Life Sciences Pennsylvania
Written Testimony
Submitted to the Pennsylvania House Committee on Commerce March 22, 2024
March 25 Informational Hearing on Right to Repair

To Chair Conklin, Chair Emrick and Members of the Pennsylvania House of Representatives Committee on Commerce:

Thank you for the opportunity to submit written testimony on the issue of "Right to Repair."

Life Sciences Pennsylvania (LSPA) is the statewide trade association for the commonwealth's life sciences community. Since our founding in 1989, the mission of LSPA has been to ensure Pennsylvania is a life sciences leader by facilitating the formation, growth, and success of the life sciences ecosystem through public policy advocacy and facilitating strategic connections. Our organization represents more than 900 members, including small biotech companies, medical device and diagnostic makers, pharmaceutical manufacturers, patient advocacy organizations, academic research institutions, investment firms with R&D-based portfolios and myriad service providers related to the development of groundbreaking therapies, cures, and technologies.

Specific to the issue of Right to Repair are our medical technology member organizations. Life Sciences PA has 91 medical technology entities in its membership and, according to our 2022 report on the Pennsylvania Life Sciences Industry, there are more than 400 medical technology entities across the state. These companies are devoted to researching and developing medical devices and diagnostics that allow people to live longer, healthier, and more productive lives. The companies in our membership develop and manufacture everything from catheters and imaging equipment to novel devices in oncology and robotic surgery.

Patient safety is of the utmost importance to our medical technology members. The devices and diagnostics our members bring to patients go through years of development and thorough review by the U.S. Food and Drug Administration (FDA) – the recognized gold standard, worldwide in technology review for safety and efficacy.

Medical devices, like most complex equipment, need periodic maintenance and repair. Proper servicing of these life-saving and life-sustaining devices is vital to their safe and effective functioning and the safety of patients and device users. As part of their commitment to patient safety, original equipment manufacturers (OEMs) dedicate extensive resources to establishing comprehensive servicing programs to ensure their devices are properly maintained and continue to meet safety and effectiveness requirements determined by FDA.

Legislation has, and continues to be discussed, in states throughout the country that would allow third-party repair servicers to attempt to repair these complex devices, and no longer rely on OEMs. Often times these proposals give unregulated third-party servicers unlimited access to service manuals and other proprietary OEM information, and would serve to put patients and device users at greater risk. Access to the latest manuals is no substitute for the extensive training, knowledge and expertise provided by the OEM. Life Sciences PA has serious concerns about any Right to Repair legislation in

Pennsylvania that would allow third-party servicers to interfere with medical devices. In fact, A 2018 report by the FDA found more than 4,300 adverse events – including 294 serious injuries and 40 deaths – from devices repaired by unauthorized third-party providers.

To provide greater context on the issue, we asked several of our member organizations to give their thoughts on the matter. ActiveProtective in Montgomery County gave the following statement:

> *ActiveProtective is a medical device startup committed to revolutionizing falls management and improving the lives of older adults. Our flagship product, the Tango Belt, integrates cutting-edge technology into a wearable device to mitigate fall-induced major hip injuries, a leading cause of disability and fatal injury in older adults. The Tango Belt was designated a Breakthrough Device by the FDA to recognize its potential to significantly improve upon the standard of care.*
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> *The Tango Belt incorporates proprietary technology that is both sophisticated (sensors, microprocessors, etc.) and requires special handling during manufacturing (high pressure cold-gas inflator, pyrotechnic activator, etc.). In order to ensure the product meets its intended use following FDA market authorization and the safety of service workers, it is imperative that service only be performed by professionals authorized and trained by ActiveProtective.*

For these reasons and those outlined above we believe medical technologies should be uniquely considered in this process and request a full exemption for medical device manufacturers in any subsequent legislation.

Thank you for your consideration in this matter. If you have any questions, please contact me or our Senior Vice President, Policy & Public Affairs, Kurt Imhof.

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