LIFE SCIENCE TENNESSEE

2020 STATE POLICY RECOMMENDATIONS

- **Value of Life Science Technologies:** Life Science Tennessee (LST) will focus on the value of our industry in developing life-saving drugs and therapies contributing to the health of Tennesseans and Tennessee's economy.
- **SBIR/STTR Matching Program:** We ask legislators to establish recurring 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.
- **Rare Disease Advisory Council:** We ask legislators to support SB2124/HB2505 establishing an advisory council to educate the public about rare diseases and promoting development and access to effective treatments.
- **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.

Recognize the Importance and Value of Medical Innovation

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 **urges opposition to the closed-formulary model in the TennCare II Waiver request**. Introduction of a closed-formulary model would block Tennessee's most vulnerable patients from accessing cutting-edge care by putting government bureaucracy between these patients and their doctors. TennCare has stated in the draft waiver a desire to save money on prescription drugs by limiting or eliminating access to many drugs available for specific disease classes, including only approving one drug per formulary class. It would also seek to exclude new, innovative drugs approved through any of the FDA's accelerated approval processes. This statement ignores the fact that drugs approved through the FDA's accelerated pathways meet strict safety and efficacy requirements and are in the accelerated approval process because they are necessary to treat serious and life-threatening diseases for which there is no better cure or treatment.

We also ask you to **oppose legislation that singles out price caps on pharmaceutical manufacturers and innovators (SB1939/HB1931)**. 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 and aspects involved in determining drug pricing.

We ask that you **reform Tennessee's step therapy protocols (SB1935/HB1866) to protect patient-provider relationships**. Step therapy is a process that requires patients to try and fail on one or more medications chosen by their insurer before they can access the treatment recommended by their physician. Step therapy protocols vary widely among insurers and can interfere with the patient-provider relationship. For patients living with serious or chronic illnesses, step therapy may prolong ineffective treatments and delay access to the right treatment.

LST believes that Tennessee's opioid crisis can be addressed through medical innovation. **We ask legislators to support the development and adoption of opioid alternatives.** LST urges legislators to support continued advancements in opioid alternatives and the deployment of these innovations by removing barriers to entry, including reimbursement challenges, as well as support of patient education on opioid alternatives (SB1912/HB1917).

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, 52 companies have leveraged $24 million federal dollars.

Last year, lawmakers increased funding for the matching program to support more companies who have already been vetted for success through a very thorough federal process. This year, LST asks that this funding be made recurring with the current appropriation of $3 million to allow the state to better meet the demand from grant winners.

Establish a Rare Disease Advisory Council

A rare disease, sometimes called an orphan 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.

An advisory council composed of qualified professionals and persons living with rare diseases will advise the TennCare Drug Utilization Review Board when reviewing products or medications for the treatment of a rare disease, as well as drugs or biological products within the emerging field of personalized medicine. We ask legislators to establish an advisory council that would promote access to effective treatments (SB2124/HB2505).

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, adds no value, and 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 TNBofP 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 TNBofP.

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