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Evolving antitrust strategies for healthcare deals in 2023

Moderator: Yasin Keshvargar

Speakers: Jesse Solomon and Suzanne Munck af Rosenschold

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Your Presenters

Moderator

Yasin Keshvargar
Partner
+1 212 450 4839
yasin.keshvargar@davispolk.com

Yasin is a partner in our Capital Markets practice. He advises clients ranging from early-stage privately held companies to well-known seasoned issuers on governance, SEC reporting and strategic transactions with a focus on the healthcare sector.

Speakers

Jesse Solomon
Partner
+1 202 962 7138
jesse.solomon@davispolk.com

Jesse is a partner in our Antitrust & Competition practice. He guides clients in securing U.S. and worldwide competition clearances for complex transactions, including in pharmaceuticals, healthcare and technology.

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Suzanne Munck af Rosenschold
Counsel
+1 202 962 7138
suzanne.munck@davispolk.com

Suzanne is a counsel in our Antitrust & Competition practice. A former FTC official, she represents pharmaceutical and healthcare clients in merger and non-merger matters before the FTC and the DOJ.

Agenda

Ambitious antitrust enforcement

01

Historical consensus is being challenged

For over a century, US courts have stated that the objective of antitrust is to *promote competition*

- "Consumer welfare" standard: antitrust laws protect "competition, not competitors" (*Brown Shoe*)
- Focus on economic effects: price, output, innovation, product quality
- Courts have not evaluated antitrust based on broader social policy considerations, e.g., national industrial policy
- Can antitrust laws extend to proxies for consumer welfare (labor; downstream businesses)?

In recent years, progressive critics have challenged consensus, arguing that the antitrust laws have been interpreted too narrowly and that, therefore:

- The economy is too concentrated, with many industries dominated by a small group of large firms
- Competition and consumers have been harmed

As these views have gained acceptance, we are seeing support for aggressive "reform" (or at least aggressive rhetoric) globally, including among US, EU, and UK regulators

New merger analyses

What to expect?

Public statements and enforcement to date suggest a variety of philosophy shifts:

1. Tougher review of vertical and conglomerate mergers
2. Focus on “competitive moats” and the “competitive process”
3. Challenges at far lower degrees of concentration
4. Less emphasis on market definition
5. Focus on “nascent” or “potential” competition
6. Focus on “monopsony,” or buyer power, especially in labor markets
7. Focus on key industries (Big Pharma)

Lina Khan
Chair, FTC

Jonathan Kanter
AAG, DOJ Antitrust Division

Courts are a governor on ambitious enforcement

The DOJ accepted no consent agreements in 2022, choosing to litigate rather than to settle

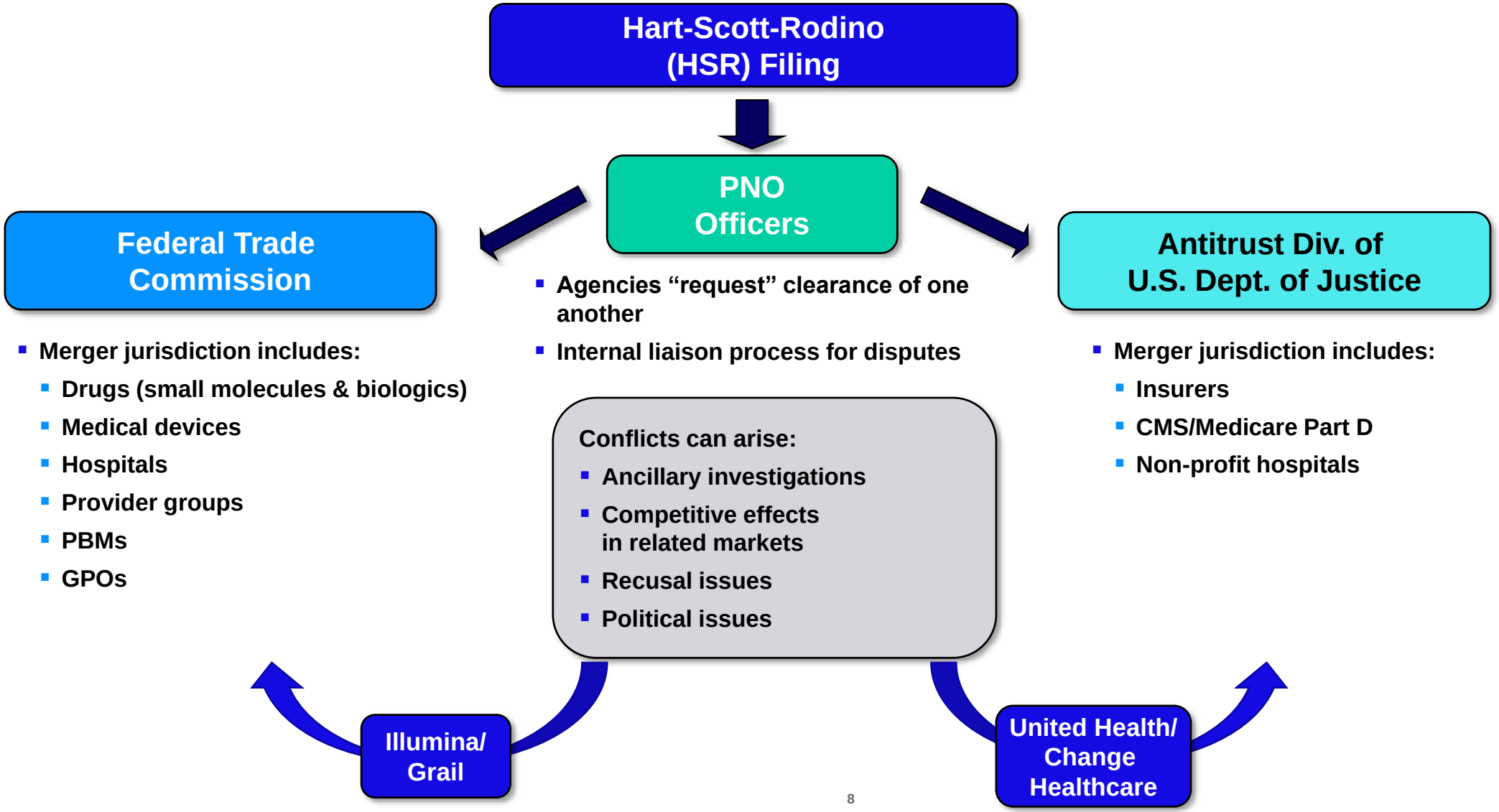
But: the DOJ – and the FTC – are *losing* most of their cases

- Mergers
  - *UnitedHealth Group / Change Healthcare* (DOJ, D.D.C.) – Defense verdict
  - *U.S. Sugar / Imperial Sugar* (DOJ, D. Del.) – Defense verdict
  - *Booz Allen / Everwatch* (DOJ, D. Md.) – Defense verdict
  - *Penguin Random House / Simon & Schuster* (DOJ, D.D.C.) – Prosecution verdict
  - *Illumina / GRAIL* (FTC, in administrative court) – Defense verdict
  - *Meta / Within* (FTC, N.D. Cal.) – Defense verdict
- Criminal
  - *DaVita* (no-poach prosecution against dialysis company, CEO) (DOJ, D. Colo.) – Acquittal
  - *Penn 1, 2, 3* (no-poach prosecution against poultry execs.) (DOJ, D. Colo.) – Two hung juries; then full acquittal

Recent healthcare cases

02

Healthcare clearance to the FTC or DOJ



Illumina / Grail

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Deal challenged in FTC's own "administrative court"

FTC and DOJ have different avenues to challenge a transaction following their investigation

- Hearing by Administrative Law Judge (FTC only)
  - In *Illumina*:
    - March 2021: Bipartisan 4-0 vote to issue complaint
    - Sept. 2022: ALJ rules for defense
    - Sept. 2022: FTC staff file notice of appeal
    - Now: matter before FTC Commissioners (who go behind a "wall"); parties have appeal right to federal court of their choice
- Preliminary injunction in Federal Court (FTC & DOJ)
  - Agencies can bring suit in any district court with venue (e.g., D.D.C. in *United*)

Illumina challenge focused on vertical issues

FTC challenged Illumina / GRAIL based on a vertical theory, with "potential competition" overlay

- Illumina alleged to be the only viable supplier of Next Generation Sequencing (NGS) products – an essential input for Multi Cancer Early Detection (MCED) tests being developed by GRAIL and rivals

- FTC alleged that Illumina could reduce GRAIL's rivals' access to the essential NGS input post-acquisition, diminishing their ability to develop MCED tests and compete against GRAIL

- FTC's argument rejected by Administrative Law Judge in 200 pp. decision on two main bases:
  - Real skepticism regarding risk of harm (esp. testimony of FTC's outside economist)
  - View that commercial "fix" implemented by parties was sufficient

Parties' preemptive commercial fix: "Open Offer"

Illumina offered future potential customers a standardized, long-term supply agreement for a period of 12 years – a fix that was crucial to ALJ's decision

"Open Offer" constraint on Illumina	FTC's claimed harm to rivals
Requirement to supply all sequencing products	**NO** ability to withhold or impede supply to GRAIL's rivals
Prohibition on increasing prices over inflation, MFNs	**NO** ability to increase prices or price discriminate
Requirement to provide access to equivalent services	**NO** ability to decrease quality of service and support
Requirement to provide access to new technology	**NO** ability to delay or deny access to new technology
Requirement to enter into development agreements if asked	**NO** ability to develop products specifically for GRAIL
Requirement to provide all required information, data (including for FDA approval)	**NO** ability to deny access to critical information, data

Parties' preemptive commercial fix: "Open Offer" (cont.)

Decision rebuffs recent agency claims that *all* remedies (structural and behavioral) are unacceptable

- "I am concerned that merger remedies short of blocking a transaction too often miss the mark. Complex settlements, whether behavioral or structural, suffer from significant deficiencies." (AAG Kanter, January 24, 2022)
- "Importantly, the Commission has been reassessing the efficacy of its approach to merger remedies…Specifically, we now strongly disfavor behavioral remedies and will not hesitate to reject proposed divestitures that cannot fully cure the underlying harm." (FTC Chair Khan, September 20, 2022)

Decision continues trend of defendants winning vertical cases on basis of a "fix"

- *UnitedHealth Group / Change Healthcare*
  - Firewalls and other safeguard policies
- *AT&T / Time Warner*
  - Arbitration in case of customer disputes

Clear take-away is incentive for "fix-it-first" rather than formal remedies – but parties may have to litigate

Other “lessons learned” from *Illumina*

Novel product markets can be hard to litigate

- ALJ found FTC’s approach to market definition “muddled” and “confusing”
  - FTC failed to support alleged market for “the research, development, and commercialization of MCED tests”
  - But ALJ looked at the evidence presented in the case to accept the alleged market

Experts’ industry experience may matter more than antitrust bona fides

- FTC hired a well-known and progressive antitrust economist: Fiona Scott-Morton (Yale)
- ALJ considered expert’s “qualifications to give opinions for this case are minimal” (i.e., lack of medical expertise)
- In contrast, defense relied on opinions of numerous experts in various fields of study (e.g., economics, immunology, and medicine)
  - ALJ often considered them to be “highly [or well] qualified to offer opinions for this case”

And a less obvious lesson: can your efficiency claims be used against you?

UnitedHealth / Change Healthcare

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Multiple DOJ concerns

Horizontal:

- United, through its subsidiary Optum, and Change are both active as providers of first-pass claims editing technology to health insurers in the U.S.
- Alleged combined market share of more than 90%

Vertical:

- Change is a leading provider of *EDI clearing house services* to insurers
  - I.e., Change has access to **claims data** of numerous health insurers (competitors of United)
- The transaction would allegedly give United:
  - access to rival insurers' competitively sensitive information (CSI), harming competition (data-misuse theory)
  - ability and incentive to foreclose rivals' access to new EDI innovations, reducing competition (foreclosure theory)

Same playbook: “Litigating the fix”

Divestiture of Change’s overlapping first-pass claims editing technology business (ClaimsXten)

- DOJ needs to account for proposed divestiture
  - Agencies have sought (repeatedly) to exclude:
    - Evidence of a fix (*AT&T / Time Warner; ASSA ABLOY / Spectrum*)
    - Evidence of efficiencies (*Penguin Random House / Simon & Schuster*)
- Proposed divestiture would restore (or even exceed) any alleged loss of competition
  - Court rejected argument that PE firm, TPG, would not be an adequate divestiture buyer
    - Significant experience with “carve-out investments” and healthcare
    - Plans to invest substantially in the divested business
    - Divested business will retain its key employees and managers
  - ClaimsXten was a highly separable asset

Take-aways include value of strong structural remedies, and the possible viability of PE firms as divestiture buyers

Same playbook: Lack of incentive or ability

Court found DOJ's "data-misuse theory" rested on speculation rather than real-world evidence

1. Optum will gain incremental access to claims data of United's rivals → Court agreed
   - But critical that DOJ did not explain how incremental data gain changed ability or incentive to misuse data (i.e., Optum already has access to non-United claims data)
2. Optum will have incentive to share the data with United → Court disagreed
   - Optum derives majority of revenue from rival health insurers; customers need to trust their data will be protected
   - United has CSI protections in longstanding firewall policies and customer contracts; history of compliance
     - In May 2022, issued guidance to address Change transaction and post-transaction data sharing principles
3. Rivals fear of data misuse will chill innovation → Court disagreed
   - Court particularly critical that DOJ presented "zero real-world evidence" and "did not call a single rival player to offer corporate testimony that it would innovate less or compete less aggressively" post transaction
4. Less innovation means less competition → Court disagreed
   - Again, Court critical of lack of evidence on this point

Court also found "foreclosure theory" conflicts with United's business strategy and practice

- No prior history of United withholding products or innovation from rival health insurers

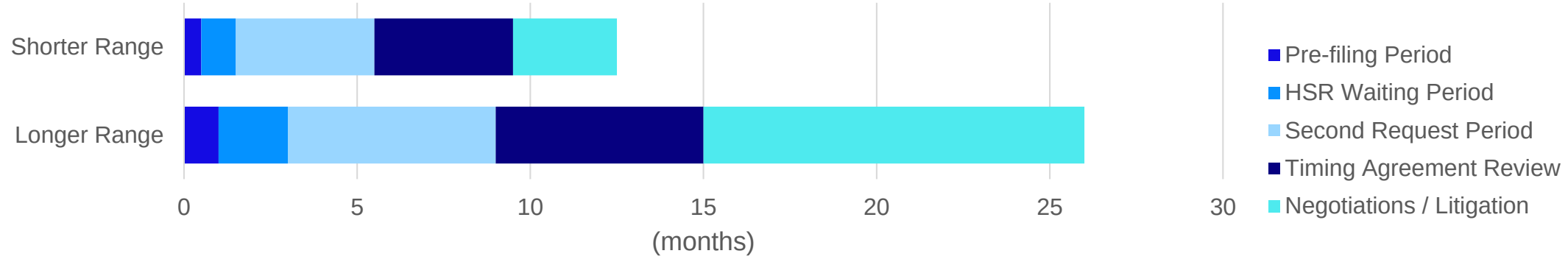
Strategies for deal negotiations

03

Implications for signing and announcing deals

Outside date

Longer potential timelines for U.S. antitrust regulatory review impact outside date



- Pre-Filing Period (2-4 weeks): Prepare HSR filing (often 2-4 weeks post-signing)
- HSR Waiting Period (1-2 months): Parties try to resolve some – or all – issues, in an effort to avoid a Second Request
- Second Request Period (4-6 months): Buyer and Seller work to respond to Second Request and negotiate timing agreement
- Post-Compliance Review (4-6 months): Agencies assess what action to take:
  - Depositions, white papers, party meetings
- Negotiations / Litigation (3-11 months): Agencies might close an investigation without action; negotiate a remedy (now highly disfavored); or litigate in court to stop the merger
- Outside date timelines becoming longer in strategic deals
  - E.g., Illumina / GRAIL: original outside date December 20, 2020; extended to December 20, 2021

Implications for signing and announcing deals

Antitrust efforts covenant

Efforts covenants govern the level of effort the parties must undertake to secure clearance

- General standards include
  - Best efforts ("Hell or High Water")
  - Reasonable best efforts
  - Commercially reasonable efforts
- Specified obligations/limitations
  - Buyer will or will not will or will not accept divestitures, enter into consent decrees, etc.
  - Buyer will or will not accept divestiture of certain business lines
  - Buyer will or will not accept divestiture of up to a certain percentage of Target's revenues, EBITDA, etc.

What is the antitrust risk profile of the proposed transaction?

- Think broadly about theories of harm: vertical, potential, conglomerate/"bundling," labor

Implications for signing and announcing deals

Reverse termination fee

Buyer pays RTF if transaction fails due parties failing to obtain antitrust clearance, e.g.:

- Cash payment
- Required commercial agreements or divestitures
- Ticking fees, e.g., buyer pays interest to seller if transaction not closed by a particular date

Typically triggered when:

- The agreement is terminated because the drop-dead date is reached without the transaction closing or because a permanent injunction in respect of antitrust matters prohibits the transaction; ***and***
- At the time of termination, all conditions (other than antitrust-related conditions) have been satisfied or are capable of being satisfied

Is the buyer prepared to pay a fee in the event that antitrust approval is not secured?

- E.g., *Illumina / GRAIL*:

  (i) reverse termination fee of $300M (additional $300M termination fee), ~7.5% of the transaction value; and
  (ii) monthly payments pending transaction termination or completion

Implications for signing and announcing deals

Non-competition agreements

FTC and DOJ take an aggressive posture against non-competes

- In January 2023, the FTC proposed a rule that would bar almost all non-competes (existing and future)
  - The proposed rule is subject to a 60-day comment period, after which the FTC can announce the final rule
  - Significant hurdles expected

How will the FTC/DOJ evaluate non-competes in the deal context

- Key open questions:
  - Non-solicits
  - NDAs
  - Gardening leave

Non-compete concerns are not specific to healthcare – but healthcare specifically in agency crosshairs

Strategies for deal clearance

04

Affirmative strategies for deal clearance

Develop an active customer engagement strategy early in the deal

- Complainants have more power than they have historically
- Be proactive – particularly if third parties might complain
  - Consider payors; KOLs; patient advocacy groups; HHS/CMS; distribution supply chain

Consider imposing a commercial fix early – even if the agency will reject it

- Complainants have more power than they have historically
- Be proactive

Develop a sound advocacy strategy

- To advocate or not? → A more complex question today than 5 years ago

Prepare for litigation

- All signs suggest that the DOJ and the FTC will continue to focus on healthcare enforcement
- 2022 track record indicates strong interest in novel theories of harm

Conclusion

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Key takeaways

1. **Ambitious U.S. agency enforcement with a preference for litigation over divestitures**

2. **Continued focus on novel theories of harm and resurgence of vertical investigations in the healthcare sector**

3. **Timing of merger review is likely to be extended in complex healthcare deals**

4. **Higher scrutiny of deal documents and integration planning efforts**