



April 29, 2024

The Honorable Gary Peters
Senator
724 Hart Senate Office Building
Washington, DC 20510

The Honorable Bill Hagerty
Senator
251 Russell Senate Office Building
Washington, DC 20510

The Honorable Raja Krishnamoorthi
Representative
2367 Rayburn House Office Building
Washington, DC 20515

In Re: H.R. 7085, the BIOSECURE Act, and S. 3558, the Prohibiting Foreign Access to American Genetic Information Act of 2024

Dear Representative Krishnamoorthi and Senators Peters and Hagerty:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) send these comments regarding H.R. 7085, the BIOSECURE Act, and S. 3558, the Prohibiting Foreign Access to American Genetic Information Act of 2024. While we appreciate the intent of the bills, we are concerned they could have unintended consequences for the tissue banking industry and the millions of patients in the United States who receive a tissue allograft transplant each year. Tissue banks contract with US agencies such as the Departments of Veterans Affairs and Defense to ensure service members and veterans have access to wound care and other tissue products, and we are particularly concerned that the proposed legislation could inadvertently prevent those patients from getting the allografts they need for the treatment of significant injuries or disease.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated

tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

The AATB and TPG appreciate your interest in protecting companies and patients in the United States from threats abroad, but we are concerned that the H.R. 7085 and S. 3558 could have significant unintended consequences and urge you to make modifications to mitigate those risks. Specifically, the legislation would prohibit the federal government from entering into contracts with biotechnology companies of concern – namely, BGI, MGI, Complete Genomics, WuXi Apptec, and related companies -- and entities that use equipment or services produced or provided by a biotechnology company of concern. While this limitation may make sense for activities involving trade secrets, high-value intellectual property, and genomic data and sensitive health information, the AATB and TPG are concerned that other, low-risk services typically performed by these companies to AATB accredited tissue banks would be restricted unnecessarily – with limited or no domestic options to replace the services performed by the companies of concern. For example, AATB and TPG members utilize these companies for activities like manufacturing of tissue-based biologics; osteoinductive assessment; sterility, endotoxin, and calcium testing; Karl Fischer Residual Moisture analysis, which verifies the water content in products; and package integrity testing to confirm the allograft tissue product will remain sterile prior to transplantation. These activities are critical to ensuring the availability and safety of the millions of tissue allografts transplanted each year.

For that reason, the AATB and TPG encourage you to revise the bills to exclude activities that do not pose a national security or patient privacy risk, such as those activities listed above; support initiatives to increase domestic capacity to perform the (low-risk) services provided by the biotechnology companies of concern described in the legislation; and, to the extent possible, delay implementation of the bill to provide for such increase in domestic capacity.

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We hope that you will find this information useful in your deliberations. The AATB and TPG stand ready and willing to assist in any way that you deem appropriate.

Respectfully,



Marc Pearce
President & CEO
American Association of Tissue Banks



Doug Wilson
Chair
Tissue Policy Group

CC: Chairman James Comer and Ranking Member Jamie Raskin, House Committee on Oversight and Accountability; and Ranking Member Rand Paul, Senate Committee on Homeland Security & Governmental Affairs