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Members of the Senate Majority Policy Committee
Hearing on Rural Healthcare Access and Technological Innovation
March 19, 2025
Testimony of Jamie Quintero, Co-Founder and Chief Operating Officers, PECA Labs

Honorable Chair and Members of the Committee,

Hello and thank you for giving me the opportunity to speak about work in pediatric medical device development and my entrepreneurial experience in this region. My name is Jamie Quintero and I am one of the cofounders of PECA Labs, a medical device company with a focus on the underserved market of pediatric cardiac congenital defects.

PECA Labs was founded back in 2012 by myself and two partners as a spin off out of Carnegie Mellon University and The Children's Hospital of Pittsburgh. Our mission has been to provide new treatment options for patients suffering from orphan diseases, which are conditions that effect less than 4000 individuals in the US or less per year. The current state of the medical device industry has resulted in little financial incentive for larger companies to develop products for these rare diseases, and regulatory barriers have made it nearly infeasible for smaller companies to bring life-saving and life-sustaining devices to market. As a result, pediatrics and others suffering from orphan diseases are, in many cases, faced with insufficient treatment options or none at all.

The path from conception to where we are today has been a bumpy and complex one. We began with the intent of translating a single heart valve design into a commercial product using off the shelf materials and outsourced production. The original business case envisioned PECA Labs as a three to five year operation with a convenient end goal of acquisition and requiring a very small amount of initial capital. The reality of working to bring this to fruition has ended up with us patenting our own material platform, taking on our own production and replanning the company with the intent of growing and operating as an enterprise indefinitely.

I say this to not just highlight a misconception about "start-ups" as a glamorous kind of work but to emphasize how far we have come in creating and stabilizing a revenue generating business. As we stand today, we have an approved vascular graft product on the market, manufactured entirely



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domestically. We currently employ 15 people here in Pennsylvania and will be doubling our headcount before the end of the year.

Our product on the market today is the exGraft, a synthetic vascular graft built on PECA Labs' proprietary polymer processing platform that can be permanently expanded. Post-operative expansion is designed to allow for increasing graft diameter, which may enable the graft to match growth in pediatric populations or help to avoid narrowing in adults. Pre-operatively, the controlled dilation may help address unique anatomies. The exGraft's capability to be balloon-expanded in the catheter lab provides cardiac care teams greater flexibility in treating patients even in facilities without a full pediatric cardiothoracic department.

None of this could have been accomplished without the grant and investment infrastructure of Western Pennsylvania. PECA Labs would not have survived had it not been two factors. Firstly, are local and regional investors, who make up the majority of the investor base we have raised capital from to date. Secondly we have to thank SBIR grants and grant funding in general. Approximately a third of the funding we as a company have received comes from grant sources. This non-dilutive funding source has been critical not only to the day-to-day survival of my company but to allow us to accomplish goals in a cost-effective enough manner to be able to function as an investment worthy business.

Please feel free to ask me anything and everything about my experience. Thank you again.

Jamie Quintero
Co-Founder and COO, PECA Labs