

**Testimony of Charles Cole
Founder & Executive Director
The Brain Injury Research Foundation**

**Before the State of Ohio House Finance Committee Wednesday, June 12, 2024
Support of HB434, relating to Ohio's TBITXL pilot program**

Chairman Edwards, Vice Chair LaRe, Ranking Member Sweeney and members of the Ohio House Finance Committee, thank you for giving me the opportunity to testify today on HB434, The Traumatic Brain Injury Treatment Accelerator Pilot Program (TBITXL). My name is Chad Cole and I am the founder and executive director of The Brain Injury Research Foundation (TheBIRF) located in Cincinnati. I am also a survivor of and a scientific research advocate for traumatic brain injuries. In 2015 I suffered a traumatic brain injury (TBI) while wakeboarding and while I was in the hospital there were zero therapeutic clinical trials actively recruiting people in the United States. Fast-forward 8 years and there are still zero FDA-approved treatments to mitigate its effects. Similar to how spinal cord injuries can paralyze your limbs, traumatic brain injuries can "paralyze" your brain. Whenever I had flare ups, I would go to the emergency room but the only thing I could tell physicians was that my brain was on fire. There was nothing doctors could do to alleviate the unbearable pain, the visual agnosia, the nausea, and the constant pressure in my head.

When I share my story with you today, please know I am not alone fighting this battle against TBI. Traumatic brain injuries affect millions of Americans, with devastating consequences for individuals, families, and communities. In Ohio, the impact is particularly significant, with TBI-related expenses costing taxpayers an alarming \$6 billion annually in medical expenses and lost wages, according to the Ohio Department of Health. Specifically, over 113,000 Ohioans received emergency room care for TBIs in 2019. As we face this silent epidemic affecting millions of individuals and families across Ohio we need solutions.

These experiences motivated me to establish a nonprofit called The Brain Injury Research Foundation with the mission to fund and develop the first drug to treat traumatic brain injuries. Our goal for the outcome of this research is to ensure no one has to experience this traumatically life changing event without therapeutic relief.

Over the past two years, the Foundation has collaborated with leading scientists across the United States to develop the Traumatic Brain Injury Treatment Accelerator pilot program (TBITXL). Within this program, the BIRF plays a crucial role as a scientific clearinghouse, ensuring the open exchange of ideas, data, and assets between research communities in academia and private industry. Our infrastructure is geared towards supporting data coordination, visualization, and analytics across these teams, thereby enhancing the productivity of scientific research.

Following a thorough examination of all 44 established therapeutic clinical trials for traumatic brain injuries conducted over the past three decades, our team has pinpointed bioproductivity as a key factor influencing the industry's notable failure rate. Bioproductivity, a comprehensive measure assessing and enhancing pharmaceutical

processes at every stage of the product lifecycle, emerges as a significant contributor to this trend. Manual approaches and subjective interpretations have inherently constrained progress towards finding a cure. In our projects, we aim to integrate the collective intelligence of leading neuroscience teams in the state of Ohio to expedite the journey from concept to commercialization beyond conventional timelines.

We are requesting the State of Ohio to fund 2 specific programs. The first program could be called PRECEPT aka Preclinical Candidate Evaluation and Screening Platform for Traumatic Brain Injuries. PRECEPT is a grant program that will market the State of Ohio as the bio-hub for traumatic brain injury research. Scientists from across the United States can apply to this grant program, and if awarded, their drugs will undergo blind testing at two different universities in Ohio.

The second program that runs parallel to PRECEPT could be called SynapFx. SynapFx is a collaborative grant initiative between multiple universities in Ohio to develop treatments for traumatic brain injuries. SynapFx will manufacture the first ever co-development of multiple new investigational drugs to treat traumatic brain injuries. We are moving away from monomodal therapies using a single drug and taking advantage of multiomics data to develop meaningful combination therapies that have real-world efficacy. Each institution in Ohio receiving a SynapFx grant will be mandated to match the award with institutional, federal, or private foundation grants, ensuring a substantial return on investment for Ohioans. In addition, these grant-receiving institutions will leverage their funding to attract out-of-state neuroscientists, enriching the research landscape in Ohio.

SynapFx and PRECEPT were conceptualized to facilitate collaboration, enabling each university to leverage their expertise across various phases of a project, thereby enhancing the rate and effectiveness of successful drug launches. It's important to note that SynapFx differs from typical grant funding programs, such as those administered by the National Institutes of Health (NIH), which issue RFPs (Requests For Proposal) and fund extramural research grants. Instead, SynapFx will orchestrate collaborative planning sessions to assign responsibilities and tasks among teams, fostering a cohesive research plan that supports cutting-edge initiatives utilizing the latest technology in bioinformatics and machine learning.

During these sessions, research teams will identify problems and pose questions pertinent to the development of drugs for traumatic brain injuries. Subsequently, a joint research proposal will be crafted and submitted to a multidisciplinary scientific review panel, comprising various organizations, including 16 universities in Ohio. This panel will evaluate the projects' objectives and scientific merit. Upon approval, teams will utilize a software program known as Synapse to collaborate, share results, and track developmental milestones.

The urgency of developing new surgical and medical interventions is underscored by a stark reality: beyond the initial 11,332 hospitalizations and rehabilitation services provided to TBI patients in Ohio in 2019, approximately 50% of individuals will face a continued decline in their daily lives or will die within five years of their injury. It is a leading cause of death and disability in people under 45 years of age, and according to the Ohio Department of Health Bureau of Vital Statistics and the Ohio

Hospital Association, TBI's currently cost taxpayers \$6 billion a year as a result of hospital expenses and lost wages. This project will keep Ohio competitive and will relieve stress off our already burdened healthcare system.

In closing, I want to thank Representative Richardson for her insightful question during the first hearing of this bill. She asked, "Will The Brain Injury Research Foundation be the sole entity deciding which projects receive funding?" As stipulated in the companion bill in the Senate, SB272, the Chancellor of the Ohio Department of Higher Education, Mike Duffey, will establish a government advisory board to oversee the administration of the program, ensuring all checks and balances are in place for complete transparency and accountability. Should the Chancellor deem it necessary to achieve the program's goals, we are prepared to yield the authority to designate funds to his office upon request.

Additionally, all professors and scientists across Ohio are invited to join The Brain Injury Research Foundation's external advisory board, augmenting the due diligence of the Chancellor's oversight committee. To date, the external advisory board includes 18 professors from 16 different universities in Ohio, and we welcome everyone to join this exciting and transformative initiative for our state.

Chairman Edwards, Vice Chair LaRe, Ranking Member Sweeney and members of the Ohio House Finance Committee, thank you again for giving me the opportunity to testify today. I can answer your questions at this time.