

Life Science Tennessee is the premier advocacy organization representing the life science industry in the state. Life Science Tennessee members include companies, individuals, research institutions, universities, and government and economic development groups.

Leadership at Life Science Tennessee has pinpointed both state and federal policy issues to support during the 2016 legislative year. The organization applauds the efforts of state legislators to assist the industry in improving patient access to life-saving drugs and therapies. For more information about Life Science Tennessee and these recommendations, please contact Abby Trotter, executive director, at 615-242-8856 or atrotter@lifesciencetn.org.

LIFE SCIENCE TENNESSEE 2016 POLICY RECOMMENDATIONS:

- **Clarify Medical Device Facility Inspection Requirements: HB 1784/SB 2607 are caption bills** that can be used to clarify the Tennessee Board of Pharmacy inspection requirements for medical device facilities in Tennessee.
- **Support SBIR Matching Bill: HB 1837/SB 2606 are caption bills** that are potential legislative vehicles to implement a Small Business Innovation Research/Small Technology Transfer Innovation Research (SBIR/STTR) matching program to ensure Tennessee start-up companies receive needed capital to fund job-creating businesses and new technologies.
- **Oppose Government Price Controls for Pharmaceuticals: Oppose HB 2206/SB 2442**, legislation that directs the Tennessee Department of Health to dictate prescription drug pricing.

Clarify Medical Device Facility Inspection

Life Science Tennessee asks state lawmakers to support the clarification of the Tennessee Board of Pharmacy's inspection authority over medical device facilities. As of now, the Board has interpreted state law such that it can regulate these facilities. This is problematic, since medical device manufacturing sites differ significantly from facilities that manufacture drugs. Additionally, Board inspection duplicates U.S. Food and Drug Administration (FDA) regulation and is therefore unnecessarily cumbersome for manufacturers.

Life Science Tennessee members report that the Board's redundant oversight is confusing, overly burdensome, and a poor use of time for inspectors trained to assess pharmaceutical facilities rather than device manufacturers. HB 1784 and SB 2607 are caption bills sponsored by Chairman Sexton and Leader Norris that could be used as an opportunity to solve this problem by eliminating required Board inspections, maintaining current medical device facility registration and fee structure and creating a grace period for facility registration. These steps will curb regulatory hurdles for Tennessee device companies and enable them to remain focused on medical advances.

Support SBIR Matching Bill

Life Science Tennessee asks legislators to bolster entrepreneurship in the state by implementing a Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) matching program. The program matches federal dollars allotted to exciting new companies in the state, thus enabling them to thrive and provide new jobs for Tennesseans.

In Tennessee, for example, companies including Cumberland Pharmaceuticals, Insight Genetics, Molecular Sensing Inc. and Advanced Plasma Products won SBIR/STTR grants in recent years. Each company used the funding to further research novel devices, diagnostics or treatments. An SBIR/STTR matching program would carry federal dollars even further for comparable companies.

Such programs have been remarkably successful in other states. Kentucky, for example, implemented an SBIR/STTR Matching Funds Program in 2006. Since then, 237 Kentucky companies have received matching funds and the program has leveraged over \$90 million in federal grant money. Implementing a similar program locally would support Tennessee's status as a premier research and development state.

HB 1837/SB 2606 are caption bills sponsored by Chairman Sexton and Leader Norris, which could be used to authorize an SBIR/STTR matching program in Tennessee.

Oppose Government Price Controls for Pharmaceuticals

Life Science Tennessee urges the Tennessee General Assembly to oppose HB2206/SB2442, which would require the Tennessee Department of Health to dictate drug prices. Implementation of this bill would set a dangerous precedent of allowing state government to single out a specific industry and regulate the price of its products. Moreover, the bill fails to provide clear guidelines on how to calculate the cost of drug development – a complex process that often spans decades.

Life Science Tennessee looks forward to thoughtful, informed discussions about the cost of care, but not harmful policies that single out one industry. Lifesaving drugs created by the pharmaceutical industry are only one piece of a complex web of care, but they are vital to the health care system. Since 1995, for example, the death rate for HIV/AIDS has dropped by 85% as a direct result of medical advances. New treatments for the disease have saved some 860,000 lives. Also, 83% of children with cancer survive to adulthood, compared to 58% in 1970. Life Science Tennessee opposes any unsound policy that jeopardizes patients' access to care and stifles innovation of lifesaving treatments.