

LIFE SCIENCE TENNESSEE

2023 Federal Policy Agenda



Life Science Tennessee (LST) is the premier advocacy organization representing companies, research institutions, universities, and economic development groups seeking to advance and grow the life science industry in Tennessee.

Leadership at LST has identified several key federal policy issues, listed below, for the 118th Congress. We applaud the efforts of federal 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 atrotter@lifesciencetn.org.

Recognize the Value of Medical Advances

Life Science Tennessee urges Congress to bear in mind the true value of medical innovation during ongoing discussions about the cost of drugs, biologics, and medical devices. New therapies for advancements in personalized medicine, vaccines, and pain management are curing previously incurable diseases and transforming care delivery to patients. These innovations limit 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.

The nation's bioscience industry employed 2.1 million employees across more than 127,000 U.S. business establishments in 2021. In Tennessee, more than 44,000 people are employed across 2,899 businesses.

If the U.S. were to initiate restrictive pricing and access, it would seriously harm investment in the next generation of medical breakthroughs.

Fund Research for Lifesaving Drugs and Therapies

NIH-funded research conducted at academic and medical institutions in communities in every state in the nation is an engine for medical progress and economic growth. NIH research fuels the pipeline of discovery and innovation necessary to prevent, treat, and cure our most vexing diseases with 8.4 percent of all NIH grants used to generate patents for new drugs, medical devices, and other medicine-related technologies. It also has a significant economic impact. For example, the human genome project, to which genetic testing companies like 23andMe owe their existence, cost around \$3.8 billion but is estimated to have generated \$796 billion in economic impact.

Tennessee's scientific community is actively engaged in investigating possible cures for diseases such as Alzheimer's, ALS, cancer, and pandemics including COVID-19.

Tennessee’s research universities conducted \$888 million in bioscience-related academic R&D in 2020. The need for this work is only increasing, and Tennessee’s scientists need adequate resources –meaning sustainable funding and continued annual growth in the NIH budget at a rate that outpaces inflation—to help solve pressing health issues. With NIH support, Tennessee can continue its trajectory as a top-tier research state. Additionally, proper funding for Tennessee scientists will contribute to the effort to maintain U.S. international leadership in biomedical research.

For FY 2024, we respectfully request an appropriation of at least \$54 billion for NIH.

Maintain Adequate Medical Device Sterilization Capacity

Ethylene Oxide (EtO) is a chemical used to sterilize more than half of medical products in the U.S., many of which can’t stand up to other forms of sterilization. The U.S. Environmental Protection Agency (EPA) is expected to revise regulations regarding EtO in the near future in response to concerns about the impact of emissions from sterilization facilities upon local communities. The medical technology industry is sensitive to these concerns and is working with the U.S. Food and Drug Administration (FDA) to reduce the amount of EtO used to effectively sterilize products, even in advance of EPA’s rulemaking. Should legislation related to EtO come before Congress, Life Science Tennessee encourages policymakers to be mindful of the FDA’s concern that “other methods of sterilization cannot currently replace the use of [EtO] for many devices. To that end, we are equally concerned about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations.”

Protect American Innovation

Our members represent the startups and investors leading to disruptive breakthroughs and the technology transfer experts at our nation’s leading research universities. There are several threats that weaken patent rights and stifle innovation. For example, the U.S. supported a waiver of international IP protections for COVID-19 vaccines, commonly known as the TRIPS waiver, and is now considering an expansion of that waiver to diagnostics and therapeutics. This would be catastrophic for our innovators, favor foreign competitors like China and India, and do nothing to address the lingering pandemic. This is an economic, public health, and national security benefit we must not sacrifice.

Patents are the basis for investment in early-stage pre-revenue companies. The ability to license a patent enables tech transfer which is the mainspring of our system of leveraging modest federal investments in basic research into much larger private investments that turn these discoveries into revolutionary cures.

