



BIOUTAH

WRITTEN STATEMENT

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BioUtah

to the

**Committee on Ways and Means
U.S. House Of Representatives**

***Access to Health Care in America:
Unleashing Medical Innovation and
Economic Prosperity***

**Presented by Kelvyn Cullimore
President and CEO of BioUtah**

**July 12, 2024
Salt Lake City, Utah**

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BioUtah appreciates the opportunity to provide testimony to the Committee on Ways and Means as part of its field hearing in Salt Lake City, Utah, entitled *Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity*. My name is Kelvyn Cullimore. I am the President and CEO of BioUtah. I took this position in 2018 to help grow, connect, and raise the profile of Utah's incredibly bold and innovative life sciences industry. From our C-suites, startups, and manufacturing floors to our academic research centers and service providers, we are immensely proud of what we're building here.

BioUtah is the state trade association for Utah's life sciences industry. We are the common voice and flag bearer for the industry comprised of medical device development and manufacturing, diagnostics, laboratories, biotechnology, and biopharmaceuticals. Together we form a community that pushes the boundaries of science, promotes innovation, and delivers technologies and treatments that improve and save lives.

I have personal experience in the industry as a medical device entrepreneur and CEO, so in many ways, the subject of this hearing and how Congress can help power innovation is very important to me personally and professionally. My father and I founded Dynatronics, a Utah-based company that designs, develops, manufactures, and distributes products for physical therapy. Innovation was the key to our success. Whether it was a new electrotherapy modality, ground-breaking ultrasound technology or a better therapeutic treatment table, developing products that benefit patients and practitioners was central to growth and achievement.

At one point, we submitted a new ultrasound product for clearance by the U.S. Food and Drug Administration (FDA). The FDA did not believe our product could do what we represented. They sent a scientist to our facility to validate our claims. Indeed, they admitted we had defied traditional beliefs about how the modality worked and they approved our new product.

Unfortunately, the advent of the medical device tax as part of the *Affordable Care Act* had a significant impact on many businesses, including ours. In the first year of implementation, we paid \$160,000 in medical device tax despite an operating loss of \$240,000. While the medical device tax was ultimately reversed, it illustrates the negative impacts of bad tax policy.

I've also had a run in public service and chairing hearings – albeit on a local level. From 2005-2018, I served as the first Mayor of Cottonwood Heights, a suburb of Salt Lake City. This was a part-time position in addition to my duties as CEO. I appreciate your willingness to serve in public office and to dedicate your talents and abilities to better governance.

My testimony will focus on Utah's life sciences industry, a view from the trenches, and federal policies needed to help encourage and sustain healthcare innovation.

Utah's Life Sciences Industry

A recent study of the top 20 life sciences states revealed that Utah's life sciences industry has been the third fastest growing bio innovation hub in the nation over the last decade. Only Massachusetts and Arizona grew at a faster pace. Moreover, only Massachusetts and New Jersey have a higher concentration of life sciences jobs than Utah. This success is characterized by a strong tradition of entrepreneurship and innovation dating back to medical device manufacturing in the 1950's and including the invention in 1973 of the first artificial heart at the University of Utah. That Utah tradition continues today with a business-friendly government, a can-do spirit of discovery and importantly, a culture of collaboration that seeds startups and supports established companies - producing a vibrant, multifaceted ecosystem that is gaining national and global recognition.

The industry's economic impact in the state speaks volumes. The November 2023 University of Utah Kem C. Gardner Policy Institute report, *Economic Impacts of Utah's Life Sciences and Healthcare Industry*, discusses the substantial reach and economic impacts of Utah's life sciences industry. Key findings include:

Facilities: Approximately 1,600 +.

Jobs: More than 182,000 Utahns are employed in Utah's life sciences industry directly and indirectly.

GDP: Over \$22 billion annually - statewide total economic impact.

Job Growth: From 2012 to 2022, the number of jobs in Utah's life sciences industry increased by 5.1% per year on average versus 3.5% in other states, and 3.4% in other Utah industries.

Wages: Estimated average annual earnings for life sciences workers (\$96,000) are nearly 50% higher than earnings for workers in other industries in Utah (\$65,000).

It's also important to note that in Utah workers in the life sciences industry are more racially and ethnically diverse than the average for the life sciences industry as a whole.

Life-Changing Innovation

In addition to its significant positive economic impacts in the state, Utah's life sciences industry is fertile ground for healthcare innovation. Utah companies large and small have developed or are advancing numerous life-changing medical products.

For instance, one of the first molecular COVID-19 tests to receive FDA Emergency Use Authorization was developed in Utah as was the saliva-based test for COVID-19. Utah companies are also creating life-saving solutions for stroke; advances in genetic-based cancer diagnostics; drug discovery for MS, Alzheimer's and other neurodegenerative diseases; treatment for Parkinson's Disease; regenerative cell-based therapies that alleviate pain and restore function in patients with degenerative diseases of the spine; improved new heart valve replacements; cutting-edge diagnostics for chronic kidney disease; brain-computer interface technology; AI-enabled drug discovery and more are all part of the Utah life sciences world.

Numerous life sciences companies founded in Utah have grown to become engines of innovation, delivering novel treatments and therapies across the globe and employing thousands of Utahns. ARUP Laboratories (diagnostics), bioMérieux (infectious disease), Merit Medical Systems (invented the first plastic syringe), and Myriad Genetics (first BRCA gene testing), are just a handful of Utah companies whose beginnings trace back decades to visionaries with a passion to transform healthcare.

Innovation Landscape, View from the Trenches

In my role as the President and CEO of BioUtah as well as in my personal experience leading a medical device company for years, I have seen first-hand the challenges faced by our industry and more specifically, how government's laws and regulations can impede or promote innovation. My observations on these challenges include the following.

Research and development (R&D) are critical components to finding solutions to medical conditions. Policies such as the federal R&D tax credit that encourage R&D accelerate those solutions. However, policies like the *Inflation Reduction Act* (IRA) or changes to R&D expensing under the *Tax Cuts and Jobs Act of 2017* can negatively impact R&D momentum.

In the same vein, reimbursement policy can incentivize or hamper innovation. Reimbursement policy which recognizes solutions that reduce healthcare costs in the long run encourages development of unique new technologies. Using metrics that measure only the short-term cost without considering the long-term savings is shortsighted. Most progress in medical solutions is iterative in nature. Early coverage and reimbursement approvals not only help patients, but lead to future improvements that further refine medical technology and enhance patient outcomes.

As one of the most regulated industries in the country, it behooves policymakers to balance the need for safe and effective products against the costs and lengthy delays incurred in bringing such products to patients. The need for innovative pathways to market will become even more pressing as technology continues to evolve.

Capital is an essential ingredient of the innovation recipe. Consequently, government policies can increase or chill the flow of capital to innovation. For instance, tax policy related to capital gains can either boost investment in innovation or redirect capital to other investment options. The ability to monetize net operating losses is another example of how tax policy could help early-stage companies not only survive but thrive as such a policy would enable them to generate much needed additional capital. Utilizing some savings from the IRA in support of such a policy could be a way of re-investing in the life sciences.

Federal Policy and Healthcare Innovation

In Utah, we are very fortunate to have a state government that supports our industry. Governor Spencer J. Cox has identified Utah's life sciences sector as a strategic economic pillar as has Salt Lake City Mayor, Erin Mendenhall. The state legislature has established the Utah Life Sciences Innovation Caucus to better understand how state policy affects the industry and innovation.

However, no matter how favorable a state's innovation landscape, misguided federal policies can undermine any local advantages and stymie success much like the medical device tax previously mentioned. To that end, we outline several issues for the Committee's consideration.

Tax Treatment

Congress should ensure a competitive tax code, including policies such as R&D expensing, R&D tax credits, bonus depreciation, interest deductibility, and small business expensing.

BioUtah supports a provision in the House-passed tax bill, H.R. 7024, the *Tax Relief for American Families and Workers Act of 2024*, that would restore the full and immediate expensing of R&D costs through 2025. Under current law, R&D costs paid or incurred in tax years beginning after December 31, 2021, are required to be amortized over five years. The five-year deduction requirement is especially hard for small companies, given their narrow operating margins and demand for capital. Yet, it is these emerging enterprises that innovate and help improve patient outcomes. Without elimination of

these amortization requirements, small companies could actually owe taxes on grants received that must be recognized as income while the expense associated with the grant would be amortized over 5 years, thus draining much needed cash at a critical stage of company development.

Another favorable tax provision of the bill would reinstate 100% bonus depreciation for property placed in service through 2025. Such favorable depreciation provisions for machinery and equipment would help companies hire workers and expand manufacturing. The Senate must now act on these tax changes to strengthen small businesses and give our life sciences companies the best chance to blossom and give patients hope.

Medicare Coverage of FDA Breakthrough Products

It's also critical that Congress prioritizes enactment this year of H.R. 1691, the *Ensuring Patient Access to Critical Breakthrough Products Act of 2023*. BioUtah thanks the Committee for moving this legislation forward last week with overwhelming bi-partisan support and encourages the full House to take up the bill. We also want to thank the committee for agreeing to fix a drafting error that inadvertently omitted diagnostics from the marked-up bill.

Currently, seniors with life-threatening or debilitating conditions often wait years before Medicare provides coverage for FDA-authorized breakthrough medical technologies, which can be a matter of life or death for many patients. Not only does this adversely affect patients, but it discourages the development of new devices and diagnostics.

Research from the Stanford Byers Center for Biodesign found that only 44 percent of novel technologies authorized by the FDA between 2016 and 2019 achieved nominal Medicare coverage by the end of 2022. H.R. 1691 would provide four years of provisional coverage for certain FDA-authorized breakthrough medical products. This temporary transitional coverage will give physicians and their patients access to the most advanced, safe, and effective treatments while facilitating additional clinical data collection to inform the Center for Medicare and Medicaid Services in its development of long-term coverage criteria. It's a "win-win" for patients and the Medicare program.

Let me share a real-world example. PhotoPharmics is a Utah company working on a phototherapy device to treat Parkinson's Disease. They received a "breakthrough product" designation from FDA, opening the door for early coverage under the prior Medicare Coverage for Innovative Technology (MCIT) final rule. This designation and the promise of timely reimbursement attracted the investment PhotoPharmics required to bring this technology to market for the benefit of patients. When MCIT was reversed by the current administration, the resulting uncertainty regarding reimbursement caused investors to pull back, delaying the company's ability to bring the product to market. We have great hope that H.R.1691 will better serve patients by breathing new life into this expedited coverage and reimbursement concept for breakthrough products.

Mergers and Acquisitions Enforcement

Finally, given the recent departure from bipartisan mergers and acquisitions (M&A) enforcement policy by the Federal Trade Commission (FTC) and Department of Justice (DOJ), the Committee should take note of the unique value and role that M&A plays in our industry.

M&A are a fundamental tool for medical innovation in Utah and across the U.S. M&A encompasses mergers, partnerships, and licensing collaborations between life sciences companies of all sizes. In Utah, life sciences M&A is a critical pathway that attracts sustained investment, R&D, and growth.

Researchers at the University of Utah and Utah State University were awarded 824 life sciences patents and launched 35 life sciences startups from 2018 to 2022. Small businesses make up the vast majority of Utah's life sciences hub. These companies may rely on M&A to gain the resources and scale needed to bring their innovations to patients.

When it comes to biopharmaceutical companies, 80% operate without a profit, and many are unable to go through the long, complex, and resource-intensive process of developing new medicines alone. Bringing a new therapy to market is like a relay race – and M&A allows companies to "pass the baton" and share existing complementary expertise, manufacturing capabilities, and other forms of support which would otherwise be too costly or overly duplicative.

To that end, BioUtah urges policymakers to take a balanced and bipartisan approach towards life sciences M&A, acknowledging the unique, differentiated, and competitive market dynamics. The FTC and DOJ's current aggressive approach could inadvertently stymie pro-competitive M&A that would spur advances in healthcare in Utah and beyond.

Tolero Pharmaceuticals is a good Utah example of the benefits of M&A. Tolero, founded in Lehi, Utah, developed a technology to address solid tumor cancers. The technology was acquired by Sumitomo Pharma, a large pharmaceutical developer, which enabled the product to be further developed and commercialized. An important side benefit is that the principals of Tolero were able to utilize the proceeds from the sale to seed and incubate many other new companies. The multiplier effect of M&A activity should not be overlooked.

Summary

In closing, BioUtah applauds Chairman Smith and members of the Ways and Means Committee for taking the time to come to Utah and learn more about our life sciences industry and challenges to our innovation economy. We also thank Representatives Blake Moore (R-UT), a member of the Committee, and Celeste Maloy (R-UT) for their participation at the hearing.

Fostering a favorable environment for life sciences discovery and expansion requires a pro-innovation tax structure, timely reimbursement, sound regulation, and a reasonable approach to M&A. In Utah, our companies have plenty of ideation, passion, and commitment. What's needed are the right policy tools so they can take root, attract capital, grow, and reinvest in their business to make a difference in patients' lives.