

Administration Focus on Protecting US Biotech Industry Could Cause Unintentional Harm By Impeding Foreign Investment and Collaborations

CFIUS Background

The Committee on Foreign Investment in the United States (CFIUS) is a Treasury-led interagency group that brings together the defense and intelligence community together with the Commerce Department, the U.S. Trade Representative, and others¹ to review and potentially block inbound investment deals (e.g., mergers, acquisitions and takeovers) that pose risks to national security. In assessing the potential risks to national security by a foreign investment transaction, CFIUS considers three issues: (i) the threat, which involves an assessment of the intent and capabilities of the acquirer; (ii) the vulnerability, which involves an assessment of the aspects of the U.S. business that could impact national security; and (iii) the potential national security consequences if the buyer were to exploit the vulnerability.² CFIUS historically had the authority to review transactions that would afford foreign persons a controlling stake in a U.S. business, but under FIRRMA its authorities have been broadened (more details on the new scope of CFIUS are provided below).

The Commerce Department administers, in coordination with other agencies, the “dual-use” export control regime that regulates the export and transfer of goods and technology that have a commercial use but also another use that could harm U.S. interests if exploited by foreign actors. Currently, many of the export controls are focused on restricting the transfer of sensitive technologies to avoid the proliferation of nuclear, chemical and biological weapons.

CFIUS and the export control regime are two distinct interagency processes that work together to protect national security. CFIUS is a transaction-based review process that implements constraints or prohibits certain inbound investment deals with foreigners that present national security concerns. The export control system prohibits certain goods and technology from being exported or transferred to certain foreign countries and nationals. Both processes are informed by intelligence assessments provided by the Director of National Intelligence.

In August 2018, the Foreign Investment Risk Review Modernization Act of 2018 was signed into law. Also known as FIRRMA, the law expanded the authority of CFIUS to include the mandatory filing of certain biotechnology deals. BIO was actively engaged with earlier rulemaking on the scope of CFIUS review including specific proposals on sensitive personal data to ensure CFIUS review is not broader than necessary to address national security concerns.

Current Developments

On September 15, 2022, President Biden [released](#) the “First-Ever Presidential Directive Defining Additional National Security Factors for CFIUS to Consider in Evaluating Transactions” which included a given transaction’s effect on U.S. technological leadership in areas affecting U.S. national security, including biotechnology and biomanufacturing, advanced clean energy, and climate adaptation technologies. In addition, recent [remarks](#) by National Security Advisory, Jake Sullivan, suggest that the

¹ CFIUS member agencies include: Treasury (Chair), Justice Department, Department of Homeland Security, Commerce Department, Department of Defense, Department of Energy, U.S. Trade Representative, and Office of Science and Technology Policy. Observers include: The Office of Management and Budget, Council on Economic Advisors, National Security Council, National Economic Council, and Homeland Security Council. The Director of National Intelligence and Secretary of Labor are ex-officio, non-voting members of the Committee.

² Congressional Research Service, “Committee on Foreign Investment in the U.S.,” July 3, 2018, <https://fas.org/sgp/crs/natsec/RL33388.pdf>, page 9.

Administration perceives maintaining the advantage in biotechnology and biomanufacturing as a national security interest in and of itself (as opposed to a more narrow focus on preventing foreign competitors from obtaining potentially harmful technologies). Accordingly, we anticipate that an even broader array of biotechnology and biomanufacturing transactions will receive heightened scrutiny from the US government. This may even go beyond foreign investment in US biotech companies and include US investment and partnerships in China.

Policy Position

While BIO understands and appreciates that biotechnology is a critical national security concern for the United States, BIO is concerned that increased CFIUS scrutiny will dampen foreign investment in the U.S. biotechnology industry—a critical source of capital-- and cause long lasting harm to the industry.

Blocking or impeding U.S. biotech investment and the export of biotechnology will benefit the biotech industries of other countries, such as China, at the expense of the American biotechnology leadership.

The biotechnology industry is global and highly mobile – companies often collaborate with foreign companies, researchers, and investors. Impeding that collaboration will hinder innovation and incentivize biotech research to be done outside of the U.S. to avoid restrictions.

Export controls and foreign investment and partnership restrictions should be narrowly tailored to ensure they do not stifle the U.S. biotech sector with burdensome restrictions with little relevance to national security.

BIO has previously worked collaboratively with U.S. policymakers to ensure rules regarding foreign transactions are not overly broad, and we look forward to continuing to do so now.