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CFIUS Risk Review Rules May Draw Attention To US Biotech

By **Richard Matheny** (September 23, 2019, 2:07 PM EDT)

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In October 2018, when the U.S. Department of the Treasury announced the new Committee on Foreign Investment in the United States pilot program addressed to critical technologies, it was first perceived by the U.S. biotech industry as a mortar round exploding in a foxhole. Scores of U.S. biotech companies strained amid the dust and rubble to understand the impact of these new rules on their ability to take foreign investment.

They would be forgiven for believing their industry was under attack, as it was featured prominently among the 27 specific U.S. industries targeted by the pilot program. And it came in the midst of a trade war with China, the largest source of foreign capital for the industry. With truth the first casualty of war, some were concerned that CFIUS reviews of foreign investment in U.S. biotechnology would quickly become the norm.

But it hasn't happened that way — at least not yet. And after the dust had settled, the impact of the pilot program on this industry has been minor.

Still, the shock and awe may yet prove healthy for an industry bracing for more incoming fire. Two new rulemakings unleashed by the Foreign Investment Risk Review Modernization Act (the legislation through which Congress has expanded CFIUS's powers) will soon reshape the relationship between the U.S. government and the biotech industry. A pending rulemaking by the Treasury Department will implement most of the balance of new authorities granted to it by Congress in August 2018. The proposed rules just dropped last week and are open for comments, as we will discuss.[1]

In preparation for the second U.S. Department of Commerce rulemaking — which will expand the scope of technologies of high concern to CFIUS — it is a good time to pause and consider the experience and lessons of the U.S. biotech industry over the past year.

How has CFIUS recently impacted foreign investments in U.S. biotechnology?

By most accounts, the dust from the mortar round that exploded in October 2018 has settled, ears are no longer ringing for the U.S. biotechnology sector and the burden of CFIUS concerns has been manageable. Most U.S. biotech firms have correctly concluded that the foreign investments they attract are not subject to the pilot program's mandatory filing rules because most of the technologies used in

the biotechnology sector are not controlled by current U.S. regulations as sensitive to the national security.

Of course, there are exceptions to the rule. Consider a company that relies on an otherwise dangerous virus that has been engineered to deliver a therapeutic drug in a novel way. That company could be engaged with a "critical technology" while operating within a pilot program industry. If so, foreign investment could trigger the mandatory filing requirement.

Other exceptions to the rule are less easily detected. Some U.S. biotechnology firms have been surprised to find they are within the pilot program for reasons largely unrelated to what they consider their core (bio)technology. Firms that develop data analytics platforms for biotechnology research, drug discovery and related activities can trigger the pilot program simply because of the encryption functionality of the software platform, and even where the encryption they use is standards-based and open source.[2]

CFIUS has asserted its pilot program jurisdiction on precisely this theory in a number of transactions. Many will be watching with interest to see whether the Treasury Department will correct what was perhaps an unintended consequence of the pilot program's jurisdictional trigger relating to encryption (a ubiquitous technology).

In these and other instances, a minority of U.S. biotechnology companies are learning that their technology is regulated under the U.S. export control laws. A discussion of ECCNs — the acronym for Export Control Classification Number, which is a key to understanding how U.S. technology is regulated — is now part of most every responsible conversation regarding foreign investment in a U.S. business.

And while most such companies find they are not engaged with a "critical technology," the U.S. biotechnology sector now braces for a Commerce Department rulemaking to expand that concept by designating certain "emerging technologies" (and later, "foundational technologies") for inclusion in it.

When it passed FIRRMA, Congress also instructed the U.S. Department of Commerce to regulate so-called "emerging and foundational technologies." In a November 2018 advanced notice of proposed rulemaking, the Commerce Department identified 14 categories to be regulated as "emerging technologies."

One of these categories is "Biotechnology," including four proposed subcategories: "Nanobiology; Synthetic biology; Genomic and genetic engineering; and Neurotech." Other proposed categories include "biomaterials"; certain artificial intelligence and machine learning technologies, including "evolution and genetic computation (e.g., genetic algorithms, genetic programming)"; and brain-computer interfaces. The contours of these categories have yet to be finalized and industry can still participate in shaping them — and should, because the impacts of this rule will be meaningful in two independent ways.

First, many companies will need once again to evaluate the ECCN question in connection with foreign investment. Some may find that even minority, non-control foreign investments are subject to a pre-investment CFIUS declaration requirement unless they are restructured to cure the control, influence, or access concerns. If faced with a mandatory declaration requirement, some will have to act on hard predictions about the likely outcome and timing of a CFIUS review that can span many months. We do expect a material increase in the CFIUS burden borne by the biotechnology sector as a result of this rulemaking.

Second, “emerging technologies” will be subjected to new export control restrictions under the Export Administration Regulations. These new controls will have a specific, measurable impact on the ability of affected U.S. biotechnology companies to export their technologies, including through sharing with foreign nationals (e.g., with foreign scientists, including in the United States).

For affected biotechnology companies, the export control consideration will challenge the cross-border collaboration model that is driving the rapid advancement of these technologies. Many will be required to seek export licenses, at some expense, delay and uncertainty. Planning for these impacts is underway at many companies expecting to be affected.

Although the pilot program’s focus on technology has helped prepare biotech firms for the “emerging technologies” rulemaking by familiarizing them with the rules, it has also generated the mistaken impression that CFIUS is only concerned with technology. That is a dangerous error, as CFIUS has long possessed the tools to review investments — in the biotechnology space, or with any U.S. business — that result in “control” of a U.S. business. As applied, “control” is a very low threshold enabling CFIUS to review investments without regard to the technology or industry sector in which they are made.

Data is an ascendant concern for CFIUS and national security.

Even where they do not engage with controlled technologies, biotechnology companies can draw the committee’s gaze in transactions involving foreign-person access to data about U.S. persons. Where the investment originates in or is tied to China, these CFIUS-related data concerns can be acute and sometimes they are unsolvable.

For example, concerns about access to health and genetic data from U.S. consumers prompted CFIUS to require that the Chinese company iCarbonX divest its interests in the U.S. precision medicine companies PatientsLikeMe and HealthTell, thwarting the parties' combined vision to analyze large data sets to improve human health.

Around that time, CFIUS required Beijing Kunlun Tech Co. Ltd. to sell its interest in the U.S. company Grindr, apparently concerned that location, message content, HIV status and other data on the Grindr platform could be exploited. And the proposed sale of German company Biotest AG to Creat Group Corp. of China only satisfied CFIUS concerns after Biotest’s U.S. operations, including its blood plasma product subsidiary, were spun off to another purchaser.

These are just three notable cases of the many in which data access has been dispositive in the fate of a transaction considered by CFIUS. Particularly for Chinese investments, there is the concern that data can be gathered, pooled and subjected to artificial intelligence algorithms, revealing critical insights, patterns of life, vulnerabilities in individuals or groups and so on. CFIUS seems to apply a “mosaic” theory to these cases, assuming that data accessible via one investment might be combined with data from others. Data anonymization is not always a viable solution for these concerns.

Because few U.S. companies are entirely free of data regarding U.S. persons, the implications here will be profound. The rule just proposed by the Treasury strives for precision regarding what data will be considered “sensitive personal data” and has two basic parts — one focused on the sensitivity of the data itself, another on the population to which it pertains.

Regarding the data types, “sensitive personal data” is, with exceptions, identifiable data of these types: data pertaining to a person’s financial distress; consumer report data; data from insurance applications;

data pertaining to one's physical, mental and psychological health; nonpublic electronic communications; geolocation data; biometric data; and various data associated with U.S. government-granted status.

The rule then ties these data to sensitive populations by limiting its impact only to U.S. businesses (1) that have collected — or plan to collect — these types of data on more than one million individuals; or (2) that target or tailor products or services to U.S. executive branch agency or certain military department personnel and contractors. One consideration for biotechnology companies running clinical trials may be whether they would trigger these thresholds.

A special distinction belongs to U.S. companies that collect "genetic information," which, regardless of population size or sensitivity, will always constitute "sensitive personal data."

These definitions will be critical because any U.S. business that maintains or collects "sensitive personal data," directly or indirectly, will be subject to CFIUS's authority to review even low-level foreign investments in such U.S. businesses where the investment confers the right to a board seat or board observer, or substantive decision-making rights regarding "sensitive personal data."

To be clear, with one exception, the proposed data rules would not impose a mandatory filing requirement; but they would give CFIUS the power to review such transactions as "covered investments." The exception is that such "covered investments" in "sensitive personal data" companies (and others not relevant here) would be subject to the mandatory, pre-investment filing requirement if the foreign person would acquire 25% or more voting interest in the company, and a foreign government holds a 49% or greater voting interest in that foreign person.

Whether or not transaction parties are required by the regulations to make a CFIUS filing, experience teaches that stakeholders among the parties, lenders funding the transactions, and others will be careful about the risks of foregoing CFIUS review where the case for its jurisdiction is evident.

The proposed Treasury rule does not purport to fully implement FIRRMA, including in ways of interest to biotechnology firms.

The proposed rule leaves untouched the "critical technologies" pilot program, changes to which would appear in a final rule to be published before Feb. 13, 2020 — and, some speculate, could see the elimination of the mandatory filing requirement of the pilot program.

The proposed rules introduce the concept of the "excepted investor," including a fabled "white list" of friendly countries whose investors may be exempted from the committee's new jurisdiction; however, the list itself remains empty for now.

And the Treasury has deferred its proposal to collect from the transaction parties a filing fee — up to the lesser of 1% of the transaction value or $300,000 — although this too is probably incoming.

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[1] On the same day, the Treasury Department proposed new rules to implement its jurisdiction over certain real estate transactions, including certain leases. Because these new rules turn on the location of owned/leased property, they could easily apply to companies in the biotechnology sector; however, we do not discuss these rules in this article.

[2] Under the pilot program, these companies are technically producing a "critical technology" — i.e., a platform controlled for export on the basis of its encryption functionalities, even if it is not in fact exported — that is either utilized in connection with activities in, or designed specifically for use in, research and development in biotechnology — i.e., one of the 27 pilot program industries.