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Foreign Investment In US Biotech Gets Greater Gov't Scrutiny

By **Carl Valenstein, Stephen Mahinka and Beverly Dale** (July 11, 2019, 1:17 PM EDT)

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In 2019, under the current administration, there is increasing scrutiny of foreign investment — particularly from China — in the U.S. biotech industry.[1] These efforts by the Trump administration began back in March 2018 with the publication of the Section 301 report by the United States Trade Representative.[2] Since then, the Committee on Foreign Investment in the United States has blocked or required mitigation in several transactions in the life sciences industry.

In early 2018, CFIUS required the divestiture of Biotest's U.S. blood plasma products and biomedical testing operations (Bio Products Laboratory Ltd.) because of the potential access by the Chinese acquirer, Creat Group, of confidential health information relating to U.S. citizens possessed by Biotest. More recently, in 2019, CFIUS required the divestiture, based on similar personal data concerns, of Chinese investments in Grindr and PatientsLikeMe, which were not notified to CFIUS before the investments were made.

While all of these transactions involved the authority of CFIUS to review transactions resulting in the acquisition of control (as broadly defined by CFIUS) of a U.S. business by foreign persons, the enactment in 2018 of the Foreign Investment Risk Review and Modernization Act, or FIRRMA,[3] gave CFIUS the authority to review noncontrolling (less than or equal to 50%) investments in certain industries, including biotechnology, where certain rights were proposed to be obtained by the investor, and to require mandatory filings (termed "declarations") where the foreign investor would be given access to "critical technology."[4]

Before FIRRMA, submissions to CFIUS were entirely voluntary, but the foreign investor proceeded at its own risk if it chose not to clear the transaction with CFIUS before closing. The CFIUS actions in the Grindr and PatientsLikeMe cases show how real those risks can be for foreign investors.

The publication by CFIUS in October 2018 of the interim pilot program regulations[5] caught the biotech community off guard because biotechnology was one of the 27 industries covered and the regulations became effective with respect to transactions that closed after Nov. 10, 2018. The publication by CFIUS of the pilot program regulations caused many biotech companies that were negotiating deals with foreign investors (the rules did not single out Chinese

investors) to scramble to determine if they had “critical technology” as currently defined and, if so, to restructure their transactions to avoid CFIUS review to the extent possible.

Given the currently narrow definition of critical technology,[6] it is unclear how many biotech transactions have been notified to CFIUS under the mandatory pilot program; CFIUS has not published any data to date. We are aware that certain transactions involving Chinese investors that could not be restructured were abandoned, but, again, there is no reliable data on the extent of the impact since CFIUS does not report on or disclose its decisions.

At present, the definition of “critical technology” for biotechnology covers biodefense and biowarfare technologies controlled by the U.S. Department of State on the Munitions List of the International Traffic in Arms Regulations,[7] the list of “select agents and toxins” in certain biologics and agriculture regulations, certain nuclear materials and items appearing on the U.S. Department of Commerce Commodity Control List under the Export Administration Regulations.[8]

Many early stage biotech companies have never gone through the exercise of classifying their technology for export purposes, although many were technically subject to the “deemed export” rules because of their employment of non-U.S. scientists even if they weren’t exporting their technology abroad. In many cases, these early stage biotech companies don’t have “critical technology” as currently defined.

Two important rulemakings are underway that could materially affect the biotechnology industry further, and the proposed regulations are likely to be published in the next couple of months. First, CFIUS will be publishing draft regulations to implement FIRRMA, which must be finalized by March 2020. It is expected that the pilot program regulations are likely to be expanded and many provisions of FIRRMA, such as the rules on “critical infrastructure,” real estate, protected personal information and filing fees are likely to be implemented.

Second, the Department of Commerce’s Bureau of Industry and Security, or BIS, will publish draft rules defining those “emerging” and “foundational” technologies referenced in Section 1758 of the Export Control Reform Act of 2018,[9] enacted along with FIRRMA, which may have an even more profound effect on the biotechnology industry because they have the potential to expand both export controls, including “deemed export” controls, on biotechnology and the scope of transactions subject to mandatory CFIUS review, because designated “emerging and foundational” technologies will automatically become “critical technologies” for CFIUS purposes.

In November 2018, BIS published an advance notice of proposed rulemaking[10] indicating that it was considering including as “emerging and foundational technology” such biotechology industry-related products and processes as nanobiology, synthetic biology, genomic and genetic engineering, genetic algorithms and programming, neurotech, and biomaterials.

In response, a variety of stakeholders ranging from leading industry advocacy groups to multinational corporations submitted comments to try to convince BIS to strike the right balance between regulating technology important to national security and not inhibiting foreign investment in biotechnology and collaboration among biotech companies across borders. The new regulations are expected to be released in draft form so there will be another opportunity for the biotechnology community to weigh in on these important issues.

A separate but equally important development focusing particularly on Chinese participation in the U.S.

biotechnology market is the joint outreach by the National Institutes of Health and the Federal Bureau of Investigation to recipients of NIH grants with respect to the controls in place to prevent against the unauthorized export and/or theft of federally funded research. This has created concern in the biotech scientific community, both commercial and academic, regarding the employment or recruitment of Chinese origin scientists, regardless of whether they have U.S. citizenship.[11]

This effort is part of the broader U.S. government initiative to combat what it considers unfair Chinese trade practices generally and, in particular, in the biotechnology industry and the potential for loss of what it considers to be critical technology. Notwithstanding these U.S. government initiatives, Chinese participation in the U.S. life sciences industry remains strong, funded in part by investments encouraged by the Chinese government's Made in China 2025 program.

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[1] Stephen Paul Mahinka and Carl Valenstein, Trade Rep Hints At More CFIUS Scrutiny of Biotech Deals (May 23, 2018), https://www.law360.com/articles/1046398/trade-rep-hints-at-more-cfius-scrutiny-of-biotech-deals.

[2] Office of the United States Trade Representative, Executive Office of the President, Findings of the Investigation into China's Acts, Politics, and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act of 1974 (March 22, 2018), https://ustr.gov/sites/default/files/Section 301 FINAL.PDF.

[3] Foreign Investment Risk Review Modernization Act of 2018 ("FIRRMA") passed into law as part of Title XVII "Review of Foreign Investment and Export Controls" of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, H.R. 5515, 115th Cong., PL 115-232, 132 Stat. 2174 (2018) at Sec. 1701 et seq.

[4] Id. at Sec. 1706.

[5] Determination and Temporary Provisions Pertaining to a Pilot Program to Review Certain Transactions Involving Foreign Persons and Critical Technologies, 83 Fed. Reg. 51322, Vol. 83, No. 197 (Oct. 11, 2018) (to be codified at 31 C.F.R. pt. 801 et seq).

[6] Id. In the interim rule, 801.204 is titled "Critical technologies" and contains a detailed definition of the term.

[7] 22 C.F.R. 121.1.

[8] 15 C.F.R. 730 et seq.

[9] The Export Control Reform Act of 2018 passed into law, with FIRRMA, as part of Title XVII "Review of Foreign Investment and Export Controls" of the John S. McCain National Defense Authorization Act for

Fiscal Year 2019, H.R. 5515, 115th Cong., PL 115-232, 132 Stat. 2208 (2018) at Sec. 1741 et seq.

[10] Review of Controls for Certain Emerging Technologies, 83 Fed. Reg. 58201, Vol. 83, No. 223 (Nov. 19, 2018). Note: this rulemaking is still only in the Advanced Notice of Rulemaking stage. The ANPRM was published, the comment period was extended to January 10, 2019 by a notice published in December 2018 and that was the last official word on this review.

[11] Kenneth J. Nunnenkamp and Giovanna M. Cinelli, The National Institutes of Health and National Security: The Long Tentacles of Foreign Influence (Aug. 27, 2018), https://www.morganlewis.com/pubs/the-national-institutes-of-health-and-national-security-the-long-tentacles-of-foreign-influence.