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Bipartisan, Bicameral Legislation Targeting Foreign Biotechnology Companies of Concern May Impact Recipients of Government Funding, Contracts

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On January 25, 2024, bipartisan members of the US House of Representatives introduced legislation – the BIOSECURE Act – aimed at preventing certain foreign biotechnology firms deemed to present threats to US national security interests from obtaining US government funding and imposing related US government contracting restrictions (see House Bill 7085). A substantively identical bipartisan bill also was introduced in the US Senate (Senate Bill 3558). Together, the House and Senate bills are related to ongoing congressional concerns, as well as an investigation by the House Select Committee on Strategic Competition between the United States and the Chinese Communist Party, which focuses on possible access by certain Chinese companies to American citizens' genetic information and other sensitive health data.

As currently drafted, the BIOSECURE Act would prohibit federal agencies from contracting with the following:

- BGI (formerly Beijing Genomics Institute), MGI, Complete Genomics, WuXi Apptec, and any subsidiary, parent affiliate, or successor of such entities; or
- Any entity from China, Russia, Iran or North Korea designated on a list published by the Director of the Office of Management and Budget, in consultation with the Secretary of Defense, Attorney General, Secretary of Health and Human Services, Secretary of Commerce, Director of National Intelligence, Secretary of Homeland Security and Secretary of State (each of the foregoing a **"Biotechnology Company of Concern"**).

Notably, the BIOSECURE Act also seeks to prohibit the US government from entering into, extending or renewing a contract with any entity that uses biotechnology equipment originating from – or services provided by – a Biotechnology Company of Concern. This may cause companies receiving government funding to terminate the use of biotechnology equipment or receipt of services linked to a Biotechnology Company of Concern.

Preliminarily, biotechnology equipment is defined broadly to include equipment, instruments, apparatus machines or devices (including components and accessories thereof) designed for use in research, development, production or analysis of biological materials. Examples of biotechnology equipment include genetic sequencers, mass spectrometers, polymerase chain reaction machines, and software, firmware, or other digital components specifically designed for use in – and necessary to operate – such equipment. Biotechnology services are defined broadly to include any service for the research, development, production, analysis, detection or provision of information, including data storage and transmission related to biological materials. Biotechnology services include advising, consulting or support services for the use or implementation of any biotechnology equipment and genealogical information. Additional biotechnology equipment or services may be added to the scope.

Although the current House and Senate bills remain in the early stages of the legislative process, bipartisan support and textual similarities may increase the likelihood that some version of the bills may become law. In anticipation thereof, life sciences companies should consider assessing the scope of their existing or contemplated federal contracts (including subcontractor arrangements with federal government contractors), understanding and possibly revising relevant termination provisions, and evaluating their equipment inventories and other activities relating to Biotechnology Companies of Concern.

Cooley will continue to monitor the progress of the House and Senate bills. Please feel free to contact a member of our team with any questions.

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