Biotechnology Innovation Organization
1201 New York Avenue, NW
Suite 1300
Washington, DC, 20005
(202) 962-9200

H. Morgan Griffith
Chairman, Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

May 4, 2026

Dear Chairman Griffith:

Thank you for the opportunity to testify in front of the Subcommittee on Health on Wednesday, February 11, 2026, at the hearing entitled "Lowering Health Care Costs for All Americans: An Examination of the Prescription Drug Supply Chain."

Pursuant to the Rules of the Committee on Energy and Commerce, attached you will find my responses to Members' questions for the record. My responses will be listed below each Member's name and question in the format requested by the Committee. Please let me know if there you have any follow-up questions or concerns regarding this transmittal.

Thank you again for the invitation and for holding the Subcommittee hearing.

Sincerely,

John F. Crowley
President and CEO
Biotechnology Innovation Organization

The H. Morgan Griffith (R-VA)

1. Do you consider the list price of a drug the real price of the drug or a starting point for negotiation?
a. Do you consider the true price of a drug the list price or net price?

There have recently been a number of policy proposals to set the price of drugs. However, price-setting proposals fail to address the real drivers of access and affordability issues. Regardless of how proposals are designed, they continue to focus narrowly on the list price of drugs while ignoring the flaws in our system that allow roughly half of every dollar spent on medicines to flow to entities that didn't make them. Middlemen, such as PBMs and insurers, decide which medicines patients can access, what hoops they need to jump through, and how much they pay out of pocket – often failing to pass savings from rebates, discounts, and other price concessions directly to patients. Focusing on the list price of drugs alone fails to confront these underlying dynamics and does little to lower costs for patients at the pharmacy counter. Patients need lower out-of-pocket costs without sacrificing access, choice, or innovation.

The Earl L. "Buddy" Carter (R-GA)

1. In your testimony, you advocate for updating the Biologics Price Competition and Innovation Act (BPCIA) to deem all biosimilars interchangeable. What would you say to those who might question whether the benefits of increased biologics competition would be outweighed by concerns regarding differences in efficacy between biosimilars and the branded reference biologic?

N/A.

The Honorable Raul Ruiz (D-CA)

1. In a response statement to changes made to the Childhood Immunization Schedule, your organization stated that the US vaccination schedule came from *"decades of a rigorous, public-facing, science-based process*" and that the actions undertaken by Secretary Kennedy and the CDC, have upended the "*America first gold standard…..[by changing] the schedule without any clear medical or scientific reason."* These troubling actions to undermine our vaccine infrastructure continue, such as through pressure from members of the ACIP to question FDA's safety determinations of vaccines, which both of your organizations have said are based on "rigorous, evidence-based research." In fact, the night

before the hearing, we learned of more upheaval in our vaccine infrastructure by the Administration when Moderna said that FDA refused to review their mRNA flu shot even though the FDA had previously indicated support for the company's study plan.
a. Have any of your members cited the uncertainty in the U.S.'s vaccination infrastructure and policies as a reason to halt new trials?

Vaccine development relies on a stable regulatory and policy environment that provides transparency and predictability. Each step in the development, approval, and recommendation process – spanning FDA regulatory review, Advisory Committee on Immunization Practices (ACIP) deliberations, and CDC recommendations – has associated risk for manufacturers. Maintaining clarity and consistency across these steps helps ensure continued confidence in the process among all stakeholders. When each of these steps is perceived to involve additional or unpredictable risk, including inconsistencies across federal agencies or changes in agency processes, timelines, or communications, it increases the development risk for manufacturers. This leads to environments where manufacturers must assess whether investments in new clinical trials can be justified. While companies make development decisions based on multiple factors, our members have indicated that instability and unpredictability in the U.S. vaccine regulatory and policy environment are among the considerations that may factor into decisions to initiate new trials and continue investment in the U.S. for vaccine candidates. It is therefore vital that the vaccine policy environment be stabilized to ensure that research on novel breakthroughs for unmet medical needs continues in the U.S.

2. Moderna specifically cited that policy uncertainty in the United States has led the company to stop any plans for late-stage studies of some experimental vaccines aimed at preventing infectious diseases and infections. Yet it appears that the inconsistencies from the administration are only ramping up.
a. From your position representing companies leading in biotechnology and vaccine development, what is the impact of the Secretary's campaign of misinformation and inconsistent policies on any future late-stage vaccine trials?

Manufacturers engaged in all stages of vaccine development, and biotechnology development more broadly, rely on stable regulatory and policy environments that provide transparency and predictability, while maintaining rigorous scientific standards. Uncertainty directly affects investor confidence, research and development portfolio decisions, and willingness to advance next-generation vaccines and platforms. At baseline, vaccine development requires substantial capital, infrastructure, and, on average, 10-15 years of clinical trial commitment prior to final review and approval by the US Food and Drug Administration (FDA). When federal health

leadership advances statements and policies that are inconsistent with broad scientific consensus it introduces additional significant risk across every phase of the vaccine development lifecycle. Late-stage clinical trials for vaccines specifically require hundreds of millions of dollars, long term manufacturing scale-up, and close coordination with federal partners. Federal messaging that appears to question the value, safety, or regulatory pathway for vaccines, leads to manufacturers facing concerns about whether trial endpoints, review standards, or post marketing commitments could shift mid-study, undermining the case to continue their research. Late-stage trial feasibility also becomes a concern when public confidence in vaccines is low. Preventive vaccines are disproportionally affected because participants are generally healthy and must weigh individual risk alongside broader public health benefits prior to participation. Erosion of trust and confidence in vaccines broadly can make trial enrollment slower, more costly, or even impractical. Over time, these dynamics will influence where biotechnology companies choose to invest their limited resources. If the U.S. environment is unpredictable or deemed too risky, it may lead companies to consider investments in other disease areas or geographic regions outside the U.S. Ultimately, this reduces the U.S. leadership in clinical research, limits U.S. patient access to biopharmaceutical innovations, and weakens our domestic preparedness for future infectious disease threats.

The Honorable Jake Auchincloss (D-MA)

1. I am concerned that the staff at FDA have been eviscerated and demoralized. Last year, there were reports that the Administration laid off 3,500 employees from across the agency. We still cannot get answers on where these staff were taken from, how many may have been brought back, or how many may be conflicted out of their jobs in reviewing product application because they are rightfully fed up with how they have been treated by the Administration and have decided to leave the agency. What we do know is that data from FDA, which we only have because it is mandated by statute that they report it, posted on their website shows that the drug and biologics centers continued to lose staff through the first quarter of FY 2026. Part of the user fees that FDA and industry negotiate and that Congress has authorized are designated to go toward hiring efforts. To me it looks like they are having trouble doing that because of the turmoil under this administration.
a. What happens if FDA isn't able to maintain agreed-upon staffing levels?

We are encouraged by the Commissioner's recent statements signaling the hiring of 1,000 staff. Like any organization that experiences resource gaps, FDA will need to assess its overall capabilities, and we would encourage a focus on ensuring core review activities are prioritized. BIO has over 1,000 members with significant biotechnology drug development expertise and we

welcome an opportunity to further partner with the agency in moving American innovation forward. BIO and its members are fundamental to the PDUFA program which supports a strong FDA and enables American innovation.

2. Former FDA leaders have stated that the qualifications and types of people that have left the agency will have "a profound effect as we talk about novel endpoints and other issues of emerging science." We have already heard that some biotech companies don't see FDA as the gold standard because of the inconsistencies in their regulatory decisions and lack of predictability in their reviews. Your organization released a statement in December when Dr. Pazdur retired saying that his "departure raises serious concerns about the repeated turnover in key leadership occurring at the FDA. "You said that this constant turmoil is undermining America's leadership in biotechnology, creating unprecedented regulatory instability and unpredictability, and risks ceding this critical sector to China." You are clearly concerned about the loss of this expertise.
a. Can you tell us what happens to drug applications that your member companies have before FDA when they agency loses their regulatory expertise and waiver in their decision-making?

Late last year we were very concerned about FDA leadership departure and staff turnover. We have raised these concerns with FDA and are working toward understanding issues experienced by our member companies. To this end, we have introduced the "BIO Regulatory information Data Gathering and Engagement (BRIDGE) portal". BIO intends to track this information and engage with FDA as needed. BIO continues to encourage clear and timely communication between sponsors and the Agency to enable a predictable, consistent, and transparent and science-based decision which is essential for maintaining U.S. innovation and global leadership.