

- **Value of Life Science Technologies:** Life Science Tennessee (LST) will focus on the value of our industry in developing life-saving drugs and therapies and contributing to Tennessee's economic growth.
- **SBIR/STTR Matching Program:** We ask legislators to renew and increase 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.
- **Laboratory Personnel Requirements:** We will work with our members and other medical laboratories with facilities in Tennessee to update state law regarding the unnecessary requirement for laboratory personnel to attain specific training in certain scientific fields (MTs or MLTs), rather than the broad range of scientific training needed to staff modern laboratories.
- **State of Tennessee Open Records Policy:** We will seek to protect exemptions for proprietary information obtained through sponsored research at our state's academic institutions.
- **Medical Device Facility Bill Implementation:** We will continue to monitor the Medical Device Facility bill as it moves through the administrative process to eliminate undue and inconsequential assessments.
- **Life Science Caucus:** We encourage legislators to join the Tennessee General Assembly Life Science Caucus chaired by Sen. Haile and Rep. White.

Recognize the Importance and Value of Pharmaceuticals

New therapies, such as cancer immunotherapies, a cure for hepatitis C, and highly effective cholesterol drugs, are transforming care for patients fighting debilitating diseases. These innovations limit the growth of health care costs overall by effectively treating patients and keeping them out of hospitals. Many companies in the state research and develop life-saving drugs and therapies, while providing high-paying jobs to Tennesseans. Life Science Tennessee asks state lawmakers to oppose any legislation that would inhibit research and development of life-saving drugs and therapies and innovate new cures for patients.

Life Science Tennessee also urges caution regarding drug pricing or transparency legislation that would single out the pharmaceutical industry. While we welcome the vigorous public debate on the subject, we emphasize the true complexity involved in pricing drugs. Pharmaceutical pricing is driven by several parts of the health care sector including pharmacy benefit managers, insurance companies, and hospitals—all of whom may keep rebates instead of passing them on to consumers. Moreover, the share of spending on retail medicines remains the same as it was 50 years ago. We ask legislators to consider all parties involved in determining drug pricing.

Expand Commercialization with the SBIR/STTR Matching Program

Life Science Tennessee asks legislators to continue its support of the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) matching program that was first signed into law in 2016. 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. To date, 24 companies have leveraged more than \$15 million federal dollars.

We ask lawmakers to consider increasing funding for the matching program to allow us to support more companies who have already been vetted for success through a very thorough federal process. With the current appropriation, we are short of meeting the demand from grant winners.

Modernize the Tennessee Medical Laboratory Act

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. The State of Tennessee itself has experienced the heavy burdens of its own requirements, so much so that it exempted state-owned laboratories from these requirements in the last legislative session.

HB 382 (Rep. Ron Gant) & SB 318 (Sen. Shane Reeves) seek to 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.

Protect Proprietary Research

A process is currently underway in the Tennessee General Assembly to protect and review exemptions to Tennessee's Public Records Act. This process will continue through the legislature's Joint Government Operations Committee later this year.

Life Science Tennessee and our member companies are interested in an exemption that protects proprietary information obtained through sponsored research at our state's academic institutions. Our interest in this process is both an effort to protect academic research, as well as propriety research attained to bring new life science technologies to market. States with the most vibrant economies have at least one critically shared characteristic: they have nationally-ranked research universities that are actively engaged in projects funded by the private sector. Protecting the research at these institutions is vital to the vibrancy of Tennessee's research-based economy.

Clarify 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. The industry believes that the TNBoP's current process is unnecessary to the device manufacturing and distribution process, that it adds no value, and that it is a lesser and duplicative process of national and international authorities that already regulate the industry.

We wish to update lawmakers to let them know that our industry is working with TNBoP to determine the best regulatory policies. 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.

Join the Life Science Caucus

We encourage legislators to join the Tennessee General Assembly Life Science Caucus chaired by Sen. Haile and Rep. White. The Caucus is focused on learning more about the life science sector and how the industry fits into the health care chain. If you are interested in joining the caucus, please email Megan Lane at megan@lane-gr.com

For more information, contact Abby Trotter, Executive Director, at 615-242-8856 or atrotter@lifesciencetn.org