

WEBINAR

*CFIUS for Life Sciences
Companies: What You Need
to Know*

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Speakers: Jason Chipman, Rosemary Reilly

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WEBINAR

Speakers



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Agenda

- Overview on Committee on Foreign Investment in the United States (CFIUS)
- CFIUS Reforms: Implications for Life Sciences Companies
- Practical Steps to Avoid Deal Complications



Political and Security Environment

Sec. Ross on auto import probe: “Economic security is military security” (CNBC, May 2018)

“National security is broadly defined to include the economy, to include the impact on employment, to include a very big variety of things,” Ross said in a [Squawk Box](#) interview. “Economic security is military security. And without economic security, you can't have military security.”

Director of National Intelligence Dan Coats (U.S. Senate Testimony, May 11, 2017):

“Given China’s aggressive approach relative to information gathering . . . [there should be] a review of CFIUS in terms of whether or not it . . . needs to have some changes or innovations to address the aggressive Chinese actions not just against or companies, but across the world.”

Defense Innovation Unit Experimental (DIU-X), *China’s Technology Transfer Strategy* (2018):

“China is investing in the critical future technologies that will be foundational for future innovations both for commercial and military applications: artificial intelligence, robotics, autonomous vehicles, augmented and virtual reality, financial technology and gene editing. The line demarcating products designed for commercial vs. military purposes is blurring with these new technologies.”

***Top Senate Democrat Urges Trump to Block Chinese Deals Over North Korea* (Reuters, 2017):**

“In a letter to Trump, Senate Democratic leader Chuck Schumer urged him to use his authority through [CFIUS] to pressure Beijing by suspending approval of ‘all mergers and acquisitions in the U.S. by Chinese entities.’”



Committee on Foreign Investment in the United States (“CFIUS”)

- CFIUS is an Executive Branch interagency committee, formed in 1975, chaired by the Treasury Department that is charged with assessing the impact of foreign investment on U.S. national security
- CFIUS Agencies:
 - ✓ Department of Treasury (Chair)
 - ✓ Department of Defense
 - ✓ Department of Homeland Security
 - ✓ Department of Justice
 - ✓ U.S. Trade Representative
 - ✓ Department of State
 - ✓ Department of Commerce
 - ✓ Department of Energy
 - ✓ Director of National Intelligence (ex officio)
 - ✓ Department of Labor (ex officio)
 - ✓ Other participants with observing role (e.g., NSC, NEC)
- Other Departments may be invited to participate for specific transactions, such as the Department of Agriculture or Department of Transportation



CFIUS Jurisdiction

— Voluntary CFIUS Filings

- CFIUS has authority to review all transactions involving a “*foreign person*” obtaining “*control*” of a “*U.S. business*”
 - “Control” does not require majority equity ownership; it covers instances where a foreign person has obtained the right to influence important matters
 - “*U.S. business*” means any entity, irrespective of the nationality of the persons that control it, engaged in interstate commerce in the United States
 - “*Foreign person*” means (a) any foreign national, foreign government, or foreign entity, or (b) any entity over which control is exercised by a foreign national, foreign government, or foreign entity
- A CFIUS filing is voluntary, but CFIUS has broad authority to initiate an investigation of any covered transaction that is not filed and that may raise national security issues
- No minimum dollar amount of transaction; CFIUS has blocked deals in the \$2 million range



FIRRMA – CFIUS Reforms

- August 13, 2018, President signs Foreign Investment Risk Review Modernization Act (FIRRMA) into law
- Key CFIUS reforms through FIRRMA:
 - CFIUS jurisdiction may be expanded to capture *any* non-passive investment in a U.S. critical technology company, critical infrastructure company, or company with large U.S. person data sets
 - CFIUS jurisdiction may be expanded to review certain foreign acquisitions of real estate in proximity to sensitive facilities
 - Changes timeframe for review (45-days for review and 45-days for investigation)
 - Mandatory filings may be required for transactions involving critical infrastructure companies, critical technology companies, and companies with large amount of personally identifiable information



CFIUS Pilot Program

CFIUS Pilot Program makes two changes to the CFIUS regime:

- Jurisdiction to review any “**pilot program covered investment**,” which is:
 - Any direct or indirect investment by a foreign person in a pilot program U.S. business that does not result in control of the U.S. business but affords the foreign person with:
 - access to any material nonpublic technical information,
 - membership or observer rights on the board of the U.S. business, or
 - any other involvement in the operation of the U.S. business’s use of critical technologies (other than voting shares)
- A **mandatory notification** for all pilot program covered transactions, which include both (i) a pilot program covered investment and (ii) an investment in which a foreign person acquires “control” of a pilot program U.S. business



Pilot Program U.S. Businesses and Critical Technologies

Pilot Program U.S. Business

- Any U.S. business that produces, designs, tests, manufactures, fabricates, or develops critical technology that is:
 - Utilized in connection with the U.S. business's activity in one or more pilot program industries; or
 - Designed by the U.S. business specially for use in one or more pilot program industries

Critical Technology

- Critical technologies effectively include any technology or products subject to U.S. export control restrictions



Pilot Program Industries

- The pilot program covers over two dozen targeted industries in an Annex to the regulations, including aircraft manufacturing, electronic computer manufacturing, telephone apparatus manufacturing and many others
- Notably, the industries include:
 - NAICS Code: 541714, Research and Development in Biotechnology (except Nanobiotechnology)
 - NAICS Code 541713, Research and Development in Nanotechnology



FIRRMA – Export Reforms

- Commerce Department to create interagency group to identify “**emerging and foundational**” technologies that are (i) important to the defense community and (ii) not otherwise subject to export controls
- Commerce Department’s Advance Notice of Proposed Rulemaking:

| <u>Category</u> | <u>Subcategory</u> |
|-----------------------|--|
| Biotechnology such as | <ul style="list-style-type: none"> • Nanobiology; • Synthetic biology; • Genomic and genetic engineering; or Neurotech |
| Advanced Materials | <ul style="list-style-type: none"> • Adaptive camouflage; • Functional textiles; • Biomaterials |



CFIUS Reforms: Implications for Life Sciences Companies

- Mandatory filing requirement is creating a new hurdle for life science M&A and investment deals
 - The first question a life sciences company has to determine is if it qualifies as a pilot program U.S. business
 - If it is not a pilot program U.S. business, then it will not trigger mandatory filing in either situation
- If a life sciences company determines that it is a U.S. business producing, designing, testing, manufacturing, fabricating, or developing critical technology, then the next question the company must answer is whether or not its work with critical technology is:
 - a) utilized in connection with the U.S. business's activity in one or more pilot program industries, or
 - b) designed by the U.S. business specially for use in one or more pilot program industries



CFIUS Reforms: Implications for Life Sciences Companies

- Case Study: Novartis AG's acquisition of Endocyte Inc.
 - On Nov. 10, 2018, Novartis and Endocyte filed a short form declaration with CFIUS under the pilot program for Novartis AG's \$2.1 billion acquisition of Endocyte
 - CFIUS has four options when reviewing a short form declaration: 1) clear the transaction, 2) request formal notice of the transaction, 3) initiate a review of the transaction, or 4) determine that it cannot complete the review
 - CFIUS determined that it could not complete the review of the transaction
 - This puts the acquiror in a place where it has no safe harbor but also is not forced into a CFIUS process
- Case Study: Patients Like Me's sale of majority stake to iCarbonX
 - In 2017, Patients Like Me, a company that sells a service for patients to find people facing similar health issues, sold a majority stake to a Chinese investor, iCarbonX
 - Media reports suggest that 700,000 patients use the service
 - CFIUS forced a review in 2018/2019
 - iCarbonX is being forced to divest its stake in the business



Practical Steps to Avoid Deal Complications

- Identify whether any foreign investors are involved
- Conduct diligence early
- Consider using questionnaires to determine if critical technology is implicated
 - When a CFIUS filing is mandatory, filing must be submitted 45 days prior to closing; obtaining CFIUS clearance prior to closing is not required
- If you think a CFIUS filing may be required, parties may negotiate investor's obligations to accept CFIUS conditions
 - Consider the need for unilateral or bilateral waivers for CFIUS-related costs and penalties, and indemnification terms
- If the deal is closing prior to obtaining CFIUS clearance, consider adding limitations on investors Pre-CFIUS-Approval Exercise of Rights
 - NVCA has built conditional language into the model Term Sheet and model financing documents



Practical Steps to Avoid Deal Complications

Drafting techniques to avoid potential CFIUS issues

- Contract out of control provisions for foreign investor
- Note any provisions in the charter allowing for the exercise of redemption rights in the event of CFIUS-mandated divestiture of shares
- Be mindful of investor-imposed closing conditions regarding CFIUS filings, including springing CFIUS covenants
 - For example, investor may seek to add language in the term sheet such as:
“Notwithstanding [], Investors shall have no obligation to take or accept any action, condition, or restriction as a condition of CFIUS clearance that would have a material adverse impact on the Company or the Investors’ right to exercise control over the Company.”
 - Company should add mitigation commitment language
- Consider if the Limited Partner Exception can apply to avoid mandatory CFIUS filing



Pilot Program Limited Partner Exception

A foreign party may invest indirectly in a pilot program U.S. business via a U.S.-managed investment fund *and* participate as a member of the fund's advisory board without triggering CFIUS jurisdiction, if:

- the fund is managed exclusively by a general partner, a managing member or an equivalent;
- the foreign person is *not* the general partner, managing member or equivalent;
- the advisory board or committee does not have the ability to approve, disapprove or otherwise control the fund's investment decisions or decisions of the fund manager relating to the fund's portfolio companies;
- the foreign investor does not otherwise have the ability to control the investment fund, including the authority to approve, disapprove or otherwise control investment decisions of the investment fund; control decisions made by the general partner or equivalent; or unilaterally dismiss, prevent the dismissal of, select or determine the compensation of the general partner or equivalent; and
- the foreign investor does not have access to material nonpublic technical information of the pilot program U.S. business due to its participation on the advisory board or committee



Other Practical Steps to Avoid Deal Complications

- Be mindful of timelines and the process of CFIUS filings
- Engage in CFIUS conversations with investors early on
- Consult your attorneys as needed
- Stay alert to CFIUS developments and rulings to see if, and how, CFIUS elaborates on the definitions of critical and emerging technologies



Questions

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