



Deal Maker's Boot Camp: Regulatory ABCs of M&A

December 14, 2023

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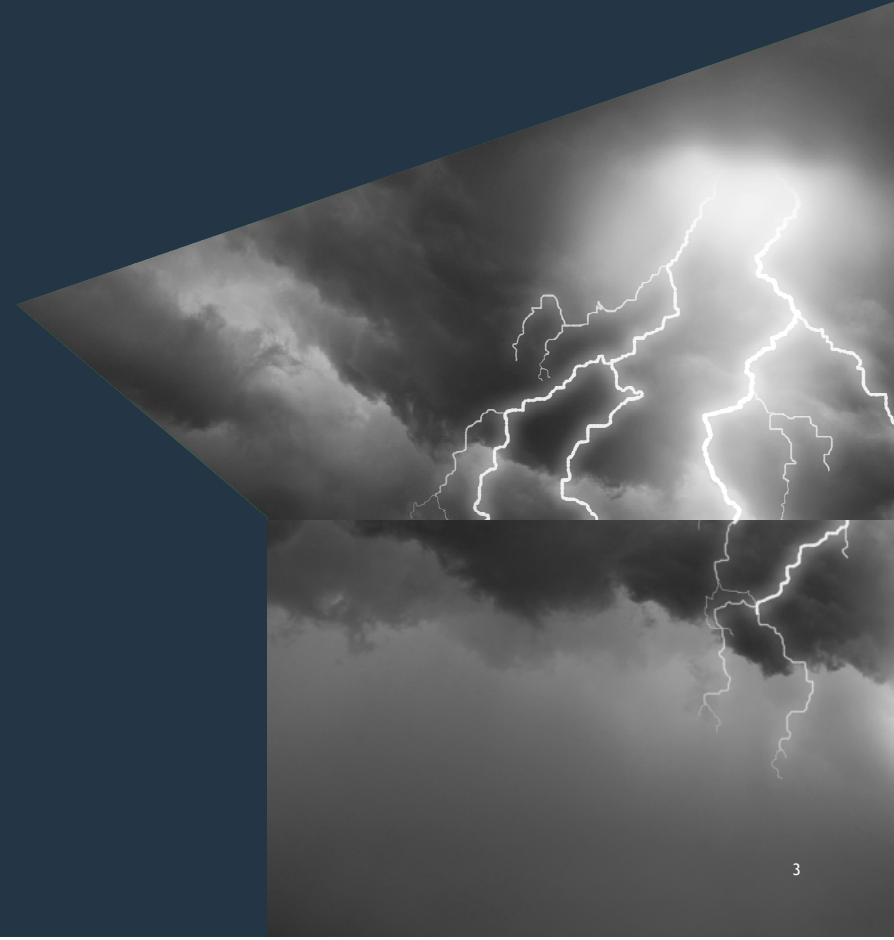
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Learning Objectives

- CFIUS, HSR, IRA, FTC, DOJ, FDA, etc.: what do these letters actually mean, and what do you need to know?
- Critical trade, national security, antitrust, regulatory and policy considerations that impact M&A transactions

Stormy Weather Ahead:

HSR Clearance in an Unpredictable and
Aggressive Antitrust Climate



Overview

- ➔ The Biden Administration made antitrust enforcement a priority
- ➔ What is the process for review by the Antitrust Agencies?
- ➔ Proposed changes would overhaul the process and analytical approach for mergers
 - Procedurally, proposed changes to HSR form will increase the cost and time to start the waiting period
 - Substantively, the proposed new Merger Guidelines broaden the scope of potential merger enforcement, including for private equity, increasing time and cost further
 - Courts, however, have proven to be the equalizer
- ➔ What do you need to know?



Antitrust Has Become a Topic of National Interest



“

I'm...commit[ting] the federal government to full and aggressive enforcement of our antitrust laws. No more tolerance for abusive actions by monopolies. No more bad mergers that lead to mass layoffs, higher prices, fewer options for workers and consumers alike.”

--President Biden (Jul. 9, 2021)

U.S. Antitrust Leaders Continue to Talk Tough

FTC Democrat Commissioners



Rebecca
Slaughter



Lina Khan,
Chair



Alvaro
Bedoya

DOJ AAG



Jonathan
Kanter

- ➡ FTC and DOJ believe that antitrust enforcement has been too lax, resulting in concentrated markets
- ➡ Prefer not to settle merger concerns and instead challenge deals in court
 - DOJ's first settlement was in Assa Abloy/Spectrum, which DOJ would likely have lost without a settlement
 - FTC is more willing to settle, but on more onerous terms than in the past

Hart-Scott-Rodino Pre-Merger Notification

- HSR Act captures “big” transactions involving “big” parties involving interstate commerce
 - Transactions > \$111.4 million may be reportable
 - Filing thresholds are adjusted annually to changes in gross national product
 - HSR filing fees are now \$30,000 - \$2.25 million based on transaction size
- HSR covers acquisitions of minority interests (<50%) and majority acquisitions (≥50%)
- Many technical exemptions to HSR

- ✓ HSR Reportability rules are Byzantine; consult counsel
- ✓ Failure to file carries risk of civil penalties, which are currently \$50,120/day per violation



HSR Process

- HSR filing triggers waiting period (typically 30 days) before the parties can close
- Government uses initial waiting period to determine whether an in-depth investigation is warranted
- Where government identifies concerns, parties may “pull and re-file” HSR filings to give government 30 more days to review
- Important to use this time effectively to explain why the transaction will not harm competition
- The initiation of an in-depth investigation extends the waiting period until 30 days after the parties substantially comply with a broad request for information (a “Second Request”) but, in practice, parties typically give the agencies more time



If the parties cannot persuade the agencies to clear the transaction within 60 days, be prepared for a step function increase in the cost and time to decision (average ~ 11 - 12 months from announcement)

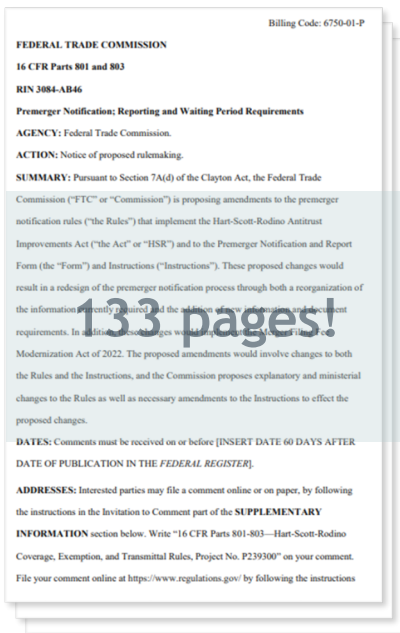
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Illustrative HSR Investigation Timeline

Average length of merger investigations: ~11-12 months over past 4 years



Proposed Overhaul to HSR Form would Dramatically Increase time and Cost to File



Proposed changes...

- Require parties to provide *substantially more documents and information* than is required by the current HSR form
- Significantly increase the burden on all HSR filers regardless of whether any competitive relationship between filing parties exists
- May increase time and cost to prepare HSR filings by **4 - 7x**
- Exact a high toll on investment firms with wide-ranging investments

Changes also amplify *risk that Agencies will deem a filing “deficient”* and cause the waiting period to restart

Key Proposed Changes to HSR Form

Category	Current Rule	Proposed Change
Item 4 documents	Unless interim drafts are provided to the full board of directors, filers must only provide final versions of certain documents prepared by or for officers or directors that analyze the competitive aspects of the transaction or its potential to generate synergies (these are so-called “Item 4” or “4(c)/(d)” documents)	The Proposed Rulemaking will require filers to provide additional Item 4 documents, including: <ul style="list-style-type: none">• Draft Item 4 documents (not just the final version)• Item 4 documents that are prepared by or for “supervisory deal team leads”• Board reports and certain semi-annual and quarterly ordinary course business plans that evaluate the competitive aspects of any overlapping product or service
Identification of minority investors	The current rules require each filer to disclose minority shareholders (5% or greater but less than 50%) of the acquiring and acquired entity. For limited partnerships, however, only the general partner(s), regardless of percentage held, must be listed. The acquiring entity must also disclose the minority shareholders of the acquiring person (the ultimate parent) and provide information for overlaps involving minority holdings.	Will require significantly more information about minority investors, including: <ul style="list-style-type: none">• The minority holders of all entities within the chain between the acquiring person and the acquiring entity.• The limited partners that hold 5% or greater but less than 50% of each entity within the chain.
Identification of officers, directors, and board observers	The current rules do not require the identification of officers, directors or board observers.	Sweeping new requirements to identify officers, directors, and board observers, including: <ul style="list-style-type: none">• The officers, directors, and board observers (or in the case of unincorporated entities, individuals exercising similar functions) of all entities within each of the acquiring person and the acquired entity.• Any other entities for which these individuals currently serve, or within the two years prior to filing have served, as officers, directors, or board observers. <p>*This requirement covers all entities within the acquiring person without regard to those entities’ involvement in the transaction.</p>



Proposed changes will result in searching for more documents from more people, and will require synthesizing significantly more information about the parties and the transaction

⚠️ Stormy Weather Ahead

Proposed New Merger Guidelines Reflect Aggressive Approach and Attempt to Tip Scales in Agencies' Favor

Under the Agencies' proposed approach...

🔗 Horizontal Mergers

- Lower thresholds for market concentration and merger's effect on concentration to trigger presumption of illegality
- Define a market share of 30% as the threshold for determining whether a firm is "dominant"
- "5 → 4" mergers will be more difficult to clear

⚙️ Introduces new ways to conclude merger is unlawful, including that it...

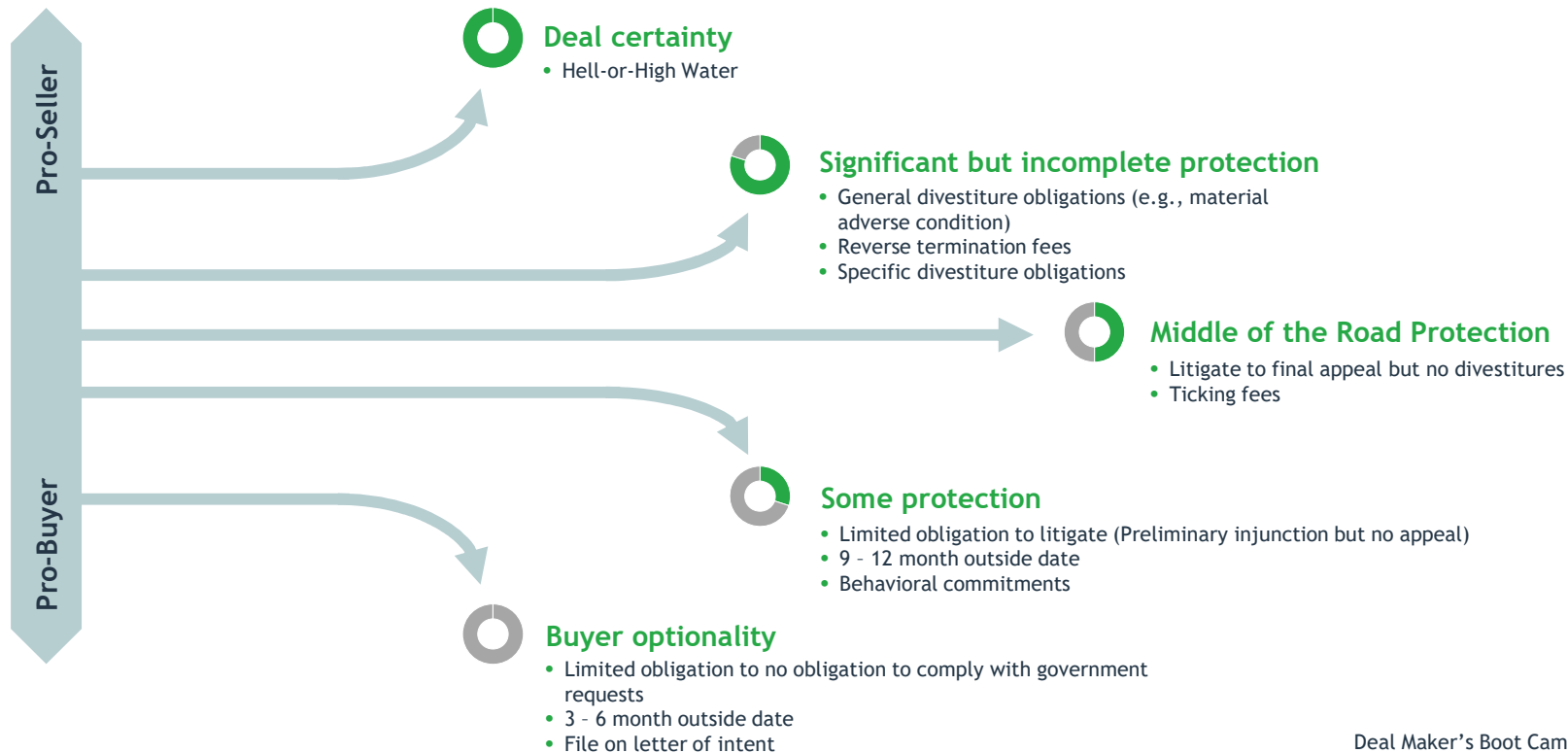
- "Entrench[es]" or "extend[s]" a dominant position
- "Contribut[es] to a trend towards consolidation"
- Harms competition involving multi-sided tech platforms by depriving access to participants or creating conflicts of interest
- Harms labor



🔗 Vertical Mergers

- 50% share anywhere in the supply chain → vertical merger presumed unlawful
- Reject behavioral commitments not to engage in the claimed anticompetitive behavior (e.g., contractual commitments) as a relevant factor in the analysis

Antitrust Risk Allocation in an Aggressive Antitrust Climate



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What Do You Need to Know?

- ➡ If enacted, HSR reforms will result in more time and cost to file (5 - 10 business days → 10 - 20+ business days)
- ➡ 30% “market” share anywhere in supply chain creates substantive antitrust risk
- ➡ Agency interest in new and untested theories increases importance of advance work to resolve concerns within 60 days



- ➡ If agency concerns cannot be resolved within 60 days → clients can expect step function increase in time and cost for antitrust clearance
- ➡ Litigation can be the equalizer, but it's expensive and should budget \geq 18 months in deal documents to complete district court litigation and get a decision

Appendix

Other Notable Proposed Changes to HSR Form (1)

Category	Current Rule	Proposed Change
Descriptions of horizontal and vertical competition	Filers are required to report revenue for overlapping NAICS codes, identify the overlapping entities, describe geographies in which the filing parties both derive revenue, and identify prior acquisitions. The scope of information required to be provided is limited to horizontal overlaps (i.e., the parties are competitors).	More detail about the competitive relationship between the parties, including: <ul style="list-style-type: none">• Identifying current and potential future horizontal overlaps. For each overlap, filers must provide sales, customer contact information, and other information about the parties' relationships.• Detailed narrative explanations of any vertical relationships between the parties, including descriptions and copies of any contracts between the parties, and contact information for relevant customers and vendors.
"Other Types of Interest Holders that May Exert Influence"	The current rules do not require the identification of "other types of interest holders that may exert influence."	The Proposed Rulemaking creates new requirements to identify other types of interest holders that may "exert influence" over any entity within the chain between the acquiring person and the acquiring entity. This includes: <ul style="list-style-type: none">• Providers of credit totaling 10% or more of the value of the entity.• Holders of non-voting securities, options or warrants the value of which equals or exceeds 10% of the entity or could be converted to 10% of the company.• Having nomination rights for board members or board observers.• Having agreements to manage entities related to the transaction.

Other Notable Proposed Changes to HSR Form (2)

Category	Current Rule	Proposed Change
Filings Based on Indications of Interest (e.g., Letters of Intent (LOI))	Currently, filers are permitted to file on the basis of “a contract, agreement in principle or letter of intent to merge or acquire” and an affidavit attesting the good faith intention to complete the transaction. Filing on an LOI, which is a common practice, enables parties to file HSR on the general metes and bounds of a transaction while continuing to negotiate the finer points of an agreement. There currently is no obligation to file a draft or final agreement, either upon HSR filing or after the HSR filing is submitted.	The Proposed Rulemaking will require parties to provide a term sheet or draft agreement with “sufficient detail” about the proposed transaction (although the Proposed Rulemaking indicates that typical LOI and other indications of interest do not meet the Agencies’ view of “sufficient detail,” the Proposed Rulemaking does not define what “sufficient detail” means other than requiring, elsewhere, a description of the timeline of key dates and conditions for closing). The Proposed Rulemaking, therefore, will make it more difficult to file strictly on indications of interest like an LOI.
Labor and Employment	The current rules do not require any information about labor and employment from the filing parties.	The Proposed Rulemaking creates a new “Labor Markets” category of information to screen for potential adverse competitive effects on labor. Among other requirements, the Proposed Rulemaking will require filers to: <ul style="list-style-type: none">• Identify their five largest employee categories by six-digit Standard Occupational Classification (SOC) code, an employee classification system developed by the Department of Labor Statistics.• For each of the top five overlapping SOC codes, provide overlapping geographies using the Employee Research Service’s-defined commuting zones, which the Department of Agriculture developed.
New information requirements	Additional information not required by the current HSR form	Other new requirements of the Proposed Rulemaking include: <ul style="list-style-type: none">• Certifying implementation of a document hold for every transaction• Identification of the filer’s communications and messaging systems• Providing information about certain foreign subsidies and defense/intelligence contracts• Submission of full English-language translation for all foreign-language documents.

CFIUS



CFIUS: What Is It?



Who? The Committee on Foreign Ivestment in the United States

Consists of:

- 9 Executive Branch departments, headed by Treasury
- 5 observing members
- Others can be added for specific reviews (e.g., Transportation)

What? Conducts national security reviews of “covered transactions”

How? CFIUS has authority to:

- Direct a filing / initiate a review of “non-notified” transactions
- Suspend pending transactions
- Require mitigation measures to address national security concerns in exchange for clearance
- Recommend the President block or order divestiture

Why? (do parties need to consider filing?)

- CFIUS can issue penalties for failure to make a mandatory filing up to value of transaction
- CFIUS review can delay or prevent closing
- CFIUS can mitigate or unwind a covered transaction in perpetuity unless it has cleared and provided a safe harbor

Jurisdiction: The Basics

Control transactions

“any transaction . . . by or with any foreign person that could result in foreign control of a U.S. business”

- U.S. business includes **collections of assets** that can function as a business
- Control is lower standard than in corporate context and includes some minority protections

Certain non-controlling investments

Certain non-controlling investments in TID U.S. Businesses that afford the foreign person certain “covered investment” rights

TID U.S. Businesses:

- Produce, design, test, manufacture, fabricate, or develop **critical technologies**;
- Own or operate certain **critical infrastructure**; or
- Maintain or collect **sensitive personal data** of U.S. citizens



Covered Investment Rights:

- Access to **material non-public technical information**;
- **Board rights** (membership or observer); or
- Involvement in **substantive decision-making**

Certain real estate transactions

Any transaction involving a purchase or lease by, or concession to, a foreign person of “covered real estate” near specified sensitive government facilities and ports that affords a foreign person specified “property rights”

- Covers greenfield transactions

CFIUS Considerations by Deal Phase

Phase	Actions
Planning	<ul style="list-style-type: none">• Consider potential national security consequences of transaction• Engage a CFIUS team, as warranted
Diligence	<ul style="list-style-type: none">• Assess potential national security vulnerabilities / threats• Finalize assessment on CFIUS jurisdiction and mandatory filing requirements
Negotiation	<ul style="list-style-type: none">• Plan CFIUS timeline into the deal• Address CFIUS risk in negotiation / condition closure on approval• Develop joint CFIUS strategy• Consider mitigation strategies
Executory Period	<ul style="list-style-type: none">• Finalize and submit (draft and final) notice• Engage with CFIUS in response to any follow-up questions• Negotiate mitigation measures if needed
Post-Closing	<ul style="list-style-type: none">• Ensure compliance with any mitigation requirements going forward

Planning and Diligence

? Does CFIUS have jurisdiction?

Analyze

- Whether there is U.S. business/TID U.S. business
- Whether acquirer is foreign person
- Transaction structure and rights of foreign person

Note:

- An entity can be both U.S. person and foreign person
- Foreign funds with U.S. GP may be U.S. persons
- Foreign person LPs can trigger jurisdiction depending on rights

? Is filing mandatory?

Determine whether:

- There is a covered transaction in a TID U.S. business with critical technology that would require government authorization for export to foreign acquirer or certain persons in ownership chain
- A foreign government will acquire “substantial interest” in a TID U.S. business

? Is filing advisable?

Consider:

- Vulnerability of U.S. business
- Threat posed by foreign person
- Consequences to national security

If so, decide between two filing options:

- Short-form declaration - quicker but decision not guaranteed
- Long-form notice

National Security Assessment

Illustrative Considerations



The foreign person presents a **threat**

- The buyer is from a country of concern
- The buyer has close commercial ties to a country of concern
- The buyer is controlled by or is subject to laws that require it to provide information to a government of a country of concern
- The buyer has a history of noncompliance with U.S. laws and regulations (e.g., sanctions, export control)



The U.S. business exposes a **vulnerability**

- The U.S. business deals in export-controlled goods or technologies or its technology could close a gap in a country of concern
- The U.S. business collects personal information of U.S. citizens
- The U.S. business serves government customers, directly or indirectly or abrupt shutdown likely to cause national security concerns
- The U.S. business may constitute “critical infrastructure” or serve “critical infrastructure” customers
- The U.S. real estate is located in close proximity to certain sensitive military or government sites



CFIUS assesses the potential national security consequences of the interaction of the identified threat and vulnerability

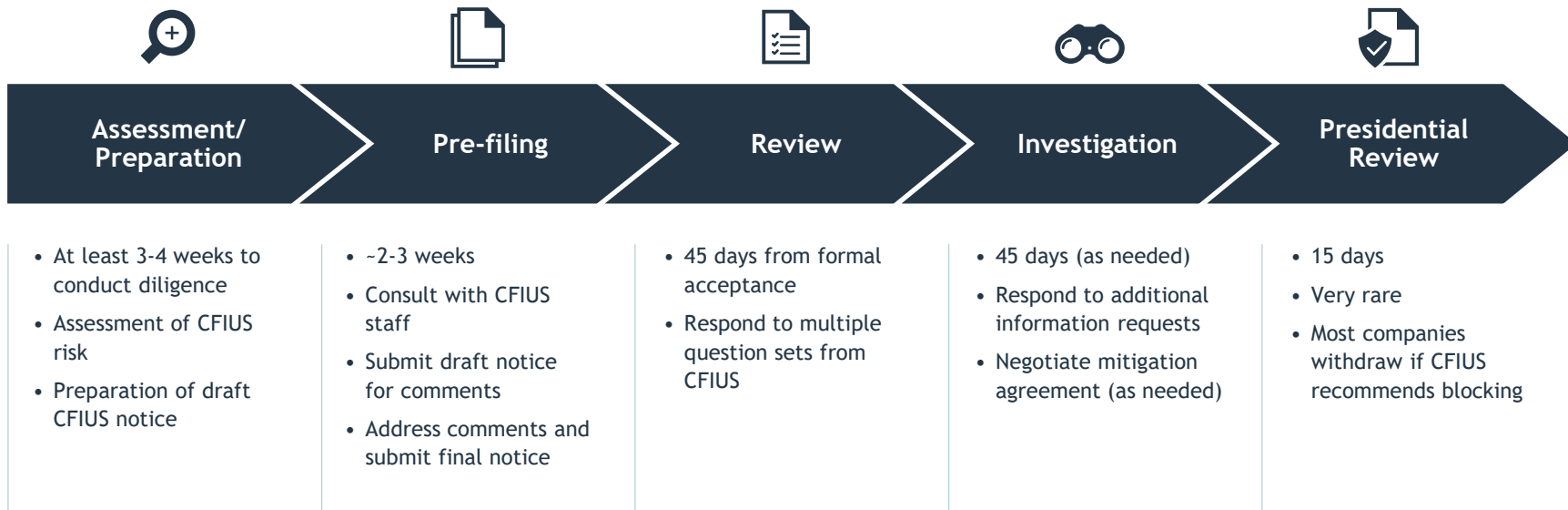
Negotiation

- Structure agreement to account for filing and risk
- Parties may consider the following:
 - **Representations** regarding key CFIUS issues, such as mandatory reporting and foreign person/U.S. person status
 - **Indemnities** associated with representations (e.g., penalties for failure to make mandatory filing)
 - **Covenants** to shape how the parties will engage in the CFIUS process
 - **Closing conditions** to obtain CFIUS and other regulatory approvals
 - **Termination provisions** and **termination fees** associated with failure to obtain CFIUS clearance prior to outside date



Execution: Representative Timeline

The CFIUS Process for Notices (declaration process is shorter)



Execution and Post-Closing: Mitigation Measures

- ✓ Measures must, from CFIUS's perspective, be effective, enforceable and monitorable
- ✓ Parties often only have a few days or a week to negotiate mitigation measures that will require ongoing and indefinite compliance obligations
- ✓ Measures can vary in scope based on underlying national security concerns, but common terms include:
 - Divest or wall-off enterprises posing national security risks
 - Limit board membership and voting rights of the foreign person
 - Invite U.S. national security figures to join the board of directors
 - Develop compliance programs and hire compliance personnel
 - Make non-controlling, minority investments with limited (passive) ownership rights
 - Adjust the ownership structure to minimize potential concerns
 - Annual reporting and auditing requirements
- ✓ CFIUS monitors and enforces compliance



Outbound Investment

Investment Review Globally



- ➡ **More than 30 countries** have created or strengthened their investment review mechanisms; sometimes mandatory
- ➡ **Exact jurisdiction varies**, but sector-based approaches almost always cover companies with export-controlled technology and critical infrastructure
- ➡ **United States generally top source** of reviewed transactions
- ➡ **Mitigation more common** than blocking
- ➡ **Timelines vary**

U.S. Regulation of Outbound Investment

- August 2023 Executive Order on outbound investment to China (including Hong Kong and Macau)
- Rulemaking process that will lead to prohibitions and notification requirements on certain investments by U.S. persons in China/Chinese entities involving semiconductors, quantum computing and artificial intelligence
- Advanced Notice of Proposed Rulemaking for public comment, which sets out details about how Treasury is considering implementing the Executive Order
 - Focus on active capital (e.g., PE and VC funds, operating companies)
 - Final rule expected 2H2024
- Potential legislative action
 - Notification requirements and/or prohibitions on transactions in specified sectors in China and other “countries of concern”
 - Prohibitions on transactions with specified Chinese entities

Health Care & Life Sciences

Deals — Diligence

Industry / Business	Key Potential Regulators
FOOD <ul style="list-style-type: none"> • Human and Animal • Alcoholic Beverages 	<ul style="list-style-type: none"> • Food & Drug Administration (FDA) • Federal Trade Commission (FTC) - as to advertising • US Dept. of Agriculture (USDA) • Alcohol & Tobacco Tax and Trade Bureau (TTB)
DRUGS <ul style="list-style-type: none"> • Prescription drugs and biologics • Over the counter drugs • Drug ingredients • Drug manufacturers • Contract manufacturers, marketers 	<ul style="list-style-type: none"> • FDA • Centers for Medicaid & Medicare Services (CMS) • FTC - as to advertising • Department of Health & Human Services, Office of the Inspector General (HHS OIG)
MEDICAL DEVICES <ul style="list-style-type: none"> • Hardware • Software • Diagnostics 	<ul style="list-style-type: none"> • FDA • CMS • FTC - as to advertising • HHS OIG
COSMETICS	<ul style="list-style-type: none"> • FDA, FTC - as to advertising
HEALTHCARE SYSTEMS AND PROVIDERS	<ul style="list-style-type: none"> • CMS, State Attorneys General*

FDA, CMS, USDA, TTB do not have transaction approval authority

*State AGs and/or other state entities have transaction review and approval in certain jurisdictions of transfers of ownership and/or changes in ownership, debt ratios, etc. of certain healthcare systems, hospitals, etc.

Deals Diligence

1

Many key documents relating to potential ongoing legal and regulatory matters with FDA, CMS, FTC and others will not be publicly available: be sure to request, inquire, follow up:

- E.g., regulatory correspondence to/from FDA on a pending new drug application (NDA) is not public; final warning letters and final approvals are public.

2

Consider the need for engaging non-legal expert advisors

- E.g., manufacturing plant inspectors re: food, drug, device, etc.

3

Review legal docket findings not only for the potential liability/value it represents, but as a signal of potential operational or compliance deficiencies of the target overall that justify additional diligence

- E.g., whistleblower employment litigation

4

Perform diligence on the target's compliance program itself (not just a review of standard operating procedures): DOJ, HHS OIG guidance plus industry codes of conduct

Deals Drafting Tips

Indemnifications need to significantly take into account personal injury liabilities arising from mass tort claims as to marketed products or clinical studies

Reps and warranties as to compliance with laws, regs, industry standards for the specific sector.

Examples:

- Pharmaceuticals/devices: R&W as to compliance with “Good Manufacturing Practices” under domestic and foreign regulations
- Beverages: Compliance with applicable product labeling requirements
- Hospital Systems: Compliance with applicable CMS regulations on reimbursement
- Pharmaceuticals/Devices: Federal and state laws on “transparency”

Reps and warranties as to an effective Compliance Program re:

- The 2023 DOJ’s general “Evaluation of Corporate Compliance Programs” guidance
- The 2023 HHS OIG “General Compliance Program Guidance”
- Compliance with industry codes, e.g., PhRMA, AdvaMed

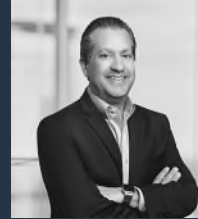


Questions?



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Thank You!
