Written Testimony of
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Chairman Griffith, Chairman Guthrie, Ranking Member DeGette, Ranking Member Pallone, and distinguished members of the subcommittee, thank you for the opportunity to appear before you today on behalf of the Biotechnology Innovation Organization (BIO), the country's premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations.

Fifty years ago, a small company called Genentech started the biotechnology revolution. What was planned as a 10-minute meeting between an entrepreneur and a biochemist turned into a three-hour gathering that changed the world. These two men, Herb Boyer and Bob Swanson, believed in a new DNA technology that now – five decades later – has saved millions of people worldwide and transformed how we treat patients for some of the most difficult diseases.

Biotechnology has turned death sentences into curable illness. Lives of pain and confinement into those of freedom and joy. And it has brought newfound hope to patients with the promise of happier, healthier times. The industry is filled with people who believe deeply in what we do. Many have personal stories that tie them to this work. They are in this field because they want to improve people's lives and make the world a better place.

I am one of them. Twenty-five years ago, my two youngest children, Megan and Patrick, were diagnosed with Pompe disease, a rare and fatal neuromuscular disorder. At the time, there was no treatment — no hope beyond comfort care. I left my job, went back to graduate school, and eventually helped start a small biotech company dedicated to developing an enzyme replacement therapy. That therapy — born from the ingenuity and perseverance of American scientists and approved by the FDA — gave my children a chance at life. Today, Megan and Patrick are living full, meaningful lives.

That experience taught me two things I will never forget: first, that access to groundbreaking medical innovation can save lives, and second, our health care system is complex, and that each piece must work well to best serve patients.

When I speak today about America's biotechnology ecosystem and health care system, I speak not only as a CEO, but as a father who owes everything to innovation and the people who make it possible. I also speak as someone who wants to ensure that the next 50 years are promising and productive for the patients relying on affordable access to the next generation of medical advances.

The Current Landscape

Today, the biotechnology sector generates over $3 trillion in annual economic output, employs nearly 2.3 million Americans, and supports 8 million additional jobs across the country. At the heart of this

economic strength is a uniquely American innovation-driven ecosystem: approximately 76% of all new medicines originate in small, start-up biotech companies.

These emerging companies often partner with bigger companies that have the manufacturing, regulatory, and commercialization capabilities needed to move experimental medicines from the lab to the pharmacy. This sort of collaboration -- between federal agencies, universities, and biotech startups, and between small firms and larger ones -- drives medical progress and economic growth, and it is why the United States continues to lead the world in medical innovation.

This leadership is national in scope. While hubs like Boston, San Francisco, New Jersey, and the Research Triangle are widely recognized, the biotech sector is thriving in many regions of the U.S. – from the fast-growing biosciences industries in Texas and Ohio to research hubs in Missouri, Connecticut, and Arkansas. Building on this broad geographic footprint is essential to maintaining American leadership in life sciences.

Yet the pathway from scientific discovery to approved therapy is long and uncertain. Just 10% of biotech R&D will ultimately lead to a new approved therapy. If successful, the journey can still take an average of 10–15 years and cost more than $2.6 billion. Investors will only fund this work if developers can rely on a predictable environment that includes strong intellectual property (IP) protections, clear regulatory pathways, and a market-based system for determining the value of innovative medicines.

A National Security Imperative

This challenge is compounded by growing global competition. Maintaining America's leadership in biotechnology is a national security imperative, particularly in the face of aggressive efforts by China to systematically expand and consolidate its biotech footprint. China is no longer merely copying American biomedical innovations; it is making deliberate, large-scale, and long-term strategic investments aimed at becoming the global leader in the discovery and development of innovative medicines.

The bipartisan National Security Commission on Emerging Biotechnology (NSCEB) has warned that China is rapidly closing the innovation gap with the United States. In a recent survey by TD Cowen—an investment partner for many biotech startups—more than half of survey respondents expect China to surpass the United States in medicine development within six years. This is an alarm bell. We are in danger of ceding our competitive advantage to China.

As in semiconductors, China recognizes the value of global leadership in biopharmaceuticals and is taking steps to be the dominant player in this space, including funding innovation hubs, leveraging advanced AI in drug discovery, and streamlining clinical trials and regulatory approvals. At the same time, the Chinese Communist Party's regime is exerting greater control over pharmaceutical supply chains, data flows, and intellectual property. These actions threaten not only U.S. competitiveness, but also the long-term health security of American patients and that of our allies.

To confront these threats, secure America's biotech future, and build a more affordable and accessible American health care system, we must take proactive, strategic action. We must continue to find ways to strengthen the FDA's regulatory process, spur innovation through Congressional action, avoid policies that weaken the innovation ecosystem, and – critically – embrace actions that will reduce costs and improve both affordability and outcomes for Americans.

FDA Predictability and Efficiency

Let's start with the U.S. Food and Drug Administration (FDA). The U.S. biotechnology ecosystem depends on the FDA as the global gold standard. The FDA's approval of a medicine represents years of hard work by company leaders, scientists, researchers, regulators, and patients. When the FDA's processes are predictable, science-driven, and transparent, patients benefit first. If we are to keep pace with global innovation, the FDA must continue to evolve — embracing its role as both gatekeeper and catalyst for biomedical progress. I commend the Committee for its efforts in recently enacting the reauthorization of the Rare Pediatric Disease Priority Review Voucher Program in the *Consolidated Appropriations Act of 2026,* which provides stability and confidence for biotech innovators who are leading the way in the discovery of breakthrough treatments for children with rare diseases.

Today, the FDA stands at an inflection point. Amid rapid scientific and technological change, the Agency has an extraordinary opportunity to harness expertise and modernize its policies and operations to meet the needs of 21st-century innovation. While I applaud Commissioner Makary and his leadership team for thinking innovatively about regulatory reform, if we want to increase patient access and lower health care costs, we need a renewed commitment to an efficient, predictable, and transparent regulatory review process. To achieve this, the FDA needs to be appropriately staffed with well-trained subject matter experts and maintain a healthy culture focused on relentlessly delivering innovation to patients. Anything less will mean fewer novel medicines make it through the pipeline, while also driving up the costs for those that do – and those that don't.

If we want to lower health care costs, we need an FDA that is running smoothly and removing unnecessary barriers. I think we can get there, while keeping the best parts of the recent changes. At the same time, we need to maintain strong oversight from Congress. To ensure that the FDA can continue to lead the world, BIO respectfully offers three overarching policy strategies:

- **Reduce the Time, Cost and Complexity of Early Drug Development.** Processes for opening clinical sites and preparing IND submissions are costly, duplicative, and inconsistent. Standardizing expectations and applying risk-based flexibility will lower barriers in the US without compromising patient safety.

- **Strengthen the FDA's Regulatory Review: Predictability and Efficiency.** Predictable processes, along with frequent and consistent communication are essential to innovation. By improving first-cycle success rates, advancing modern trial methodologies, and reducing inspectional bottlenecks, the FDA can help maintain the United States' status as the preferred market for global clinical development.

- **Support New Models for Ensuring Access to Necessary Expertise.** Innovation moves quickly, and no single entity — not even the FDA — can maintain expertise across every emerging field, especially after reducing its workforce by 20%. HHS, FDA, and Congress need to creatively consider hiring the necessary expertise into the FDA and engaging the broader ecosystem in a sustained manner to help the Agency keep pace with scientific advances and apply policy consistently.

<u>The Danger of Most-Favored Nation Pricing</u>

It is also important to avoid government adoption of policies like Most-Favored Nation (MFN). Tying prices in the United States to the prices set by foreign governments with socialized health care systems

undermines everything that makes America's innovation ecosystem exceptional while failing to address the real drivers of affordability for patients in our country.

BIO strongly opposes codifying MFN, whether through legislation or mandatory demonstrations, because these approaches would jeopardize patient access to next-generation medicines without delivering meaningful savings for patients. It does not make medicines more affordable for U.S. patients, does not encourage foreign countries to pay their fair share, and would constrain American biotech firms from investing in research, growth, and jobs.

These policies would discourage investment, disincentivize new research and development in the United States, and as a result, weaken U.S. leadership in biotech. This opens the door for adversarial nations such as China to accelerate their own biomedical ambitions. The impact of MFN would be especially harmful to small and midsize biotech companies, which are responsible for discovering more than 50% of all new FDA-approved treatments, employ more than 70% of the American biotech workforce, and are involved in nearly 75% of American clinical trials. Despite this, more than a third of these companies operate with less than a year of cash, have on average just one or two commercially available medicines, and are reliant on investor funding. Simply put: MFN would inflict great harm on these innovators while allowing foreign governments, including China, to benefit.

The President is right to leverage trade negotiations to level the playing field for American innovators. The recent trade deal with the United Kingdom, which requires them to pay a greater share of the costs of American innovation in exchange for tariff protection, is exactly what is needed to protect the innovation pipeline without threatening American patients seeking medical treatments or the very biotech industry striving to bring these treatments to market.

At home, policymakers should address the real cost barriers that directly affect patients at the pharmacy counter. We can lower patient costs without decimating American medical innovation and threatening access to new medicines.

<u>There is a better way: simplify the system and cut hidden supply chain costs.</u>

The most sensible and patient-centric approach starts with simplifying a healthcare system burdened by the abusive practices of middlemen, insurers, and tax-exempt hospitals. Standing between patients and their medicines is a messy, bureaucratic delivery system that distorts and inflates the cost of medicines paid by consumers. Due to years of consolidation and vertical integration, just a handful of powerful entities control the medicines patients get can, where they can get them and how much they must pay out of pocket. Just three companies control 80% of all prescriptions sold in the United States, eroding market competition and patient choice.

The system is broken, and it needs to be simplified if we want to make meaningful progress toward reducing costs and increasing access.

First, the U.S. is the only country in the world where 50 cents of every dollar spent on medicine goes to middlemen, most notably Pharmacy Benefit Managers (PBMs). PBMs and insurers generally pocket these dollars and negotiated savings rather than pass them on to patients at the pharmacy counter. On behalf of BIO, we thank you for passing PBM reform in last week's appropriations package, but there's more to be done.

Second, in the United States, hospitals account for the largest share of health spending, over three times higher than prescription drugs, yet patients pay more out of pocket for medicines than for hospital costs due to how insurance companies engineer the benefit designs. Shining light on these complex schemes will allow Americans to understand exactly where their dollars are going, and to whom.

And third, wealthy hospital systems regularly mark up the price of medicines, especially cancer drugs, to boost profits. In some cases, hospitals will charge six or seven times more than what they paid for a medicine. These markups occur despite many nonprofit providers receiving medicines at substantial discounts under the 340B program, which diverts more than $80 billion into hospital coffers, raising premiums and other costs for patients, employers, and taxpayers. The program is overdue for reforms that infuse greater transparency and true accountability.

A Roadmap for 21st Century Access

There is no medical reason for limiting patient access to clinically appropriate, physician-prescribed medicines. BIO and our members are committed to seeing that no person ever goes a day without the medicines they need. The greatest obstacles patients face are insurance company policies designed to throw up financial barriers for patients and systemic or paperwork barriers for clinicians. Dismantling these barriers is at the core of what we call a 21st Century Access and Affordability initiative. It is modeled after the outstanding work that this committee did on 21st Century Cures.

Barrier One: Economic Barriers for Patients

When patients think or discuss "drug prices," they think in terms of their out-of-pocket costs, such as co-pays, deductibles, and coinsurance. These are not the price of their medicines. They are what patients pay. All these variables are controlled by health insurance companies and their associated PBMs, which use financial barriers to prevent patients from getting the care they need.

The data are clear. When insurers and PBMs make medicines unaffordable—either because of high deductibles or expanding coinsurance—patients are less likely to take their medicine as prescribed by their doctor. This creates not only greater health risks for individuals, but also situations where patients are more likely to need more expensive health care services. That is not a recipe for an efficient and affordable healthcare system.

By removing these barriers and holding insurers accountable to uphold their responsibility for providing care to Americans at a reasonable cost, we can show that we trust patients and physicians, and that excessive cost-sharing creates individual financial hardship, worse health outcomes and greater national health care spending.

Policy Solutions for this barrier include:

- **Out-of-Pocket Costs Cap.** Congress should create a new prescription drug out-of-pocket spending cap for patients in private health plans, coupled with the ability for patients to spread their costs evenly throughout the year. This is now the standard in Medicare Part D—providing millions of seniors with lower costs and more predictability, and it is a policy achievement that has received bipartisan support.

- **Ensuring Copay Assistance Counts Toward Spending Cap.** As part of an effort to create an out-of-pocket spending cap in the commercial market, Congress must also pass the *HELP Copays Act*, H.R. 6423, to ensure that copay assistance from drug manufacturers counts toward patients' out-of-pocket costs. As deductibles, coinsurance and other cost-sharing requirements have risen sharply in recent years, copay assistance has helped fill gaps in private insurance. However, insurers and PBMs often refuse to count copay assistance toward patients' out-of-pocket expenses—forcing people to pay higher costs. To maximize relief for patients, any out-of-pocket limit in the commercial market must prohibit insurers and PBMs from circumventing the cap and shifting more costs onto patients.

- **Addressing PBM's Anticompetitive Practices.** PBMs play a central role in determining what medicines patients have access to and what they pay out of pocket. Investigations by Congress, the Federal Trade Commission and other experts have warned that PBMs engage in business practices that make medicines unaffordable. For example, they collect tens of billions of dollars in rebates and other discounts, yet these savings are often not shared directly with patients. PBMs also charge fees tied to the list price of medicines, which means PBMs are more profitable when the price of medicine is higher.

  These tactics have eroded competition in the market and increased the cost of innovative medicines. To lower drug costs for patients, Congress should go further to delink PBM fees from drug prices by passing legislation such as the *DRUG Act*, H.R. 2214. Policymakers should also require that any savings PBMs negotiate be passed through to patients at the pharmacy, as outlined in the *Pharmacists Fight Back Act*, H.R. 6609. Members on both sides of the aisle have expressed strong interest in these proposals. The transparency measures enacted from the *PBM Reform Act* in last week's *Consolidated Appropriations Act of 2026* were a bold first step. Additional reforms would help restore competition in the market and deliver meaningful relief for the American people.

- **Expansion of First-Dollar Coverage, and Predictable Cost Sharing for Medicines**. Pharmacy deductibles serve no purpose for people with chronic diseases, and high upfront costs force many patients to delay or abandon treatment early in the year. There should be no beginning-of-the-year financial burdens placed on patients. Further, plans should offer flat copays over coinsurance to help make out-of-pocket costs more predictable. These reforms would help ensure patients can start and stay on their prescribed treatments without delay, improving adherence and preventing avoidable health complications that drive up health care costs**.**

- **Ban Accumulators, Maximizers, and "Alternative Funding Programs" (AFPs).** Plans and PBMs employ a variety of tactics that prevent patients in private coverage from benefiting from assistance offered by manufacturers. These tactics include not counting patient assistance toward out-of-pocket limits or carving out certain medicines from insurance coverage. These tactics must be banned so that patients benefit, not PBMs.

- **Copay Assistance for Medicare Patients.** Today, approximately 10 million Americans benefit from some form of patient assistance or copay support programs. These programs are now a vital lifeline in an insurance system that often discriminates against people who need medicines through high deductibles, coinsurance and other cost-sharing requirements. Outdated federal

rules, however, prohibit Medicare beneficiaries from receiving copay assistance. Reasonable guardrails should be put in place that maintain the spirit and integrity of federal anti-kickback rules, while also ensuring Medicare beneficiaries get the assistance they need.

Barrier Two: Systemic and Paperwork Barriers for Clinicians

Health insurance companies also create systemic barriers designed to slow the provision of care and influence how clinicians practice medicine. These policies, known collectively as utilization management, substitute the judgment of the payer for the counsel of a patient's care team.

Utilization management can include onerous prior authorization requests in which needless paperwork is created for physicians and their staff. Such requirements not only keep patients from getting medicine in a timely fashion but also make the practice of medicine less efficient and more expensive by taking physicians away from the patient.

Utilization management also encompasses what's known as fail first policies in which certain medicines prescribed by physicians will not be covered by insurance until a patient documents negative side effects or a lack of efficacy stemming from a treatment preferred by insurers—running roughshod over physicians' experience and clinical judgment.

Unfortunately, utilization management barriers has become the norm, not the exception – and that must change.

Policy solutions for this barrier include:

- **Prior Authorization Reform**. Efforts at both the federal and state levels should enshrine the presumption that care prescribed by a provider is medically necessary. Bills such as the *Improving Seniors' Timely Access to Care Act*, H.R. 3514, would accomplish this goal.
- **Step Therapy Ban for Certain Life-Threatening Diseases**. Addressing abusive step therapy ("fail first") policies in public and private coverage should be prohibited for certain groups of vulnerable patients, including those with rare diseases and chronic conditions. Legislation such as the *SAFE Step Act*, H.R. 5509, would go a long way towards addressing these burdensome practices that impede patient access to care.
- **Step Therapy Safeguards for All Patients**. New guardrails must be put in place to ensure that utilization management requirements and step therapy are only used when consistent with FDA labeling and best practices. And, once a patient has undergone step therapy, they should not be required to do it again nor should they have to do so when they change coverage.

Our Commitment: Medicines that meet the moment

Biopharmaceutical developers have a responsibility when it comes to ensuring access, too. It starts with creating medicines that tackle clear unmet needs or introduce competition and choice in established markets. It also means pricing innovation according to the value it delivers to patients, the health system, and society. We have made good on that promise since the start of the biotechnology revolution, and we continue to find new ways to keep that promise.

Companies are continuing to innovate not just when it comes to developing medicines, but also in how we can improve the patient experience and access to these treatments, at a lower cost. While these are

important steps that will make a meaningful difference in the lives of patients, these efforts alone cannot fix structural problems in American health care that are making life-changing medicines increasingly unavailable and unaffordable.

When value and clinical impact can be delivered to the bedside, there is a moral obligation for the health care system to provide that care. I've seen what happens when the system works well. It's a rare disease patient sitting up after receiving a novel therapy. It's a cystic fibrosis patient breathing free for the first time in years. But above all, it's a health care system that engenders trust, faith, and optimism from American families and our broader society.

When the biotechnology industry started 50 years ago, our nascent industry needed to show the power of our advances – and we ultimately did. Society and our health care system adapted and opened their arms to new possibilities. It didn't happen overnight, but despite diversions, our path leads forward and the horizon is bright.

Yet science operates within a society that must believe in it, accept it, and help advance it for the betterment of mankind. The men and women who work at America's biotech startups—including many of your own constituents—take seriously the responsibility to advance life-changing breakthroughs. Now, we need a health care system that is equally serious about efficiently getting cures and therapies to people in need.

If we act and embrace true systematic reform, we'll look back at this time in another 50 years as the moment when this nation and its leaders stepped forward to do the hard work required to untangle our health care system, put patients' interests first, and create new hope and a better future for the American people.

There is not a moment to lose. Lives depend on it. Thank you for your leadership and commitment to this critical mission. I look forward to your questions.

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