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Hearing on "Fueling Innovation: The Role of Small Businesses in America's Bioeconomy"
U.S. Senate Committee on Small Business & Entrepreneurship

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Senator Young and Distinguished Guests:

Thank you for the opportunity to testify on the role of small businesses in America's bioeconomy.

I am honored to share my perspective as a co-founder of LyoWave, Inc., an Indiana-based startup company launched in 2023 based on inventions at Purdue University. LyoWave's mission is to overcome key bottlenecks of producing biotech-based products, focusing first on lyophilization. Lyophilization, also referred to as aseptic freeze-drying, is a critical manufacturing operation that allows stabilization of complex biologic molecules so they can be processed, stored and delivered to patients and users. Lyophilization, although a decades-old technique, is a workhorse of modern biotechnology. We are not developing a faster horse but replacing it altogether with a multi-terrain vehicle that can move novel and legacy biotech products to market safely, at speed and scale.

The past is prologue to the future, and the history of lyophilization underpins the origin of American leadership in biotechnology in the 20th century and the urgency we now have to recapture it. Eighty-five years ago, in spring 1941, prior to America's entry into World War II, the U.S. Army and Navy deployed a massive industrial program to supply blood plasma to save wounded soldiers in the battlefields in Europe. The program used the technology we now call lyophilization in drying blood plasma in sterile conditions. This technology was invented at an American university, UPenn, in collaboration with Philadelphia-based Sharpe & Dohme Co., which later merged with the pharmaceutical giant Merck. The Army Medical Procurement Agency issued purchasing orders on behalf of the Army and Navy and supplied equipment and manufacturing instructions for 11 firms across the country for processing blood plasma collected by the Red Cross.[1] More than 6 million Americans donated blood to provide powdered "life for the wounded." Maj. Gen. Normal Kirk, surgeon general of the U.S. Army, referred to freeze-dried blood plasma as "the foremost lifesaver"

[1] https://achh.army.mil/history/book-wwii-blood-chapter11

of injured U.S. soldiers in WWII and one of the critical medical technologies that contributed to the Allies' victory.

In less than a year, a whole new industry was established with processing equipment and standards supplied by the Army and Navy, representing an unprecedented win of a public-private partnership. Beyond the immediate battlefield treatment of wounded soldiers, the dry blood plasma program set the stage for the major medical breakthroughs of peacetime, to stabilize and make possible mass manufacture of the first antibiotic, penicillin[2]. With the established national network of manufacturers and after Europe's capacities were critically disrupted, the U.S. became the main provider of life-saving medicines for much of the world. The fermentation plants and human expertise developed for penicillin and other early antibiotics became the critical enabling capability for manufacturing the biotechnology-based medical treatments pioneered in America in the 1970s.

Now lyophilization is used to manufacture recombinant protein drugs including those for treatment of heart attacks and autoimmune diseases, antibody-drug conjugates for newest targeted cancer therapies, vaccines and viral vector-based genetic medicines, and many diagnostic reagents. Additionally, most injectable antibiotics on the essential medicines list[3] are manufactured in a lyophilized form. However, lyophilization also is a very long and costly process requiring space-like vacuum conditions. In 2015, through the NIST Advanced Manufacturing Technology Consortia (AMTech) program[4], Purdue University with key industry and academic partners established the Advanced Lyophilization Technology Consortium (LyoHUB) to develop a technology roadmap[5] to identify critical challenges and strategies for innovation. The need for deep disruptive technological changes in lyophilization became clear, and one identified opportunity was to use modern high-power radio frequency semiconductor technologies instead of the approaches developed decades ago for the industrialization of dry blood plasma production.

Through initial internal research at Purdue's College of Engineering, we developed a prototype of a high-frequency microwave setup with power sources for satellite communication to augment the traditional lyophilization equipment, accelerating its throughput by multiple times. A competitive funding award in 2021 from The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)[6] allowed us to partner with Merck and IMA Life to test the new microwave-assisted lyophilization on real biologics, otherwise not available for university researchers, and further advance the prototype's biomanufacturing readiness. These were the first real molecules and cells as passengers for the vehicle rather than the horse of lyophilization. Through the NIIMBL-organized "Dancing with Venture" events, I learned about VC funding routes for taking

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[2] E. W. Flosdorf, *Freeze-Drying: Drying by Sublimation*. Reinhold Pub. Corp., New York, 1949. https://archive.org/details/freezedryingdryi0000earl/page/n5/mode/2up

[3] https://www.fda.gov/media/143406/download?attachment

[4] https://www.nist.gov/oam/programs/advanced-manufacturing-technology-consortia-amtech-program

[5] https://pharmahub.org/groups/lyo/lyohub_roadmapping

[6] https://www.niimbl.org/projects/tunable-rf-microwave-drying-of-biologics/

biomanufacturing innovations to market. To me, as a trained applied mathematician and engineer, that frankly was a totally new and somewhat scary domain.

Biotech manufacturing innovation is talent- and capital-intensive. That's why sustained innovation networks such as those enabled by university-industry centers like LyoHUB, national manufacturing institutes like NIIMBL and other public-private partnerships are critical to develop teams, demos, data and IP that enable transitioning inventions to market through company creation. Helped by Purdue's resources for entrepreneurship training (e.g., regional I-Corps and Firestarter programs) and the amazing alumni and advisor network, our co-founder team attracted perfect VC investors for our series seed round in May 2024. This allowed us to license IP from Purdue, lease space, and have co-founders Dr. Drew Strongrich and Dr. Ahmad Darwish start their jobs at LyoWave to "make, market and sell" our race car replacement of the workhorse of biotech. With the SBIR Phase 1 award last year, we were able to add critical mechanical and software engineering expertise to the team and deliver the first LyoWave TurboDry microwave lyophilization system, made in Indiana, with installation at a customer site on the U.S. East Coast. Unlike the university-developed prototype that would hardly fit into a minivan, the highly integrated system with custom-built electronics by LyoWave fits into a carry-on bag. It can be installed in less than an hour on existing R&D-scale lyophilization equipment. We now are in the steep climb to transition it to CGMP-compliant large-scale aseptic production systems.

Based on the experience I have shared, I offer these recommendations to bolster biomanufacturing innovations by early-stage technology innovator companies:

- Continue and strengthen established programs like SBIR/STTR and further motivate small-business participation in programs on reshoring end-to-end manufacturing of critical bio/pharma products (e.g., by ASPR).
- Establish incentives for adoption of advanced technologies by biotech manufacturers to offset regulatory acceptance costs. The Advanced Manufacturing Technology Designation Program rolled out by the FDA recently is a good first step.
- Create a network of regional shared-use facilities for test-driving and de-risking new biomanufacturing technologies. Such facilities with GMP-relevant manufacturing equipment would become a speedway for innovation in biomanufacturing.

Thank you for the opportunity to provide my perspective. I look forward to answering your questions.