

Testimony of Richard J. Morello

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“Fostering a Fiscal Environment for Healthcare Innovation: A Local Case Study with Global Impact”

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Introduction

Good afternoon, Chairman Smith, Congressman Schweikert, Members of the Subcommittee, and Esteemed Members of the Salt River Pima-Maricopa Indian Community Council. Thank you for the opportunity to testify at this field hearing today. My name is Rick Morello and I serve as chief executive officer of CND Life Sciences, a fast-growing neurodiagnostics company founded in 2017 and based just a few miles from here at the Pima Center in Scottsdale.

Our mission is to transform the way neurodegenerative diseases like Parkinson’s and dementia with Lewy bodies are diagnosed and ultimately treated so that patients and families across our vast population have a chance to experience better health outcomes despite the severe challenges of these age-related disorders.

After a decade of research, CND’s three neurologist founders – two of whom are on faculty at Harvard Medical School and one who continues to play a major role at the Neuroscience Institute at HonorHealth in Scottsdale – knew that there was a more accurate, convenient, cost-effective, and potentially groundbreaking way for physicians to diagnose patients who exhibit signs and symptoms of these neurodegenerative disorders earlier in the disease process. These debilitating conditions take decades to develop and are often misdiagnosed when the underlying pathology is less clear. To the CND founders, there was a promising solution hiding in plain sight: our skin.

They understood that brain-based diseases like Parkinson’s are systemic in nature and can implicate many different central and peripheral nerve structures and processes. Skin, of course, is filled with nerves and has close connections to biological pathways in our brains. Therefore, it was not a surprise to our founders that a precise laboratory method could be developed to detect, visualize, and quantify a protein known to be the pathological marker of these diseases by examining nerves in the skin.

On March 20, 2024, that vision became a solidified reality when the *Journal of the American Medical Association* (JAMA) published CND's groundbreaking, NIH-supported, multicenter study demonstrating that CND's Syn-One Test had a 95% positivity rate in detecting the abnormal form of the alpha-synuclein protein through small skin biopsy samples of patients diagnosed with Parkinson's disease, dementia with Lewy bodies, and related disorders. Three tiny pieces of skin collected through a simple 15-minute procedure in a neurologist or primary care office could provide incredibly important insights about the brain. The immediate media coverage and reaction by the scientific and patient communities were substantial. Many noted how the Syn-One Test could be part of something extremely exciting in the field by offering an easy method to detect early signs of these diseases and provide the means for emerging therapeutic interventions to be delivered in clinical practice.

Establishing great science, however, is just one critical path in the long journey of maximizing the impact and sustainability of healthcare innovation. Today, CND is humbled and fortunate to say that the Company has grown from 5 employees and a few customers in early 2020, when Covid was shutting many small businesses, to a thriving life sciences firm with over 100 employees and 1,300 clinician customers in 47 states, supported by loyal investors from everyday angels to organizations like HonorHealth here in Scottsdale. Growing from nothing to something while pursuing innovation is filled with uncertainties, challenges, and risks, and without the help of federally supported mechanisms and fiscally advantageous opportunities here in Arizona, CND's mission would have been in serious jeopardy.

Surviving the Start-up Gauntlet: Actualizing the Promise of Innovation

The statistics on innovation failures are stark. About 75% of start-ups backed by venture capital fail¹ and perhaps up to 90% of all entrepreneurial attempts end up closing, most within the first five years. In the world of healthcare and life sciences, actualizing innovation is a truly high risk, high reward endeavor affecting a broad array of stakeholders - from the patients who are the ultimate beneficiaries of breakthroughs, to the families that support them, to everyday people who take on sustainable jobs that deliver the products and services that innovation hatches. Founders and companies who accept the innovation challenge go into the often-treacherous journey with a lot to lose, but those who have conviction to address an unmet need with ingenuity and a plan to address the myriad of obstacles have a chance. Having the right economic and regulatory ecosystem supported by modern policies and programs that facilitate cost-effective healthcare innovation is absolutely essential.

¹ <https://corpgov.law.harvard.edu/2023/09/29/startup-failure/>

It is hard to imagine CND ascending to this stage in our evolution without the benefits of this supportive ecosystem. First, CND made the crucial but easy decision to call Arizona and the greater Phoenix area our home. While a good part of our Syn-One Test technology was licensed from a Harvard-affiliated health system in Boston, the favorable economic climate for life science companies in Arizona was clear. From our very beginnings, we had access to great talent, great universities, and real estate we could rely on, afford, and expand with growth. The cost difference on real estate alone was four times higher in Boston than here. We are proud to call the Pima Center our home and have blossomed from our original 1,000 square feet of lab space in Phoenix to nearly 30,000 square feet of facilities at Pima employing over 70 individuals in Arizona and countless service providers. Thank you to the Salt River Pima-Maricopa Indian Community for providing us this amazing location.

CND also benefitted greatly from federal grants that focused on small business innovation and health advancement. We applied for and were awarded over \$10 million in R&D oriented funds over a two-year period, with one grant supporting our major clinical study demonstrating the validity of the Syn-One Test technology, and two others now catalyzing the exploration of early detection (and possible prevention) of Parkinson's disease and related disorders. These funds were truly transformational not just for CND but the entire field of diagnostics and biomarker testing for neurodegenerative diseases.

CND was also able to apply grant funds to support the acquisition of key capital equipment for our laboratory and be positioned for early growth. These are big-ticket item investments that would be extremely difficult to make at the beginning stages of a company like CND, which has a promising vision and foundational assets to solve a major unmet medical need but does not have straight-line access to private capital.

In considering the impact of the federal grant funding noted above, the return on investment to the government is already becoming apparent. As an accurate, convenient, and more cost-effective alternative to expensive imaging and other testing modalities, Syn-One is promoting easier access for patients and more definitive diagnostic evaluations. This utility often leads to the avoidance of unnecessary tests and office visits that can stem from diagnostic uncertainty. Additionally, by applying Syn-One earlier in the disease process, patients and families can take certain steps to decrease the likely costs and burdens of disease and be better positioned for future therapies that might alter its course.

Finally, CND also continues to capture the amazing support from the local Arizona ecosystem, including being a member of the Arizona Bioindustry Association (AZBio) and working collaboratively with the Arizona State University Biodesign Institute on discovery projects that could have major cost-efficiency and innovation returns for CND over the long

term. We are proud to say that CND's mission has truly arrived on a world stage with Arizona and the Pima Center being the foundational centers of everything we do.

Federal Footing: Fostering Innovation and a Path for Growth

As I conclude my remarks for the Committee, I would like to underscore some key learnings from CND's experience as a company striving to solve major medical challenges that could have far-reaching impact for millions of patients and the healthcare system as a whole. Our work has just begun and the road ahead is filled with both opportunities and risks.

I cannot say enough about the importance of the federal government's role in fostering and facilitating a favorable economic ecosystem in which innovation can emerge and thrive. Indeed, the private capital markets will continue to be a primary source of funds for good ideas and promising companies. But relying on those avenues alone is insufficient.

In the critical area of healthcare, the United States has both a major advantage and a major conundrum. We are a true mecca for breakthroughs, standout technology, world-class academic institutions, amazing clinicians and care centers, and intellectual vigor. But with these invaluable assets comes the undeniable barrier of cost. The next decades of healthcare innovation must move our treatment system to one that prioritizes prevention and suppression of serious illnesses for all patients across all communities. Innovation will seize opportunities in everything from telehealth to the application of actionable data at our fingertips so that care is delivered early, conveniently, and effectively for 350 million people. In the area of neurodegenerative diseases, we are on the cusp of transformation, where there is real hope for detecting conditions like Parkinson's and Alzheimer's before they manifest into debilitating stages that wreak havoc on patients, families, and the healthcare system at large. Precision diagnostics will play an important role, and having an ecosystem that supports policies and programs that encourage and facilitate innovations will be essential. Meaningful R&D incentives, favorable capital purchase structures, flexible Medicare reimbursement approaches, efficient FDA review processes, and other policy areas will all be essential. Ultimately, we are confident the country has the will and skill to allow innovation to be the driving force of thoughtful change and progress we have always relied on it to be.

Thank you again for allowing me to provide these perspectives to the Committee today.