

- **Value of Life Science Technologies:** Life Science Tennessee (LST) will focus on the value of our industry in developing life-saving drugs and therapies that contribute to the health of Tennesseans and Tennessee's economy.
- **Medical Lab Personnel:** We ask legislators to level the playing field for non-government owned laboratories and allow these labs access to a larger pool of qualified candidates.
- **SBIR/STTR Matching Program:** We ask legislators to restore funding for the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) matching program to expand opportunities for our most promising state-grown technologies.
- **Support a strong life science workforce:** Skilled workers are essential to life science growth in Tennessee.
- **Rare Disease Advisory Council:** We ask legislators to support the ongoing work of the Council to educate the public about rare diseases and promote the development of and access to effective treatments.
- **Medical Device Facility Bill Implementation:** We will work with the TN Board of Pharmacy to ensure that Tennessee's regulations and inspections are not duplicative in their attempt to safeguard patients.
- **Support the adoption and widespread dissemination of FDA-approved vaccines to fight disease and epidemic:** In a pandemic, a vaccine is only as good as its widespread adoption by the public.

Recognize the Importance and Value of Medical Innovation

New therapies for advancements in personalized medicine, vaccines and pain management are curing previously incurable diseases and transforming care delivery to patients. The innovations limit the growth of health care costs overall by effectively treating patients and minimalizing hospitalizations. Many companies in our state research and develop these life-saving therapies, while providing high-paying jobs to Tennesseans.

We must continue to support the industry that brings cures to the market and also support the accessibility of these medicines and therapies to patients.

Modernize Medical Laboratory Personnel Requirements

Tennessee is one of the top three most regulated states for its oversight of clinical laboratory personnel. The state's undue and unwieldy regulation and licensure process is restrictive to diagnostic labs—both startups and established labs—that want to grow their businesses and expand and improve diagnostics for Tennessee patients and beyond. The State of Tennessee itself has experienced the heavy burdens of its own requirements, so much so that it removed itself by exempting state-owned laboratories from those requirements in the last legislative session.

HB 226/ SB 982 seeks to make permanent Executive Order #36 and modernize the Tennessee Medical Laboratory Act, leveling the playing field for non-government owned laboratories and allowing these labs access to a larger pool of qualified candidates.

According to the most recent report from BIO, Tennessee has more than 8,000 employees in the medical laboratory and diagnostics industry. The clinical diagnostics and precision medicine industry has experienced substantial growth in recent years across the globe and is forecast to grow at a rate between 10 to 12 percent annually up to 2023. We should not impose burdensome restrictions on this growth.

Expand Commercialization with the SBIR/STTR Matching Program

Life Science Tennessee supports renewed funding for the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) matching program, which continues to be one of the state's most promising ways to support the commercialization of high-value startups in Tennessee. The SBIR/STTR program is a competitive awards based-program whose goal is to transform federally funded research and development into public benefit through commercialization efforts. It was designated as a federal program by President Ronald Reagan in 1982.

Tennessee's SBIR/STTR matching program, administered by LaunchTN, was first signed into law during the 2016 session and funded in the 2017, 2018 and 2019 sessions. The matching program is an important tool that bolsters entrepreneurship in the state by matching federal dollars allotted to exciting, job-creating new Tennessee companies. It's a small budget item with a big reward as it incentivizes the best and brightest companies and professionals in Tennessee to build their technologies here.

To date, 52 companies have leveraged almost \$24 million federal dollars. These funds have helped Tennessee small businesses hire additional employees, build better technologies, and obtain more capital to further growth here at home. As of June 2020, 60% of companies had gone on to raise over \$53 million in private capital, and 58% have since generated revenue.

LST asks for the restoration of SBIR/STTR funding so that the state can continue to meet the needs of grant winners.

Support a strong life science workforce for Tennessee

In 2020 Life Science TN strategically aligned with BioTN, a 501c3 non-profit supporting STEM-based education and workforce development programming across the state. Recently a report from the American Association for the Advancement of Science (AAAS) stated that Tennessee's STEM-based jobs generated \$16.5 billion in state and local tax revenues and is on track to grow more than 20 percent over the next 10 years. Life Science TN asks for the continued support of STEM education to support a skilled life science workforce and the high-tech jobs of Tennessee's future.

Continue to Support the TennCare Rare Disease Advisory Council

In the 111th General Session, Tennessee established an advisory council composed of qualified professionals and persons living with rare diseases to advise the TennCare Drug Utilization Review Board when reviewing products or medications for the treatment of a rare disease, as well as advise other state departments on policies that impact those living with a rare disease. We ask legislators to continue to support the Council.

A rare disease is defined as a disease that affects fewer than 200,000 people. There are 7,000 known rare diseases affecting approximately 30 million men, women and children in the United States. While the exact cause for many rare diseases remains unknown, 80 percent of rare diseases are genetic in origin and can be linked to mutations in a single gene or in multiple genes, which can be passed down from generation to generation.

Challenges to a person who has a rare disease include delays in obtaining a diagnosis, misdiagnosis, shortages of medical specialists who can provide treatment and lack of access to therapies and medication used to treat rare diseases. Researchers have made considerable progress in developing diagnostic tools and treatment protocols as well as in discovering methods of prevention and treatment, but much more remains in the search for new therapies.

Continue to Support Clarification of Medical Device Facility Inspection

Life Science Tennessee is working with the TN Board of Pharmacy (TNBoP) to ensure that Tennessee's regulations and inspections of our state's medical device facilities are an effective tool that contributes to safeguarding patients. A compromise process is underway to help retain TNBoP oversight, but also simplify and streamline this oversight by having device firms report their compliance from such agencies as the FDA, ISO, or Medical Device Single Audit Program (MDSAP) periodically to the TNBoP. We wish to update lawmakers to let them know that our industry is working with TNBoP and hopes this process will be completed soon.

Support the adoption and widespread dissemination of FDA-approved vaccines to fight disease and epidemic

Vaccines support our immune system's complex and robust defense mechanisms by preemptively giving the body the tools it needs to fight germs, bacteria, or viruses. To end the COVID-19 pandemic, scientific researchers, biopharma companies, and government have worked together a breakneck pace to bring vaccines that are safe and effective in fighting the novel coronavirus. However, developing vaccines is only part of the battle. We will not find relief from this pandemic unless we ensure all families and communities have access to vaccines—and have confidence in taking them. We ask all legislators to work to build trust in our industry's unprecedented response to this pandemic and to support the widespread adoption and dissemination of vital vaccines for COVID-19 and other diseases.

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