Impact of Biden's New Executive Orders on the Life Sciences and Biotechnology Industries

Presenters

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Executive Order 14081
National Biotechnology & Biomanufacturing Initiative (NBBI)

- Investment in the strengthening the supply chain and lowering prices through use of bio-based production of APIs
- Investment in US bio-manufacturing capacity
- Create programs at FDA (CDER/CBER) to
  - Develop research programs within FDA for advanced manufacturing technologies
  - With FDA's Office of Counter-Terrorism create regulatory science benchmarks and strategies for platform technologies and to drive collaboration with the private sector
  - Develop an Advanced Manufacturing Innovation Hub in CDER
  - Provide pre-submission meetings to companies to discuss advanced manufacturing techniques
  - Work to harmonize requirements to promote innovation on ICH Q13 (continuous manufacturing)

Executive Order 14081
National Biotechnology & Biomanufacturing Initiative (NBBI)

- Support pre-doctoral research through NIH, research at Frederick National Lab and other DOD sites
- Report on regulatory gaps and ambiguities in regulatory framework due in 180 days (OSTP and Economic Policy are involved)
- Implementation Plan by Sept 2024

Potential Benefits of EO for Life Sciences Industry

- Attract additional expertise to FDA to review and advise on new technologies
- Attract Additional expertise to US in bio-manufacturing
- Sensitize FDA to regulatory roadblocks to solidifying US manufacturing capability and capacity
- Provide alternative pathways (HHS/White House) to issues that are preventing forward movement

Executive Order 14081
National Biotechnology & Biomanufacturing Initiative (NBBI)

- $1 billion from the Defense Department for bioindustrial domestic manufacturing
- $500 million from the Agriculture Department for fertilizer production grants
- $270 million from the Defense Department for "defense supply chains," such as the production of fire-resistant materials
- $200 million from the Defense Department for biosecurity and cybersecurity improvements
- $200 million from the Commerce Department for bioeconomy boosts in New Hampshire, Virginia, North Carolina, Oregon and Alaska
- $178 million from the Energy Department for bioresearch innovation awards
- $100 million from the Energy Department for efforts to convert biomass to usable fuels and chemicals, which includes better recycling practices of biobased plastics
- $93 million from the Agriculture Department for developing new forest resource products
- $68 million from the Agriculture Department for expanding the National Institutes of Health biotech entrepreneurship program
- $60 million from the Energy Department for reducing greenhouse gas emissions related to this executive order
- $40 million from the Department of Health and Human Services to increase pharmaceutical manufacturing
- $32 million from the Agriculture Department for forest resource grants
- $20 million from the Energy Department to predict and aid biotech and biomanufacturing risks
- $20 million from the National Science Foundation for a biosciences data center
- $14 million from the Commerce Department for biotech research
- $10 million from the Agriculture Department for studies on biobased products

Executive Order 14081
National Biotechnology & Biomanufacturing Initiative (NBBI)

- Compared to CHIPS Act
  - $52B Investment
  - Legislative Authority vs Executive Order
  - Specific amounts ($39B) to establish domestic production of leading-edge logic ad memory chips that require sophisticated manufacturing processes I the US.
  - Specific budget ($11B) for CHIPS R&D and development of National Semiconductor Technology Center
  - Specific incentives program to encourage large scale US investment in manufacturing and supply—Already have large investments by Micron and Intel
  - US Secretary of Commerce Gina Raimondo fully engaged in advancing the chip strategy

Chinese vs US Investment in Bio-Manufacturing—”Made in China” program

- $40B over last 5 years in bio-manufacturing and R&D
- Establishment of regional biotech hubs and bio-clusters where academia, education, and industry collaborate.
- Subsidy of 40% of R&D expenses for an innovative new drug developed in China from Ph I-III and approved
- Government support to contract manufacturing equal to 20% of transaction cost
- Incentives to bring back and keep STEM personnel in China

UNIQUE CFIUS CONCERNS FOR LIFE SCIENCES TRANSACTIONS

- There has been a significant increase in FDI in the US life sciences industry, including both medtech and biopharmaceutical companies.
- Although overall Chinese FDI has declined considerably since its peak year in 2016, Chinese venture capital investment in the US life sciences industry remains remarkably resilient because of the Chinese government's "Made in China 2025" and other industrial policies.
- According to a recent report by the Rhodium Group, "In 2020 the number of VC rounds per industry fell in most industries.
  - The exception was Health, Pharmaceuticals and Biotechnology, which was by far the top target for Chinese venture capital in the US by the number of venture capital transactions (132 individual rounds)."

UNIQUE CFIUS CONCERNS FOR LIFE SCIENCES TRANSACTIONS

- Because most US life sciences companies do not have "critical infrastructure" or "covered real estate" for CFIUS purposes, the determination of whether clearance with CFIUS is required or recommended will generally turn on
  - whether the company has "critical technology" or "sensitive personal data" for CFIUS purposes
  - whether the noncontrolling transaction has been structured in a way to wall the foreign investors off from the "critical technology" and "sensitive personal data."

WHAT "CRITICAL TECHNOLOGY" DO LIFE SCIENCES COMPANIES HAVE?

- Determining if a life sciences company has "critical technology" for CFIUS purposes can be a fact-intensive exercise because it involves ascertaining if an export license would be required for the foreign investor(s) in question, and many emerging companies have not classified their technology or equipment for export control purposes.
- Most companies choose their technology/equipment for scientific reasons without attention to export control or CFIUS implications.
  - This can result in surprises since most science-based companies think about scientific developments and regulatory approval from an FDA standpoint but do not take into consideration export-control implications, including the need for deemed export licenses for foreign lab workers.
- In general, the analysis is more complicated for biopharmaceutical companies, particularly in the biologics space, than for medtech companies.

WHAT "CRITICAL TECHNOLOGY" DO LIFE SCIENCES COMPANIES HAVE?

- CFIUS counsel have detailed checklists that they use with their life sciences company clients to help them make the classifications, but sometimes it is necessary or advisable to obtain a formal classification from the US government.
- There are specific International Traffic in Arms Regulations (ITAR) controls on biodefense or biowarfare technology as well as Department of Energy (DOE) controls on nuclear medicine.
- If a company has "select agents" regulated by the Centers for Disease Control and Prevention (CDC), then it will have "critical technology."

WHAT "CRITICAL TECHNOLOGY" DO LIFE SCIENCES COMPANIES HAVE?

- The Department of Commerce may fill under Section 1758 of the Export Control Reform Act of 2018 ("ECRA") the largely empty buckets for "emerging and foundational technologies" relating to biotechnology included in the definition of "critical technology."
- In November 2018, the Department of Commerce announced an Advance Notice of Proposed Rulemaking (ANPRM) for "emerging technologies" that included the fields of nanobiology, synthetic biology, genomic and genetic engineering, and neurotech.

WHAT "CRITICAL TECHNOLOGY" DO LIFE SCIENCES COMPANIES HAVE?

- On October 5, 2021, the Department of Commerce, Bureau of Industry and Security (BIS) published a final rule amending the Export Administration Regulations to include new controls on genetic editing software and related technology.
- This final rule "updated the Australia Group Common Control List for dual-use biological equipment by adding controls on nucleic acid assembler and synthesizer 'software' that is capable of designing and building functional genetic elements from digital sequence data."
- BIS previously identified this software, in a notice of proposed rulemaking on November 6, 2020, as potential emerging technology essential to US national security that have the capability of being misused for biological weapons purposes.
- BIS published on September 12, 2022 an ANPRM relating to advanced peptide synthesizers (covering peptides over 100 in length). The concern focuses on the ability to use this equipment and the associated materials to produce biological weapons.
- Current interagency conflicts may further delay the proposed regulations, and the biotech and medtech industries will challenge any additional export controls as undermining further collaboration and scientific development.

WHAT IS "SENSITIVE PERSONAL DATA"?

- "Sensitive personal data" is broadly defined as comprising personal, financial, and healthcare information of US citizens, including identifiable data that is in applications for insurance; nonpublic email or messaging among users of a US business's products or services; biometric data; geolocation data; or personnel security clearance data.
- "Identifiable data" will be treated as "sensitive personal data" if it is maintained or collected by a US business
  - (1) that targets or tailors products or services to US security personnel, including contractors, or
  - (2) that has maintained or collected such data, or has a demonstrated business objective to do so, on more than one million individuals at any point in the preceding 12 months.

WHAT IS "SENSITIVE PERSONAL DATA"?

- Sensitive personal data also includes genetic data, which is not subject to the above limitations on security personnel or minimum size of data population.
- In an attempt to narrow the scope of genetic data covered, and following concerns expressed by the life sciences industry regarding the proposed rules, CFIUS limited the definition in the final rules to "the results of an individual's genetic test, including any related genetic sequencing data."
- Genetic tests are defined by reference to the Genetic Information Non-Discrimination Act of 2008, are limited to identifiable genetic tests, and exclude any data derived from US government databases and given to third parties for research purposes.

CONCERNS AND STRATEGIES FOR TRANSACTIONS

- Is there a way to structure the transaction so CFIUS would not have jurisdiction?
  - This is legitimate and not considered evasion.
    - Examples include a license/collaboration agreement with no equity investment, which is not considered a covered transaction unless the agreement gives access to "critical technology," "material non-public technical information," or "substantive decision-making."
    - Another approach in venture deals is to use the standard NVCA screening language to avoid having CFIUS Triggering Rights (more than 9.9% ownership, no board or observer rights, no access to material non-public technical information or rights to substantive decisionmaking) until the transaction is cleared by CFIUS.
- Although a mandatory filing may not be required, should a company still consider filing?
  - A company may want to consider filing if the closing should be conditioned on CFIUS clearance because of the national security risk profile, such as TID business; supply-chain concerns; a foreign government as an investor; US government nexus through contracts, funding, or governmental or military customers; or a watched technology, among other concerns.

TO FILE OR NOT TO FILE – THAT IS THE QUESTION

- Although many venture deals are structured to avoid CFIUS jurisdiction, there is a fast-track declaration process that is being used where a mandatory filing is required.
- If the mandatory filing requirements apply, one can file a short-term declaration that will be reviewed in 30 days, but CFIUS may require a full joint submission or give a regulatory "shrug" indicating that it has had insufficient time to make a determination.
- Some parties are willing to accept the risk and close on a regulatory "shrug," even though it provides no protection from a later CFIUS review.
- By contrast, full joint submissions can take one to two months to prepare and be accepted by CFIUS, and three to four months to complete even in routine cases.
- The declaration process is rarely used for Chinese investment transactions because of heightened scrutiny.
- Non-notified outreaches by CFIUS are virtually automatic with respect to Chinese investment in life sciences companies.

Noteworthy CFIUS Cases involving Life Sciences Companies

- Sale by Biotest of US Plasma Operations to obtain CFIUS clearance of acquisition of Biotest by Creat (2018)
- Divestiture required by CFIUS of non-notified investment by iCarbonX in PatientsLikeMe (2019);
- Ekso Bionics China JV abandoned following notification by CFIUS that national security issues could not be mitigated (2020)
- Asymchem acquisition of Snapdragon abandoned because of CFIUS required mitigation (2022)
- CFIUS recently delayed the acquisition of US-listed biotechnology company F-star Therapeutics by Hong Kong-listed Sino Biopharmaceutical. The committee said it required an additional 45 days to review the transaction. It is important to note that the extended review does not equal to an outright deny of approval, so there is still a chance the deal might be cleared.

TWO New EOs relating to Biotechnology

- Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy on September 12.

See Executive Order Outlines New Federal Biotechnology/Manufacturing Goals – As Prescribed | Morgan Lewis

- Executive Order on Ensuring Robust Consideration of Evolving National Security Risks by the Committee on Foreign Investment in the United States - The White House on September 15.

See https://www.morganlewis.com/pubs/2022/09/biden-issues-cfius-executive-order-what-has-changed-and-what-remains-the-same>

- Will there be a third Executive Order on outbound transactions?
- What actions will USG take to limit foreign "adversary" participation in US supply chain?

New CFIUS EO

- Overall, the Executive Order (EO) does not foundationally change the Committee on Foreign Investment in the United States (CFIUS or the Committee) process or the statutory authorities as outlined in the Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA), or address outbound investment which is the focus of other ongoing Biden-Harris administration efforts. In the press conference announcing the EO, an administration official clarified that "the executive order does not expand or limit the legal authorities or jurisdiction of CFIUS, which remains broadly focused on assessing and mitigating any national security risks arising from covered transactions."
- It does, however, identify key areas where further and more expansive activity should be expected—those in Section 1 of the EO, which are described as evidence of the "evolving national security landscape and the nature of the investments that pose related risks to national security."

New CFIUS EO (Cont.)

- At the outset, it is important to highlight what the EO does *not* do:
- It does not change CFIUS' jurisdiction—whether by retraction or expansion.
- It does not require CFIUS to implement the guidance in any particular manner—i.e., there is no express requirement that CFIUS update its regulations in order to incorporate the president's EO.
- It does not significantly add to the factors the Committee already considers as part of its analysis, some of which are included in regulations and others of which are found through the sometimes-extensive question/answer engagement between CFIUS and the parties to a transaction.
- It does not alter US interest in encouraging foreign investment as balanced against national security concerns.
- While the EO is encouraging for the additional transparency evident in Sections 2 and 3, it does not markedly alter the national security review landscape process, but does indicate where additional CFIUS energy is likely to be focused in the near future.
- Although the EO does not foundationally change the CFIUS process, the EO does include insight which can better inform the risks associated with cross-border investments. In that vein, the EO includes the following new guidance:
- CFIUS is directed to consider the impact of aggregate investments within industry sectors. Section 3(i) outlines in greater detail the areas of concern when performing this analysis. As a result, CFIUS's "case-by-case" approach must be balanced against this directive.

New CFIUS EO (Cont.)

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- The EO provides key terms that require further definition to assess how any risks of industry sector consolidation may impact whether, when, and what to file with CFIUS. Those terms include, but are not limited to:
    - "incremental investment" and "a series of acquisitions in the same, similar or related United States businesses"
    - "a sector or technology"
    - "part-by-part" ceding of a sector or technology
    - "domestic development" in a sector or technology
    - "control" in a sector or technology
    - "actions" by a foreign person "or their relevant third-party ties that might cause the transaction to pose such a threat"
    - "a series of acquisitions in the same, similar or related United States businesses involved in activities that are fundamental to national security or on terms that implicate national security"

KEY TAKEAWAYS:

- There has been a significant increase in cross-border investment (FDI) in the US life sciences industry, including both medtech and biopharmaceutical companies.
- Determining if life sciences companies, particularly those in the venture capital and start-up communities, have "critical technology" or "sensitive personal data" that would trigger CFIUS-filling can be a fact-intensive exercise because it involves determining if an export license would be required for the foreign investor(s) in question, and many emerging companies have not classified their technology or equipment for export control purposes.

KEY TAKEAWAYS:

- In any transaction involving a foreign person and a US biotechnology business, there is a potential CFIUS issue that should be analyzed early on given the complexity of the rules.
- There is heightened scrutiny of Chinese investment in the US biotechnology industry, particularly with respect to transactions that may affect the US supply chain or critical or leading technology.
  - Companies planning to seek foreign investment or offering themselves for sale to foreign persons should conduct self-CFIUS due diligence to identify the CFIUS concerns early on because they might affect transaction structure. Companies should also consider the implications for future US governmental funding of taking on foreign, particularly Chinese, investors.
  - Foreign investors/purchasers need to conduct CFIUS due diligence and do a risk assessment of how to address CFIUS and other national security issues and the overall deal completion risk that they present.

Biography

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Kathleen Sanzo is the leader of the Morgan Lewis FDA & Healthcare practice and co-chair of the firm's life sciences industry team. Kathleen centers her practice on regulatory and compliance issues connected to FDA regulated products. She leads and counsels clients on all legal and regulatory issues concerning product development and testing, manufacturing and marketing of prescription, OTC drug, biologic and vaccine products, and orphan drugs; food, dietary supplements, and cosmetic product manufacture, approval, marketing, and distribution; food, drug, and device compliance and enforcement matters; and consumer product issues regulated by the US Consumer Product Safety Commission (CPSC) and state enforcement agencies.

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Suzanne Filippi exclusively focuses on US and global corporate transactions in the life sciences industry, representing both multinational pharmaceutical companies and public or private biotechnology companies. Drawing on her deep life sciences industry knowledge, Suzanne counsels clients in a wide range of corporate transactions, with an emphasis on complex license and collaboration agreements, co-commercialization/co-promotion matters, and mergers, acquisitions, and externalizations in the life sciences sector. She is recognized by clients for her collaborative energy, solutions-minded approach, and keen understanding of the unique, mission-focused nature of life sciences companies and their patient populations.

Biography

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Carl Valenstein focuses his practice on domestic and international corporate and securities matters, mergers and acquisitions, project development, and transactional finance. He counsels extensively in the life science, telecom/electronics, and maritime industries, and has worked broadly in Latin America, the Caribbean, Europe, Africa, Asia, and the Middle East. He previously served as co-chair of the International Section of the Boston Bar Association and co-chairs the firm's environmental, social, and governance (ESG) and sustainable business and Cuba initiatives. Carl is the leader of the Boston office corporate and business transactions practice.

Our Global Reach

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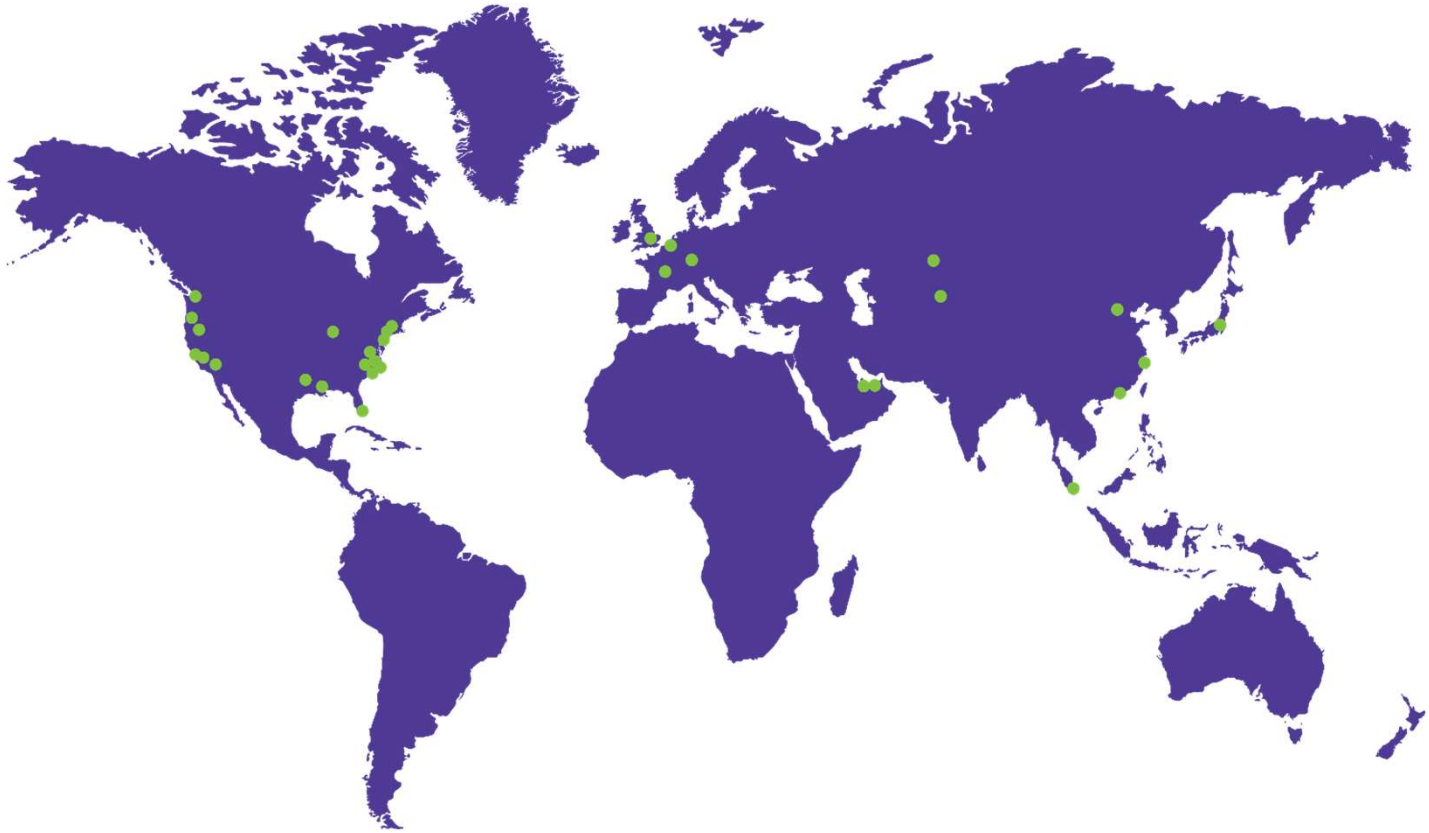

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