the efficacy standards, but no one credible is making that argument today,” he told me in March. “Global competitiveness is based on the fact that when a drug is approved in the U.S., it does what’s said on the label.”

But most of the two dozen or so other experts I spoke with disagreed. “They’ve already perverted the law,” Joseph Ross, a professor of medicine at Yale and co-director of CRITT, the Yale watchdog group, told me. “The idea that they’re going to make it even worse is, I think, a very real one.”

After so many years of antagonism, those who spent their careers fighting with and for the agency seemed to agree that something vital was slipping away. What good were transparency initiatives, they asked themselves, for people who trusted dietary supplements but not vaccines? Or who glorified public figures like Kennedy, who made millions spreading dangerous falsehoods, but viewed an entire class of underpaid civil servants as inherently corrupt? Reasonable people could certainly disagree about where to draw the line between access to new medical treatments and protection from harmful ones. But to be reasonable people in the first place, they needed accurate information — and a shared set of facts.

“There are certain norms that are understood, that shape policy discussions,” Sharfstein told me. “If someone decides those norms aren’t applicable anymore, it becomes very difficult to do the work of the agency.”

Kennedy’s disdain for the F.D.A. was clear, but as far as Califf, who retired from the agency on Jan. 20, could tell, the health secretary’s vision for the agency’s future remained muddy. He seemed to want to challenge the consensus on well-proven medicine (like M.M.R. vaccines, fluoridated drinking water and the abortion pill mifepristone) but also to unleash a catalog of products with little to no evidence behind them, including cod-liver oil for measles and chelating compounds, which remove metal from the blood, for autism. He insisted that “gold standard” science, including randomized controlled clinical trials, should guide the nation’s health policies. But he rejected any study that contradicted his stated views or the views of his supporters (including that vaccines cause autism); he accepted any study that supported those positions, regardless of its quality or scope; and he dodged or outright ignored anyone who pointed out the glaring contradiction.

‘They’ve already perverted the law. The idea that they’re going to make it even worse is a very real one.’

Watchdogs and institutionalists alike seethed with frustration. Did the health secretary want more regulation or less? What was his overarching philosophy? How could any agency possibly accommodate so many paradoxes? But whatever the weakness of Kennedy’s logic, his arguments had a sort of strategic brilliance to them. By insisting that the agency was corrupt, he could marshal both sides of a longstanding divide — those who wanted stronger regulations and those who wanted none — to his own cause. If the F.D.A. was down-to-its-bones wrong, then anything Kennedy said against the agency was right, no matter how contradictory or confused. Did regulations need to be stricter or more lenient? The answer was yes. The unifying principle was him.

In late April, Kennedy announced plans to eliminate synthetic, petroleum-based dyes from the human food supply. He seemed to brush past all the strictures that, in Califf’s experience, made slow and difficult work of such seemingly simple goals. In fact, he spoke as if the agency itself were superfluous and meaningful change could be achieved by fiat. When reporters asked why no industry representatives had attended the briefing and whether any of them supported the plan, he shrugged the question off. “We don’t have an agreement,” he said. “We have an understanding.” He did not mention — and perhaps did not know — that the food and beverage industry had made similarly vague promises in the past, to no avail, or that neither he nor the F.D.A. had the authority to compel companies to comply with the new directive or to punish them if they didn’t.

By May, Kennedy and his deputies were taking direct aim at vaccines. They announced that new clinical trials would be required for Covid boosters, even though the shots have long been considered both safe and effective. At the C.D.C., Kennedy himself would soon fire the entire 17-person expert committee that advises federal health officials on vaccine recommendations (not whether shots

should be approved, but who should receive them). Their replacements — eight people with little to no relevant expertise and some with obvious conflicts of interest — quickly revoked the government's longstanding recommendation of a subset of flu vaccines that contain the preservative thimerosal. Vaccine skeptics suspect the preservative of causing autism, despite numerous studies showing the compound to be harmless.

One thing that appeared not to have changed was the F.D.A.'s relationship with drug makers. In June, Makary and his deputies began a six-city listening tour with drug-industry executives that was, despite all the talk of radical transparency, closed to the public. (According to Nixon, the communications director at H.H.S., the tour was focused on industry stakeholders, and public transparency would be preserved through other forums.) Later that month, Makary announced a voucher program that would shorten drug review times from 10 to 12 months to just one or two for companies whose products met certain criteria. He also laid out a new list of agency priorities in The Journal of the American Medical Association that, for drugs, seemed to come down to two things: faster reviews and more approvals. "Their paper reads like it's straight from pharma's playbook," Ramachandran told me. "They criticized expedited drug reviews for years, especially with respect to Covid vaccines, saying that it turned the F.D.A. into a rubber stamp. But now they want to do the exact same thing for as many other drugs as possible."

Reports from inside the agency remained bleak. Some of the civil servants fired in February and April were now being invited back (the office of generic drugs had been reinstated), but most were not. Those who remained were being asked to volunteer for essential tasks for which there was now no dedicated staff. Scientists and technicians still did not have ready access to the scientific journals they needed to do their work. More than one drug review had been delayed, and political appointees had interfered in several others. And, ultimately, Vinay Prasad, the agency's new chief medical and scientific officer, overrode expert recommendations on the Novavax and Moderna Covid-19 boosters slated for this fall. As expected — and perhaps as intended — many of the F.D.A.'s remaining employees were now looking for jobs outside the government.

Califf was not so much surprised by those developments as saddened. The F.D.A. was deeply imperfect. It was lumbering and often opaque, and it had gotten many things wrong in its long history. But the agency had also been built around a set of principles — scientific inquiry, impartial judgment, collective responsibility — that represented the best of what a functioning government could do for its people. Now it was being deliberately dismantled, and a generation's worth of experience and expertise was being thrown away.

As if that weren't enough, the stewards of that legacy — the people who had worked long hours for low pay and faced constant criticism, all so that they might do what Frances Kelsey once did when she kept thalidomide off the market — were being treated like criminals. In Califf's opinion, there was no good reason for any of it. "History will see this as a huge mistake," he mused. "The F.D.A. as we've known it is finished."

Read by Janina Edwards Narration produced by Krish Seenivasan and Emma Kehlbeck
Engineered by Ted Blaisdell

Corrected on July 9, 2025: An earlier version of this article misstated the type of drug that Vioxx is. It is an anti-inflammatory drug, not a heart medication.

We acknowledge mistakes in our reporting with corrections. If you spot an error, please let us know at corrections@nytimes.com. Learn more.

Jeneen Interlandi, a staff writer at The New York Times Magazine and the Opinion section of The Times, writes about public health.

A version of this article appears in print on , Page 20 of the Sunday Magazine with the headline: The Collapse of the F.D.A.

July 13, 2026

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable John Thune
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Chuck Schumer
Minority Leader
United States Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Johnson, Leader Thune, Leader Jeffries, and Leader Schumer:

The undersigned 57 organizations represent millions of Americans living with chronic and acute diseases — patients, caregivers, and families whose lives depend on improved treatments and the discovery of cures. We have grave concerns about the Office of Management and Budget's proposed rule, Regulation for Federal Financial Assistance, proposed on May 29. If allowed to become final, this rule will have profound implications on biomedical research and ultimately the patients we represent. We respectfully ask for your leadership in ensuring this proposed rule is withdrawn and does not take effect.

Our organizations are part of United for Cures, a collaborative network of patient advocacy organizations dedicated to protecting life-saving biomedical research that has – for decades – led the world in delivering treatments and cures to communities across the United States. Nearly every American family is touched by serious, complex and chronic illnesses that are directly impacted and can benefit from continued investment in medical research and treatments. According to polling conducted for United for Cures in March, 95% of American voters believe it is important for the U.S. to be a global leader in medical research.

Many organizations, including United for Cures, asked for an extension of the only 45-day comment period to ensure that the full implications of the proposed rule can be understood and discussed. Unfortunately, our requests for extension were denied. We now ask for your leadership in urging that this rule be withdrawn before it is allowed to take effect on October 1 so that Congress and the American public can fully consider its significant implications as well as the increases in federal regulation that this proposal would bring.

While the proposed rule would cover grant-making for more than 40 different departments and agencies, our organizations are very concerned about the impact on biomedical research and the future of treatments and cures in the United States. Under this proposal:

- **Research grants could be terminated at any time, for any reason, with little to no recourse.** This would leave patients participating in clinical trials without further treatment, potentially wasting millions of dollars in federal funding and taking hope away from individuals who are benefitting from cutting-edge treatments. Federal agencies can already terminate grants if there is cause; however, this rule would take away a grantee's ability to object to, request a hearing, or appeal a termination decision in any other circumstance. The uncertainty caused by this would create a chilling effect on researchers and institutions proposing multi-year, lifesaving trials – cutting short the pipeline for discoveries and treatments.

- **The U.S. would further cede the role of global scientific leader to other countries, including China.** With the termination and slow spending of billions of dollars in federal research grants in the last 18 months, some of the most experienced and promising young U.S. researchers have been lured to Europe, Canada, and China; this proposed rule would likely exacerbate this, given the tight restrictions it places on international collaboration and the uncertainty around grant termination. This proposed rule would make it harder – not easier – for America's scientists to develop the next generation of cures to compete against other countries, including China.

- **Federal funding priorities could be undermined and administered in a way that is inconsistent with Congressional intent.** Under its Article I authorities, Congress appropriates federal funds; the Executive Branch is to administer federal programs based on the laws passed by Congress. This proposed rule would both lock in many of the current OMB practices, including threats of pocket rescission, delaying agency funding and grant opportunities, or dramatically expanding the use of multi-year grant funding.

- **Unelected, political appointees — not scientific experts — would determine which research is funded.** Because this proposes to create a new federal regulation, this rule would carry forward into future administrations, adding a permanent level of politicization to science that will harm future scientific and medical developments. Tying the ability to award and — particularly — to terminate grants at will to inherently political determinations, which are likely to change from administration to administration, could result in the destabilization of the entire biomedical research system regularly.

In all, more than 300 different changes to federal grant making have been proposed that — if finalized — will have far-reaching consequences on U.S. global leadership in biomedical and scientific research for years to come.

Again, we urge you to push for this rule to be withdrawn so that the proposed changes can be fully understood and debated by Congress. Thank you for your continued leadership and for prioritizing the health of our country.

Sincerely,

AiArthritis
Alliance for Aging Research
ALS Association
ALS Network
ALS United
Alzheimer's Los Angeles
American Association of Colleges of Nursing
American Diabetes Association
American Heart Association
American Lung Association
American Parkinson Disease Association
Angelman Syndrome Foundation
Arthritis Foundation
Association for Frontotemporal Degeneration
Asthma and Allergy Foundation of America
Autism Science Foundation
Autoimmune Association
Blood Cancer United
Breakthrough T1D (formerly JDRF)
Cancer Nation
Celiac Disease Foundation
Chronic Disease Coalition
Colorectal Cancer Alliance
COPD Foundation
Crohn's & Colitis Foundation
Cystic Fibrosis Foundation
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Epilepsy Foundation of America
EveryLife Foundation for Rare Diseases
Foundation for Angelman Syndrome Therapeutics
Friends of Cancer Research
Genetic Alliance
Huntington's Disease Society of America
Hypertrophic Cardiomyopathy Association
I AM ALS
Immune Deficiency Foundation
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)
Lewy Body Dementia Association
Lupus Foundation of America
Lymphoma Research Foundation
The Michael J. Fox Foundation for Parkinson's Research
The Myositis Association
Muscular Dystrophy Association
National Health Council
National Multiple Sclerosis Society
National Patient Advocate Foundation
National Psoriasis Foundation
Pancreatic Cancer Action Network (PanCAN)
Parent Project Muscular Dystrophy
Parkinson's Foundation
Partnership to Fight Chronic Disease
Pulmonary Hypertension Association
PXE International
Susan G. Komen
UsAgainstAlzheimer's
ZERO Prostate Cancer