



**Friday, September 24, 2021**

**9:00 - 11:00 A.M.**

**Virtual (via Google Meet)**

**Meeting Minutes**

### **Welcome and Introductions**

Dr. Perman gave opening remarks and reviewed the ground rules of a virtual meeting. He called the meeting to order and carried out a roll call to confirm attendance.

#### *Board Members in Attendance*

- Jay Perman, MD, Chancellor – University System Maryland [Chair]
- Richard A. Bendis, President and CEO – BioHealth Innovation Inc.
- Jarrod Borkat, Vice President Corporate Strategy – Emergent Biosolutions
- Rebecca Fisher, PhD, Deputy Director, Congressionally Directed Medical Research Programs – U.S. Army Medical Research and Development Command
- Wendy Perrow, MBA, CEO – Oncogenomics, LLC
- Martin Rosendale, CEO – Maryland Technology Council
- Joseph F. Sanchez, PhD, MBA, Director, North America R&D Science Engagement – AstraZeneca
- Bob Storey, Principal – The MVR Company
- Frank F. Weichold, MD, PhD, Senior Advisor, Office of Regulatory Science and Innovation, Office of the Commissioner – U.S. Food and Drug Administration
- Christy Wyskiel, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures – Johns Hopkins University

#### *Board Members not in Attendance*

- Jesse Christopher, MBA, CEO – Longeviti Neuro Solutions
- Laurie E. Locascio, PhD, Vice President for Research – University of Maryland, College and the University of Maryland, Baltimore
- Sanjay K. Rai, PhD, Chief Academic Officer and Senior Vice President for Academic Affairs – Montgomery College
- Arti Santhanam, PhD, Executive Director – Maryland Innovation Initiative Program, TEDCO (Ex-Officio)
- Kelly M. Schulz, Secretary – Maryland Department of Commerce (Ex-Officio)
- Brian Stamper, Director of Manufacturing – Kite Pharma

#### *Department of Commerce Attendees*

- Margia Argüello, MS, MBA – Senior Manager, Business Development, BioHealth and Life Sciences
- Ulyana Desiderio, PhD – Director, BioHealth & Life Sciences
- Heather Gramm – Senior Director, Strategic Industries & Entrepreneurship
- Tamar Osterman – Senior Business Development Representative, Carroll and Frederick Counties

- Lani Sinfield, Esq – Program Manager

#### *General Public Attendees*

- Dorn Carranza, PhD – U.S. Food and Drug Administration (FDA), OSEL
- Brandy Carter, PhD – BioTechnical Institute of Maryland
- Ann Ciekot – Public Policy Partners
- Edward Margerrison, PhD – U.S. Food and Drug Administration, OSEL
- Pamela Metz Kasemeyer – Schwartz, Metz & Wise, P.A.
- Travis McCready, JD – JLL
- Tina Morrison – U.S. Food and Drug Administration, OSEL

Dr. Perman reminded everyone about the Board’s charge to maintain Maryland’s preeminence in the life sciences industry and gave an overview of the meeting’s agenda.

#### **Review and Acceptance of June 2, 2021 Meeting Minutes**

Dr. Perman asked for feedback on the minutes of the June 2, 2021, LSAB meeting. Hearing none, he asked for a motion to approve the minutes which was made by Mr. Bendis and seconded by Mr. Borkat. The meeting minutes were approved unanimously.

#### **Accelerating Medical Technology Innovation with Regulatory Science Tools**

Dr. Margerrison gave a presentation on accelerating medical device innovation with appropriate and publicly available regulatory science tools. He covered regulatory science tools and their use in precompetitive space for product development, the difference between medical device development tools and consensus standards, and how the FDA’s Center for Devices and Radiological Health (CDRH) uses these tools. Dr. Margerrison described some examples of publicly available regulatory science tools: 1) virtual and physical phantoms (e.g., Photoacoustic Imaging physical phantom); 2) Centers for Medicare & Medicaid Services and related datasets (e.g., virtual family); 3) lab methodologies (e.g., color hazard and risk calculator, methods for extractables and leachables testing); and 4) best practices (e.g., material selection for specific applications). Future plans include expanding “owners' manuals,” the current regulatory sciences tools and product catalog of 120 towards a library that is the go-to place for evaluations and acceleration of innovation in the precompetitive space.

#### **Supporting Maryland Medical Technology Ecosystem**

Bob Story led the discussion on how companies can better engage with the regulatory process to de-risk innovation at an early stage of development and how to increase the awareness of all the resources available for the business community. He discussed an example of recent collaboration between the National Cancer Institute’s Small Business Innovation Research center and the CDRH on evaluation datasets as medical device development tools for testing cancer technologies. Another example discussed was the National Institutes of Health’s Rapid Acceleration of Diagnostics (RADx®) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing in collaboration with the FDA and other federal agencies. Ms. Perrow and Dr. Margerrison discussed the use of virtual family/population, a set of anatomically correct whole-body models for thermal, electromagnetic, and fluid dynamic simulations. The Board discussed coordinating resources and expertise across the state, including universities, federal agencies, and incubators to support start-ups. Mr. Storey shared some ideas of engaging the Advanced Medical Technology Association and positioning Maryland as a strong partner for the FDA in de-risking medical technology innovation.

### **BioTechnical Institute of Maryland Introduction**

Dr. Carter gave an overview of the BioTechnical Institute (BTI) of Maryland's mission to train and place entry-level biotechnicians in Maryland's rapidly expanding biotech industry. The BTI Laboratory Associates Program provides tuition-free training in basic laboratory skills to bright, ambitious, unemployed, and under-employed residents of the region. Since its founding in 1998, BTI has successfully trained more than 500 students and placed nearly 400. BTI also provides 15 fee-based workshops annually on relevant topics to industry professionals through BioSciConcepts, BTI's social venture.

Dr. Carter shared BTI's future plans: expand and revise the curriculum to include biomanufacturing; replicate the program in other parts of the state; create articulation agreements with Maryland universities; develop relationships with new biotech companies moving into the area; strengthen the pipeline between BTI and employers; increase number of cohorts ran per year; cultivate a relationship with Baltimore City public schools to introduce K-12 students to life sciences; identify city agencies to increase the capacity to offer wrap-around services to participants that will assist in alleviating barriers.

The Board expressed strong support for the BTI's mission and thanked Dr. Carter for her leadership. Dr. Sanchez and Dr. Carter discussed ongoing efforts in advocating for removal of degree requirements from some job descriptions that would make it easier for trained talent to enter the life sciences industry.

### **LSAB-MTC Workforce Development Task Force Update**

Dr. Sanchez gave a year-end update on the task force's activities, reporting that all three working groups are on track on meeting their goals: 1) develop resources for navigating biotech career paths and coordinate a marketing campaign to promote these careers to talent and talent influencers (i.e., BioHub Maryland); 2) plan and coordinate a high-touch, inclusive outreach program to local and out of state talent; and 3) coordinate stakeholders to improve process and scale of trainee experiences.

Board members congratulated the task force on its progress and thanked Dr. Sanchez and Mr. Stamper for their leadership. Mr. Jarrod asked how the Board can continue supporting these efforts and Board members agreed to raise awareness and contribute to content on the BioHub Maryland website. Dr. Fisher shared information about the U.S. Army Educational Outreach Program which offers opportunities for training and education in relevant STEM areas, including internship opportunities in Maryland.

### **Maryland Biotechnology Investment Incentive Tax Credit Discussion**

Ms. Gramm gave a short introduction of the Maryland Biotechnology Investment Incentive Tax Credit which is designed to incentivize private investment in early-stage biotech companies. Ms. Sinfield provided an overview of the modifications made in 2021 with the goal of improving access to the program to more companies. Ms. Sinfield reviewed the application process, the qualifications and summarized the growth of the program which in FY2020 qualified 18 companies, approved 162 investor applications resulting in total private investments of \$23.5 million.

The Board is supportive of the program, noting that most investors who applied received the credit. Mr. Borat and Mr. Bendis suggested raising the awareness of this program at the next BioHealth Capital Region Forum and Investor Conference.

**Closing Remarks**

Dr. Perman thanked everyone for attending and actively participating in the meeting. Members wishing to submit items for the next meeting's agenda should contact Dr. Desiderio. Dr. Perman adjourned the meeting at 10:45 a.m.