SMARTLABS
STATEMENT FOR THE RECORD

HOUSE ENERGY AND COMMERCE
HEALTH SUBCOMMITTEE HEARING:
"THE FUTURE OF BIOMEDICINE: TRANSLATING BIOMEDICAL RESEARCH INTO PERSONALIZED HEALTH CARE"

DECEMBER 8, 2021

Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee, we thank you for the opportunity to submit this statement regarding the future of biomedicine.

My name is Amrit Chaudhuri and I am the Co-Founder and Chief Executive Officer of SmartLabs. SmartLabs was founded in 2015 to reimagine biopharma lab infrastructure with a transformative new platform that delivers multi-purpose lab infrastructure to support the wide range of workflows required for end-to-end R&D – from the discovery stage through the manufacturing of therapeutics.

Recent scientific advances in personalized medicine are putting cures within reach of millions of patients. New therapies can disrupt the tragic legacy of genetic diseases that pass suffering from one generation to another.

Despite the many scientific breakthroughs of dedicated researchers underwritten by millions in NIH and other federal investment, the pace of translating discoveries into approved therapies is slowed by outdated approaches to resourcing biopharma research and manufacturing. The still evolving field of precision (or personalized) medicine focuses on genetic and cell-based therapies serving smaller patient populations – a paradigm shift in health care better served by more localized research, development, production, and delivery of medicines. Public and private R&D infrastructure must transform to realize the promise of personalized medicine. The same lab infrastructure requirements that apply to personalized medicine can also support pandemic preparedness.

Traditional Approaches to R&D Infrastructure Are Slowing Medical Progress

Traditional R&D infrastructure is slowing the transition of new modalities from discovery to treatments for patients and limits our ability to respond in public health emergencies. Public and industry leaders need multipurpose labs that can scale and pivot on-the fly.

1. ***Public and industry leaders need multipurpose labs that support end-to-end drug development.*** Research and manufacturing infrastructure are typically designed for a singular purpose and each major step in the drug development process – discovery, *in vivo*, and clinical or small-scale manufacturing – reside in different

facilities. Aggregating multipurpose workflows in a single facility can reduce the time and complexity of tech transfers required to move through each stage of drug development.

2. ***Speed to scale-up lab and manufacturing infrastructure and pivot is critical for personalized medicines and public health emergencies.*** Customization of labs usually requires significant upfront capital investment and buildout timelines. Cell and gene therapies often serve small patient populations and the capital investment can be cost-prohibitive. Researchers can wait months or years for renovations to support the new and changing workflows required for personalize medicine. FDA approvals also come earlier in the process than a typical therapeutic to address acute clinical need, which can compress the time to market but only if the infrastructure can scale-up quickly.

3. ***Geographic distribution of a common lab infrastructure that supports advanced, flexible R&D is critical for human talent and supply chain challenges.*** Geographic distribution of R&D labs is critical for accessing unique know-how, supporting material and methods transfer from universities, enabling workforce growth around key capabilities, and for providing supply chain and manufacturing redundancy. Personalized medicine companies are especially sensitive to these issues. They often scale up and recruit for human talent in multiple geographies, and these geographies can shift as they move from research to manufacturing. They also require unique technologies that are developed by universities and other centers of excellence. Investors in personalized medicine companies often see a benefit for early-stage companies to be nearby their offices. Manufacturing is best when there is redundancy and geographic separation in both supply chain and the manufacturing facilities.

Federal Policy Should Support the Development of Next Generation R&D Infrastructure to Support Novel Therapies

Through the launch of the "Critical Path Initiative," the FDA as early as 2004 recognized the need to transform the way in which the next generation of typically smaller volume, more complex cures are discovered and commercialized. Flash forward to the 2016 landmark 21st Century Cures Act, and this recognition has been firmly established through Congress mandating formulation of standards to support the development of regenerative medicine (including personalized manufacturing processes and controls).

Also in 2004, the enactment of the Project Bioshield Act and creation of the Biomedical Advanced Research Development Authority (BARDA) promoted Centers for Innovation in Manufacturing "CIADMs," to create flexible manufacturing capacity to scale-up for countermeasures and envisioned clinical trial or contract research networks.

Despite the government's forward-looking vision, the execution of this vision has been hampered by high costs, limited flexibility and extended timelines that create bottlenecks and stifle needed innovation – for pandemic preparedness and response as well as discovery and delivery of advanced precision medicine treatments for cancers and other illnesses. Only three CIADMs were ever launched and the majority of private R&D infrastructure is built off the traditional, static model.[1] The time is now for federal government policies and programmatic funding to support and incentivize the SmartLabs concept of flexible, multifunctional R&D infrastructure.

The Future of Biomedicine is Fast, Localized, Lower-Cost, Customized R&D Infrastructure

SmartLabs builds and operates Managed Research Centers (MRCs) that allow clients to access private suites with complete operational support. This innovative structure shreds economic barriers for clients entering the market, places them in control of their own success, and allows them to operate and succeed in a completely privatized, secure environment. Clients license multi-year contracts for teams of 10-200 scientists. SmartLabs deploys labs configured for their specific workflows in 2-4 weeks. These lab configurations are easily updated, and the lab footprint can change functionality and size easily as needed. Our MRCs reduce the time and cost to get new therapies approved years ahead of scheduled, improving patient health outcomes. SmartLabs' program can save 2-24 months in scale up time and up to 95% in upfront capital expenditures.

The SmartLabs platform allows biopharma clients – from startups to multi-nationals – to operate their own research and manufacturing operations on outsourced, qualified infrastructure. Biopharma companies, especially companies developing cellular and genetic therapies for small populations, can use a SmartLabs MRC as a more flexible and cost-effective model to develop and deliver personalized medicines or to pivot during a public health emergency. To date, SmartLabs has supported over 20 of the top personalized medicine companies.

A National Grid for Translational R&D

SmartLabs MRCs provide the first ever world-class shared infrastructure and quality management systems that accelerates the pace of science. It offers many benefits for personalized medicine companies across all phases of their journey from research to commercialization.

In addition to the infrastructure shifts required to unlock the power of personalized medicine, the COVID-19 pandemic exposed vulnerabilities in our ability to quickly scale-

[1] U.S. Department of Defense, "HHS Reserves and Rapidly Expands Manufacturing Capacity for COVID-19 Vaccines at Texas Center for Innovation in Advanced Development and Manufacturing," https://www.defense.gov/News/Releases/Release/Article/2311228/hhs-reserves-and-rapidly-expands-manufacturing-capacity-for-covid-19-vaccines-a/.

up R&D and production of critical countermeasures without causing supply chain disruptions of other essential medicines. One of the most effective COVID-19 vaccines was designed in just 48 hours.[2] Now, almost two years after the discovery of the COVID-19 vaccine, we are still grappling with the human suffering caused by delays in translating that discovery into a vaccine that could be manufactured and distributed to the world's population.

In a pandemic or other public health emergency, every hour counts and delays to customize infrastructure accelerates the challenges faced by personalized medicine companies. It is critical to access key know-how and workforce elements, and also have immediate access to R&D labs to validate solution paths toward a diagnostic, vaccine or therapeutic. A standardized, multifunctional national grid can enable local production of therapies or vaccines, leapfrogging over some of the R&D and manufacturing challenges we encountered during the COVID-19 pandemic.

Unfortunately, there are likely to be additional pandemics to which the federal government and its private sector partners need to be better prepared to respond. Fortunately, policy changes can encourage the modernization of R&D infrastructure to dramatically accelerate the timeline from drug discovery to clinical use.

The value to the public is clear – a smarter approach to infrastructure can accelerate the time it takes to translate a discovery into a treatment for millions of Americans. By developing a modern R&D and manufacturing network, we can both ensure a pathway to bring future innovation to patients in need and also support US leadership in life science innovation.

SmartLabs applauds the Subcommittee for its leadership on policies and programs to usher in a new era of scientific discovery and adoption. Scientific advances are accelerating, but the path to turn discovery to a vaccine or a cure relies on outdated approaches. Our technology has demonstrated a new way is possible. We hope that government policymakers and other stakeholders will support scaling our approach, and look forward to working in partnership to create a more resilient future.

Respectfully Submitted By:
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[2] Derek Thompson, "How mRNA Technology Could Change the World." *The Atlantic*, https://www.theatlantic.com/ideas/archive/2021/03/how-mrna-technology-could-change-world/618431/.