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Committee on Ways and Means
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Chairman Smith, Ranking Member Neal, Congressman Moore, and Members of the Committee, thank you for the opportunity to testify today. I am honored to share my perspectives as President and CEO of Arcutis Biotherapeutics, a biopharmaceutical company based in California.

About Arcutis Biotherapeutics, Inc.

Arcutis Biotherapeutics, Inc. is a young medical dermatology company dedicated to developing meaningful innovations to solve the most persistent challenges facing patients with immune-mediated dermatological diseases. Our unique dermatology expertise and our dermatology development platform drive our innovation, with a focus on unmet needs in the treatment of immune-mediated skin diseases such as plaque psoriasis, atopic dermatitis, and seborrheic dermatitis. In addition to my capacity as CEO of Arcutis Biotherapeutics, I also serve on the Board of Directors of the Biotechnology Innovation Organization (BIO). My comments below are not unique to Arcutis and broadly reflect the views of hundreds of innovative U.S. biopharmaceutical companies.

Arcutis was founded in 2016, and we raised three rounds of private financing prior to going public in January 2020 on the NASDAQ exchange (ARQT). Arcutis was created out of a recognition that innovation in the medical dermatology space had atrophied, forcing many patients to rely on outdated and suboptimal treatments. We have focused our efforts on developing novel treatments for immune-mediated dermatological diseases and conditions, including plaque psoriasis, atopic dermatitis, seborrheic dermatitis, and scalp psoriasis. We received our first FDA approval in July 2022, and have received FDA approval for two additional treatments since (the third earlier this week), in addition to continuing to invest in an innovative portfolio of drug candidates.

Our three FDA-approved products are all different versions of topical medications for the treatment of plaque psoriasis, seborrheic dermatitis, and atopic dermatitis. All contain an ingredient called "roflumilast" that inhibits a key enzyme inside of cells in the body, and the inhibition of that enzyme reduces the inflammation and itching associated with all three of those conditions. Our products differ from preexisting topical anti-inflammatory drugs in their unique combination of high efficacy, low side effects, and the ability to be used anywhere on the body for any duration. This profile means that clinicians and patients do not have to make trade-offs between efficacy and safety, as is often the case with older therapies. We have also formulated our products to be cosmetically pleasing to patients, which aids in compliance to treatment. Our products are covered by most commercial insurance plans in the US and by Medicaid in several states, and we are currently negotiating Medicaid coverage in the remaining states along with Medicare Part D coverage.

Since our founding, we have grown from 3 employees to nearly 350 staff today, with operations in all 50 states and employees in 39 states. Our team has deep medical dermatology expertise, and our executive team includes leaders who have worked on more than 50 FDA-approved products, and we are proud to have 3 dermatologists and 8 dermatology clinicians on staff. Our headquarters are in Westlake Village, California, we manufacture our products in San Antonio, Texas, and we have a small office near here in Park City, Utah.

Innovation in The U.S. Biopharmaceutical Sector

The U.S.-based biopharmaceutical sector plays a vital role in improving public health in the United States and around the world. We develop breakthrough products and treatments that give individuals suffering from medical conditions the ability to live fuller, healthier lives and give hope to those still waiting for a cure. The biotech industry contributes to the strength of the U.S. economy and is a key element of our national security. From research to manufacturing to commercialization, we generate high-paying jobs in a wide variety of fields.

Biotech innovation, however, is a highly risky and costly endeavor. It relies on a delicate ecosystem that has delivered revolutionary medical breakthroughs over the past half century. Disruptions to this ecosystem have the potential to significantly reduce investment flows into the biopharmaceutical sector, resulting in fewer innovations for patients and a diminished economic footprint in the United States.

We all agree that a strong biotech industry is critical for U.S. economic growth and national security, and it is an imperative that the U.S. maintains our role as the undisputed world leader in this field. But our current leadership in biotech can't be taken for granted. While today the US is the source of two-thirds of innovative drugs worldwide, as recently as the late 1970s, Europe developed twice as many innovative drugs as America, until ruinous government policies across the Atlantic destroyed a once vibrant European industry. Foreign adversaries recognize the value of robust life sciences within their borders and are committed to establishing their own global leadership. They look at U.S. policies that impact the sector closely. If we do not maintain the appropriate balance of incentives, we risk weakening our influence on the future of healthcare, biopharmaceutical innovation, and biopharmaceutical manufacturing throughout the world.

I appreciate the opportunity to share how the biotech industry will continue to excel if we have clear regulatory frameworks, robust legal protections, creative tax incentives, and a motivated workforce. Patients in America and around the world depend on us.

Biopharmaceutical Innovation: Transforming Lives, Giving Hope, and Driving Economic Prosperity in America

Transforming Lives and Giving Hope

Biopharmaceutical innovations transform the way we treat patients, improve health outcomes, and give hope to individuals who suffer from medical conditions. When we gain deeper understandings of disease pathways, we can develop increasingly targeted treatments with improved efficacy and safety. When we transform the pipeline of new therapies, we can profoundly improve quality of life

around the world. We can revolutionize medicine by delivering cures for once incurable diseases. In the last quarter century, American life expectancy has continued its steady increase upwards, with roughly one-third of that improvement directly attributable to biopharmaceutical innovations.[1] For example, the American Cancer Society estimates that cancer death rates in the United States declined by one-third since 1991, saving 3.8 million Americans from death, and much of that improvement is due to better cancer treatments.[2] Biopharmaceutical innovation also gives hope to the over 90 percent of rare disease patients who are still waiting for treatments tailored to address their medical condition.

Driving Economic Prosperity and Biotech's Relationship to National Security

Biopharmaceutical companies not only make incredible contributions to humankind through their scientific research efforts but also contribute to economic growth in the United States. One of the hallmarks of the American biotech sector is its embodiment of the quintessentially American entrepreneurial spirit. U.S.-based SME biotech firms are a critical innovation force in the biomedical industry. These life sciences start-ups and emerging biotech companies create inclusive and high-paying jobs for American workers and are responsible for over 73% of the global pipeline of new drugs in development and 85% of all orphan-designated products in development.[3]

Collectively, the innovative U.S. biotech sector includes early-stage startup biotech firms, pre-commercial SMEs, emerging commercial-stage firms like my own, and larger multinational biotechnology companies that directly employ 2.14 million people across more than 127,000 U.S. business establishments. The industry has grown its employment base by 11% since 2018, while the overall economy shed 1.5% of its jobs base due to steep job losses experienced during the initial pandemic wave and economic shutdowns of 2020.[4] Average wages have also been growing and the sector stands out as a major job generator among knowledge- and technology-driven sectors for the U.S. economy. Our sector's economic impact on the U.S. economy totaled $2.9 trillion dollars in 2021, as measured by overall output.[5]

In 2020, the U.S. also had over 1,500 facilities across the country manufacturing FDA-approved human-use products under Good Manufacturing Practice (GMP) regulations, a gold-standard level of manufacturing not required in most other countries.[6] These biopharmaceutical manufacturing operations span across 47 States, the District of Columbia, and Puerto Rico.[7] There are currently 40 States that have five or more manufacturing facilities producing FDA-approved medicines; New Jersey, California, and Pennsylvania have 180, 174, and 104 registered manufacturing facilities, respectively.[8]

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[1] *Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015,* Jason D Buxbaum et al, Health Aff, 2020 Sep;39(9):1546-1556; doi: 10.1377/hlthaff.2020.00284

[2] *Cancer Statistics 2023,* Rebecca Siegal et al, CA, https://doi.org/10.3322/caac.21763

[3] *2019 Emerging Therapeutic Company Trend Report*, David Thomas and Chad Wessel. BIO Industry Analysis. 2019.

[4] *The Bioscience Economy: Propelling Life Saving Treatments, Supporting State and Local Communities 2020*, TEConomy/BIO, https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life

[5] *Id*

[6] The Economic Impact of the U.S. Biopharmaceutical Industry:. (2022). TEConomy, PhRMA. https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf

[7] *Id*

[8] *Id*

The U.S. biopharmaceutical industry generated more than $131 billion in employee income in 2020, averaging more than $145,000 in annual compensation per worker, which is directly invested back into the U.S. economy.[9] The U.S. biopharmaceutical manufacturing industry has a significantly higher-than-average productivity measure, exceeding $380,000 in value added per worker per year (compared to a $163,000 for other non-pharmaceutical U.S. manufacturing jobs).[10] For every one biopharmaceutical job, the industry supports an additional 3.92 jobs in the U.S. economy.[11] In total, the biopharmaceutical industry provided $359 billion in wages and benefits to Americans in 2020.[12] It is also important to note that many of these manufacturing jobs do not require a college degree.

There have been years in which the biotechnology industry has contributed more than $400 billion into the domestic economy, equal to over two percent of the U.S. gross domestic product (GDP).[13] There have been other studies which estimate the biotechnology industry contributes between 5-7% of the U.S. GDP.[14] In terms of scale, the size of the U.S. biotechnology industry is approximately equal to the worldwide semiconductor industry.[15]

Biopharmaceuticals and U.S. National Security

The strength of the U.S. biopharmaceutical industry contributes both directly and indirectly to U.S. national security. It contributes to the economic prosperity that is the foundation of our national power. The vibrancy and productivity of the biopharmaceutical sector is a testament to our market-based economic model, and stands in stark contrast to the command economies of our adversaries. Our contributions to improving health worldwide enhances our "soft" diplomatic power globally. Biopharmaceutical innovation also plays a key role in ensuring the health of US servicemen and women. For instance, consider the implications, if the US military were forced to rely on foreign-developed vaccines or treatments in some future pandemic. And it is vital that the U.S. remain at the cutting edge of emerging technologies like synthetic biology and gene editing, to ensure that we have the ability to defend against the malign use of such technologies by our adversaries.

Promoting the strength and resiliency of the U.S. biopharmaceutical sector and harnessing the innovative potential of the American private sector should be a cornerstone of our government's public health, economic and national security policy.

Maintaining U.S. Leadership in the Life Sciences

Maintaining U.S. leadership in biopharmaceutical innovation depends on a carefully balanced legal, regulatory and economic ecosystem that preserves strong incentives to innovate and to drive science forward despite the risks for failure. A domestic policy environment that does not robustly support the U.S. biopharmaceutical sector would consequently impact the health and resilience of the U.S. economy and U.S. national security.

Without proper attention to the domestic environment for biotech innovation, we will lose ground to other countries, and most troublingly, to our economic adversaries. A strong domestic biotech

[9] *Id*
[10] *Id*
[11] *Id*
[12] *Id*
[13] Carlson, R., Sbragia C., & Sixt, K (2021). Beyond Biological Defense: Maintaining The U.S. Biotechnology Advantage. https://warontherocks.com/2021/09/beyond-biological-defense-maintaining-the-u-s-biotechnology-advantage/
[14] *Id*
[15] *Id*

industry is essential for our national security, but the robust biotech ecosystem in the United States is at risk both from recent overt policy choices and through long term neglect of the critical elements necessary for the domestic industry to grow and thrive. We have seen what can happen in other critical industries like semiconductors, when neglect or misguided policies causes the U.S. to lose our leadership position, which necessitated a substantial investment via the CHIPs and Science Act to help restore the atrophied U.S. semiconductor industry. It is my hope that we learn from this experience and continue to create the right domestic environment to foster innovation and maintain U.S. leadership in the biotech industry, thereby avoiding a future need to rebuild what we have lost.

To ensure this, we need a predictable regulatory process to bring cures to patients safely and quickly. Patients also need efficient markets without unnecessary barriers to access once new drugs are approved. The industry needs supportive legal regimes that protect our intellectual property and allow productive merger activity so that promising products do not wither on the vine. We also need to invest in robust domestic biomanufacturing capabilities and a skilled workforce across the country to make the next generation of life-saving and life-improving treatments here at home. Finally, biotech entrepreneurs need sufficient access to capital to see treatments through the lengthy, expensive, and risky journey through the development process. All too often, promising technology fails to move forward simply due to a lack of funding.

Ultimately, the unchecked deterioration of the ecosystem that supports biopharmaceutical innovation has significant short-, medium-, and long-term implications for the broader U.S. private sector and, consequently, for our nation's economic interests and leadership in the life sciences.

Preserving Incentives to Innovation and Ensuring Access to Biomedical Breakthroughs

Ensuring Access to Biomedical Breakthroughs

Biotech companies ultimately exist to help people living with disease, and as such we are committed to championing broad access to transformative and disruptive therapies so that all patients can benefit from the achievements of modern biotechnology. Policies that myopically focus all of the scrutiny on the biopharmaceutical innovators are doing a disservice to addressing the genuine barriers that affect Americans' access to cutting-edge biotechnology innovations.

A significant factor in the high and ever increasing cost of innovative therapies in the United States is the proliferation and growing power of "middle men" who extract substantial economic value from the biopharmaceutical sector. These middle men … including insurers, pharmacy benefits managers (PBMs) and their group purchasing organizations, as well as distributors and others in the supply chain … are in most cases pocketing more than half of what is paid for treatments. For example, my company currently only realizes about 40 cents of every dollar paid for our treatments, with the remainder going to intermediaries between us and the patients we serve.

The market structure for PBM services has evolved haphazardly, without adequate consideration of the full consequences of its framework and marketplace consolidation. The three largest PBMs currently control 80% of the PBM market, and when combined with the three next largest, that figure raises to almost 96%. This gives them immense power to set prices, control access to treatment, deny coverage and generate corporate profits. Drug manufacturers must negotiate with PBMs for formulary status so that patients prescribed their medication will be able to access them.

The rising concentration of pricing power by PBMs is a fundamental factor in the increasing cost sharing paid by patients. The fixation on discounts in the form of rebates paid to PBM or insurer has also led to practices that may hamper competition in certain therapeutic categories by preferring products that generate the highest rebate for payors, not necessarily those products that are more clinically appropriate or less expensive for the patient.

As the PBM industry becomes more concentrated, they are also merging with insurers. This trend bears the close attention of consumers, law makers and regulators. When a health insurer merges with a PBM, the overall incentives of the merged organization may change. As the PBM operations and strategy hold sway in the new entity, insurers direct patients toward biopharmaceutical treatments that generate the highest profit margins and the largest rebates. Patients then pay more for drugs and health insurance premiums and receive less efficacious medical treatments. A PBMs' pursuit of rebates could also spill over into other areas of care, including specialty pharmaceutical products and cancer therapies. Consequently, these powerful conglomerates effectively control pharmaceutical innovation and direct patients toward treatments that offer higher PBM/insurer profit margins rather than higher value care.

Insurers' and PBM's control over which drugs are reimbursed, and under what conditions, has also allowed them to exert significant power over physicians' ability to choose the right treatment for their patients. The proliferation of so-called "utilization management" criteria like prior authorizations and step edits has substantially restricted doctors' freedom to tailor individual treatment plans for their patients. In many cases, these UM criteria require physicians to use older and often less effective or less safe medications, sometimes even for uses that are not FDA approved, or steer physicians to use costlier medications that are more financially advantageous for the insurer or PBM. Recent efforts in Congress such as the Lower Costs, More Transparency Act (HR5378) and similar legislation in the Senate are important positive steps in the right direction of reforming our dysfunctional drug reimbursement system.

Another major barrier to Americans' access to innovative therapies is patient out-of-pocket costs. While the IRA included a new $2,000 out-of-pocket cap in Medicare, this does nothing to help the hundreds of millions of Americans covered by commercial insurance. Insurers and PBMs continue to increase patient out-of-pocket costs through higher patient copays for prescriptions, the expansion of high deductible plans, and increased use of patient "co-insurance", where patients are required to pay a percentage of a prescription's costs instead of a flat copay. As a result, patients may struggle to afford and adhere to their medications as insurers and PBMs seek to shift more cost-sharing responsibility to patients.

A recent investigation – which included interviews with more than 300 current and former PBM employees as well patients, physicians and pharmacists, found "…the largest P.B.M.s often act in their own financial interests, at the expense of their clients and patients."[16] Congress should move forward with PBM reforms that rein in these shadowy tactics that fly in the face of physician expertise, hurt patient access to needed therapies, and drive up overall health care system costs. To that end, Congress should pass the bipartisan Help Ensure Lower Patient (HELP) Copays Act that, among other things, would require copay assistance to count toward a plan's cost sharing requirements.

[16] https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html

One special area that warrants urgent action is the need to protect patient access to orphan drugs that treat rare diseases. While the IRA exempts some orphan drugs from Medicare price negotiations, this exemption only applies to drugs approved to treat a single rare disease. This policy fails to recognize how orphan drug development occurs today. Orphan drugs initially developed and approved for one condition often prove effective against other rare diseases following additional clinical testing. But the IRA disincentivizes researchers and investors from pursuing such costly follow-on research to find new orphan designations and approvals because, if their efforts prove successful, the drug would no longer be exempt from government price controls. Incentives for orphan drug development should be structured to maximize the potential clinical benefit of each new medication, ensuring that patients with rare diseases have the broadest possible access to effective treatments. The bipartisan, bicameral Optimizing Research Progress Hope and New Cures (ORPHAN Cures) Act would fix this harmful flaw in the IRA and help clear the way for ongoing research and investment into finding new treatments for patients who suffer from rare diseases.

Preserving Incentives to Innovate

Developing drugs is extraordinarily risky. Approximately 9 out of 10 new drugs that enter clinical trials ultimately fail.[17] This high failure rate contributes to the high costs of the small percentage of new medicines that successfully complete development. Still, our current system has been remarkably effective at producing life-saving medicines and the price of medications comes down over time as drugs go off-patent and generics enter the market. This carefully balanced system has led to dramatic improvements in health and life expectancy, and has made the United States the world leader in drug development.

Unfortunately, policymakers continue to pursue policies that will curtail incentives for drug development across all disease areas. The Inflation Reduction Act (IRA) gave Washington bureaucrats the power to "negotiate" prices for drugs covered by Medicare. But these will be negotiations in name only. Drugmakers who don't comply with this price setting process face crippling penalties. By imposing arbitrary price caps, the government will prevent firms from investing in future innovation. A 2021 study found that price controls would lead to 135 fewer drugs being developed through 2039.[18]

Lawmakers provided newly approved medications a period of exemption from the IRA's price controls. In doing so, they divided drugs into two categories: "biologics" and "small molecules". Biologics received 13 years of exemption following FDA approval while "small-molecule" drugs receive nine years. What the authors of these provisions failed to understand is that half of the cumulative sales of a new medication following FDA approval accrue in years 10 through 13. The implication for investors today is clear: direct your funding to biologics, where the potential revenue is significantly higher. This discrepancy fails to capture that small-molecule drug development is similarly risky, just as costly, and is clinically valuable and critical to patients. And for many diseases, for instance mental illnesses, small molecules are the preferred treatment modality. This is why we need Congress to urgently pass the bipartisan Ensuring Pathways to Innovative Cures (EPIC) Act, which would fix this so-called "pill penalty" by bringing the small-molecule exemption to 13 years

[17] *Innovation in the Pharmaceutical Industry*, Di Masi et al, J Healht Econ, 2016; 47:20-33

[18] https://ecchc.economics.uchicago.edu/2021/11/30/issue-brief-the-impact-of-hr-5376-on-biopharmaceutical-innovation-and-patient-health/

and ensuring that private investment continues to flow to both promising biologics and small molecule drugs.

Exacerbating this policy scenario brought on by the IRA, U.S. biopharmaceutical companies are also contending with an array of challenges to the domestic and international legal ecosystems that protect intellectual property (IP) rights. IP rights are the currency used by innovative biotech companies to encourage investment in new and emerging technologies with significant promise and allow companies to safely collaborate on new treatments.

Developing a new drug has a greater than 90 percent failure rate, often takes decades, and can cost more than a billion dollars. We cannot expect rational investors to fund this work if we cannot demonstrate that we have secure and enforceable rights to our technology that allows investors to eventually recoup their investment. Investors scrutinize our patent portfolio as part of any due diligence. It can make or break a company long before we have our first approved product. The uncertainty around the ability to control and enforce our IP rights discourages investment in this space, especially into pre-revenue early-stage biopharmaceutical companies whose most important assets are their IP. The threat to the delicate balance of investment risk cannot be understated in an already highly competitive environment.

The strength of the domestic and global IP system is critical to realize and deliver promising biotechnology solutions to humanity by providing a framework to unite and empower biotech innovators to improve lives. Strong and predictable IP systems cultivate partnerships around the world, enhance knowledge sharing, support the entrepreneurial journey, and ultimately ensure that innovation is resourced and funded so that technologies with the potential to deliver better care for patients and products for consumers are developed. Without strong and predictable patent protection, investors will shy away from investing in biotech innovation and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society. I encourage Congress and this Committee to fervently defend American IP, both against domestic and international threats.

Unique Considerations of U.S.-based Small and Medium-Sized Biotech Firms in the broader Biopharmaceutical Ecosystem

SME biotech firms account for over 73% of the global clinical pipeline and 85% of all orphan-designated products in development.[19] And approximately one-third of all new drugs approved by the FDA since 2009 were developed by biotech companies with annual revenues of less than $100 million.[20] Accordingly, policies that disrupt market dynamics for the overall biopharmaceutical sector have a particularly acute impact on SME biotech firms, which are the lifeblood of the innovative U.S.-based biotech ecosystem. Policies which promote the biotech ecosystem in the U.S. and invigorate the American entrepreneurial spirit, which is the hallmark of the biotech sector, should therefore be a cornerstone of our economic and national security agenda.

[19] *2019 Emerging Therapeutic Company Trend Report*, David Thomas and Chad Wessel. BIO Industry Analysis. 2019.

[20] *Research and Development in the Pharmaceutical Industry.* Congressional Budget Office, April 2021. https://www.cbo.gov/publication/57126#:~:text=The%20expected%20cost%20to%20develop,to%20more%20than%20%242%20billion.

Bringing a drug to market is a lengthy, expensive, and risky endeavor, costing on average upwards of $2 billion and taking over 10 years to get through the approval process. At Arcutis, we feel quite fortunate that it only took six years and nearly $1 billion from our founding to our first FDA approval. With an industry average 10 % success rate, attracting investors is a never-ending challenge in an already very competitive marketplace. Congress has many tools to help encourage investment in small biotechs, however. Below are some policy recommendations that can create an improved environment that facilitates access to essential capital.

Use the Tax Code to Unlock Innovation

Even pre-revenue biotechs benefit from changes to the tax code. For example, restoring full deductibility for R&D expenses will help save many small and medium-sized biotechs from substantial new tax liabilities caused by the switch to five-year amortization. Many small biotechs have been hit hard by this change even though they have no product on the market and thus no sales revenue. It is preposterous for small firms to pay tax bills when they have no revenues and no profits due to a quirk in the tax code. Funding should be spent on research, not tax consultants. The "Tax Relief for American Families and Workers Act" (H.R. 7024) passed by the House of Representatives earlier this year would restore the R&D deduction.

Another way to help small and mid-sized biotechs is to unlock their Net Operating Losses (NOLs). Due to the high costs of drug development, small biotechs generate substantial NOLs over the course of bringing a product to market. Allowing smaller biotechs to receive the value of a portion of these NOLs immediately could provide much-needed funding at a time when capital is both essential and scarce. In addition, reforming Section 382 so small biotechs' NOLs are not limited if they accept new investment would preserve these valuable tax assets without violating Section 382.

High-paying biotech jobs make substantial contributions to the economy both directly and indirectly but are one of the primary drivers of the high cost of drug development. For instance, roughly half of my firm's expenses are labor and benefits for our staff. Tax benefits like the payroll R&D credit help offset these high costs and should be expanded and improved. Other tax incentives for training and maintaining a highly skilled workforce can be critical to help a small biotech attract or develop top talent.

Finally, creating and expanding incentives like the capital gains exemption under Section 1202 for Qualified Small Business Stock for investment in exceedingly risky areas like biotech will make investments more attractive to cautious investors and help encourage greater private investment in nascent biopharmaceutical companies.

Reauthorize and Expand the SBIR/STTR Grant Programs

The Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) grants are critical for early-stage companies. Both programs need to be expanded to provide improved access to this critical funding.

Reduce Burdensome SEC Reporting Requirements

Small public companies must spend millions to comply with onerous SEC requirements to report information that is of low or no value to investors. Exempting small companies from these

requirements would allow these smaller companies like mine to reinvest that money in their life-saving mission.

Biotech, Big Pharma, and Beyond - An Interconnected Bioscience Ecosystem Contributing to Economic Prosperity

The innovative U.S. biotech sector, spanning early-stage startup biotech firms, pre-commercial SMEs, emerging commercial-stage firms, and larger multinational biotechnology companies contribute tremendously to global public health and to the U.S. economy. Multi-way collaboration between private sector members of the life sciences community with governments, universities, foundations, and non-profit entities is a hallmark of the biotech sector. Innovation is increasingly driven by horizontal collaborations with partners, leveraging expertise residing across a range of organizations and disciplines. Policies, therefore, that impact the broader ecosystem will have an impact on the ability to cultivate long-lasting scientific collaborations and, as a result, impact the degree and speed to which innovative treatments are ultimately developed and delivered to patients in need.

As firms of all sizes face increased pressure on margins across the health care system, there are strong incentives to reduce costs. Biotech firms may out-license early-stage drug development and transfer technology to partners, either domestic or foreign-domiciled companies, at an earlier stage, and potentially at a lower valuation, than had been anticipated. Companies may also be forced to explore the need to offshore certain research and development efforts, including conducting cutting-edge clinical studies. Companies may also be compelled to explore alternative or supplementary manufacturing arrangements in foreign countries for approved drug products. Investing in biomanufacturing, strengthening local workforce, and ensuring cutting-edge clinical studies are conducted in the U.S. so that patients here are the first to benefit from biotech innovations should be a core tenet of our public health, economic, and national security agenda in the life sciences.

Finally, the interconnected bioscience ecosystem – and U.S. leadership in the life sciences – is not necessarily confined to the biopharmaceutical space. Policies that promote biopharmaceutical innovation have the potential to also strengthen the broader U.S. biotechnology ecosystem where innovators are applying biotechnology solutions to address food security, sustainability, and climate concerns. A robust policy and investment ecosystem in the biopharmaceutical space not only promotes U.S. leadership in the biopharmaceutical sector but also contributes to infrastructure and a skilled workforce development that is translatable across biotech sectors, bringing American scientific ingenuity and leadership to the world along with increased economic opportunity, jobs, and prosperity across diverse regions of the United States.