Volume 2, Number 4 July–August 2024

THE JOURNAL OF FEDERAL AGENCY ACTION

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Publishing Staff
Publisher: Leanne Battle
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Cover Art Design: Morgan Morrissette Wright and Sharon D. Ray

This journal's cover includes a photo of Washington D.C.'s Metro Center underground station. The Metro's distinctive coffered and vaulted ceilings were designed by Harry Weese in 1969. They are one of the United States' most iconic examples of the brutalist design style often associated with federal administrative buildings. The photographer is by XH_S on Unsplash, used with permission.

Cite this publication as:

The Journal of Federal Agency Action (Fastcase)

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A Full Court Press, Fastcase, Inc., Publication

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729 15th Street, NW, Suite 500, Washington, D.C. 20005
https://www.fastcase.com/

POSTMASTER: Send address changes to THE JOURNAL OF FEDERAL AGENCY ACTION, 729 15th Street, NW, Suite 500, Washington, D.C. 20005.

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ISSN 2834-8796 (print)
ISSN 2834-8818 (online)

Editor's Note
Time to Unpack

Victoria Prussen Spears*

Michelle A. Mantine, a member of the Board of Editors of *The Journal of Federal Agency Action* and a partner in the Pittsburgh office of Reed Smith LLP, and Katie Rose Kenawell, an attorney with the firm, are back with another article for this journal. We also have a lot more for you here!

Merger Guideline 6

In our lead article, titled "Entrenching a Dominant Position: Unpacking Merger Guideline 6 and Its Practical Implications," Michelle A. Mantine and Katie Rose Kenawell examine the legal authority behind Guideline 6 of the 2023 Merger Guidelines published by the Federal Trade Commission and the Department of Justice, unpack how the government is using the phrase "dominant position," and explore the scope and use of the terms "entrenching" or "extending" in relation to Guideline 6.

Dealer

Then, in the article titled "Securities and Exchange Commission Expands 'Dealer' Definitions to Capture Liquidity Providers," Eden L. Rohrer, Richard F. Kerr, Jessica D. Cohn, and Raymond F. Jensen of K&L Gates LLP analyze final rules adopted by the Securities and Exchange Commission to expand the definitions of "dealer" and "government securities dealer" in Sections 3(a)(5) and 3(a)(44) of the Securities Exchange Act of 1934.

The EPA

The article that follows, titled "Environmental Protection Agency's 2024-2027 Enforcement Priorities Officially Take Effect,"

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 235–238.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

is by Wayne J. D'Angelo and Zachary J. Lee of Kelley Drye & Warren LLP. Here, the authors review the U.S. Environmental Protection Agency's 2024-2027 National Enforcement and Compliance Initiatives.

The FDA

Greer O. Lautrup, Daniel J. Roberts, and Stephanie Slater of Sidley Austin LLP are the authors of the next piece, titled "Navigating the Regulatory Landscape in the Digital Age: A Guide to the Food and Drug Administration's New Guidance on Remote Regulatory Assessments." In this article, the authors review new draft guidance published recently by the Food and Drug Administration on remote regulatory assessments.

Interior

The U.S. Department of the Interior's Bureau of Ocean Energy Management recently issued a final rule with new standards for when supplemental financial assurance or bonds will be required from offshore oil and gas companies operating in federal waters. Jim Noe and Elizabeth Leoty Craddock of Holland & Knight LLP discuss this development in their article, titled "Interior Department Announces Rule on Financial Assurance for Offshore Oil and Gas."

Connected Vehicles

The article that comes next is titled "U.S. Government Acts on Connected Vehicle Privacy and National Security Concerns." In this piece, Sara M. Baxenberg, Scott D. Delacourt, Stephen J. Conley, and Stephanie Rigizadeh of Wiley Rein LLP review federal government developments in the connected vehicle space of interest to automakers, suppliers, and wireless providers.

The DOJ

Thomas M. Burnett and Daniel G. Murphy of Reinhart Boerner Van Deuren s.c., are the authors of the article titled "Fueled By

Whistleblower Claims, Department of Justice Reports Record Year for False Claims Act Recoveries." Here, they examine a report from the U.S. Department of Justice regarding settlements and judgments the government obtained under the False Claims Act in fiscal year 2023.

FINRA

Elizabeth A. Marino, Lara C. Thyagarajan, Paul M. Tyrrell, Kenneth Ashton, and Greg Chiuve of Sidley Austin LLP discuss new guidance issued by the Financial Industry Regulatory Authority that modernizes its regulatory framework related to remote workplace locations. The title of their article is "Financial Industry Regulatory Authority Issues Long-Awaited Guidance Regarding Residential Supervisory Locations and Remote Branch Office Inspections."

PFAS

In our prior issue, we published the first part of a two-part article titled "Overview of PFAS Regulations in the United States and What Foreign Companies and Their U.S. Subsidiaries Need to Know." There, Reza Zarghamee, Shinya Akiyama, and Lauren Johnstone with Pillsbury Winthrop Shaw Pittman LLP described poly- and perfluoroalkyl substances (PFAS), the types of products that include it, and the recent wave of litigation involving PFAS contamination, which has involved settlements above $10 billion. Here, the authors conclude their article with a discussion of developments in federal and state regulation of these chemicals and specific scenarios in which these developments may affect foreign corporations. They conclude by recommending that businesses that manufacture, distribute, use, or dispose of PFAS or products containing PFAS stay abreast of these developments and develop proactive strategies to minimize their potential liability.

Enjoy the issue!

Note

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attorney at a leading New York City law firm before joining Meyerowitz Communications. Ms. Spears, who also is Editor of *The Journal of Robotics, Artificial Intelligence & Law*, *The Global Trade Law Journal*, and *The Global Regulatory Developments Journal*, may be contacted at vpspears@meyerowitz communications.com.

Entrenching a Dominant Position: Unpacking Merger Guideline 6 and Its Practical Implications

Michelle A. Mantine and Katie Rose Kenawell*

In this article, the authors examine the legal authority behind Guideline 6 of the 2023 Merger Guidelines published by the Federal Trade Commission and the Department of Justice, unpack how the agencies are using the phrase "dominant position," and explore the scope and use of the terms "entrenching" or "extending" in relation to Guideline 6.

In December 2023, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (collectively, the Agencies) published the 2023 Merger Guidelines, which represent the Agencies' efforts to increase antitrust enforcement associated with mergers and acquisitions. While stricter than the version immediately prior, the 2023 Guidelines are meant to clarify what the Agencies will investigate and potentially challenge while still leaving room for the Agencies to consider the practical realities of any given market. The language is deliberately flexible to allow prosecutorial discretion in challenging mergers that could increase the market power of an already powerful firm:

> *Guideline 6*: Mergers Can Violate the Law When They Entrench or Extend a Dominant Position. The Agencies examine whether one of the merging firms already has a dominant position that the merger may reinforce, thereby tending to create a monopoly. They also examine whether the merger may extend that dominant position to substantially lessen competition or tend to create a monopoly in another market.[1]

This article examines the legal authority behind this Guideline, unpacks how the Agencies are using the phrase "dominant position," and explores the scope and use of the terms "entrenching" or "extending" in relation to Guideline 6.

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 239–246.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

Legal Authority for Merger Guideline 6

Congress has given the Agencies a wide latitude of authority to investigate and challenge allegedly anticompetitive mergers and acquisitions. This legislation is colloquially known as the Clayton Act, more specifically Section 7 of the Clayton Act. The Clayton Act is less well-known than the Sherman Antitrust Act but in the context of mergers, it may be even more important. It provides:

> No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, *the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly*.[2]

As enacted in 1914, the statute was only meant to address stock acquisitions, not asset acquisitions. However, as time went on, it became clear that asset acquisitions could have the same problematic and anticompetitive effects as stock acquisitions. It became more and more common to call for amendments to expand the scope of this law. The Supreme Court wrote, "[t]he dominant theme pervading congressional consideration of the 1950 amendments was a fear of what was considered to be a rising tide of economic concentration in the American economy."[3]

The reason to target mergers and acquisitions specifically "is to cope with monopolistic tendencies in their incipiency and well before they have attained such effects as would justify a Sherman Act proceeding."[4] Today, this problem is colloquially known as the issue of "unscrambling the egg." John Kwoka and Tommaso Valletti, contributors to Oxford Academic's *Industrial and Corporate Change* journal, wrote a piece titled "Unscrambling the Eggs: Breaking Up Consummated Mergers and Dominant Firms."[5] In the article, they postulate that "a policy of breakups can have a much greater chance at success compared to efforts to regulate such firms through rule-making conduct remedies."[6]

However, the contributors concede that the practice is "generally dismissed as impractical." This impracticality makes the Sherman

Act difficult to enforce, hence the introduction of the Clayton Act. The issue of "unscrambling the egg" is also why preventing mergers from further entrenching a firm in a dominant position has become so important to the current FTC's view on antitrust enforcement in 2024.

From the Agencies' Point of View, What Does It Mean to Have a Dominant Position?

The Guideline explains that the first step in analysis will be to answer just this question. The Guideline notes that, "[t]o undertake this analysis, the Agencies first assess whether one of the merging firms has a dominant position based on direct evidence or market shares showing durable market power."[7] The issue of dominance hinges largely on market share evidence, given that the Agencies do little to define "dominance" in any other way. As further explanation, the Agencies write:

> For example, the persistence of market power can indicate that entry barriers exist, that further entrenchment may tend to create a monopoly, and that there would be substantial benefits from the emergence of new competitive constraints or disruptions. The Agencies consider mergers involving dominant firms in the context of evidence about the sources of that dominance, focusing on the extent to which the merger relates to, reinforces, or supplements these sources.[8]

In some ways, this explanation is circular. It seems to say, vaguely, that dominant positions are indicated by market power and sources of dominance. However, if a firm were displaying these same qualities, of increasing market power and increasing dominance, and yet only held a tiny fraction of the market shares, it would not be considered dominant. It would be considered disruptive to the industry and effectively competitive.

Maybe the question of how to define an unlawful dominant firm is akin to the classic Supreme Court adage from *Jacobellis v. Ohio*, coined by Justice Potter Stewart in a concurrence. Perhaps the Agencies are deliberately leaving flexibility when it comes to defining a firm that is already in a dominant position. Perhaps the Agencies are telling firms that they do not know what will constitute a dominant position in every single case.

But when a powerful dominating firm pursues a merger, the Agencies will surely not equivocate. The FTC and DOJ will surely, "know it when [they] see it."[9] Ambiguity and flexibility as to the first question offer a useful balance to the strict, numerical metrics that will answer the next question.

To Entrench or Extend: What Does It Mean in the Context of Merger Guideline 6?

The Answer Is Tied to the 30 Percent Threshold and HHI

In the 2010 and 2020 Merger Guidelines, there was no threshold to presume a merger was substantially lessening competition. Now, the 2023 Guidelines essentially presumes illegal mergers that create more than a 30 percent market share.[10] Although picking a certain percentage, such as 30 percent, may seem like an arbitrary line drawing, it is actually a return to historical precedent.

In 1963, the U.S. Supreme Court considered this issue in *United States v. Philadelphia National Bank*. The Supreme Court looked at a proposed merger between Philadelphia National Bank and Girard Trust Corn Exchange Bank.[11]

At the time, the two banks were the second and third largest of the 42 commercial banks headquartered in the larger Philadelphia metro area.[12] Geographically, this market only encompassed the city of Philadelphia and three contiguous counties in Pennsylvania.[13] Compared to the geographic markets the FTC and DOJ are considering in 2023, this is a very small area. Given increased globalization and the internet, geographic markets today can mean the entire country.

The Supreme Court evaluated the proposed merger to determine whether, under the Clayton Act, the proposed merger would "substantially . . . lessen competition in any line of commerce in any section of the country."[14] In answering the question, the Court held:

> The merger of appellees will result in a single bank's controlling at least 30% of the commercial banking business in the four-county Philadelphia metropolitan area. Without attempting to specify the smallest market share which would still be considered to threaten undue concentration, we are clear that 30% presents that threat.[15]

Therefore, the 2023 Merger Guidelines are returning the threshold for a presumption of illegality to that of a pre-globalized world. Even in the 1960s, some economists rebuked this presumption. It can be problematic when, for example, a merger "yields economies but at the same time increases market power."[16] Increasing economies may allow firms to cut costs and therefore pass onto consumers the savings.

Entrenching Versus Extending

The Merger Guideline specifies that either entrenching or extending a firm in a dominant position can violate the law. Seemingly, the two concepts are similar, but the Agencies have taken care to include them both and delineate between the terms. Table 1 presents an in-depth comparison of the markets they reference, examples from the Guidelines, and relevant case law, respectively.

Table 1

Entrenching	**Extending**
Original Market where the firm already has a dominant position	New Market that the firm is entering by exercising its dominance
"through exclusionary conduct, weakening competitive constraints, or otherwise harming the competitive process." 2023 Merger Guidelines p. 18	"merger might lead the merged firm to leverage its position by tying, bundling, conditioning, or otherwise linking sales of two products." 2023 Merger Guidelines p. 21
FTC v. Procter & Gamble Co., 386 U.S. 568, 577-78 (1967) (the "entrenchment of a large supplier or purchaser" can be an "essential" showing of a Section 7 violation).	*Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 480 n.29 (1992) ("The Court has held many times that power gained through some natural and legal advantage such as a patent, copyright, or business acumen can give rise to liability if 'a seller exploits his dominant position in one market to expand his empire into the next.'" (citing *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 611 (1953))).

The Use of HHI

The Herfindahl-Hirschman index (HHI) is a numerical mechanism for measuring market concentration. The Merger Guidelines explain that "[t]he HHI is defined as the sum of the squares of the market shares; it is small when there are many small firms and grows larger as the market becomes more concentrated, reaching 10,000 in a market with a single firm."[17] The example given by the Guideline drafters reads:

> For illustration, the HHI for a market of five equal firms is 2,000 (5 x 202 = 2,000) and for six equal firms is 1,667 (6 x 16.672 = 1667).[18]

In order to measure a market for competition, the Agencies use the HHI. The index allows the Agencies to ask another threshold question when determining that a merger is anticompetitive. In addition to asking whether the combined market share is above 30 percent, the Agencies can also ask how the HHI of the market as a whole was affected.[19]

In 2010, the Merger Guidelines dictated that if the market's post-merger HHI was above 2,500, it was presumptively anticompetitive. Now, the new Guidelines have lowered the threshold HHI to 1,800.[20] Therefore, markets that are less concentrated than before will be presumptively anticompetitive.

Similarly, in 2010, a market's increase in HHI had to reach 200 before it was considered presumptively anticompetitive. Now, a firm must only increase their post-merger HHI by 100 to be presumed anticompetitive, as shown in Table 2.[21]

Table 2

	2010 Guidelines	2023 Guidelines
Post-Merger HHI	2,500	1,800
Increase in HHI	200	100

Conclusion

Why do the DOJ and FTC want to contain firms that are already in a dominant position? In some cases, economists argue that these new thresholds will not serve consumer welfare because they could prevent firms from merging whose efficiencies would

outweigh their anticompetitive effect. If firms merging can make their processes a lot more efficient, then they can lower prices even below what they would have been in a perfectly competitive state.

However, others see antitrust and competition law as serving more purposes than merely keeping costs down. As Judge Learned Hand wrote in *United States v. Aluminum Co. of America*,[22] "[t]hroughout the history of these [antitrust] statutes it has been constantly assumed that one of their purposes was to perpetuate and preserve, for its own sake and in spite of possible cost, an organization of industry in small units which can effectively compete with each other."

As he suggests, effectively competitive small units of business can come at the cost of efficiency. This could mean economic efficiency: two firms merging can usually achieve similar goals more efficiently as one unit, saving money because they do not have to duplicate efforts. This is likely what Judge Hand was referring to as "possible costs" in 1945.

The twenty-first century, however, may have a distinctive set of efficiencies that Americans value more highly than small business units for their own sake. For instance, efficiency via mergers can help decrease emissions companies create. And yet, antitrust laws make it difficult for companies to agree to lower their carbon footprint without being accused of collusion.[23]

Alternatively, growing concentration in the social media and metaverse markets help perpetuate the network effect.[24] In a speech in 1999, then Principal Deputy Assistant Attorney General A. Douglas Melamed explained that "the defining characteristic of network industries is that they involve products that are more valuable to purchasers or consumers to the extent that they are widely used."[25] If the government took the classic trust-busting approach to Facebook, for instance, users would be able to connect with fewer people and therefore the individual small units would create far less value than the one network as a whole.

Antitrust laws have to balance the value of competition with the value of efficiencies. While the inherent value of firms competing has remained a sort of bedrock in the jurisprudence, the efficiencies are less stable. Efficiencies change with the real-world practicalities, and therefore make antitrust enforcement an ever-moving target. As such, it is unsurprising that the 2023 Merger Guidelines, including Guideline 6, are written with flexible language to give the Agencies plenty of prosecutorial discretion.

Notes

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1. 2023 Merger Guidelines, https://www.ftc.gov/system/files/ftc_gov/pdf/2023_merger_guidelines_final_12.18.2023.pdf.
2. 15 U.S.C. § 18 (emphasis added).
3. Brown Shoe Co. v. United States, 370 U.S. 294, 315 (1962).
4. S. Rep. No. 1775, 81st Cong., 2d Sess. 4-5.
5. Industrial and Corporate Change, Volume 30, Issue 5, Oct. 2021, Pages 1286-1306, https://doi.org/10.1093/icc/dtab050.
6. Id.
7. 2023 Merger Guidelines, p. 18.
8. Id.
9. Jacobellis v. Ohio, 378 U.S. 184, 197 (1964).
10. 2023 Merger Guidelines, p. 6.
11. U.S. v. Philadelphia Nat. Bank, 374 U.S. 321, 330 (1963).
12. Id.
13. Id.
14. Id. at 355.
15. Id. at 364.
16. Oliver Williamson, Economies as an Antitrust Defense: The Welfare Tradeoffs, 58 Am. Econ. Rev. 18, 21 (1968).
17. 2023 Merger Guidelines, p. 5.
18. Id. at n.13.
19. 2023 Merger Guidelines, p. 5.
20. Id.
21. 2023 Merger Guidelines, p. 6.
22. United States v. Aluminum Co. of America, 148 F.2d 416, 429 (C.A. 2d Cir.).
23. Juliet Eilperin & Steven Mufson, Justice Dept. Launches Antitrust Probe of Automakers Over Their Fuel Efficiency Deal with California, https://www.washingtonpost.com/climate-environment/justice-dept-launches-antitrust-probe-of-automakers-over-their-fuel-efficiency-deal-with-california/2019/09/06/29a22ee6-d0c7-11e9-b29b-a528dc82154a_story.html.
24. A. Douglas Melamed, Principal Deputy Assistant Attorney General, Network Industries and Antitrust, https://www.justice.gov/atr/speech/network-industries-and-antitrust.
25. Id.

Securities and Exchange Commission Expands "Dealer" Definitions to Capture Liquidity Providers

Eden L. Rohrer, Richard F. Kerr, Jessica D. Cohn, and Raymond F. Jensen*

In this article, the authors analyze final rules adopted by the Securities and Exchange Commission expanding the definitions of "dealer" and "government securities dealer" in Sections 3(a)(5) and 3(a)(44) of the Securities Exchange Act of 1934.

The U.S. Securities and Exchange Commission (SEC) has voted 3-2 to adopt two new rules that significantly expand the definitions of a "dealer" and "government securities dealer" in Sections 3(a)(5) and 3(a)(44) of the Securities Exchange Act of 1934 (the Exchange Act). Exchange Act Rules 3a5-4 and 3a44-2 (together, the Final Rules) require certain market participants, particularly those who take on significant liquidity-providing roles in the markets, referred to as "de facto market makers" by the SEC, to register with the SEC under Section 15 or 15C of the Exchange Act, respectively; become members of a self-regulatory organization (SRO); and comply with federal securities laws and regulatory obligations applicable to dealers.[1]

This article provides a detailed analysis of the Final Rules, their potential impact to market participants, and other regulatory developments for dealers. In short:

- The Final Rules significantly expand the definitions of a "dealer" and "government securities dealer" by defining the phrase "as a part of a regular business" in those definitions;
- The Final Rules establish two nonexclusive qualitative standards to determine whether market participants are providing significant liquidity;
- The Final Rules exclude persons that have or control total assets of less than $50 million and exclude investment

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 247–265.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

companies registered under the Investment Company Act of 1940, central banks, sovereign entities, and international financial institutions; and

- Over 40 market participants will have to register as dealers or government securities dealers, including most proprietary and principal trading firms, some private funds, investment advisers and family offices, and crypto automated market makers.

The Final Rules were published in the Federal Register on February 29, 2024, and took effect April 29, 2024, with a compliance date one year later of April 29, 2025.

Section 3(a)(5) of the Exchange Act defines the term "dealer" to mean "any person engaged in the business of buying and selling securities . . . for such person's own account through a broker or otherwise" but excludes "a person who buys or sells securities . . . for such person's own account, either individually or in a fiduciary capacity, but not as a part of a regular business."[2] Similarly, Section 3(a)(44) of the Exchange Act defines the phrase "government securities dealer." This language excluding activities that are "not as a part of a regular business" is often referred to as the "dealer/trader distinction." Many market participants, particularly proprietary or principal trading firms, have long relied on this distinction to conclude that they are not subject to SEC registration under previous guidance that focused on activities such as market making or underwriting and not on the impact to market liquidity.

The Final Rules significantly alter this landscape by defining what it means to be engaged in the business of buying and selling securities "as a part of a regular business" as well as the phrase "own account" to address SEC concerns that certain market participants, particularly proprietary or principal trading firms, act as de facto market makers without registration and with limited regulatory oversight. In this regard, the SEC indicated in the Adopting Release of the Final Rules (the Adopting Release) that the Final Rules "were designed to define the types of activities that would cause a person to be regarded as a de facto market maker and therefore subject to registration as a dealer under sections 15 and 15C of the Exchange Act."[3] However, the SEC explicitly stated in the Adopting Release that the Final Rules are not the exclusive means of establishing that a person is a dealer or government securities dealer. Amendments were initially proposed on March 28, 2022 (the Proposed Rules)

and were modified to address the many comment letters submitted by industry participants.[4]

Overview of the Final Rules

Qualitative Standards

The Final Rules establish two nonexclusive qualitative standards that constitute dealer activity "as a part of a regular business." Specifically, under the Final Rules, a person buying and selling securities, or government securities, for its own account would be deemed to engage in such activity "as a part of a regular business" if the person engages in a "regular pattern" of buying and selling securities that have the effect of providing liquidity to other market participants by:

- Regularly expressing trading interest that is at or near the best available prices on both sides of the market for the same security and that is communicated and represented in a way that makes it accessible to other market participants (the expressing trading interest standard); or
- Earning revenue primarily from capturing bid-ask spreads, by buying at the bid and selling at the offer, or from capturing any incentives offered by trading venues to liquidity-supplying trading interest (the primary revenue standard).

The expressing trading interest standard is intended to capture "the hallmark de facto market making activity in which dealers make a market in a security, standing ready to trade on both sides of the market on the same security on a regular ongoing basis." In other words, market participants that provide critical sources of liquidity. The SEC declined, however, to offer any guidance on what it means to express interest "at or near the best available prices[,]" explaining that it would be a question of facts and circumstances related to a given security.

The term "primarily" in the primary revenue standard means the person derives the majority of their revenue from either of the sources described and, therefore, would likely be in a regular business of buying and selling securities or government securities for its own account.

In the event a market participant satisfies either of the qualitative prongs of the Final Rules, they would be required to register as a "dealer" or "government securities dealer," as applicable, with the SEC and become a member of an SRO, unless they satisfy the terms of one of the exclusions included in the Final Rules.

Definition of "Own Account"

The Final Rules define "own account" to mean an account:

- Held in the name of that person, or
- Held for the benefit of that person.

As a result, the expressing trading interest standard would not capture market participants that place orders or request quotations on behalf of their clients as agents or trustees for the benefit of their underlying clients. While the SEC indicated that this (in combination with deleting the aggregation standard discussed below) was designed to limit the Final Rules' applicability to advisers and private funds, it remains to be seen whether those entities' other activities will require them to register.

Exclusions

The SEC recognized that certain market participants are already subject to extensive oversight or may be less likely to pose certain financial and operational risks to the market. In this regard, the Final Rules prescribe three exclusions for certain specific market participants. If a market participant satisfies any of the three categories below, they would not be deemed to engage in buying and selling securities, or government securities, "as a part of a regular business[,]" so long as the market participant is:

1. A person that has or controls total assets of less than $50 million (the Asset Threshold),
2. An investment company registered under the Investment Company Act of 1940, or
3. A central bank,[5] sovereign entity,[6] or international financial institution.[7]

Notably, an "international financial institution" refers to a specific type of entity that provides financing for national or regional development in which the U.S. government is a shareholder or contributing member. It does not include trading entities organized and operating outside of the United States.

Market participants satisfying one of the exclusions would not be required to register with the SEC as a dealer or government securities dealer under the Final Rules. As discussed below, in the event a market participant satisfies any previously adopted standard for "dealer" or "government securities dealer" registration, such participant would still be mandated to register as such.

Asset Threshold

Market participants who meet the qualitative standards but who do not meet the Asset Threshold are not deemed to be engaged in buying and selling securities "as part of a regular business." Therefore, a preliminary question in determining the applicability of the Final Rules is whether a person has or controls total assets of less than $50 million. The SEC stated that providing this exception was appropriate because even though a person who has or controls less than $50 million might still be engaged in the qualitative activities, the frequency and nature of such a person's securities trading is less likely to pose the types of financial risks to the market associated with the significant dealer activities that the Final Rules were designed to address.

The Asset Threshold is critical in determining whether a market participant is required to register and yet the Adopting Release devotes three paragraphs to the discussion. Neither the Final Rules nor the Adopting Release provide any clarity on how those assets should be calculated. In the Adopting Release and in footnote 215 of the Adopting Release, the SEC reasoned that the Asset Threshold is not an arbitrary standard and is parallel with Financial Industry Regulatory Authority (FINRA) Rule 4512(c)'s "established and well understood standard for distinguishing between 'retail' and 'institutional investors.'"[8] The Adopting Release also referred to a similar net worth test for institutional counterparties for security-based swap dealers, but the Asset Threshold is distinct from the SEC's "de minimis exemption" for security-based swap dealers, which is instead based on the aggregate gross notional value of the entity's

"dealing" swaps over the course of the preceding 12-month period (and varies based on asset class).[9]

However, the Final Rules do not describe whether the $50 million threshold is limited to securities assets traded in the account(s). The comparison to FINRA Rule 4512(c) is confusing because that definition is a net worth test that includes securities assets, as well as real estate, commodities, and other assets. The FINRA institutional investor definition is a test of financial sophistication that impacts suitability and communication obligations with respect to those customers. If the dealer threshold is in fact a net worth test, then it could lead to odd outcomes related to frequent trading with smaller amounts of funds with no conceivable impact on the markets. Another important consideration is whether the Asset Threshold includes securities traded on margin. Also unclear is how a firm whose assets hover around $50 million should prepare given that the Asset Threshold did not include an average over any period of time.

As discussed further below, the Asset Threshold exclusion is not an exclusion from the "dealer" definition for all purposes, but only for purposes of the Final Rules that focus on de facto market making. Outside of this context, the question of whether any person, including a person who has or controls less than $50 million in total assets, is acting as a dealer, as opposed to a trader, will remain a facts-and-circumstances determination. For example, an underwriter with assets below $50 million would still be required to register as a dealer.

Anti-Evasion

Under the Final Rules, no person shall evade the new registration requirements in the Final Rules by (1) engaging in activities indirectly that would satisfy either of the qualitative prongs, or (2) desegregating accounts. In the event a market participant indirectly satisfies either qualitative prong or purposely desegregates its accounts to avoid the registration requirements of the Final Rules, such participant will be subject to potential SEC enforcement.

No Presumption

The last provision of the Final Rules, which provides for some clarity on the expanded definition of "dealer" or "government

securities dealer," is the "no presumption" provision. Market participants who do not satisfy the qualitative factors or who may meet an exclusion may still be required to register. Simply put, the Final Rules state that there is no presumption that a market participant is not a "dealer" nor a "government securities dealer" if they do not satisfy the qualitative standards outlined in the Final Rules. Existing precedent and SEC interpretations and standards continue to apply.

Key Modifications from the Proposed Rules

The Final Rules were modified to narrow the scope of the Proposed Rules in response to commenters' concerns, and those modifications offer some guidance.

Eliminated First Proposed Qualitative Standard: Pattern of Trading

The first proposed qualitative standard was intended to capture a person's pattern of trading and would have deemed market participants "[r]outinely making roughly comparable purchases and sales of the same or substantially similar securities in a day" as engaging in buying and selling securities "as a part of a regular business." Commenters raised a number of concerns with this standard, including that it was over-inclusive and would capture persons investing in the ordinary course. The SEC eliminated this proposed qualitative standard from the Final Rules.

Revised Second Proposed Qualitative Standard: Expressing Trading Interest

The second proposed qualitative standard sought to identify a person who "routinely" expresses trading interests. "Routinely" was defined to mean that "a person must express trading interests more frequently than occasionally, but not necessarily continuously, both intraday and across time."

In the Final Rules, the SEC replaced the term "routinely" with "regularly." The SEC indicated that whether a person's activity is regular will depend on the facts and circumstances, including the liquidity and depth of the relevant market for the security. Additionally, the term "regularly" aligns with the language of the

existing definition and the phrase "part of a regular business." The expressing trading interest standard was also modified from the Proposed Rules to add the phrase "for the same security" to the standard. This was intended to clarify that the standard applies when a person is on both sides of the market for the same security and thus has the effect of providing liquidity.

Eliminated Quantitative Standard

The SEC proposed a quantitative standard that would have established a bright-line test under which persons engaging in certain specific levels of activity in the U.S. Department of the Treasury market would be defined to be buying and selling government securities "as a part of a regular business," regardless of whether they meet any of the qualitative standards. That standard, which applied only to government securities dealers, would have required registration for market participants who "[i]n each of four out of the last six calendar months, engaged in buying and selling more than $25 billion of trading volume in government securities as defined in Section 3(a)(42)(A) of the Exchange Act." The majority of commenters raised several issues and concerns with a standard based on trading volume, including that it would capture nondealing trading activity, such as hedging, risk-reducing activity, and arbitrage trading. The SEC eliminated this proposed quantitative standard from the Final Rules.

Narrowed Definition of "Own Account" but Added "Anti-Evasion"

In response to concerns raised by commenters regarding the application of the new dealer regime to registered investment advisers and private funds as proposed, the definition of "own account" was modified in the Final Rules by removing the aggregation standard but adding a two-prong anti-evasion provision in an effort to prohibit persons from willfully evading the registration requirements.

The SEC had proposed to define "own account" to include accounts "held in the name of a person over whom that person exercises control or with whom that person is under common control." Commenters raised concerns that the proposed definition

of "own account" would capture separately managed accounts and investment advisers trading on behalf of their clients, including those exercising discretion over unrelated client accounts. Furthermore, the proposed aggregation standard would force market participants to constantly monitor their trading activities across all subsidiaries and client accounts. The SEC acknowledged these concerns, and many others, and revised the definition of "own account" in the Final Rules to remove the aggregation concept. As a result, the SEC added an anti-evasion provision in order to "deter the establishment of multiple legal entities or accounts to evade appropriate regulation."

Added Official Sector Exclusions

In addition to excluding registered investment companies in the Proposed Rules, the Final Rules include an additional express exclusion for central banks, sovereign entities, and international financial institutions.

Who Is Affected by the Final Rules?

According to the SEC, it has identified up to 43 entities that may be affected by the Final Rules and required to register, based on data from the Trade Reporting and Compliance Engine (TRACE) and Form PF. However, the actual impact will likely be far greater, as the SEC admitted it did not have data from the all of the different potential parties, thus making the exact number difficult to estimate. Below, we discuss a number of the types of market participants expected to be required to register as "dealers" or "government securities dealers."

Proprietary or Principal Trading Firms

The SEC observed the growth of proprietary trading firms in recent years, including that such proprietary trading firms had by far the highest trading volume among nonregistered firms and that such firms' trading volume was roughly comparable to those of the most active registered dealer firms, including particularly in the interdealer segment of the U.S. Treasury market.

Private Funds, Registered Investment Advisers, and Family Offices

The SEC did not adopt an express exclusion for private funds or registered investment advisers, noting that a private fund or investment adviser may be engaged in dealing activity for its own account. In the proposing release, the SEC indicated that private funds "are not subject to the extensive regulatory framework of the Investment Company Act." Commenters described the difficulties with applying the dealer framework to private fund advisers and private funds, noting that liquidity could be negatively affected if private funds were to modify or cease their trading activity. However, the SEC indicated that it expects that only a limited number of private funds (fewer than 16) will be affected by the Final Rules due to the revised definition of "own account." Although single-family offices generally are excluded from registration as investment advisers, they could be subject to a much more stringent dealer regulatory regime if their trading meets the qualitative standards.

Crypto Assets and Automated Market Makers

The Final Rules would apply to any crypto asset that is a "security," as defined by Section 3(a)(10) of the Exchange Act, or a "government security," as defined by Section 3(a)(42) of the Exchange Act. In response to requests from commenters for the Final Rules to not apply to crypto asset securities that are traded through centralized trading platforms or in the so-called decentralized finance (DeFi) market, the SEC instead clarified in the Adopting Release that "there is nothing about the technology used . . . that would preclude crypto asset securities activities from falling within the scope of dealer activity." Accordingly, regardless of the technology used to engage in crypto asset securities trading and transactions, if the market participant executing the transactions meets the definition under the Final Rules, or other precedent and interpretations, that market participant is subject to registration as a dealer.

While the Adopting Release did not shed much light on the topic, the questions posed by SEC Commissioner Hester M. Peirce and answers by SEC Trading and Markets Director Haoxiang Zhu did. Peirce inquired how the Final Rules would apply to DeFi automated market makers, explaining that they are essentially software protocols that establish smart contracts enabling users to provide pools of

liquidity. Zhu stated that, as with respect to other market participants, whether a DeFi protocol or its governing body is required to register as a dealer would be determined on a facts-and-circumstances basis, and he also noted that the market participants posting liquidity in pools could also be captured by the Final Rules if they meet the conditions. Zhu also stated that the developers that wrote the code would not be required to register unless they also used the software to engage in activity meeting the definition of "dealer" or "government securities dealer." Peirce also questioned if, given the difficulties that other prospective crypto registrants have encountered, the automated market makers would even be able to register.

Pension Funds

While the Final Rules do not define the phrase "pension fund" or exclude pension funds, the Adopting Release indicates that the Final Rules are not expected to capture a governmental plan, including public pensions, or state administrators managing state funds or city administrators managing the city pension funds. In most cases, those entities would not likely be expected to meet the expressing trading interest standard or the primary revenue standard.

Impact on Affected Parties: Imposing Dealer Requirements

SEC Registration and SRO Membership: Regulatory Oversight and Examination

Affected parties must register as dealers or government securities dealers with the SEC under Section 15 or Section 15C, respectively, and become a member of an SRO (FINRA being the only current option). FINRA member firms operate under a FINRA membership agreement and must conduct their business consistent with the membership agreement. Dealers and government securities dealers are subject to SEC and FINRA rules. The Exchange Act subjects such parties to inspections and examinations by the SEC staff and FINRA.

Exchange Act Rule 15b2-2 generally requires the examining SRO to inspect newly registered dealers for compliance with applicable financial responsibility rules (discussed below) within six months

of registration and for compliance with all other regulatory requirements within 12 months of registration. Thereafter, examinations are periodic. SEC-registered dealers must also become members of the Securities Investor Protection Corporation (SIPC). Government securities dealers are not required to be members of SIPC.

Net Capital Requirements

Dealers and government securities dealers are subject to certain financial responsibility and risk management rules under SEC and FINRA rules. Specifically, Rule 15c3-1 under the Exchange Act (Net Capital Rule) requires registered dealers to maintain minimum amounts of net liquid assets at all times, calculated on a moment-to-moment basis. Dealers are required to hold at all times more than one dollar of highly liquid assets for each dollar of unsubordinated liabilities (e.g., money owed to customers, counterparties, and creditors). Government securities dealers are required to comply with capital requirements in 17 C.F.R. § 402.2 rather than with the Net Capital Rule. The requirements generally serve the same risk-limiting purpose as the Net Capital Rule. It is unclear how these net capital requirements will implicate the non-dealer-related activities of a private fund.

Recordkeeping and Reporting Requirements

Dealers and government securities dealers registered with SEC must comply with federal securities laws and regulatory obligations and applicable SRO membership and U.S. Treasury rules and regulations, including transaction and other reporting requirements, operational integrity rules, and books and records requirements. For example, dealers have reporting obligations to Consolidated Audit Trail (CAT), if they transact in CAT-reportable securities, and TRACE, if they transact in TRACE-eligible securities. There are also various recordkeeping requirements under the Exchange Act, SRO rules, and, in some instances, state regulatory requirements.

FINRA Rules

FINRA imposes other rules on its members, including registration and qualification of personnel and supervisory and conduct

rules. Many of these rules were designed to provide protection to customers. Previously, the proprietary trading firms were seen as customers themselves, benefitting from those rules when they traded through brokerage accounts.

For example, a dealer registered with the SEC and a member of FINRA is subject to Rule 5130, which prohibits member firms from selling new issues (e.g., initial public offerings (IPOs)) to restricted persons. Generally, a dealer, along with the owners that would be listed on Form BD (e.g., 5 percent direct owners, 25 percent indirect owners) would be considered "restricted persons" and subject to the new issue restrictions. FINRA member firms are also prohibited from purchasing new issue securities. Accordingly, hedge funds that buy IPO shares and also engage in trading activities now requiring dealer registration would no longer be permitted to invest in IPOs, forcing them to choose between one or the other activity.

FINRA members also have a duty of best execution under FINRA Rule 5310, which may conflict with a private fund adviser's fiduciary duty to achieve best execution for its client, the fund.

Compliance Costs

In addition to the compliance implementation costs, affected parties will incur ongoing annual costs to maintain FINRA membership, including, among others, the gross income assessment, trading activity fee, and registration fees. Furthermore, FINRA member firms are required to file an application with, and receive approval from, FINRA if the firm anticipates a material change in its business operations, which would create additional expenses and regulatory requirements. SEC-registered dealers are also subject to state licensing and registration requirements, including paying annual fees for the firms and personnel.

Dissents

The Final Rules were accompanied by sharp dissents from SEC Commissioner Peirce and Commissioner Mark T. Uyeda. Commissioner Peirce expressed concerns that the Final Rules "will distort market behavior and degrade market quality" by turning traders, previously considered customers, into dealers and "obliterating" the dealer/trader distinction. Commissioner Peirce cited

to long-standing SEC guidance describing the relevant factors to determine dealer status, which include intentional activities, such as having regular clientele, holding themselves out as buying or selling securities at a regular place of business, having a regular turnover of inventory, and generally providing liquidity services in transactions with other professionals, rather than focusing on the singular and ultimate effect of providing liquidity.

Commissioner Peirce further described potentially "absurd" results for market participants who currently do not have the characteristics of dealers but who as a result of "executing any of a number of common trading, investing, and risk management strategies could turn a market participant into a dealer if doing so happens to provide significant liquidity to the market" and subject them to the dealer regulatory regime, stripping them of the protections they now have as customers. She predicted that the costs of complying with the regulatory regime penalizes important liquidity providers and will cause many to cease activities, which could cause harm to the markets in times of volatility. She rejected contentions that the Final Rules will provide more data to regulators, pointing to existing market surveillance tools, such as CAT, TRACE, and Form PF. Further, Peirce raised serious implementation challenges, including ambiguity, which may lead to registration of firms not intended to be included, a too-short implementation period, and unpredictable interactions with other rules.

Commissioner Peirce also asked a number of questions to the SEC staff, requesting more information on why private funds and pension funds were not excluded from the Final Rules given their similarities to registered investment companies and the potential impact of the Final Rules on automated market makers, to name a few. Commissioner Uyeda shared many of Commissioner Peirce's sentiments, stating that, under the Final Rules, the SEC's amendment to the definition of "dealer" extends beyond its statutory authority and the "lack of any limiting principle" creates the potential for "arbitrary and capricious government action." He cautioned that the action may have the effect of reducing liquidity in the U.S. Treasury markets, making them more volatile and increasing debt costs to taxpayers. He commented that the Final Rules target proprietary trading firms and private funds and "following Form PF, the adoption of private fund adviser rules, securities lending disclosure, and short position and short activity reporting, this action feels like another salvo in the Commission's war on private

funds." He argued that it "makes no sense to use liquidity provision as the basis for legally distinguishing between dealers and traders."

Commissioner Uyeda described the important role that proprietary trading firms and private funds played in providing liquidity, competition, and tighter spreads in the public debt markets in times of market stress at the same time that banks faced limitations resulting from the supplemental leverage ratio. He argued that there are already tools available to constrain and monitor proprietary trading firm risk. When trading through other broker-dealers as customers, proprietary trading firms are subject to margin limitations of Federal Reserve Regulations T, U, and X, as well as FINRA Rule 4210. If they trade directly through broker-dealer-provided direct market access, they are subject to Rule 15c3-3, the "Market Access Rule."

Commissioner Uyeda stated that the Net Capital Rule is designed to protect customers during a wind-down but is not appropriate for firms that do not have customers. Further, he made interesting observations rejecting assertions in the Adopting Release that a dealer can have no customers, arguing that historically the definition recognized that dealers did have customers. He referred to earlier definitions of "broker" and "dealer," referring to how they effect customer transactions. Those definitions described that while brokers, acting as agents, trade for the account of the customer, a dealer takes the opposite side of a customer's trades in the dealer's own account. Uyeda criticized the SEC's "regulation by enforcement" in redefining brokers and dealers as they relate to customer orders and cited the recent enforcement matters referred to below. Ultimately, both Commissioner Peirce and Commissioner Uyeda voted against adopting the Final Rules and expressed their continued concerns over the potential possibility of negative effects on market participants and the markets. The Final Rules were supported by Chair Gary Gensler, Commissioner Caroline A. Crenshaw, and Commissioner Jaime Lizárraga.

Compliance Date

The compliance date for the Final Rules is April 29, 2025. However, the compliance date applies only to market participants who are already engaged in activities covered by the Final Rules prior to the compliance date. FINRA provides for a 180-day review

period for a new member application, so in order to obtain compliance with the Final Rules, impacted firms should complete their analysis of the Final Rules in time to submit an application and obtain FINRA approval prior to the compliance date. FINRA has expressed a commitment to expedite the application process for market participants captured by the Final Rules.

Other Regulatory Developments for Dealers

Recently, the SEC has taken two other significant steps in connection with dealer status to bring proprietary trading firms under its jurisdiction and the jurisdiction of FINRA.

Amendments to Exchange Act Rule 15b9-1

On August 23, 2023, the SEC adopted amendments to Exchange Act Rule 15b9-1 that narrowed the exemption from FINRA membership for certain SEC-registered dealers (the Rule 15b9-1 Amendments). Previously, certain proprietary trading firms could register with the SEC and become members of exchanges, one of which would act as its designated examining authority. Those firms were not required to become a member of FINRA if the firm (1) was a member of a national securities exchange, (2) carried no customer accounts, and (3) had annual gross income derived from purchases and sales of securities otherwise than on a national securities exchange of which it is a member in an amount no greater than $1,000 (the de minimis allowance). Furthermore, the de minimis allowance did not apply to income derived from transactions for a registered dealer's own account with or through another registered broker or dealer (known as the proprietary trading exclusion). The Rule 15b9-1 Amendments essentially did away with the de minimis allowance, requiring proprietary trading firms who trade through other brokers or dealers and on alternative trading systems to become FINRA members.

Under the Rule 15b9-1 Amendments, a dealer is now required to become a FINRA member if the dealer effects transactions other than on an exchange of which it is a member, unless: (1) such transactions result solely from orders that are routed by a national securities exchange of which the firm is a member to comply with Rule 611 of Regulation NMS or the Options Order Protection and

Locked/Crossed Market Plan, or (2) are solely for the purpose of executing the stock leg of a stock-option order. The Rule 15b9-1 Amendments became effective on November 6, 2023, and the SEC has announced a compliance date of September 6, 2024.

FINRA has adopted a short-form membership application process for those SEC-registered dealers who are now required to become members. Firms are eligible for the short-form membership application process if they have been a member of a national securities exchange with which FINRA has had a regulatory services agreement for the 12-month period prior to August 23, 2023, and are not seeking an expansion of their activities. Absent a membership agreement, it is not always clear what activities and products are covered. Firms applying for membership under the streamlined process must submit their short-form application by May 9, 2024 (although FINRA has requested earlier submission by March 8, 2024). FINRA has published Regulatory Notice 23-19 to explain these changes.[10]

While the short-form application is straightforward enough, impacted firms have a heavy lift to identify and come into compliance with FINRA rules. Previously, those firms were subject to SEC rules (such as net capital, recordkeeping, and filing Form BDs, U4s, and U5s) and the rules of the exchanges in which they were members.

However, now those firms also must comply with FINRA rules where there is some, but not complete, overlap. In fact, there are many FINRA-specific rules, including personnel registration, transaction reporting, and FINRA fees and assessments, to which these impacted firms were not previously subject. The compliance gap analysis is labor-intensive, and firms will be pressed to meet the compliance deadline, which formally is September 6 but actually is triggered when the firm becomes a FINRA member.

SEC Enforcement Against Unregistered Dealers

In recent years, the SEC has aggressively pursued enforcement actions against microcap convertible lenders under the theory that their investment activity renders them "dealers" within the meaning of Section 15(b).

Historically, those firms had relied on the traders exemption.

The first case, and the case on which the SEC relies in subsequent cases in the dealer enforcement strategy, was *SEC v. Big Apple*

Consulting USA, Inc.[11] On April 9, 2015, the U.S. Court of Appeals for the Eleventh Circuit affirmed the 2013 lower court decision of the U.S. District Court for the Middle District of Florida, which determined that the defendants violated Section 15(a) by acting as an unregistered dealer.

The appellate court relied on an analysis centered on whether the defendants operated a "business" for "profit or gain." The evidence that Big Apple Consulting USA Inc. and MJMM Consulting LLC's entire business model depended on the purchasing of stocks at deep discounts and then selling those stocks for profit, and the high priority the defendants placed on generating a profit from these trades, convinced the court that Big Apple and MJMM had acted as dealers.

The appellate court's analysis in *Big Apple Consulting USA* has influenced and framed multiple litigated, settled, and pending cases, and we continue to see more enforcement activity.[12] Those cases bear close scrutiny by investors who have previously relied on the traders exemption.

Conclusion

In conclusion, while the impact of the Final Rules is uncertain on the effect on liquidity in the markets, we can expect significant changes to the markets. Given the short implementation period, market participants should begin their assessment promptly.

Notes

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1. Since this article was written, industry groups have sued the SEC in two cases. The first, National Association of Private Fund Managers, Alternative Investment Management Association, Limited and Managed Funds Association v. Securities and Exchange Commission, No. 4:24-cv-00250 (N.D. Texas Mar. 18, 2024), alleged, in part, that the SEC failed to adequately address the economic consequences of the Final Rules which place unnecessary regulatory burdens on private funds and would irrationally decrease liquidity. The second, Crypto Freedom Alliance of Texas and Blockchain Association v. Securities and Exchange Commission, No. 4:24-cv-00361 (N.D. Texas Apr.

23, 2024), alleged that the Final Rules exceeded the SEC's statutory authority in defining dealers and ignored issues raised by stakeholders on how the Final Rules would apply to digital assets and decentralized finance. As of yet, the lawsuits have no impact on the effectiveness of the Final Rules, although the court could issue a stay.

2. Compare to the definition of "broker" in Section 3(a)(4) as "any person engaged in the business of effecting transactions in securities for the account of others."

3. https://www.federalregister.gov/documents/2024/02/29/2024-02837/further-definition-of-as-a-part-of-a-regular-business-in-the-definition-of-dealer-and-government.

4. https://www.sec.gov/news/press-release/2022-54.

5. For the purposes of the Final Rules, "central bank" means a reserve bank or monetary authority of a central government (including the Board of Governors of the Federal Reserve System or any of the Federal Reserve Banks) and the Bank for International Settlements.

6. For the purposes of the Final Rules, "sovereign entity" means a central government (including the U.S. government), or an agency, department, or ministry of a central government.

7. The Final Rules define "International Financial Institution" as one of a number of named international development banks and funds, such as "the African Development Bank; African Development Fund … and any other entity that provides financing for national or regional development in which the U.S. Government is a shareholder or contributing member."

8. FINRA Rule 4512(c)(3) defines an "institutional account" as a "person (whether a natural person, corporation, partnership, trust or otherwise) with total assets of at least $50 million." The rule also includes banks, savings and loans, insurance companies, registered investment companies, and registered investment advisers.

9. Compare 17 C.F.R. § 240.15Fh-3(f)(4), with 17 C.F.R. § 240.3a71-2.

10. https://www.finra.org/rules-guidance/notices/23-19.

11. 783 F.3d 786 (2015); See also SEC v. Big Apple Consulting USA, Inc., Fed. Sec. L. Rep. P 97, 368 (2013).

12. See SEC v. Almagarby (recently affirmed in part and reversed in part by the Eleventh Circuit); SEC v. Crown Bridge Partners; SEC v. Fierro; SEC v. GPL Ventures LLC; SEC v. Keener d/b/a JMJ Financial; SEC v. LG Capital Funding LLC; SEC v. Morningview Financial, LLC; SEC v. River North Equity LLC.; and, most recently, SEC v. Aryeh Goldstein.

Environmental Protection Agency's 2024-2027 Enforcement Priorities Officially Take Effect

Wayne J. D'Angelo and Zachary J. Lee*

In this article, the authors review the U.S. Environmental Protection Agency's 2024-2027 National Enforcement and Compliance Initiatives.

Members of the regulated community this year should remain particularly vigilant for heightened enforcement and compliance activity from the U.S. Environmental Protection Agency (EPA or the Agency) and delegated state enforcement authorities in areas identified in the EPA's 2024-2027 National Enforcement and Compliance Initiatives (NECIs or Initiatives).[1] EPA updates the NECIs every four years, and uses them as guiding posts for determining how to prioritize issue areas and expend resources accordingly.

As 2023 ended, EPA Administrator Michael Regan tweeted that "[o]n day one as Administrator, I committed EPA to aggressively deliver on [President Biden's] climate and environmental agenda.... EPA has been hard at work reducing harmful pollution across the country, and we have no intention of slowing down."[2] The EPA's Assistant Administrator for the Office of Enforcement and Compliance Assurance (OECA) corroborates this posture in a memorandum announcing the 2024-2027 NECIs. Indeed, the memo outlines what OECA perceives to be "the most serious and widespread environmental problems facing the United States," and discusses the enforcement and compliance areas the EPA will prioritize in response to these issue areas. The memo encourages state-delegated enforcement and compliance agencies to do the same.

Although OECA's core enforcement program does not discriminate in the types of cases it chooses to pursue, OECA more aggressively attempts to discover, pursue, and prosecute cases that fall

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 267–273.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

within one of the NECI categories. OECA relied on three criteria in formulating this set of Initiatives:

1. The need to address "serious and widespread" environmental issues and "significant" violations that effect human health and the environment, especially is "overburdened and vulnerable communities";
2. Areas where "federal enforcement authorities, resources, and/or expertise" are needed to "promote a level playing field"; and
3. Alignment with the EPA's Strategic Plan.[3] Numerous factors go into the EPA's determination that a community is "overburdened and vulnerable," though EPA's EJScreen[4] is the main tool the EPA uses to map and screen these factors onto any given geographical area.

Members of the regulated community should review their location on EJScreen and determine the demographic considerations the EPA may take into account when conducting inspections and investigations at their facilities. Indeed, beyond being implicated in almost every NECI, environmental justice (EJ) has been a top priority for EPA and the Biden administration generally.[5]

This article briefly discusses the three new 2024-2027 NECIs. It also discusses the three NECIs carried over into this cycle from the previous, as well as the three discontinued NECIs.

New NECIs

Mitigating Climate Change

Whereas the Strategic Plan identifies climate change as the EPA's top priority, it is wholly unsurprising to see climate change mitigation listed as a NECI. To effectuate this Initiative, the EPA intends to leverage enforcement authority in three specific vocabularies:

1. Methane emissions from oil and gas facilities;
2. Methane emissions from landfills; and
3. The use, importation, and production of hydrofluorocarbons (HFCs).

Methane and HFCs are both climate change precursors. In terms of the EPA's tools available to address methane, the memo

specifically notes that the EPA will be "focusing on long-standing air pollution requirements, such as New Source Performance Standards at oil and gas facilities and landfills."

HFCs are common to the heating, ventilation, air conditioning, and refrigeration (HVACR) industry. They are currently subject to a strict phase-out schedule under the American Innovation and Manufacturing Act. OECA thus will likely focus criminal and civil enforcement of the AIM Act by focusing on the HVACR industry.

Addressing Exposure to Per- and Polyfluoroalkyl Substances

Consistent with the Biden administration's plans to execute on their PFAS (per- and polyfluoroalkyls) Strategic Roadmap,[6] OECA has decided to focus on PFAS contamination throughout the country, though the EPA admits that the regulatory framework for enforcement "continues to develop." The EPA's focus here will be on achieving site characterization, controlling ongoing releases, permit compliance, and endangerment issues when they arise.

The EPA intends to do this through examining existing authorities like the Resource Conservation and Recovery Act (RCRA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Safe Drinking Water Act (SDWA), and the Clean Water Act.

PFAS are ubiquitous in the environment and in daily life. They are commonplace in numerous consumer products, including nonstick cookware; personal care products; stain-resistant carpets and upholstery; and water-resistant fabrics used in rain jackets, umbrellas, and tents. Industry should also be aware that PFAS are a central ingredient in many aqueous film forming foams, a fire suppressant used to extinguish flammable liquid fires like fuel fires.

Despite the omnipresent nature of these chemicals, the EPA notes that it will focus on "implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment, such as major manufacturers and users of manufactured PFAS, federal facilities that are significant sources of PFAS, and other industrial parties." And now that two specific types of PFAS—PFOA (perfluorooctanoic acid) and PFOS (perfluorooctane sulfonic acid)—are listed as hazardous substances under CERCLA, OECA notes that it "does not intend to pursue entities where equitable factors do not support CERCLA responsibility, such as farmers, water utilities, airports, or

local fire departments, much as OECA exercises CERCLA enforcement discretion in other areas."

Protecting Communities from Coal Ash Contamination

The EPA posits that noncompliance with the coal combustion residual (CCR) requirements under RCRA is more widespread than initially anticipated, and thus the EPA seeks to intensify enforcement activity here, specifically in EJ communities.

Retained and Modified NECIs

Reducing Air Toxics in Overburdened Communities (Modified from Previous Cycle)

This initiative from the 2020-2023 cycle focused on addressing health and environmental effects from ozone National Ambient Air Quality Standards exceedances, usually stemming from volatile organic compounds and hazardous air pollutant (HAP) emissions. Under the modified NECI, each EPA region will look at their most overburdened communities (based on fenceline monitoring) and pick which HAPs it seeks to prioritize.

Although the EPA admits regions will decide which HAPs they wish to focus on, the EPA does encourage investigation of several specific HAPs, including benzene, ethylene oxide, and formaldehyde.

Chemical Accident Risk Reduction (Continued from Previous Cycle)

Operating under the assumption that many facilities insufficiently manage risk surrounding chemical accidents under Section 112(r) of the Clean Air Act (CAA), the EPA has decided it will continue its focus under this NECI by inspecting and addressing noncompliance at facilities using anhydrous ammonia (NH_3) and hydrogen fluoride (HF).

Originally promulgated in the 2017-2020 cycle, then again in the 2020-2023 cycle, this NECI's original goals focused aggressively on widespread noncompliance regarding storage and handling for a litany of chemicals. Now, it appears OECA will narrow its

enforcement and compliance focus to NH_3, predominately used as an agricultural fertilizer and a refrigerant, and HF, commonly used in petrochemical manufacturing.

Note that on March 11, 2024, the EPA finalized changes[7] to its Risk Management Program under CAA Section 112(r) to include new chemical accident prevention program requirements, emergency preparedness requirements, transparency requirements, and other changes to regulatory definitions expanding the Program's authority.

Increasing Compliance with Drinking Water Standards (Continued from Previous Cycle)

This priority officially became a NECI in the 2020 cycle, and was initiated to ensure the compliance of nearly 50,000 regulated drinking water systems with the SDWA. The EPA is continuing to pursue these SDWA compliance goals, and notes it will "ramp up field presence, pursue strategic enforcement to reduce noncompliance, and offer more compliance assistance to prevent and address public health risks." Overburdened communities will receive particularized attention from OECA here.

NECIs "Returned to Core Enforcement"

Besides the six NECIs described above, the following three 2020-2023 NECIs have been relegated down to the EPA's "core enforcement" program. Although no longer national priorities, the EPA, its regional offices, and state-delegated authorities still find these Initiatives to be important and will continue to conduct inspections and pursue enforcement actions accordingly, especially in EJ communities that may be particularly vulnerable to the relevant issue.

Reducing Toxic Air Emissions from Hazardous Waste Facilities

Originally promulgated in 2017, this NECI focused on RCRA organic air emissions standards in overburdened communities. The EPA relegated this NECI down to the core enforcement program, citing success in over 100 enforcement cases, the development and

deployment of training programs, and numerous ongoing monitoring and compliance actions.

Stopping Aftermarket Defeat Devices for Vehicles and Engines

OECA touts successes here like the development of a national enforcement program, resolution in over 130 cases, and achieving "general deterrence through robust enforcement." The EPA does note that they will continue to "investigate and pursue enforcement against upstream manufacturers and distributors of defeat devices," as well as continue to provide training and coordinate outreach initiatives with states and industry groups.

Reducing Significant NPDES Noncompliance

Finally, the EPA notes that it be demoting this NECI given there has been a 50 percent reduction in "significant noncompliance" in this area. The EPA claims that prior to this NECIs listing, National Pollutant Discharge Elimination System (NPDES) noncompliance was over 20 percent, meaning one out of every five permittees had "significant violations" of their permit every quarter, every year.

With a dramatic reduction of such violations accomplished, the EPA "can now clearly see which facilities are in violation of their permit and can prioritize these facilities for enforcement or technical assistance."

Notes

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1. https://www.epa.gov/system/files/documents/2023-08/fy2024-27necis.pdf.

2. https://twitter.com/EPAMichaelRegan/status/1732474994599280839.

3. https://www.epa.gov/planandbudget/strategicplan.

4. https://www.epa.gov/ejscreen.

5. https://www.whitehouse.gov/environmentaljustice/.

6. https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

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Navigating the Regulatory Landscape in the Digital Age: A Guide to the Food and Drug Administration's New Guidance on Remote Regulatory Assessments

Greer O. Lautrup, Daniel J. Roberts, and Stephanie Slater*

In this article, the authors review new draft guidance published recently by the Food and Drug Administration on remote regulatory assessments.

The U.S. Food and Drug Administration (FDA) has published a new draft guidance on remote regulatory assessments (RRAs). This guidance, "Conducting Remote Regulatory Assessments—Question and Answers,"[1] represents the FDA's current approach to the use of RRAs, including when and how the FDA will conduct RRAs, how companies should respond, how the FDA will use RRAs, and the potential consequences for refusing a remote inspection.

Background

During the COVID-19 epidemic, the FDA introduced RRAs to provide oversight when travel restrictions prevented the FDA from conducting on-site inspections. The FDA released draft guidance, "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency," in April 2021, which was updated in October 2023. In July 2022, the FDA released "Conducting Remote Regulatory Assessments—Questions and Answers Draft Guidance for Industry." This newest draft guidance with the same title is an update to the July 2022 guidance discusses how the FDA will use RRAs on a going-forward basis and also provides answers to frequently asked questions about the RRA process.

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 275–278.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

Remote Regulatory Assessments

An RRA is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. The FDA clarifies in the draft guidance that an RRA is not considered an "inspection," which involves the physical on-site presence of FDA officials. The FDA emphasizes that RRAs complement the FDA's existing authority to conduct inspections under Section 704(a)(1) of the Federal Food Drug and Cosmetic Act (FDCA) but do not limit FDA authority to conduct in-person inspections.

Types of RRAs

RRAs can be either mandatory or voluntary.

Mandatory RRAs are conducted for establishments subject to Section 704(a)(4) of the FDCA (i.e., drug establishments) and importers as defined in 21 CFR 1.500 that are subject to the Foreign Supplier Verification Program (FSVP) under Section 805(d) of the FDCA. When initiating a mandatory RRA, the FDA informs the establishment of the section under which the mandatory RRA is requested.

- For drug establishments, the FDA issues a Form 4003 FDA Inspection Records Request, or uses a similar method, to request records or other information. The guidance notes that the FDA would provide a sufficient description of the records/information requested and rationale for requesting these records in advance of or in lieu of an inspection.
- Importers subject to the FSVP would receive notification from the FDA with Form FDA 482d Request for FSVP Records for imported foods.

Note that failing to respond, withdrawing participation, and/or refusing to provide records upon a lawful request may be viewed as a violation and considered a refusal under Section 301(e) or (f), or 807, of the FDCA. The guidance states that the FDA intends to take appropriate action against persons and products that are in violation of the FDCA. The FDA can use mandatory RRAs alone to take enforcement action. Actions[2] can include and are not limited

to warning letters, import alerts, and refusal of product offered for import into the United States.

Voluntary RRAs are not mandated by statute or regulation. Any type of establishment regulated by the FDA can be contacted for a request to participate in a voluntary RRA. The FDA would notify the establishment by phone, email, or letter and include the purpose and planned scope of the RRA and the right to refuse to participate in the voluntary RRA. Declining a voluntary RRA will not result in enforcement action; however, it may take the FDA longer to assess an establishment when factors prevent the FDA from conducting a timely on-site inspection.

How the FDA Will Use RRAs

Regulatory purposes of an RRA can include the evaluation of establishments for pending market submissions, determining compliance with FDCA or Public Health Service Act requirements, assessing the need for inspection follow-up to a reported concern or defect, supporting enforcement actions (e.g., regulatory meeting, warning letter, import action, recalls), and determining the priority of establishments for inspections (particularly surveillance).

The FDA notes in the draft guidance that it does not plan to conduct RRAs and on-site inspections simultaneously. However, an RRA could precede, prompt, or be a follow-up to an inspection. When an RRA precedes an inspection, The FDA will generally conclude the RRA prior to initiating the inspection. The FDA would confirm RRA observations during the subsequent inspection and potentially include them on the Form FDA 483. The FDA may also use an RRA to assist in verifying corrective actions from an inspection.

RRAs can include the following:

- Review of records and other information (such as electronic systems);
- Virtual meetings with the site to review electronic systems, operations, and/or standard operating procedures; and/or
- Use of livestream and/or prerecorded video to examine facilities, operations, data, and other information.

Conclusion of an RRA

As with an on-site inspection, at the conclusion of an RRA, the FDA may conduct a closeout meeting with site management. At that meeting, the FDA may present a written list of observations, defined in the draft guidance as observed conditions and/or practices that, in the judgment of the FDA employee(s) conducting the RRA, indicate a potential violation of the laws enforced by the FDA. Notably, the FDA does not intend to issue a Form FDA 483 Inspectional Observations at the conclusion of an RRA.

Nonetheless, the FDA encourages establishments to respond during the meeting and/or provide written responses to the RRA observations within 15 U.S. business days. Responses or corrective actions submitted to the FDA during that time frame generally will be considered before further FDA action or decision. When the FDA considers the RRA closed, the FDA will provide a written copy of the narrative portion of the RRA report to the company—a process similar to the Establishment Inspection Report following an on-site inspection. The FDA notes that once the RRA is closed, the report and supporting documents, with any applicable redactions, are available for public disclosure upon request.

Notes

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1. https://www.fda.gov/media/160173/download.

2. FDA issued warning letters to drug establishments from 2021 to 2023 for violation of Section 301(e) of the FDCA when they failed to respond to the FDA records requests under Section 704(a)(4) of the FDCA. The FDA also issued import alerts in 2023 based solely on information provided in an RRA.

Interior Department Announces Rule on Financial Assurance for Offshore Oil and Gas

Jim Noe and Elizabeth Leoty Craddock*

In this article, the authors discuss a final rule issued recently by the U.S. Department of the Interior's Bureau of Ocean Energy Management with new standards for when supplemental financial assurance or bonds will be required from offshore oil and gas companies operating in federal waters.

For a decade, the U.S. Department of the Interior has wrestled with financial assurance (or bonding) requirements for offshore oil and gas companies. Over the past 10 years, the Interior Department has released—and later revised and superseded—guidance on the requirement for offshore lessees to provide the department with financial assurance or bonding to secure end-of-life decommissioning obligations that secures the lessee's liability for plugging and abandoning wells and removing offshore platforms, pipelines, and other infrastructure installed in federal waters.

In 2020, the Trump administration proposed new financial assurance regulations, but the final rule was never published in the Federal Register.[1] In recent months, the Interior Department has faced criticism from government watchdogs to issue the long-awaited new financial assurance rules, especially after several high-profile bankruptcies involving offshore oil and gas companies left billions of dollars of decommissioning liability with former lessees, who remain jointly and severally liable for decommissioning liability.[2]

The Interior Department's Bureau of Ocean Energy Management (BOEM) has now announced a final rule with new standards for when supplemental financial assurance or bonds will be required from offshore oil and gas companies operating in federal waters.[3]

The Final Rule

The final rule requires offshore oil and gas lessees to post supplemental financial assurance in the amount of the estimated

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 279–282.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

decommissioning liability—as determined by BOEM's sister agency, the Bureau of Safety and Environmental Enforcement—unless (1) the current lessee or a current co-lessee carries an investment credit rating of at least BBB– (for S&P and Fitch) or Baa3 (for Moody's), or an equivalent "proxy" rating determined by BOEM using the lessee's or a co-lessee's financial statements, or (2) the proven reserves of the relevant lease exceed the estimated decommissioning liability by three or more times.[4]

The final rule also requires lessees that file an administrative appeal of an order to provide the newly required supplemental financial assurance to post an appeal bond in the amount of the estimated decommissioning liability set forth in the order. If the lessee's appeal is successful, the amount of the appeal bond in excess of any required supplemental financial assurance would be returned to the lessee. If the appeal is unsuccessful, the appeal bond could be replaced with or converted into bonds or other forms of acceptable financial assurance to cover the supplemental financial assurance demand.

Additionally, the new rule clarifies that the Interior Department can disapprove an assignment of a lease when the transferor or transferee is not in compliance with applicable regulations, including the financial assurance requirements.

Comments on the Final Rule

The final rule attracted thousands of public comments, and the rule split the industry into competing positions. The large, international oil and gas companies that have mostly divested their shallow water oil and gas properties (which carry the most significant decommissioning liability, compared to the more recently developed deep water properties) but that nonetheless still carry joint and several liability for decommissioning liability supported the rule. They argued that current lessees should be financially capable of performing all of their regulatory and lease obligations, including decommissioning.

However, the independent oil and gas companies that have been purchasing the shallow water properties from the large, international oil and gas companies over the past 20 to 30 years almost uniformly opposed the final rule. They argued that it is unnecessary in light of the continuing liability of all former lessees of properties,

including the large, international oil and gas companies, and that any additional supplemental financial assurance should be limited to properties where no such solvent former lessee exists.

The independent offshore oil and gas companies also argued that the unnecessary financial burden will significantly impact offshore oil and gas production and could further weaken the financial strength of the independent producers. The Interior Department's new rule states that 391 entities will be impacted by the final rule, of which approximately 279 (69 percent) are considered small businesses under the Regulatory Flexibility Act.[5] According to the Interior Department's estimates, the final rule will result in the issuance of almost $7 billion in additional bonds or financial assurance—a significant increase over the approximately $1.5 billion to $2 billion in existing bonds issued to the federal government and the $3 billion in private bonds issued in the private sales transactions. Several surety industry representatives filed comment letters, raising concern that the additional $7 billion in bonding or security capacity does not currently exist.

Notes

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1. See Risk Management, Financial Assurance and Loss Prevention, 85 Fed. Reg. 65904 (Oct. 16, 2020).

2. See U.S. Government Accountability Office, Report to Congressional Requesters, Offshore Oil and Gas: Interior Needs to Improve Decommissioning Enforcement and Mitigate Related Risks (January 2024) (GAO-24-106229). See also Offshore Oil and Gas Resources: Actions Needed to Better Protect Against Billions of Dollars in Federal Exposure to Decommissioning Liabilities (December 2015) (GAO 16-40). All current and former lessees of offshore oil and gas properties are jointly and severally liable for decommissioning obligations, including the obligation to immediately perform maintenance and monitoring of wells and offshore facilities. 30 C.F.R. §§ 556.604(d), 556.605(e), 250.1701, and 250.1708. This joint and several liability attaches to decommissioning obligations that accrued during the former lessee's ownership period and continues to exist even if the lease has long been assigned to other parties. Id.; see also 30 C.F.R. § 250.1702. This joint and several liability regime has appeared to be effective in shielding the federal government from assuming decommissioning liability from bankrupt or insolvent lessees. Indeed, in the Fieldwood Energy LLC bankruptcy (Bankr. S.D. Tex. Case No. 20-33948), several billons of dollars of decommissioning

liability was abandoned and absorbed by former lessees as a result of the joint and several liability regime without any significant liability being left to the federal government.

3. https://www.doi.gov/pressreleases/interior-department-takes-action-protect-taxpayers-offshore-oil-and-gas.

4. The new rule applies to lessees and other grant holders of offshore oil and gas properties.

5. The Biden administration's U.S. Small Business Administration Office of Advocacy filed a comment letter opposing the Final Rule because of the disparate impact on small entities.

U.S. Government Acts on Connected Vehicle Privacy and National Security Concerns

Sara M. Baxenberg, Scott D. Delacourt, Stephen J. Conley, and Stephanie Rigizadeh*

In this article, the authors review federal government developments in the connected vehicle space of interest to automakers, suppliers, and wireless providers.

Concerns regarding how connected vehicles use and provide access to consumer and automotive data have recently been top of mind across the federal government, spurring multiple developments, including two new rulemaking proceedings at the Department of Commerce (Commerce) and the Federal Communications Commission (FCC or Commission) and a congressional request for additional action by the Federal Trade Commission (FTC).

Stakeholders in the connected vehicle space, including automakers, suppliers, and wireless providers, should monitor these developments closely as they likely will have impacts for the future of connected cars in the United States.

Commerce Issues ANPR Seeking Comment on the Security of Connected Vehicles

The Biden administration, in cooperation with Commerce, has announced an investigation[1] into national security risks from connected cars that incorporate technology from China and "other countries of concern." According to the press release, the White House is focused on "[n]ew vulnerabilities and threats" that "could arise with connected autos if a foreign government gained access to these vehicles' systems or data."

Commerce's investigation into this issue commenced with the Department's Bureau of Industry and Security (BIS) releasing an Advanced Notice of Proposed Rulemaking (ANPR) seeking

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 283–287.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

comment from the auto industry and the public on connected vehicles' national security risks and potential mitigation.[2] The BIS ANPR specifically requests comment on, among other things, details about the supply chain for connected vehicles in the United States, including information about integral hardware or software, and what impact international supply chain disruptions might have on the U.S. connected vehicle market.

The BIS ANPR also seeks comment on the relationship between automotive manufacturers in the United States and their international suppliers. According to the ANPR, particularly useful responses may include the type of information that is shared between automotive manufacturers of connected vehicles in use in the United States and their international suppliers "in the normal course of business, how this information is shared, what access or administrative privileges are typically granted, and if suppliers have any capability for remote access or ability to provide firmware or software updates."

BIS will use information gathered from the record to develop regulations governing the use of technology in connected vehicles from certain countries.

FCC Announces NPRM Focused on Protecting Domestic Violence Survivors from Abuses of Connected Car Features

The day before the White House's announcement, FCC Chair Jessica Rosenworcel announced[3] that she has circulated a Notice of Proposed Rulemaking (NPRM) to the other commissioners that, if adopted, would begin a proceeding aimed at preventing domestic abusers from using connected car features to harass and intimidate their partners.

According to the FCC's press release, the NPRM would "examine how the agency can use existing law to ensure car manufacturers and wireless service providers are taking steps to assist abuse victims and seek comment on additional steps the Commission can take to safeguard domestic violence survivors." To this end, the NPRM would seek comment on "the types and frequency of use of connected car services" available on the market and "whether changes to the Commission's rules implementing the Safe Connections Act are needed to address the impact of connected car services

on domestic violence survivors." The NPRM also reportedly would seek comment on "proactive[]" steps connected car service providers can take to protect survivors.

As described in the FCC's press release, media reports[4] of connected car services being used to stalk and harm abuse victims[5] served as the impetus for Chair Rosenworcel's proposal. Following these reports, Rosenworcel has sent letters to automakers[6] and wireless service providers[7] asking them a series of questions about connectivity options in vehicles sold in the United States. Rosenworcel's questions focused on topics such as connected car applications that track vehicle locations; automakers' policies and procedures to remove connected features upon request; and companies' retention, sharing, and selling of drivers' geolocation data collected by connected apps, devices, or other vehicle features.

The NPRM comes on the heels of new FCC regulations implementing the Safe Connections Act of 2022,[8] which seeks to ensure that domestic violence survivors can separate the phone lines from accounts shared with their abusers and can retain access to wireless service once the lines are separated. The Commission released an order[9] adopting the rules on November 16, 2023. Under the order, wireless providers must comply with several requirements such as authenticating the identities of survivors who make line separation requests, establishing "secure remote means" in various languages and accessibility formats for survivors to submit line separation requests, and separating phone lines within two business days after receiving a request. Providers also will be required to omit calls and text messages to certain domestic violence hotlines from customer-facing logs. Compliance with the order will be required beginning later this year.

Shared vehicle ownership is different in kind from a joint wireless service account comprised of multiple phone lines, and exploitation of connected car features in a domestic abuse situation raises distinct concerns than what the Safe Connections Act was designed to address. The NPRM may give some insight into whether and how the Commission believes the Act could be applied in the connected vehicle context. The FCC press release suggests that the new NPRM is being voted on through the Commission's "circulation" process rather than at an FCC open meeting, which means that the agency will not release a public draft of the item before it is adopted.

Congress Implores FTC Action on Automakers' Data Privacy Practices

Senator Ed Markey (D-MA) has sent a letter[10] urging the FTC to investigate automakers' data privacy practices. Citing concerns with misuse of consumer data, such as tracking domestic violence victims, and linking to the same media reports as the FCC, Markey urged the FTC "to use the full force of its authorities to investigate the automakers' privacy practices and take all necessary enforcement actions to ensure that consumer privacy is protected."

Looking Ahead

The timing and focus of the federal actions mentioned above suggest that the Biden administration, Congress, and federal agencies are intently focused on issues surrounding connected car privacy and security. Stakeholders in the automotive industry should track the Commerce and FCC proceedings closely, participate in the rulemaking processes, and keep abreast of further regulatory developments at the FTC or other agencies in the near future.

Notes

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Fueled by Whistleblower Claims, Department of Justice Reports Record Year for False Claims Act Recoveries

Thomas M. Burnett and Daniel G. Murphy*

In this article, the authors examine a report from the U.S. Department of Justice regarding settlements and judgments the government obtained under the False Claims Act in Fiscal Year 2023.

The U.S. Department of Justice (DOJ) and whistleblowers obtained more than $2.68 billion in False Claims Act (FCA) settlements and judgments in fiscal year 2023—a record year for FCA enforcement. The DOJ highlighted these record recoveries in its annual FCA statistics press release[1] and in remarks[2] delivered to the Federal Bar Association's qui tam conference, Principal Deputy Assistant Attorney General, Civil Division, Brian Boynton, emphasized the government's continued commitment to robust FCA enforcement.

The FCA is one of the government's most important tools to combat alleged fraud against the government and protect taxpayer dollars. The FCA makes it unlawful to submit false claims (defined broadly as "any request or demand . . . for money or property") to the government, or to cause such claims to be submitted.[3] The consequences of violating the FCA are significant. The FCA authorizes the imposition of civil penalties, treble damages, and fee awards, allowing the government (and whistleblowers) to recover substantial sums. Every year for the past 15 years, FCA recoveries have exceeded $2 billion. Perhaps not surprisingly, given the amounts at stake (and the obvious financial benefit to whistleblowers, in particular), FCA enforcement activity has steadily increased over the years, with no signs of slowing down in years to come. In 2023, the nearly $2.7 billion recovered came from the resolution of 543 separate cases—another record high, up from 351 cases in 2022.

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 289–293.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

Whistleblowers Continue to Drive Record Recoveries Under the FCA

The FCA incentivizes whistleblowers to report fraud. It protects whistleblowers from retaliation, and it compensates them for generating suits, whether the claims are ultimately pursued by the government or by the whistleblowers themselves in so-called qui tam actions. Whistleblowers typically receive between 15 percent and 30 percent of the overall recovery. Of the $2.68 billion recovered in 2023, $2.3 billion, or approximately 85 percent, came from whistleblower suits (up from $1.9 billion in 2022). As a result, whistleblowers received more than $349 million for their disclosures of fraud and abuse. This trend is unlikely to change. In 2023, whistleblowers filed 712 new suits (up from 652 in 2022), marking the fourth time since 2013 qui tam filings exceeded 700.

Sharp Increase in DOJ-Initiated Suits and Investigations

This is not to suggest that the government relies exclusively on whistleblowers for purposes of FCA enforcement. Indeed, the government has increased its own enforcement efforts in recent years. In 2023, the government opened 500 new FCA matters that were not the result of whistleblowers' disclosures. That number is up from 305 such matters in 2022. The government also issued more than 1,500 civil investigative demands (CIDs) in 2023. Similar to a subpoena, a CID is a discovery tool used by the government to obtain documents, information, and testimony in connection with its investigation of FCA claims.

Enforcement Priorities for 2024 and Beyond

While the government's "focus is always evolving," Boynton identified certain areas of particular interest to the DOJ, including health care, cybersecurity and pandemic fraud. He also stressed the DOJ's growing concern with the role of third parties, such as private equity investors, in the submission of false claims.

Health Care

As in years past, the health care sector remains a leading focus of FCA enforcement activity, accounting for more than $1.8 billion of the $2.7 billion in total recoveries for the year. In his remarks, Boynton made clear that the government intends to closely scrutinize alleged kickbacks for referrals, schemes involving medically unnecessary services or substandard care (particularly in nursing home settings), participants in the Medicare Advantage (Part C) program, and claims relating to the opioid crisis.

Cybersecurity

Boynton likewise touted the DOJ's Civil Cyber-Fraud Initiative, which uses the FCA to bring enforcement actions against contractors that put government data and systems at risk by allegedly violating cybersecurity requirements applicable to those doing business with the government.

Pandemic Fraud

The DOJ also plans to continue using the FCA to pursue pandemic-related fraud, including in connection with the Paycheck Protection Program (PPP) and other relief programs. In 2023 alone, the DOJ resolved 270 FCA matters involving PPP loans.

Private Equity

In his remarks, Boynton emphasized the DOJ's heightened interest in the role third parties—private equity firms, in particular—play in submitting false claims. He made clear that the DOJ has private equity in its crosshairs and intends to aggressively pursue investors who dictate business practices or benchmarks that may knowingly encourage or cause the submission of false claims.

So, What Should Businesses Do to Minimize Those Risks?

- *Build a Robust Compliance Program—Or Reassess an Existing One*. Evaluate your compliance efforts and/or programs to

determine whether they are adequate to detect and investigate alleged improprieties and prevent fraud and misconduct in the future. Consider whether your compliance program reflects the size and nature of your business and risk profile.

- *Invest in Building a Culture of Compliance*. Apply your compliance program earnestly and in good faith. Give employees a mechanism for raising and addressing concerns without pursuing a whistleblower claim. Listen to their concerns, investigate them diligently and objectively, and document your efforts.
- *Consider the Influence of Owners, Investors, or Other Third Parties*. As Brian Boynton said, "One reason why the False Claims Act has been so successful is its wide reach. It covers those who submit false claims and those who cause such claims to be submitted. It is no defense that an individual or entity did not sign or transmit the specific claim at issue if their conduct played a significant and foreseeable role in advancing the scheme." The DOJ has made clear that it intends to aggressively pursue third parties that it suspects had a hand in causing the submission of false claims. This includes non-managing ownership (i.e., private equity). Carefully consider whether changed business practices or revenue targets could encourage compliance failures or false claims.
- *Consult with Legal Counsel*. Consider seeking the assistance of counsel when assessing compliance risks, building your compliance program, or responding to inquiries from the government. While doing so certainly comes with a cost, the cost of involving counsel early pales in comparison to the exposure you face in an FCA investigation or whistleblower suit.

Conclusion

The record FCA recoveries in 2023, ever-increasing whistleblower activity, and the government's renewed commitment to FCA enforcement in 2024 and beyond once again highlight the substantial risks facing individuals and companies that do business with the government. Companies should be proactive and take steps to mitigate compliance risks and minimize their exposure to FCA

liability—in this area, an ounce of prevention is always worth far more than the cost of defending an FCA claim against the government or whistleblowers.

Notes

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1. https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.

2. https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-brian-m-boynton-delivers-remarks-2024.

3. 31 U.S.C. § 3729(a)(1)(A).

Financial Industry Regulatory Authority Issues Long-Awaited Guidance Regarding Residential Supervisory Locations and Remote Branch Office Inspections

Elizabeth A. Marino, Lara C. Thyagarajan, Paul M. Tyrrell, Kenneth Ashton, and Greg Chiuve*

In this article, the authors discuss new guidance issued by the Financial Industry Regulatory Authority that modernizes its regulatory framework related to remote workplace locations.

The Financial Industry Regulatory Authority (FINRA) has issued Regulatory Notice 24-02 (Notice) to announce the adoption of FINRA Rules 3110.18 and 3110.19 and remind firms of their obligations once the rules become effective.[1] In addition, the Notice announces the end of the COVID-19 temporary relief from certain regulatory obligations described in Regulatory Notice 20-08 (the Notice 20-08 Relief).[2]

As a reminder, FINRA Rule 3110.18 will establish the Remote Inspections Pilot Program, and FINRA Rule 3110.19 will establish the criteria for designating an associated person's private residence as a Residential Supervisory Location (RSL). In addition to announcing the applicable deadlines associated with FINRA Rules 3110.18 and 3110.19, the Notice provides that an increase in the number of offices or locations could constitute a material change in a firm's business operations requiring approval under FINRA's Membership Application Program (MAP) rules. FINRA urges firms to consider any potential MAP implications when contemplating an increase in offices resulting from RSLs designations and the end of the Notice 20-08 Relief.

Firms should immediately assess the new rules to determine whether they intend to rely on them and for whom RSLs will need

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 295–300.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

to be established, draft and adopt appropriate policies and procedures related to the implementation of the rules, and assess whether they need to do a materiality consultation with FINRA related to the sunset of the Notice 20-08 Relief and establishment of RSLs. Likewise, to the extent possible, firms should commence the process of updating Forms U4 and BR to reflect offices of employment address and new branch offices.

Effective Dates

In this Notice, FINRA announced the following effective dates:

- End of the regulatory relief described in Notice 20-08: May 31, 2024;
- Effective date of FINRA Rule 3110.19: June 1, 2024; and
- Effective date of FINRA Rule 3110.18: July 1, 2024.[3]

End of Notice 20-08 Relief

Citing the end of the public health emergency due to COVID-19, firms will no longer be able to rely on the Notice 20-08 Relief. Specifically, beginning June 1, 2024, firms that have been relying on the Notice 20-08 Relief must comply with the following obligations:

1. Maintain updated Form U4 information regarding the office of employment address for registered persons who relocated due to COVID-19 within the specified time frame by filing an appropriate amendment as prescribed in Article V, Section 2 of the FINRA bylaws.
2. Submit or update branch office applications on Form BR for any office locations or space-sharing arrangements established because of COVID-19 that have not otherwise been registered or updated with FINRA through Form BR as prescribed in Article IV, Section 8 of the FINRA bylaws.

Accordingly, firms that relied on the Notice 20-08 Relief from the above-listed obligations must ensure that Forms U4 and BR reflect current registration and address information for each of their offices and locations by July 1, 2024.

Implementation of FINRA Rule 3110.19

Key Events Associated with the Implementation of FINRA Rule 3110.19: Private Residence/Supervisory Activities

FINRA Rule 3110.19 will allow an associated person's private residence where supervisory activities are conducted to be considered a nonbranch location of the associated person's firm, subject to certain conditions and controls. Specifically, the firm and the relevant associated person at each prospective RSL must meet specified conditions and eligibility requirements to be able to avail themselves of the RSL designation. Firms should familiarize themselves with the list of events that can render ineligibility for designation as an RSL under FINRA Rule 3110.19(c) to ensure compliance.

Firms that choose to designate locations as RSLs will also be required to provide FINRA with a current list of their RSLs by the fifteenth day of the first month of each quarter, starting on October 15, 2024. The lists submitted to FINRA on October 15, 2024, will reflect the locations firms have designated as RSLs during the period June 1, 2024, through September 30, 2024. FINRA is developing a process in the FINRA Gateway through which firms will be able to submit their lists to FINRA. FINRA anticipates that this process will be available to firms no later than May 31, 2024. Firms can then begin designating RSLs on June 1, 2024.

MAP Considerations Associated with the Designation of RSLs Under FINRA Rule 3110.19

The designation of RSLs is likely to cause an increase in the number of firm office locations. The Notice draws attention to the importance of firms considering whether an increase in the number of firm offices due to the designation of RSLs will result in a "material change in business operations" that would require the firm to file an Application for Approval of Change in Ownership, Control, or Business Operations under FINRA Rule 1017. Firms should consult FINRA Rule 1017, IM-1011-1, and Notice to Members 00-73 to assess whether a change in the number of firm offices would constitute a "material change in business operations" for the purposes of FINRA Rule 1017.

FINRA encourages firms that are uncertain whether an increase in several firm offices or locations would constitute a "material

change in business operations" for the purposes of FINRA Rule 1017 to seek guidance from its MAP Group through the materiality consultation process.

Implementation of FINRA Rule 3110.18

Key Events Associated with the Implementation of FINRA Rule 3110.18: Remote Office Inspections

As a reminder, FINRA Rule 3110.18 establishes a voluntary, three-year remote inspections pilot program (Pilot Program) to allow eligible member firms to fulfill their Rule 3110(c)(1) inspection obligation of qualified branch offices, including offices of supervisory jurisdiction and nonbranch locations remotely, without an on-site visit to such offices or locations, subject to specified terms. A firm must affirmatively opt in to participate in the Pilot Program and, once enrolled, must affirmatively opt out of the program if it chooses to no longer participate. Similar to the process for FINRA to be able to collect required lists of RSLs under FINRA Rule 3110.19, FINRA is developing a process in the FINRA Gateway by which firms will be able to submit opt-in and opt-out notices to FINRA.

A firm that elects to participate in the Pilot Program for the period of July 1, 2024, through December 31, 2024, must submit its opt-in notice no later than June 26, 2024. The Notice explains that June 1, 2024, is currently the first date on which a firm may submit an opt-in notice, but this may change if the FINRA Gateway process for submitting opt-in notices is ready earlier than expected. A firm that chooses to opt out of the second year of the Pilot Program (which will cover the period from January 1, 2025, through December 21, 2025) must submit its opt-out notice by December 27, 2024. December 27, 2024, is also the date by which a firm that did not participate in the first year of the Pilot Program may opt in for the second year.

Data Required to Be Submitted Under FINRA Rule 3110.18

A firm that elects to participate in the Pilot Program must submit the following data to FINRA through a new process that will become available in the FINRA Gateway:[4]

- Quarterly data for each pilot year as specified in Rule 3110.18(h)(1)(A)-(F) (due by October 15, 2024, for the first year of the Pilot Program);
- Supplemental written supervisory procedures for conducting remote inspections in compliance with Rule 3110.18(h)(1)(G), and if applicable, any subsequently amended procedures (due by October 15, 2024, for the first year of the Pilot Program);
- For a firm participating in the first year of the Pilot Program (from July 1, 2024, through December 31, 2024), additional data and information covering January 1, 2024, through June 30, 2024 (due by December 31, 2024, for the first year of the Pilot Program); and
- Acting in good faith using best efforts, calendar year 2019 inspection data and information as specified under Rule 3110.18(h)(3) (due by December 31, 2024, for the first year of the Pilot Program).

Additional Guidance

Firms will await the additional guidance FINRA indicated is forthcoming related to the operational processes for RSL designations and remote inspection pilot notices.

Going Forward

The above new rules are welcome changes made by FINRA to modernize its regulatory framework related to remote workplace locations, but as FINRA noted in its rulemaking process, firms will need to assess their supervisory systems and controls and make enhancements as necessary to supervise activities conducted from these locations and to comply with other applicable regulatory requirements. Notably, the Notice highlights potential MAP implications resulting from an increase in remote office locations. Accordingly, firms contemplating an increase in remote work locations due to the sunsetting of the Notice 20-08 Relief or the designation of RSLs should assess their supervisory processes and controls, including written supervisory policies and procedures, and make any necessary enhancements.

In addition, considerations should be given to whether an increase in remote office locations constitutes a material change of business operations requiring FINRA approval under MAP rules or to seek guidance through FINRA's materiality consultation process. Also, firms should start identifying their representatives who will need Form U4s updated to reflect addresses for their remote work locations and, if possible, consider updating Form U4 information in advance of the July 1, 2024, due date.

Notes

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1. https://www.finra.org/sites/default/files/2024-01/Regulatory_Notice_24-02.pdf.

2. https://www.finra.org/sites/default/files/2020-03/Regulatory-Notice-20-08.pdf.

3. FINRA Rule 3110.17, which is the current, temporary FINRA rule regarding remote inspections, will sunset on June 30, 2024.

4. Due dates associated with each type of data is indicated in parentheses.

Overview of PFAS Regulations in the United States and What Foreign Companies and Their U.S. Subsidiaries Need to Know—Part II

Reza Zarghamee, Shinya Akiyama, and Lauren Johnstone*

This two-part article overviews the status of poly- and perfluoroalkyl substances (PFAS) regulation in the United States. The first part, published in the prior issue of The Journal of Federal Agency Action, *described PFAS, the types of products that include it, and the recent wave of litigation involving PFAS contamination, which has involved settlements above $10 billion. The conclusion of this article, published here, discusses developments in federal and state regulation of these chemicals. A brief discussion of specific scenarios in which these developments may affect foreign corporations follows. This part then ends by recommending that businesses that manufacture, distribute, use, or dispose of PFAS or products containing PFAS stay abreast of these developments and develop proactive strategies to minimize their potential liability.*

Federal Regulatory Developments

The U.S. Environmental Protection Agency (EPA) and the federal government have taken incremental steps to regulate poly- and perfluoroalkyl substances (PFAS) since the early 2000s. For example, in 2002, the EPA initiated a phaseout of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) by major domestic manufacturers, but no recall of products.[1] This was followed in 2006 by a PFOA Stewardship Program, which secured commitments from eight major manufacturers and users of the chemical to manage and dispose of their product stocks.[2] Since the early 2000s, the EPA has promulgated regulations either creating or clarifying the need to submit notifications—Pre-Manufacture Notifications (PMNs) and Significant New Use Notifications (SNUNs)—to the EPA under Section 5 of the Toxic Substances

The Journal of Federal Agency Action / July–August 2024, Vol. 2, No. 4, pp. 301–315.
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ISSN 2834-8796 (print) /ISSN ISSN 2834-8818 (online).

Control Act (TSCA) before the marketing and commercial distribution of certain PFAS-containing products.[3]

In September 2021, under the Biden administration, the EPA published its PFAS Strategic Roadmap, which delineated the actions that the EPA planned to take in the short- and long-term to address PFAS.[4] Among other things, the Roadmap calls for the significant expansion of PFAS regulation above and beyond just PFOA and PFOS.[5] In addition, the Roadmap calls for the refinement of analytical techniques for sampling and identifying PFAS and further research into feasible remedial technologies. Notable regulatory efforts undertaken pursuant to the Roadmap include, without limitation:

- *Listing PFAS as "Hazardous Substances" Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).*[6] In August 2022, the EPA proposed listing PFOA and PFOS and their salts and isomers as CERCLA "hazardous substances." Subsequently, in April 2023, the EPA issued an advance notice of proposed rulemaking to list seven additional PFAS:
    1. Perfluorobutanesulfonic acid,
    2. Perfluorohexanesulfonic acid,
    3. Perfluorononanoic acid,
    4. Hexafluoropropylene oxide dimer acid (sometimes called GenX),
    5. Perfluorobutanoic acid,
    6. Perfluorohexanoic acid, and
    7. Perfluorodecanoic acid.

  Once finalized, these proposed listings will bring sites contaminated with the pertinent PFAS under the scope of CERCLA, the primary federal environmental remediation statute. It stands to impose joint and several liability on past and present owners and operators of properties contaminated with these substances, as well as on transporters and parties that arrange for the disposal of these ubiquitous chemicals. Thus, entities with no operational nexus to PFAS, may walk into PFAS-related liabilities merely based on holding a real estate interest in a contaminated property. Furthermore, given that CERCLA is the model for most state environmental cleanup statutes, the expectation is that the states, too, would list these substances in

their analogous laws once the EPA has added them to the "hazardous substances" list. CERCLA listing will provide another statutory basis for private party litigation, as Sections 107 and 113 authorize potentially responsible parties to bring suit against one another to recover response costs. Expanding the list of hazardous substances will create an impetus for regulators to require sampling for these potential contaminants at sites where remediation is underway or not yet completed. It may also serve to "reopen" investigations at sites where remediation had been completed and compel responsible parties to incur costs for which they have not yet planned.

- *Establishing an Enforceable Maximum Contaminant Limit (MCL) for Six PFAS Under the Safe Drinking Water Act.*[7] This measure will have a twofold impact.

  First, it will establish an enforceable federal limit for these PFAS, such that regulated public water systems will incur liability in the form of penalties and injunctions for exceeding them. This, in turn, will precipitate lawsuits against the violating utilities by customer, as well as by the utilities against the parties responsible for contaminating the water supply.

  Second, because MCLs inform environmental remediation efforts, the codification of an MCL will establish a de facto remediation target for the six PFAS in groundwater. In this connection, it is relevant that the EPA has proposed, as an MCL, four parts per trillion for PFOA and PFOS. This standard is orders of magnitude lower than the cleanup levels for most other deleterious contaminants, such as volatile organic compounds, and many in the regulated industry conclude it is predicated on an overly conservative interpretation of toxicity data. The Proposed Rule was issued March 2023.[8] Coupled with the broad sweep of CERCLA liability, this proposed regulation stands to greatly increase the costs and duration of PFAS-related remediation projects.

- *One-Time PFAS Reporting Rule Under TSCA Section 8(a)(7).* In late September 2023, the EPA issued a pre-publication of a final rule[9] that would require businesses to provide information to the agency regarding their manufacture or importation of PFAS since 2011. The reporting deadline is

> October 11, 2025. The information that must be reported is largely similar to that which is required to be submitted every four years under the TSCA Chemical Data Reporting (CDR) rule. However, the one-time PFAS reporting rule does not contain many of the exemptions that apply to CDR. Not only is there no weight-based reporting threshold, but the EPA has chosen not to allow the article exemption. As a result, in addition to manufacturers and importers of bulk chemicals, businesses that import articles, or manufacture them in a way that forms new PFAS (e.g., through heat treatment), will have to obtain information from entities that are upstream in the supply chain. This may be particularly difficult in the case of articles, as unlike bulk chemicals and mixtures, manufactured parts and complete products typically are not distributed in commerce with Safety Data Sheets or specifications that enumerate all the chemicals present within them. Aside from facilitating EPA efforts to prioritize specific PFAS for further investigation and restrictions, the information that the EPA receives will assist federal and state agencies in prioritizing specific operations for potential investigations and enforcement. Moreover, pursuant to the Freedom of Information Act, such information stands to be made available to the public, including environmental and consumer advocacy groups and plaintiffs' firms. Such groups, as well as governmental agencies, may have a vested interest in tying certain businesses to known areas of PFAS contamination.

In total, the measures specified in the PFAS Strategic Roadmap and issued in the proposed rules stand to regulate PFAS' introduction into commerce, use, and remediation. Over two dozen congressional bills are pending that require implementation of the PFAS Strategic Roadmap or otherwise touch on PFAS.

State Regulatory Developments

Numerous states also have undertaken legislative and regulatory actions to address PFAS, with dozens of bills introduced and enacted throughout the country. Besides continuing to initiate lawsuits against businesses believed to have contributed to PFAS

contamination, states currently are implementing three broad categories of actions to address PFAS:

1. *Drinking Water and Groundwater Cleanup Standards*. To date, many states have issued guidance or regulations establishing drinking water or groundwater remediation standards for PFAS.[10] These standards span a wide range of numerical limits, which reflect the fluid state of information and diversity of opinion regarding the consequences of PFAS exposure.
2. *Commercial Regulation of PFAS-Containing Products*. In this connection, a number of states have codified laws requiring business entities such as manufacturers, packagers, importers, suppliers, and distributors of PFAS-containing products to provide consumer warning statements or labels. More than a dozen states, such as Maine and Minnesota, have issued or proposed laws requiring manufacturers and importers of products with intentionally added PFAS to notify the state environmental agencies, and to cease introducing PFAS-containing products into state commerce by certain dates.[11] As with the one-time PFAS reporting rule under TSCA Section 8(a)(7), compliance with these laws will require subject businesses to investigate their global supply chains and/or provide information to their customers regarding the PFAS content of the products that they themselves supply.
3. *PFAS Evaluation at Remediation Sites*. Another state approach is to require responsible parties at remediation sites to evaluate the potential for PFAS contamination near drinking water resources through research into past and present property uses, as well as environmental sampling. For example, in 2019, California initiated a Phased Investigation Plan to obtain data on PFAS in effluent and drinking water.[12] The investigation, which is ongoing, will proceed in three phases: the first two phases will cover primary manufacturing sites, landfills, and properties, such as airports, where releases of PFAS-containing firefighting agents are more likely, while the third phase will cover secondary manufacturers of PFAS-containing products.

   Similar measures have been initiated in New York and New Jersey, where state environmental agencies

have directed responsible parties at active remediation sites—including, in the case of New Jersey, sites that have received conditional closure predicated on institutional or engineering controls—to evaluate the potential for PFAS contamination based on historical operations and, if such potential is found to exist, to develop sampling and investigation plans.[13] Additionally, states such as North Carolina are now issuing mandatory PFAS questionnaires in connection with all permit applications and renewals.

Besides increasing the litigation risk to businesses identified as having used PFAS in past or present operations, these state initiatives stand to influence the manner in which companies approach remediation projects. For example, given the New Jersey Department of Environmental Protection's apparent willingness to "reopen" cleanup sites that have been closed out subject to controls, parties performing remediation will have to weigh the costs of achieving conditional closure on a shorter time frame and at lesser cost versus taking more time and incurring greater cost to achieve unconditional closure.

States are also using their subpoena authority more expansively to obtain information that may serve as the basis for bringing PFAS-related enforcement actions or lawsuits.

Wave of State and Private-Party Litigation

The immediate origins of the current PFAS litigation wave date back to 2012, when the EPA required public water systems regulated by the Safe Drinking Water Act to sample for PFOA and PFOS, the two most widely studied PFAS substances, as well as four other PFAS substances, under the unregulated contaminant monitoring rule.[14] The sampling identified concentrations of these two PFAS contaminants at public water systems across the United States, spurred additional investigations of the nation's water supply, and prompted lawsuits.

The initial wave of private-party litigation targeted two categories of defendants: (1) PFAS manufacturers, and (2) water utilities. In 2018, DuPont and its former subsidiary Chemours paid $671 million to resolve approximately 3,500 claims involving

releases from the Washington, West Virginia, facility where Teflon—which contains PFOA—was manufactured.[15] Around the same time, class action lawsuits were brought against water utilities in Colorado, Michigan, New York, and Pennsylvania.[16] Because PFAS in water utilities is from contamination from third-party sites, the water utilities themselves became plaintiffs in litigation. Around the same time as the DuPont settlement, 3M, another major primary manufacturer of PFAS, agreed to pay $35 million to a water utility in Alabama to cover the costs of remediating PFAS in the public water system.[17] Primary manufacturers are still the focus for litigation, but the web is increasing to include secondary manufacturers and processers as well.

Several states also have initiated litigation against companies alleged to have introduced PFAS into the environment. Notable efforts include those by state attorneys general in California, Illinois, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, New York, and North Carolina. The defendants in these lawsuits have included primary and secondary manufacturers of PFAS, as well as the Department of Defense (due to its use of aqueous film forming foam (AFFF)). The settlements reached to date have been considerable. For example, in 2018, 3M settled for $850 million with Minnesota for releases of PFAS in the Twin Cities Metro Area.[18] Of this amount, $720 million were allocated toward drinking water restoration and natural resource projects. 3M faces similar liability exposure for PFAS-related contamination in other states.

Another sizable settlement involved Wolverine Worldwide, a prominent secondary manufacturer of PFAS. This company incorporated 3M's Scotchguard water-proofing agent into its leather products, the disposal of which resulted in PFAS impacts to drinking water resources near Rockford, Michigan.[19] In February 2020, Wolverine Worldwide entered into a consent decree with the state of Michigan and local townships to pay nearly $70 million toward extending a municipal water system to about 1,000 homes with private wells that were affected by the contamination.[20] Michigan, in fact, is estimated to have one of the highest concentrations of PFAS sites of any state, and in 2019, the Michigan attorney general's office issued a call for private attorneys to assist in bringing suit against responsible parties.

Much of the recent PFAS settlement activity has been consolidated in MDL-2873 in a federal district court in South Carolina.

This MDL is a consolidation of over 7,000 lawsuits related to PFAS contamination from AFFF, a component of Class B firefighting foam. The defendants include a wide array of companies, including primary manufactures of PFAS chemicals present in the AFFF, as well as the manufacturers and distributors of the AFFF itself. AFFF has been in use by the Department of Defense, airports, and other industrial facilities since the 1970s. The cases consolidated in this MDL fall into three large categories:

4. Lawsuits to recover the costs of remediating PFAS contamination in public water systems,
5. Personal injury suits, and
6. Natural resource damages claims.

Thus far, two proposed settlements have been obtained with respect to the first category of lawsuits, and the amounts at issue are staggering. In June 2023, Dupont and its affiliated entities, Chemours and Corteva, entered into a proposed settlement for $1.185 billion. Soon after, 3M agreed to pay between $10.3 billion and $12.5 billion (depending on how many public water systems detect PFAS impacts). These settlement amounts reflect the difficulties of remediating PFAS in water, and because the proposed settlements are accompanied by releases and indemnities, a legitimate concern on the part of other MDL defendants and governmental agencies involves the risk shifting that may set in if it turns out that the cleanup costs are greater than were initially anticipated. In such a scenario, secondary manufacturers and end users of PFAS would have to bear the risks of the cost overruns. This risk to secondary manufacturers and end users holds true outside the context of the MDL. Thus, the resolution of claims involving primary manufacturers is of concern to a wider array of businesses.

Environmental Groups

Environmental advocacy groups in the United States are very much interested in PFAS, and the state and federal initiatives discussed above have made it easier for such groups to identify potential litigation targets. Specifically, in May 2020, the Environmental Working Group developed an interactive map, which, as of May 2024, includes 6,189 sites with PFAS contamination across all 50 states.[21] Compiled using publicly available information from

numerous sources, including the EPA website, the map organizes the sites into three categories:

1. Military installations,
2. Drinking water systems, and
3. Other known sites.

In many cases, the map specifies the cause of the contamination (e.g., releases of AFFF), the types of PFAS involved, and any analytical data. This information can provide adequate information with which prospective claimants can identify potentially responsible parties and substantiate a claim. In certain instances (more common for the "other known sites" category), the map will even identify the name of the business or property owner, thus obviating the need for further research on the part of prospective claimants. The Environmental Working Group has indicated that the map is "dynamic," meaning that it will be kept up to date as new information is obtained.

Other advocacy groups, such as Mamavation,[22] have started publicity campaigns for PFAS in products. For example, Mamavation will take certain drugstore products, grocery store items, and cosmetics, send these products to laboratories to be tested for PFAS indicators, and publish whether PFAS is present in these common products. This awareness may even trigger lawsuits as consumers argue they were misled by manufacturers and distributors that these products did not contain PFAS. This is even more likely if the product has been advertised as "clean," "organic," "green," or any similar term. In addition, plaintiffs' firms may use this information in order to initiate PFAS-related lawsuits, especially as they grow in resources due to large PFAS settlements.

Specific Concerns for Foreign Businesses

Foreign companies may be affected by the regulatory climate surrounding PFAS in various ways. In this section, we will consider how the different causes of actions and actual and prospective regulations may apply to such companies:

- *Scenario #1—Product Liability*. Product liability may attach to any foreign company in the chain of business that distributes PFAS in the United States. This would include

both primary manufacturers and secondary manufacturers, including those based outside the United States, as well as U.S. subsidiaries involved in importing the PFAS-containing products to the United States.

- *Scenario #2—Toxic Tort Litigation (Besides Product Liability)*. As indicated, toxic tort liabilities arise from common law actions, which can be brought by any public or private entity, provided that they are the party that has suffered injury and the specific elements of each cause of action (e.g., negligence, trespass, nuisance, personal injury, inherently dangerous activity, etc.) are satisfied. Toxic tort liabilities generally attach to businesses proximately responsible for causing harmful exposure. In the case of PFAS, this means the entities that release PFAS into the environment, either through accidental spills or deliberate industrial processes and disposal practices. Foreign parent corporations that serve as chemical suppliers should be insulated from such liability, as long as they do not exercise undue operational control over those aspects of their subsidiaries' business that may give rise to releases (e.g., how to dispose of industrial wastes). Similarly, trading companies that arrange for the importation of PFAS-containing products should not incur such liability, as long as they do not exercise operational control over the products at the time that they are released. On the other hand, U.S. subsidiaries that engage in industrial operations involving PFAS or that use and dispose of PFAS products in a way that endangers the environment would be most at risk.
- *Scenario #3—Statutory Environmental Remedial Liability*. Generally, the same businesses that have exposure for toxic tort liability may be exposed to liability under environmental remedial statutes, as these aim to hold the parties directly responsible for causing contamination (as opposed to upstream suppliers) liable for cleanup costs. To determine liability exposure, attention must be paid to the substantive requirements of the statute under which the claim is brought. As of the date of this publication, PFAS are not regulated as "hazardous substances" or "hazardous wastes" under the two main U.S. federal statutes dictating remediation and cost recovery, CERCLA and RCRA, respectively, although this is expected to soon change. On

the other hand, as mentioned above, several states have developed laws and guidance pursuant to which they have issued directives, which impose remedial liability and cost recovery on parties responsible for causing PFAS contamination. In general, the scope of entities that may incur liability under these state laws includes past and present owners and operators of PFAS-contaminated sites, businesses that arrange to dispose of or release PFAS at a given location, or companies engaged in transporting PFAS at the time that a release occurred.

That United States' statutory liability attaches to past and present owners of contaminated sites also raises liability concerns for foreign companies that do not themselves deal with chemicals but that acquire other businesses or real estate in the United States. A foreign company that acquires a fee or leasehold interest in property with PFAS contamination may incur remedial liability as an owner or operator depending on the laws of a given state (and almost certainly after PFAS is added to the CERCLA list of hazardous substances) even if the business itself never used or handled PFAS. Thus, foreign companies that engage in such transactions are encouraged to perform pre-closing acquisition-related environmental due diligence, also known as "All Appropriate Inquiries," to (1) assess their liability exposure, and (2) if such exposure exists and the applicable law provides, qualify for defenses to remedial liability for preexisting contamination that they did not cause or exacerbate.

Companies that acquire the equity of a business that is a responsible party at a PFAS remediation site should be insulated from liabilities to the extent that corporate formalities are observed. However, failure to observe these formalities may lead to veil-piercing liabilities or, if the acquiring company exercises undue control, direct liability as an operator. Furthermore, even if the acquiring corporation is not itself deemed liable, PFAS liabilities may impair the value of its investment in the subsidiary. Thus, foreign companies looking to acquire other businesses in the United States also are encouraged to perform pre-closing environmental transactional due diligence. The reason is not to enable the foreign companies to avail themselves

of the affirmative defenses to CERCLA liability, which are not available in the context of an equity transaction, but rather to gain adequate information regarding environmental conditions to inform a business decision whether or not to proceed with the transaction.

- *Scenario #4—Liability Under Consumer Protection Statute.* Currently, at least 11 states have enacted consumer protection statutes related to PFAS and further consumer protection laws are anticipated. These statutes impose requirements such as (1) prohibitions on the manufacture or distribution of specific products containing PFAS, and (2) notification requirements to state agencies regarding the presence of PFAS in products. As a result of these laws, distributors will likely ask suppliers about the presence of PFAS in their products. This may cause further supply chain and business disruptions, as businesses may discontinue procuring or (in the case of vendors) selling products after they learn that they contain PFAS. Moreover, noncompliance with these new laws could subject companies to regulatory enforcement and penalties. Because regulation of PFAS in consumer products is so novel, the promptness and extent to which these laws will be enforced in each state remains to be seen. Regulated industries, including foreign companies, should be aware that, similar to other environmental laws, most states impose per-day or per-violation penalties for noncompliance that may be aggravated by intentional or knowing violations or mitigated by good faith compliance efforts. They may also issue stop-sale orders, which can be disruptive to businesses. Furthermore, the laws incentivize plaintiffs' firms and public interest groups to independently test certain products for PFAS content and then to report noncompliant businesses to state regulators.

Under these laws, companies will have to account for a more or less ubiquitous class of chemicals. This is even more concerning when considering that regulators are employing broad definitions of PFAS for regulatory purposes. Companies will need to be careful if making any claims that can be interpreted as touching on PFAS. Generally, companies will need to be vigilant in cases where there are laws requiring PFAS disclosure. It is beneficial to businesses to be proactive in terms of determining the presence of PFAS in their products, so as to avoid a situation where the state,

a plaintiff's lawyer, or a public interest group "surprises" them with an enforcement action or injunction.

Conclusion

PFAS regulation and liability is a fluid, fast-developing topic in environmental law. Given the pervasiveness of PFAS and the health and environmental risks that PFAS pose, the liability risks are potentially significant, even to companies that do not presently know that they use PFAS. Companies that may have manufactured or used PFAS are encouraged to evaluate present and past products, supply chains, and processes to obtain a better understanding of their connection to these chemicals.

If current operations involve PFAS, then the costs and benefits of continued PFAS use should be weighed. For companies that have manufactured or distributed PFAS products, either now or in the past, it may be worthwhile to determine the scope and scale of distribution, as well as any warning statements or health and safety information that may have been issued to customers. Information on how PFAS-containing substances were disposed of or otherwise released to the environment would also be relevant.

It is important for companies to consider that when a chemical is deemed toxic, the government will deal with it, such as through remediation, and look to shift costs to industry and other third parties. This impacts the liability affecting companies, including increasing governmental investigations, enforcement actions by states for breaches of codified laws, litigation by states and private parties under common law or for breaches of statutory/regulatory provisions, and indirect liabilities due to supply chain disruptions or contractual breaches. Moreover, it would behoove any company conducting a PFAS audit of this type to do so under the direction of counsel to maximize the scope of privilege.

Finally, foreign corporations looking to acquire real property or other businesses in the United States are strongly encouraged to account for PFAS in their transactional due diligence.

Notes

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1. Significant New Use Rule, Envt. Prot. Agency, 67 Fed. Reg. 72,854 (Dec. 9, 2002) (codified at 40 C.F.R. pt. 721); Perfluoroalkyl Sulfonates; Significant New Use Rule, Envt. Prot. Agency, 67 Fed. Reg. 11,0008 (Mar. 11, 2002) (codified at 40 C.F.R. pt. 721); Perfluoroalkyl Sulfonates.

2. https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024.

3. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, Envt. Prot. Agency, 85 Fed. Reg. 45,109 (July 27, 2020) (codified at 40 C.F.R. pt. 721); Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule, Envt. Prot. Agency, 78 Fed. Reg. 62,443 (Dec. 23, 2013) (codified at 40 C.F.R. pts 9, 721); Perfluoroalkyl Sulfonates; Significant New Use Rule, Envt. Prot. Agency, 72 Fed. Reg. 57,222 (Oct. 9, 2007) (codified at 40 C.F.R. pt. 721); Perfluoroalkyl Sulfonates; Significant New Use Rule, Envt. Prot. Agency, 67 Fed. Reg. 72,854 (Dec. 9, 2002) (codified at 40 C.F.R. pt. 721); Perfluoroalkyl Sulfonates; Significant New Use Rule, Envt. Prot. Agency, 67 Fed. Reg. 11,0008 (Mar. 11, 2002) (codified at 40 C.F.R. pt. 721).

4. EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan, Envt. Prot. Agency, EPA 823R18004 (Feb. 2019), https://www.epa.gov/sites/default/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

5. Preliminary indications are that the agency will look to designate some 29 additional PFAS as high priority along the same lines as these two chemicals in the aftermath of the sampling conducted pursuant to the fifth Unregulated Contaminant Monitoring Rule; see https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule.

6. 42 U.S.C. §§ 9601 et seq.

7. 42 U.S.C. §§ 300f et seq.

8. PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (Mar. 29, 2023).

9. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping.

10. E.g., Groundwater Information Sheet: Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS), California Water Resources Control Board, https://www.waterboards.ca.gov/gama/docs/pfoa.pdf; 310 Code Mass. Reg. 22.00 Massachusetts Drinking Water Regulations.

11. Me. Stat. tit. 38, § 1614 (2021).

12. State Water Resource Control Board, PFAS Phased Investigation Approach, CA Water Boards (Mar. 6, 2019), at https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfas_consolidated_training_040319.pdf.

13. Guidelines for Sampling and Analysis of PFAS Under NYSDEC's Part 375 Remedial Programs, N.Y. State Dep't of Envt. Conservation (Jan. 2020); New Jersey Safe Drinking Water Act, N.J.A.C. 7:10; Private Well Testing Act, N.J.A.C. 7:9E; Ground Water Quality Standards, N.J.A.C. 7:9C; New Jersey

Pollutant Discharge Elimination System Rules, N.J.A.C. 7:14A, List of Hazardous Substances, N.J.A.C. 7:1E.

14. Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems, Envt. Prot. Agency, 77 Fed. Reg. 26,072 (May 2, 2012).

15. In re E.I. Du Pont De Nemours and Company C-8 Personal Injury Litigation, U.S. District Court for Southern Ohio, No. 13-2433.

16. Bell v. 3M Co., Nos. 16-CV-02351-RBJ, 16-CV,02394-RBJ, 16-CV-02352-RBJ (D. Colo.); Wolverine World Wide, Inc. v. 3M Co., No. 1:18-CV-00039-JTN-ESC (D. Mich.); New York v. 3M Co., No. 904029-18 (N.Y. Sup. Ct. June 19, 2018).

17. W. Morgan-E. Lawrence Water & Sewer Auth. v. 3M Co., No. 17-12381 (11th Cir. Jun. 4, 2018).

18. State of Minnesota v. 3M Co., No. 27-CV-10-25562 (Minn. 4th Dist.).

19. Wolverine World Wide, Inc. v. 3M Co., No. 1:18-CV-00039-JTN-ESC (D. Mich.).

20. Wolverine World Wide PFAS Settlement, Plainfield Charter Township, https://www.plainfieldmi.org/information_about/pfas_settlement/index.php.

21. https://www.ewg.org/interactive-maps/pfas_contamination/.

22. Product Investigations, Mamavation, https://www.mamavation.com/product-investigations#PFAS_%E2%80%9CForever_Chemicals%E2%80%9D_Consumer_Studies_with_Lab_Testing.