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Senate Institutional Sustainability & Innovation Committee
Office of Frank Farry (R-6)
351 Main Capitol Building
Harrisburg, PA 17120

Dear Committee Members:

Thank you for the opportunity to share my experiences about AI within the medical device and biotech industry.

I am the CEO of Cogwear, a start-up company that supports better health, peace of mind, and human performance through comfortable, wearable technology for better brain insights. Headquartered in Philadelphia and initially spun out of the University of Pennsylvania, our company founders started with a broad question: how do we understand the workings of the brain in the real world - not in a lab or MRI machine - to improve brain health, build stronger teams, and make better decisions? As neuroscientists with an extensive charter at the University of Pennsylvania, their research was stymied by the inaccessibility of brain measures: MRIs are far from portable and other measures lacked the longevity and fidelity needed.

The reality is that the brain is the black box of the body. We have vital signs for everything else (e.g. temperature and blood pressure) and wearable solutions to manage disorders (e.g., glucose monitoring for diabetics). Yet for the brain, the only options are expensive and only available in clinics and hospitals, such as MRIs and EEGs.

As a result, diagnoses are often based on subjective information like self-report and surveys. Measuring the effectiveness of treatments is hard. Healthcare providers who treat disorders like anxiety, Alzheimer's, and sports-related brain injuries often resort

to trial and error. The impact of this is tremendous within Pennsylvania and worldwide. According to data presented at the U.N. Brain Capital Summit in 2024, brain disorders are the number 1 cause of disability, the number 2 cause of death, and has a worldwide economic impact of \$2T, with \$1T going directly to care. Moving assessment and understanding from the clinic to real-world situations is what's needed to help solve these conditions, improve health, and reduce the financial costs.

Cogwear was born from this concept. This need prompted our founders to invent novel brainwave sensors that are compliant, long-lasting, and highly conductive – just the enabling technology needed. Multiple iterations later, our platform brings together an athletic headband, app, and algorithms to directly and accurately measure brain signals, anywhere, anytime – uncovering new brain insights never before understood. Cogwear is moving the standard-of-care for managing brain disorders, including Alzheimer's disease, CTE, epilepsy, and anxiety, and has established revenue-generating partnerships to fuse neuroscience insights with athletic performance, brain safety, team functions, and business applications.

There are two unique innovations that make Cogwear stand out. First, our headband sensors offer high-fidelity, clinical-grade measurement of brain waves anywhere, anytime. Designed for high-motion situations, Cogwear is the first solution that solves the problem of corrupted signals with user movement, enabling quality data whether someone is sitting in a clinic, playing sports, or walking down the street in Philadelphia.

Second, our AI-derived algorithms convert brainwaves, or EEG, to actionable insights for precision brain care. EEG is a very data-rich source of information. Much like a radio receiver tuning a specific signal, these brainwaves need to be decoded to relay specific physiologic information. New AI models, more specifically machine-learning and neural network techniques, provide better and more specific insights than have been available traditionally. As an example, human studies with our technology and over 2,000 participants have formed the basis to identify disorders such as anxiety and Alzheimer's Disease and measure them more accurately and easily than today's standard of care.

These applications are different than the AI chat-bots we may usually hear about in the public discourse. At their root, AI and machine-learning techniques are excellent pattern recognition and prediction algorithms. In our case, use of AI is not about making work easier or replacing existing jobs; rather, it's an enabler to create new

insights to drive better human health, peace-of-mind, and performance. We expect our work and new applications to augment existing medical roles and ultimately create new ones.

Cogwear is not the only company utilizing AI-techniques to unlock new capabilities. The nascent wearable brain-computer interface market itself is primed for explosive growth with attainable markets over \$20B. This sector contains both consumer-grade and FDA-cleared products and its first \$1B company valuation, achieved in 2024. Additionally, most major universities and several health systems within Pennsylvania are active in decoding brain signals using AI & machine-learning techniques. Beyond the brain, this approach to AI & machine-learning is applicable to many other areas within medicine to unlock better patient care. Examples include medical image recognition and assessment, prediction of disease onset from multiple vital signs, and ultimately enabling improved robotic surgery.

To truly provide better clinical outcomes, healthcare economics, and patient satisfaction, these new applications of AI & machine learning need to be accompanied by the same privacy expectations as patients have today. In Cogwear's case, brain data constitutes some of the most sensitive private health information available and maintaining patient privacy and confidentiality is a core value of our company. We advocate that patients control their own brain data and determine how it is used. The HIPAA-standard is one that serves healthcare applications well, and we see this as a broader approach that can be applied to manage any human biological information, within and outside of healthcare. These concerns have implications on how AI & machine learning itself is utilized. Given the power of these new algorithms and the insights they can provide about an individual, we support responsible AI – applications that maintain HIPAA-compliance, high security, and use of de-identified data only with the permission of the patient.

This rigorous security approach will have implications on how these applications are developed. Common AI servers such as ChatGPT, Gemini, or Claude cannot be used in these cases, as the analysis would be done in the public domain without the needed security constraints. This creates both a challenge and opportunity for companies active in medical applications: specifically-deployed, proprietary AI model development to fuel health outcomes.

Pennsylvania has been at the forefront of health innovation for decades through its expansive university network, multiple renowned healthcare systems, and leading biotech industries. AI is the next emerging technology that has the potential to

improve outcomes in healthcare by creating information and insights that previously were not available. With many organizations in Pennsylvania active in this area, Pennsylvania is poised to lead the responsible deployment of AI technology for healthcare, leading to better health and longevity not only for citizens our commonwealth, but for people throughout the country and worldwide.

Sincerely,

A handwritten signature in black ink, reading "David J. Yonce". The signature is fluid and cursive, with a long horizontal stroke at the end.

David J. Yonce
CEO, Cogwear, Inc.