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INSIDER TRADING IN THE CLINICAL TRIAL SETTING

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ABSTRACT

The Securities and Exchange Commission's enforcement agenda regularly includes charges of trading based on material nonpublic information about a clinical drug trial conducted to obtain FDA approval to market a new drug. Almost half of the recent cases have been accompanied by a criminal indictment.

In an academic setting, researchers and those who advise them, unlike employees of public companies, are not generally given training about the risks of securities trading. Recent developments in the law might be applied in connection with clinical trial information in ways that would not have been foreseen until recently. It is time for a comprehensive analysis of how the law of insider trading may be applied to the important endeavor of clinical drug trials. Clinical trials should not be sullied by conflicts created by unlawful trading.

This Article begins with the basic principles of insider trading, followed by a summary of how clinical trials are conducted and regulated. It then turns to the ways in which nonpublic information material to the stock price of the sponsor of the trial might be used to trade or tip.

The analysis that follows identifies a number of situations where use or disclosure of material nonpublic information about a trial could be unlawful. Employees of sponsors of the trial, clinical investigators, and even the subjects

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participating in a trial could run afoul of the prohibition on insider trading, such as when information has been used in breach of a confidentiality agreement or exchanged between an investigator and a trial participant, exchanged among trial participants, gleaned from attending medical conferences, and obtained in other settings specific to this industry. Presenting the full potential reach of the law facilitates taking steps to *avoid* violating the law.

The analysis demonstrates that anyone involved in a clinical drug trial must be attuned to the risks of misusing material nonpublic information, including in scenarios not yet pursued by the SEC. By understanding the potential reach of the law, those involved in or who learn information about a specific trial can take steps to avoid or minimize the risk of liability.

The Article concludes with recommendations to achieve this end. The Article thus presents a complete case study of an industry-specific application of insider trading law, with recommendations that can be applied to other industries.

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I. INTRODUCTION

A substantial body of federal common law delineates when it is unlawful to trade in securities based on material nonpublic information (“MNPI”) relating to the company that issued the securities.¹ This law springs primarily from Securities and Exchange Commission (“SEC” or “Commission”) Rule 10b-5,² adopted pursuant to authority granted by Section 10(b) of the Securities Exchange Act of 1934 (“Exchange Act”).³ Rule 10b-5 is the basis for a substantial proportion of all SEC civil and DOJ criminal cases for a violation of the securities laws, including insider trading.⁴

No drug can be marketed in interstate commerce without the prior approval of the federal Food and Drug Administration (“FDA”),⁵ a division of the

1. See DONALD C. LANGEVOORT, *INSIDER TRADING: REG., ENF’T & PREVENTION* § 1:10 (2022) (the two principal theories of insider trading under Rule 10b-5 “are largely federal common law concepts accepted judicially as a way of interpreting the very general language of Rule 10b-5”). See *infra* Part II.G (identifying proposed legislative changes). Most references in this Article to “insider trading” mean “unlawful insider trading.” There is no detailed discussion of state securities laws or state case law that prohibits or provides a remedy for insider trading. See STEPHEN M. BAINBRIDGE, *INSIDER TRADING L. & POL’Y* ch. 2 (2014) (discussing state law of insider trading). Most notably, Delaware courts recognize a cause of action on behalf of the company to recover insider trading profits reaped by insiders. See *Brophy v. Cities Serv. Co.*, 70 A.2d 5 (Del. 1949).

2. 17 C.F.R. § 240.10b-5. It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange, (a) to employ any device, scheme, or artifice to defraud, (b) to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or (c) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

3. 15 U.S.C. § 78j(b).

4. See, e.g., DONNA M. NAGY ET AL., *SECURITIES LITIGATION, ENFORCEMENT, AND COMPLIANCE: CASES AND MATERIALS* 23 (5th ed. 2023) (“Rule 10b-5 is the leading anti-fraud weapon in the federal securities laws.”).

5. 21 U.S.C. § 355.

Department of Health and Human Services (“HHS”),⁶ after a clinical trial.⁷

This Article evaluates many scenarios where insider trading might occur in the context of a clinical trial. While there have been many SEC enforcement actions charging insider trading based on MNPI about clinical trials,⁸ there has been scant scholarly attention to the insider trading issues peculiar to that highly regulated framework.⁹ The prevalence of these claims demonstrates that a comprehensive analysis is called for to address conduct that might be unlawful and *how to avoid it*. This Article applies both recognized and developing principles of insider trading to all stages of a clinical trial.

Parts II and III explain the core principles of the law of insider trading. Part IV describes the framework for conducting human clinical drug trials to obtain FDA approval. Parts V and VI address how the law of insider trading, as well as Rule 10b-5 more broadly, has been applied and *might be applied* where there is MNPI regarding a trial. Part VII recommends measures to reduce the risk of violating the law for anyone who might be involved in or learn about a clinical trial, including medical doctors, other investigators, and the trial participants, sometimes called “subjects,” in a clinical trial, Part VIII concludes.

II. THE FUNDAMENTALS OF THE LAW OF INSIDER TRADING UNDER RULE 10B-5

The SEC can pursue civil enforcement charges for insider trading in a federal court or at the SEC itself in an administrative proceeding.¹⁰ Only the DOJ can

6. See *Food & Drug Administration*, HHS.GOV, <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/fda/index.html> [<https://perma.cc/7HPH-CBXP>] (last updated Mar. 18, 2016) (“The Food and Drug Administration (FDA) is an HHS agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices.”).

7. 45 C.F.R. § 46.102(b). The FDA defines “clinical trial” to mean a “research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” FDA requirements are described in more detail in Part IV.

8. See, e.g., *infra* text accompanying notes 22-25 and 115-21 (discussing cases).

9. See, e.g., Allan Horwich, *The Clinical Trial Research Participant as An Inside Trader: Legal and Policy Analysis*, 39 J. HEALTH L. 77 (2006); Aaron S. Kesselheim et al., *Physicians and Insider Trading*, 175 JAMA INTERNAL MED. 1955 (2015); James R. Ferguson, *Biomedical Research and Insider Trading*, 337 NEW ENG. J. MED. 631 (1997); Robert A. Prentice, *Clinical Trial Results, Physicians, and Insider Trading*, 20 J. LEGAL MED. 195 (1999); Paul R. Helft et al., *Inside Information: Financial Conflicts for Research Subjects in Early Phase Clinical Trials*, 96 J. NAT’L CANCER INST. 656 (2004).

10. See Exchange Act Sections 21, 21A, 21B(a)(2), and 21C, 15 U.S.C. §§ 78u, 78u-1, 78u-2(b)(2), 78u-3. There is limited discussion here of the sanctions that are available. See LANGEVOORT, *supra* note 1, ch. 8 (describing civil and criminal remedies for unlawful insider trading). Throughout this Article, however, there are descriptions of the sanctions imposed or agreed to in specific cases, to demonstrate the potential severity of the consequences of engaging in insider trading. Someone who has engaged in insider trading may also be sued by an investor for

prosecute criminal charges; the SEC can, however, suggest that the DOJ do so.¹¹ What follows provides a primer of the law of insider trading sufficient to understand its potential application in the clinical trial setting.

A. The Classical Theory of Insider Trading

Under the classical, or traditional, theory of insider trading, Rule 10b-5 is “violated when a corporate insider trades in the securities of his corporation on the basis of material, nonpublic information” about the company or its securities.¹² This violates Rule 10b-5 because “a relationship of trust and confidence” exists “between the shareholders of a corporation and those insiders who have obtained confidential information by reason of their position with that corporation,” which gives rise to a duty to make public disclosure before trading or to abstain from trading.¹³ This is the “disclose or abstain” rule.¹⁴

Under the classical theory, an “insider” subject to this duty includes not only a member of the board of directors and a senior officer of the company but also *any* employee of the company that issued the securities in which the “insider” traded.¹⁵ This also includes a “temporary insider”:

Under certain circumstances, such as where corporate information is revealed legitimately to an underwriter, accountant, lawyer, or consultant working for the corporation, these outsiders may become fiduciaries of the shareholders. The basis for recognizing this fiduciary duty is not simply that such persons acquired nonpublic corporate information, but rather that they have entered into a special confidential relationship in the conduct of the business of the enterprise and are given access to information solely for corporate purposes.¹⁶

For example, the lead investigator of a clinical trial who works for an academic institution may be a temporary insider of the trial sponsor.¹⁷

B. The Misappropriation Theory of Insider Trading

Under the misappropriation theory of insider trading, a person violates Rule

damages, relying on Rule 10b-5 or Exchange Act Section 20A, 15 U.S.C. § 78t-1 (providing for private cause of action). *See* LANGEVOORT, *supra* note 1, ch. 9 (describing private claims for insider trading).

11. Exchange Act Section 21(d)(1), 15 U.S.C. § 78u(d)(1) (last sentence).

12. *United States v. O’Hagan*, 521 U.S. 642, 651-52 (summarizing the import of *Chiarella v. United States*, 445 U.S. 222, 228 (1980)).

13. *O’Hagan*, 521 U.S. at 652.

14. *See* Bainbridge, *supra* note 1, ch. 6.

15. *See* LANGEVOORT, *supra* note 1, § 3:5 (“Employees of the issuer are agents/servants of the corporation and are held to duties of loyalty that include the obligation not to profit from confidential information given to them in the course of their employment.”).

16. *Dirks v. SEC*, 463 U.S. 646, 655 n.14 (1983).

17. *See infra* text accompanying notes 22-25 (discussing case).

10b-5 when he takes confidential information for securities trading purposes, in breach of a duty owed to the source of the information, because a fiduciary's undisclosed, self-serving use of a principal's information to purchase or sell securities, in breach of a duty of loyalty and confidentiality, defrauds the principal of the exclusive use of that information.¹⁸ Trading before first making disclosure *to the source of the information* of the intent to trade based on MNPI violates Rule 10b-5; there is no requirement that the trader first obtain permission from the source to trade or, unlike the classical theory, to make *public* disclosure before trading.¹⁹

1. Relationship of Trust and Confidence

a. Caselaw

Initially it fell to the courts to determine what constituted a “relationship of trust and confidence.”²⁰ A relationship of trust and confidence might exist between employer and employee, doctor and patient, attorney and client, and among family members, as well as where there is a confidentiality agreement, requiring the application of state law.²¹

Two insider trading criminal convictions demonstrate how the misappropriation theory has been applied in a medical setting. Trading in breach of confidentiality agreements was the basis for the conviction of a medical doctor who held a senior role at one clinical trial site.²² He had been required “to maintain in ‘strict confidence’ all the information with which he was provided to enable him to perform as principal investigator.”²³ When he received confidential

18. *O'Hagan*, 521 U.S. at 652-53 (recognizing and applying misappropriation theory, resolving circuit split).

19. *Id.* See also *United States v. Falcone*, 257 F.3d 226, 232 n.3 (2d Cir. 2001) (stating that notwithstanding the damaging effect of inequality of information vis-à-vis the public, disclosure to the information source can eliminate liability under the misappropriation theory).

20. See Bainbridge, *supra* note 1, at 81-85 (discussing pre-*O'Hagan* developments and the ensuing circuit split).

21. WILLIAM K. S. WANG & MARC I. STEINBERG, *INSIDER TRADING* § 5.4.3 (3d ed. 2010) (citing and discussing cases); LANGEVOORT, *supra* note 1, §§ 6:6-6:7 (including extended discussion of major cases); Bainbridge, *supra* note 1, ch. 8C (discussing covered relationships).

22. *United States v. Kosinski*, 976 F.3d 135 (2d Cir. 2020) (affirming insider trading convictions). Kosinski was sentenced to six months imprisonment, among other penalties. *SEC v. Kosinski*, Litig. Release No. 25077, 2021 WL 1580442 (Apr. 21, 2021). In another recent case where a principal investigator was indicted for trading based on material clinical trial results, the defendant pleaded guilty and was sentenced to a year of supervised release, with the first five months under home confinement. Ivan Moreno, *Ex-UChicago Professor Avoids Prison for Insider Trading*, LAW360 (Aug. 3, 2022, 7:52 PM), <https://www.law360.com/capitalmarkets/articles/1518062/ex-uchicago-professor-avoids-prison-for-insider-trading?about=capitalmarkets> [<https://perma.cc/9JHY-N8RN>].

23. *Kosinski*, 976 F.3d at 140.

bad news about the trial, he sold the stock he owned in the trial sponsor. As more bad news emerged internally, he bought put options on the stock, presumably concluding that when the news became public the price of the stock would drop, which it did, with a corresponding increase in the value of the puts.²⁴ The defendant was held to have misappropriated the information he received by trading in breach of the confidentiality agreements and to have violated Rule 10b-5 by trading based on MNPI he received as a temporary insider of the sponsor.²⁵

In an earlier case, *United States v. Willis*, a patient allegedly confided to her psychiatrist that her husband was seeking to become the CEO of a major financial institution.²⁶ After Dr. Willis learned this information in the therapy session, he purchased stock in that company. When the husband's appointment as CEO was announced and the stock price rose, Willis sold at a profit. In denying a motion to dismiss the indictment, the court stated that “[a] treating psychiatrist’s relationship to his patient is a traditional inherently fiduciary relationship,”²⁷ and so applied the misappropriation theory to Willis’s breach of duty to the patient.

b. Rule 10b5-2

The SEC sought to bring some clarity to the concept of the relationship of trust and confidence in misappropriation cases by adopting Rule 10b5-2(b).²⁸ It provides in part that a “duty of trust or confidence” exists:

- (1) Whenever a person agrees to maintain information in confidence;
- (2) Whenever the person communicating the material nonpublic information and the person to whom it is communicated have a history, pattern, or practice of sharing confidences, such that the recipient of the information knows or reasonably should know that the person communicating the material nonpublic information expects that the recipient will maintain its confidentiality[.]²⁹

24. *Id.* at 139. The sponsor terminated the clinical trial because of adverse reactions to the drug, including one death.

25. *Id.* at 144-46 (applying temporary insider concept in misappropriation case).

26. *United States v. Willis*, 737 F. Supp. 269, 271 (S.D.N.Y. 1990) (initial opinion denying motion to dismiss indictment); *see also* *United States v. Willis*, 778 F. Supp. 205 (S.D.N.Y. 1991) (denying motion to dismiss indictment a second time, after consideration of intervening Second Circuit insider trading case).

27. *Willis*, 778 F. Supp. at 209. Willis pleaded guilty and was sentenced to a five-year term of probation and other penalties. *Inside-Trading Psychiatrist Is Spared Jail: Securities: A New York Man Who Obtained Stock Information from A Patient--The Wife of A Top Executive--Gets Probation And A \$150,000 Fine*, LA TIMES ARCHIVES (Jan. 8, 1992, 12:00 AM), <https://www.latimes.com/archives/la-xpm-1992-01-08-fi-1619-story.html> [<https://perma.cc/57BX-6JQZ>].

28. Whether this Rule is valid is beyond the scope of this Article. *See* *United States v. McKee*, 763 F.3d 304, 316 (3d Cir. 2014) (upholding Rule 10b5-2 but also stating “we are not without reservations concerning the breadth of misappropriation under Rule 10b5-2(b)(2)”).

29. 17 C.F.R. § 240.10b5-2(b).

When an insider has received MNPI from the corporation in confidence and then uses it to trade, both the classical theory and the misappropriation theory apply.³⁰

C. The Deception Theory

A third category of a violation of Rule 10b-5 violations involves obtaining MNPI by affirmative deception and subsequent trading based on that information.³¹ The seminal case involved “deceiving” a computer system, apparently using hacked credentials of an authorized person so that the system was deceived into allowing the trader access to nonpublic earnings information he used to trade.³²

D. Culpability

There is a state of mind, or culpability, requirement in every case under Rule 10b-5. Early in its Rule 10b-5 jurisprudence, the Supreme Court held that an essential element of any Rule 10b-5 claim is that the defendant acted with scienter—an “intent to deceive, manipulate or defraud.”³³ Negligence does not suffice.³⁴ This applies to Rule 10b-5 enforcement actions.³⁵ In a civil insider trading case, for example, the SEC must prove that the defendant knew, or was reckless in disregarding, that the MNPI was material and nonpublic.³⁶ In criminal

30. See *United States v. Kosinski*, 976 F.3d 135, 145 (2d Cir. 2020). “Temporary insiders are . . . forbidden from trading under both the classical and misappropriation theories without the requisite disclosure. Indeed, the only meaningful difference between the two theories is the victim of the fraud. Where, as here, a trader owes a duty to both the shareholders with whom he trades and the source of the confidential information on which he trades, he must make disclosure to both.” In complaints for insider trading, the SEC seldom specifies which theory it is relying on.

31. *SEC v. Dorozhko*, 574 F.3d 42, 49-51 (2d Cir. 2009) (obtaining MNPI through deceptive means and then trading based on that information may violate Rule 10b-5).

32. See *SEC v. Dorozhko*, SEC Litig. Release No. 21465, 2010 WL 1213430 (Mar. 29, 2010) (summarizing the court’s grant of summary judgment to SEC on remand of *Dorozhko*).

33. *Ernst v. Hochfelder*, 425 U.S. 185, 193, n.12 (1976) (footnote omitted).

34. *Id.* at 203, 215. While the Court observed that “[i]n certain areas of the law recklessness is considered to be a form of intentional conduct,” the Court did not determine whether recklessness was sufficient. *Id.* at 193 n.12. The Court has not addressed the question since *Hochfelder*; all Courts of Appeals that have addressed the issue have found scienter to include reckless conduct, variously defined. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 n.3 (2007).

35. *Aaron v. SEC*, 446 U.S. 680, 691 (1980) (“the rationale of *Hochfelder* ineluctably leads to the conclusion that scienter is an element of a violation of § 10(b) and Rule 10b-5, regardless of the identity of the plaintiff or the nature of the relief sought”). See *Dirks v. S.E.C.*, 463 U.S. 646, 663 n.23 (1983) (discussing application of scienter requirement in insider trading case); see generally LANGEVOORT, *supra* note 1, §§ 3:13, 6:12 (discussing scienter under classical and misappropriation theories).

36. See LANGEVOORT, *supra* note 1, § 5.5 (“scienter is established if the defendant knew that the information was material and nonpublic, or recklessly disregarded facts that would indicate that

cases, Section 32 of the Exchange Act requires that the government prove willful misconduct,³⁷ which means “[w]illful intentional, purposeful, and voluntary, as distinguished from accidental or negligent.”³⁸

E. Tipping

Where the person who knows MNPI cannot lawfully trade, it may be unlawful for him to disclose that MNPI to another: tipping. In the Supreme Court’s first tipping case, a company insider provided MNPI to Dirks, a stockbroker, hoping Dirks would bring public attention to what the insider believed, accurately, was a massive fraud at the company.³⁹ While Dirks was trying to bring the fraud to light, he also disclosed the MNPI to some of his customers. They sold their stock in the company before the truth was revealed, and the stock price plummeted.⁴⁰ The SEC brought an administrative proceeding against Dirks as a broker, alleging that he violated the Exchange Act when he provided MNPI to his customers.⁴¹

The Supreme Court held that insiders may not disclose MNPI to an outsider, a “tippee,” for the “improper purpose of exploiting the information for their personal gain.”⁴² “[T]he test is whether the insider personally will benefit, directly or indirectly, from his disclosure. Absent some personal gain, there has been no breach of duty to stockholders. And absent a breach by the insider, there is no derivative breach” by the tippee who trades.⁴³ The tippee is liable “when the insider has breached his fiduciary duty to the shareholders by disclosing the information to the tippee and the tippee knows or should know that there has been a breach.”⁴⁴

In assessing whether a disclosure breached a duty, the fact-finder should look to “objective criteria, *i.e.*, whether the insider receives a direct or indirect personal

the information in his possession was material and nonpublic”) (footnote omitted). In the tipping context (discussed *infra* Part II.E), see *SEC v. Obus*, 693 F.3d 276, 286 (2d Cir. 2012) (finding that “the tipper must know that the information that is the subject of the tip is non-public and is material for securities trading purposes or act with reckless disregard of the nature of the information”).

37. 15 U.S.C. § 78ff (providing criminal sanctions of up to twenty years in prison, a fine of five-million dollars (or up to twenty-five-million dollars in the case of a defendant other than a natural person) or both for “willfully violat[ing]” an SEC rule).

38. *See, e.g.*, *United States v. O’Hagan*, 139 F.3d 641, 647 (8th Cir. 1998) (ruling that “willfully” requires only the intentional doing of the wrongful acts, there is no requirement that the defendant knew of the rule or regulation that was violated).

39. *Dirks*, 463 U.S. at 646.

40. *Id.* at 649-50.

41. *In re Dirks*, Securities Exchange Act Release No. 17480, 1981 WL 36329 (Jan. 22, 1981) (finding that Dirks aided and abetted his customers’ violations of Rule 10b-5), *pet. for rev. dismissed*, 681 F.2d 824 (D.C. Cir. 1982), *rev’d* 463 U.S. 646 (1983).

42. *Dirks*, 463 U.S. at 660 (footnotes omitted).

43. *Id.* at 662 (footnote omitted).

44. *Id.* at 660 (footnote omitted).

benefit from the disclosure, such as a pecuniary gain or a reputational benefit that will translate into future earnings.”⁴⁵ For example, “there may be a relationship between the insider and the recipient that suggests a *quid pro quo* from the latter, or an intention to benefit the particular recipient.”⁴⁶ The Court exonerated Dirks because, among other factors, the persons who gave Dirks the information did so for a proper purpose, to reveal the fraud.⁴⁷

One element of tipper liability is that the tipper must have expected or reasonably expected that the tippee would trade based on the MNPI shared by the tipper.⁴⁸ A tipper may be liable when the tippee is not liable, even though the tippee traded.⁴⁹

Two aspects of tipping liability should be kept in mind when reading the analysis in Parts V and VI *infra*. First, application of the law of tipping in the clinical trial setting may focus on whether the tipper would benefit by tipping, and what the nature of that benefit might be. That is, however, only one element of tipping. Though it will not be repeated every time a tipping question is addressed here, the essential elements of (a) whether the tipper breached a duty by tipping, (b) whether the tippee understood that the tipper breached by tipping, and (c) whether the tipper had some expectation that the tippee would trade, *must eventually be addressed in order to do a comprehensive analysis*.

Second, misappropriation and tipping are distinctly different paths to liability. If X gave Y MNPI so that Y can do his job, to fulfill some sort of lawful responsibility, and then Y, instead of or in addition to the proper purpose, used that information to trade in the stock, Y engaged in misappropriation in violation of Rule 10b-5, *if* Y had a relationship of trust and confidence with X. If, however, X provided Y, the MNPI with the expectation that Y would trade and Y did trade, then X has likely disclosed MNPI to Y for an improper purpose, and, depending on what Y understood about the nature of the disclosure by X to him (*e.g.*, did Y recognize that X’s disclosure was in breach of a duty?), Y might be an unlawful tippee.

45. *Id.* at 663-64 (citations omitted).

46. *Id.* at 664 (citations omitted).

47. *Id.* at 666-67.

48. In the criminal context, see *Salman v. United States*, 137 S. Ct. 420, 428 (2016) (ruling that tipper must be shown to have expected tippee would trade). In the civil enforcement context, see *SEC v. Obus*, 693 F.3d 276, 287 (2d Cir. 2012) (ruling that test is whether tippee “may reasonably be expected [by the tipper] to use [MNPI] to his advantage,” (*quoting* *Elkind v. Liggett & Myers, Inc.*, 635 F.2d 156, 167 (2d Cir. 1980)). In *Obus*, the court stated that in a civil case “there is a valid defense to scienter if the tipper can show that he believed in good faith that the information disclosed to the tippee would not be used for trading purposes.” *Id.* at 287. See LANGEVOORT, *supra* note 1, § 4:10 (discussing various aspects of tippee scienter).

49. See, *e.g.*, *SEC v. Tome*, 638 F. Supp. 596, 617 (S.D.N.Y. 1986) (“Even if there has been a breach by the tipper of his fiduciary or similar duty of trust and confidence, the tippee only commits fraud within the meaning of Section 10(b) and Rule 10b-5 if the tippee trades on that inside information when he ‘knows or should know’ that the inside information was conveyed to him in breach of the tipper’s duty.”).

F. Proposed Legislative Changes to Insider Trading Law

Congress has made some efforts to define insider trading in legislation.⁵⁰ Most recently, on May 18, 2021, the House of Representatives passed H.R. 2655, the Insider Trading Prohibition Act.⁵¹ No action was taken in the Senate.⁵² The operative provision would have predicated liability on the misuse of information “obtained wrongfully.” The bill defined that to include information obtained by:

- (A) theft, bribery, misrepresentation, or espionage (through electronic or other means);
- (B) a violation of any Federal law protecting computer data or the intellectual property or privacy of computer users;
- (C) conversion, misappropriation, or other unauthorized and deceptive taking of such information; or
- (D) a breach of any fiduciary duty, a breach of a confidentiality agreement, a breach of contract, a breach of any code of conduct or ethics policy, or a breach of any other personal or other relationship of trust and confidence for a direct or indirect personal benefit (including pecuniary gain, reputational benefit, or a gift of confidential information to a trading relative or friend).⁵³

III. MATERIAL NONPUBLIC INFORMATION

The prohibitions discussed here apply only to information that is both material and not public. This Part explains these concepts in general terms; they are expanded upon and applied in Parts VI.C and VI.D.

The analysis of these issues is informed not only by insider trading cases, but also by other litigation under Rule 10b-5. Every public company is vulnerable to a Rule 10b-5 class action claim by investors that its public disclosures, such as press releases and filings with the SEC, misled investors.⁵⁴ Pharmaceutical companies are no exception, though they often successfully fend off the claim on a motion to dismiss.⁵⁵ One commentator reported that in the first six months of

50. LANGEVOORT, *supra* note 1, ch. 13 (including an account of prior efforts to reform the law of insider trading through legislation).

51. Insider Trading Prohibition Act, H.R. 2655, 117th Cong. (2021), *reprinted in* 167 CONG. REC. H2460 (daily ed. May 18, 2021); LANGEVOORT, *supra* note 1, ch. 13 (including an account of prior efforts to reform the law of insider trading through legislation).

52. H.R. 2655.

53. *Id.* (proposed new Section 16A(c)(1) of the Exchange Act).

54. *See* ARNOLD S. JACOBS, DISCLOSURE & REMEDIES UNDER THE SECURITIES LAWS § 12:112 (2022) (discussing cases of corporate liability for misleading statements in violation of Rule 10b-5).

55. *See, e.g.*, *Thant v. Karyopharm Therapeutics Inc.*, 43 F.4th 214 (1st Cir. 2022) (affirming dismissal of complaint that alleged that company materially misled investors in statements about a trial for its cancer-fighting drug, finding that plaintiff did not plausibly allege a materially

2022, drug companies were the second largest category of business sued in securities class actions.⁵⁶ They are also vulnerable to SEC enforcement actions for misleading investors.⁵⁷

Any ruling in a class action complaint that alleges that a *company* made deceptive statements about a drug in development is instructive on elements of insider trading by an individual in the pharmaceutical setting. For example, investor-plaintiffs in a Rule 10b-5 class action often seek to demonstrate the required element of scienter of the company or of the individual defendants in making materially false statements to the public, by alleging that members of management engaged in insider trading.⁵⁸ Any determination of what is found to be material in a class action will shed light on what information is material generally, and in particular, in a parallel insider trading case.

A. Nonpublic Information

If information can be found in an internet search, it is almost certainly not “nonpublic.”⁵⁹ Information can be public even if it is not generally available, however, such as a report by a research analyst provided only to his clients.⁶⁰ Information can also be “public” even if it does not meet the test of what a public company must do when it seeks to achieve public disclosure. For example, in 2000, the SEC adopted a regulation that required “public disclosure” of

misleading statement or omission with respect to the drug trial disclosures).

56. Kevin LaCroix, *Pace of Securities Suit Filings in First Half 2022 Slightly Below Last Year's Annual Level*, D&O DIARY (July 5, 2022), <https://www.dandodiary.com/2022/07/articles/securities-litigation/pace-of-securities-suit-filings-in-first-half-2022-slightly-below-last-years-annual-level/> [<https://perma.cc/N79B-XYAL>] (referring to companies in SIC Code 283).

57. *See* SEC v. Ferrone, No. 11-C-5223, 2014 WL 5152367 (N.D. Ill. Oct. 10, 2014) (granting summary judgment to S.E.C. on insider trading claim regarding status of clinical trial). Investors filed a class action based on the same nucleus of facts. *Compl., Campbell v. Immunosen Corp.*, No. 09-cv-00197 (S.D. Tex. Aug. 24, 2009), ECF No. 1.

58. *See supra* text accompanying notes 31-36. In the pharmaceutical field, see *Compl.* at ¶¶ 3-5, 6, 24, 28, 36, 134-37, *In re Fibrogen, Inc., Sec. Litig.*, No. 21-cv-02623 (N.D. Cal., Oct. 29, 2021), ECF No. 91 (alleging insider trading by executives as supporting allegation of scienter in Rule 10b-5 class action complaint regarding public statements regarding alleged falsified Phase III clinical trial results).

59. Robert A. Prentice, *The Internet and its Challenges for the Future of Insider Trading Regulation*, 12 HARV. J. L. & TECH. 263, 282-83 (1999) (stating that availability of information on internet may be “public” for purposes of insider trading law, though the issue is not free from doubt).

60. *See, e.g.,* *Lea v. TAL Educ. Grp.*, 837 F. App'x 20, 27-28 (2d Cir. 2020) (holding that disclosure of previously nonpublic information and of information not readily accessible by investors that is included in securities firm research report followed by significant loss in company's stock price was sufficient allegation of public disclosure of prior misleading statements for purposes of a Rule 10b-5 issue before the court).

previously nonpublic information in certain circumstances.⁶¹ “[P]ublic disclosure” includes “disseminat[ing] the information through [a] method (or combination of methods) of disclosure that is reasonably designed to provide broad, non-exclusionary distribution of the information to the public.”⁶²

An alternative test recognizes that information is no longer nonpublic “even though there has been no public announcement” where the trading of those who *do* know the information has caused the information to be “fully impounded into the price of the particular stock. Once the information is fully impounded in price, such information can no longer be misused by trading because no further profit can be made.”⁶³

B. Material Information

A fact is material if there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision. An omitted fact is material if there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the “total mix” of information made available.⁶⁴ “[W]ith respect to contingent or speculative information or events . . . materiality ‘will depend at any given time upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.’”⁶⁵ This probability/magnitude test could apply in a clinical trial setting, as more information emerges, resulting in more—or less—confidence in the outcome of the trial.⁶⁶

In a case addressing the materiality of adverse events that might have been caused by a drug already on the market, defendants argued that facts that are not statistically significant cannot be material.⁶⁷ The Supreme Court rejected that bright line rule, noting that the “FDA . . . does not limit the evidence it considers for purposes of assessing causation and taking regulatory action to statistically significant data[,]” and “[g]iven that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well.”⁶⁸

A significant movement in the price of a stock after disclosure of previously

61. SEC Regulation F.D., 17 C.F.R. § 243 (2011).

62. 17 C.F.R. § 243.101(e) (2011).

63. *United States v. Libera*, 989 F.2d 596, 601 (2d Cir. 1993).

64. *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

65. *Id.* at 238 (quoting *SEC v. Tex. Gulf Sulphur Co.*, 401 F.2d 833, 849 (2d Cir. 1968) (en banc)).

66. *SEC v. Johnston*, 986 F.3d 63, 76-77 (1st Cir. 2021) (approving probability/magnitude jury instruction in affirming judgment against defendant for having misled investors in statements relating to clinical trial). *See also infra* Part III.B.

67. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011).

68. *Id.* at 40, 43 (citations to cases and to the record omitted).

undisclosed facts is often evidence that the facts were material.⁶⁹ Disclosure of the results of a drug trial can have a significant effect on the price of the sponsoring company's stock, especially where the company's fortunes stand or fall with whether the particular drug is approved by the FDA.⁷⁰

Determining whether a fact is material depends on an assessment of all of the facts.⁷¹ “[M]ateriality has become one of the most unpredictable and elusive concepts of the federal securities laws.”⁷²

IV. AN OVERVIEW OF THE CLINICAL TRIAL FRAMEWORK

This Part describes the requirements for conducting a clinical trial sufficient to understand the application of insider trading law to that endeavor, for all persons involved—from the firm sponsoring the trial to clerical personnel who record trial data.⁷³ Because SEC enforcement actions for insider trading typically involve transactions in the stock of a public company, the focus in this Article is on clinical trials where the outcome of the trial reasonably could affect the value of the stock of a publicly traded company, the sponsor, seeking FDA approval to

69. See, e.g., *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) (holding that in an efficient stock market “the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm’s stock”). *But see*, *United States v. Bilzerian*, 926 F.2d 1285, 1298 (2d Cir. 1991) (ruling that whether a stock price moves after disclosure of the previously undisclosed facts “does not establish the materiality of the statements made”). One study addressed the difficulty of analyzing stock price movements where clinical trials are involved. See Adam Feuerstein & Mark J. Ratain, *Oncology Micro-Cap Stocks: Caveat Emptor!*, 103 J. NAT. CANCER INST. 1488, 1489 (2011).

70. See, e.g., *United States v. Kosinski*, 976 F.3d 135, 141 (2d Cir. 2020) (alleging stock price dropped 58% after announcement of termination of clinical trial); Order Instituting Proceedings, *In re Sweeney*, Securities Exchange Act Release No. 95204 (July 7, 2022) (alleging that stock dropped 71% after disclosure of discontinuance of clinical trial); Order Instituting Proceedings at ¶ 6, *In re Spector*, Securities Exchange Act Release No. 95163 (June 27, 2022) (alleging, in clinical trial insider trading case, where company “had never generated revenues and depended on products then in development for future revenues” and the drug in question “was its lead product candidate, and the only one publicly identified as having advanced to the clinical trial stage of development,” stock dropped 75% when bad news was disclosed.). *Id.* at ¶ 13.

71. See, e.g., Joan MacLeod Heminway, *Materiality Guidance in the Context of Insider Trading: A Call for Action*, 52 AM. U. L. REV. 1131, 1138-39 (2003) (“The interpretation and application of the materiality standard are highly fact-dependent and do not always produce predictable or certain planning options or judicial results.”) (footnote omitted).

72. *SEC v. Bausch & Lomb Inc.*, 565 F.2d 8, 10 (2d Cir. 1977). See also JAMES D. COX ET AL., *SECURITIES REGULATION CASES AND MATERIALS* 552 (10th ed. 2021) (making these judgments is an “ulcerating experience”).

73. For a comprehensive description of the clinical trial process from the perspective of the researcher, see DEBORRAH NORRIS, *CLINICAL RESEARCH COORDINATOR HANDBOOK* 1 (5th ed. 2019).

market the drug for profit.⁷⁴

A. The Regulatory Process

All trials seeking FDA approval to market a drug must comply with regulations in Title 21 of the Code of Federal Regulations.⁷⁵ A second set of regulations, in Part 46 of Title 45 of the Code of Federal Regulations (Part A of which is referred to as the “Common Rule”⁷⁶), may also apply, particularly where federal funding finances the trial.⁷⁷ The Common Rule is generally adhered to by a research institution, such as a medical school, in all of its human subjects research.⁷⁸ As a practical matter, most human clinical trials will comply with both portions of the Code of Federal Regulations; if the regulations differ, the regulations that offer the greater protection to human subjects are followed.⁷⁹ The

74. *Id.* at 8.

75. *See* 21 C.F.R. § 50 (2022).

76. 45 C.F.R. § 46 (2018).

77. *See* 45 C.F.R. §§ 46.101(a), 46.122 (“Federal funds administered by a federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.”).

Funding is often provided by multiple sources such as pharmaceutical companies, academic medical centers, and Federal agencies like the National Institutes of Health, *Who Conducts Clinical Studies?*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/about-studies/learn#WhoConducts> [<https://perma.cc/H963-9QPJ>] (last visited Jan. 19, 2023).

Government funding may be provided for a clinical trial even where an ultimate financial beneficiary will be a for-profit corporation that began development of the drug. DAVID AUSTIN & TAMARA HAYFORD, CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2021) (discussing generally the role of the federal government, private industry, and private investment in the development of new drugs). In most instances, the eventual sponsor is a pharmaceutical company. THERESA WIZEMANN ET AL., INST. MED. NAT’L ACADS., BREAKTHROUGH BUSINESS MODELS: DRUG DEVELOPMENT FOR RARE AND NEGLECTED DISEASES AND INDIVIDUALIZED THERAPIES: WORKSHOP SUMMARY 7 (Nat’l Acads. Press 2009).

78. *See generally* Anushya Vijayanathan & Ouzrei Nawawi, *The Importance of Good Clinical Practice Guidelines and Its Role in Clinical Trials*, 4 BIOMEDICAL IMAGING & INTERVENTION J. 1 (2008). In some cases, the research is carried out by a contract research organization (“CRO”), a third-party in the business of conducting trials. It, too, must abide by the FDA regulations addressed here. *See* 21 C.F.R. § 312.52(a) (“A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization”); *and* § 312.52(b) (“A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations.”).

79. For example, Northwestern University (“Northwestern”) expressly requires compliance with FDA regulations. NW. UNIV. IRB OFF., *App. A-2 Additional Requirements For USFDA-Regulated Research* 41, INVESTIGATOR MANUAL (2021), <http://irb.northwestern.edu/docs/investigator-manual-general-103.pdf> [<https://perma.cc/97GR-9ALL>] (generally expressly requiring

differences between the two sets of regulations do not affect the insider trading analysis that follows.

After researchers test potential new drugs in the lab and in animals, the most promising ones are moved into human clinical trials. Clinical trials follow a protocol designed to determine impacts to participants and answer specific research questions. The protocol describes the goal of the trial, principally to determine if a treatment is safe and effective.⁸⁰

Clinical trials are conducted in phases. In Phase I trials, a drug or treatment is administered to a small group of humans to learn about its safety and side effects. In Phase II, the new drug is given to a larger group (one to three hundred) to determine its effectiveness and to further study its safety. In Phase III, the new drug or treatment is given to large groups (one to three-thousand) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug to be used safely.⁸¹ After each phase of the trial the researchers decide whether the endpoints were met and whether to move to the next phase or to stop testing because the drug was unsafe or not sufficiently effective to be marketed profitably.

If the drug trials are successful in Phase III, the next step is to seek FDA approval to market the drug, as discussed below. After a new drug has been approved it may become a new standard of care in medical practice.⁸²

A Phase III trial may employ one of three principal types of study design. In a double-blind study, neither the participant nor the researcher knows which treatment each participant is receiving. In a single-blind study, the researcher knows which treatment each participant is receiving, the participant does not. In an open-label study, both the researcher and the participant know which treatment

compliance with FDA regulations) (hereinafter *Investigator Manual*). While there has been no review of the policies or forms of any other major research institution, it is reasonable to assume that Northwestern's policies and forms are, or at least approach, the state of the art, given its very substantial involvement in sponsored research, including clinical trials. *See, e.g., Our Research*, NW. FEINBERG SCH. OF MED., <https://www.feinberg.northwestern.edu/about/facts/research/index.html> [<https://perma.cc/5U8U-J59N>] (last visited Jan. 19, 2023) (presenting data on Northwestern conduct of sponsored research).

80. *See, e.g., What Are Clinical Trials and Studies?*, NIH NAT'L INST. ON AGING, <https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies> [<https://perma.cc/Q6MK-GKBJ>] (last updated Apr. 9, 2020) (explaining that clinical trials "are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective in people. Often a clinical trial is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment").

81. *FDA's Drug Review Process: Continued*, FDA, <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-continued> [<https://perma.cc/P4NH-HFF6>] (last updated Aug. 24, 2015).

82. The standard of medical care is "[t]reatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals." *Standard of Care*, NAT'L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/standard-of-care> [<https://perma.cc/C4TR-KL8Z>] (last visited Mar. 20, 2023).

the participant is receiving.⁸³ Some participants may receive a placebo, “[a]n inactive substance or other intervention that looks the same as, and is given the same way as, an active drug or treatment being tested.”⁸⁴ “The placebo effect is a beneficial health outcome resulting from a person’s anticipation that an intervention will help. How a health care provider interacts with a patient also may bring about a positive response that’s independent of any specific treatment.”⁸⁵ “The ‘gold standard’ for testing interventions in people is the ‘randomized, placebo-controlled’ clinical trial . . . Comparing results from the two groups suggests whether changes in the test group result from the treatment or occur by chance.”⁸⁶

If Phase III is sufficiently successful, the sponsor can choose to file an application to market the drug.⁸⁷ The purpose of the New Drug Application (“NDA”) is to demonstrate that a drug is safe and effective for its intended use in the population studied. All studies, data, and analyses must be presented to the FDA. If the NDA is complete, the review team has approximately six to ten months to analyze the data to determine whether to approve the drug. The team issues a recommendation, and a senior FDA official makes a decision. There may be remaining issues to address before final approval. If a developer disagrees with an FDA decision, it can appeal.

Every clinical study is led by a principal investigator (PI), who must be “qualified by training and experience as [an] appropriate expert [] to investigate the drug.”⁸⁸ The PI is [t]he person(s) in charge of a clinical trial or a scientific research grant. The principal investigator prepares and carries out the clinical trial protocol (plan for the study) or research paid for by the grant. The principal investigator also analyzes the data and reports the results of the trial or grant

83. *Blinded Study*, NAT’L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/blinded-study> [<https://perma.cc/QR9T-ZPXB>] (last visited Jan. 19, 2023).

84. *Placebo*, NAT’L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/placebo> [<https://perma.cc/9JJP-MJ8M>] (last visited Jan. 19, 2023).

85. *Placebo Effect*, NAT’L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, <https://www.nccih.nih.gov/health/placebo-effect> [<https://perma.cc/H8W8-Y5EG>] (last updated Jan. 2020).

86. *Id.* as one example, albeit one where plaintiff’s claim did not pass muster, plaintiffs alleged that investors were misled about whether a placebo “was chemically active” which “could have affected the trial’s results and thereby exaggerated ‘the drug’s efficacy.’” *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *1 (3d Cir. June 14, 2022) (affirming grant of motion to dismiss complaint on ground the plaintiffs had not adequately alleged false statements).

87. *The Basics*, NAT’L INST. HEALTH, <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics> [<https://perma.cc/BW2J-PAFV>] (last updated Oct. 3, 2022); *Step 4: FDA Drug Review*, FOOD & DRUG ADMIN., <https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review> [<https://perma.cc/8S6A-YNAV>] (last updated Jan. 4, 2018).

88. 21 C.F.R. § 312.53(a) (2023). The PI must submit a completed FDA Form 1572 to the trial sponsor. This form reflects his qualifications to serve as a PI and attests that he will comply with specific legal requirements. 21 C.F.R. § 312.53(c) (2023); NORRIS, *supra* note 73, at 11.

research.⁸⁹

“Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.”⁹⁰ While the PI for the investigation of a drug for human use need not be a medical doctor (“M.D.”),⁹¹ if the PI is not a medical doctor, “A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.”⁹² As discussed below (Parts V and VI), *any* of these people could engage in unlawful trading. The net is wide.

There is a PI at each site, with a single PI responsible for the entire trial.⁹³ Significant responsibilities of the PI may be delegated to other qualified members of the team, such as enrollment of individual participants.⁹⁴ In this Article, references to “the PI” generally include the persons designated by the PI to carry out delegated responsibilities.

Every clinical trial carried out in accordance with the Common Rule must be overseen by an Institutional Review Board (“IRB”), which performs the ethical review of the trial.⁹⁵ As explained by the FDA:⁹⁶

[A]n IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of

89. *Principal Investigator*, NAT’L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/principal-investigator>. [<https://perma.cc/NWA7-7489>] (last visited Jan. 19, 2023).

90. *Learn About Clinical Studies*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/about-studies/learn#WhoConducts> [<https://perma.cc/T69F-TFGE>] (last updated Mar. 2019); *see also Principal Investigator Eligibility for IRB Protocols*, NW. UNI., <https://irb.northwestern.edu/docs/pi-eligibility-for-irb-protocols-v.2.pdf> [<https://perma.cc/9ZME-JWNX>] (last visited Jan. 19, 2023) (presenting flowchart for determining individual eligibility to serve as PI).

91. *See id.*

92. NORRIS, *supra* note 73, at 12; *Investigator Manual*, *supra* note 79, at p. 41.

93. Jennifer L. Gold & Carolyn S. Dewa, *Institutional Review Boards and Multisite Studies in Health Services Research: Is There a Better Way?*, 40 HEALTH SERV. RES. 291, 291 (2005) (“Recent years have seen a shift away from studies performed at single academic centers to larger, multisite projects involving numerous institutions in disparate geographic locations.”).

94. *See* NORRIS, *supra* note 73, ch. V & VII (describing responsibilities of a Clinical Search Coordinator (“CRC”) or “qualified person” designated by the PI, including obtaining informed consent).

95. 45 C.F.R. § 46.102(a) (2023).

96. *Institutional Review Boards Frequently Asked Questions*, FOOD & DRUG ADMIN. (Jan. 1998), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions> [<https://perma.cc/YX9K-K2YG>]. (For detailed regulations regarding the IRB itself, *see* 45 C.F.R. §§ 46.107-109 (2023)).

the rights and welfare of human research subjects. The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.⁹⁷

An IRB must have at least one member who is not affiliated with the entity, such as the medical school, that is conducting the trial.⁹⁸

Northwestern also requires that clinical trials be conducted in accordance with the ethical principles that have their origin in the Helsinki Principles.⁹⁹ The Helsinki Principles are the most widely accepted statements of ethical principles in human clinical trials.¹⁰⁰

B. Financial Interests and Conflicts of Interest

Financial interests on the part of anyone involved in the trial are pertinent not only to the integrity of the trial itself—so that no one might have an incentive to, for example, alter trial results—but also to claims for insider trading. These considerations are important in insider trading not only as indicative of a motive to misbehave, but also to the essential element of “benefit” in a claim of tipping.¹⁰¹

Trial sponsors have a significant financial interest in the outcome of the trial they are funding, hoping that a marketable drug emerges. Those carrying out a trial on the front line, such as a PI, may have a direct or indirect financial interest in the outcome. For example, the PI might be tempted to improperly influence people to enroll or to take action to affect the outcome of the trial as it

97. An IRB must have at least one person not affiliated with the entity conducting the trial. 21 C.F.R. § 56.107(d) (2013). For an example of a confidentiality agreement between the IRB members and a university, see *Confidentiality Agreement*, U. KY. (Aug. 20, 2018), <https://www.research.uky.edu/uploads/ori-f180000-irb-member-confidentiality-agreement-pdf>. [<https://perma.cc/2ELL-CD9V>].

98. 21 C.F.R. § 56.107(d) (2023).

99. *Investigator Manual*, *supra* note 79, p. 43 (referring to *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS’N, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/#:~:text=1.,identifiable%20human%20material%20and%20data> [<https://perma.cc/56SD-TEUM>] (last updated Sept. 6, 2022) (hereinafter “*Helsinki Principles*”).

100. *Investigator Manual*, *supra* note 79, p. 43. At Northwestern, the Helsinki Principles are “the basis for Good Clinical Practices used today.” *Research Ethics*, NW. U., <https://irb.northwestern.edu/submitting-to-the-irb/getting-started/research-ethics.html> [<https://perma.cc/VJ8W-QGW2>] (last visited Jan. 19, 2023).

101. See *supra* text accompanying notes 42-43.

proceeds.¹⁰² These interests—to get the trial off the ground and to skew some action to enhance the chance that the drug will be approved, such as altering a lab result to reflect favorable data—may have securities law, and in particular insider trading, implications. That is, the PI may know material negative facts that are inconsistent with positive information publicly disclosed by the sponsor about the progress of the trial, such as recruitment or interim results. Trading while knowing the truth may be unlawful.

These interests are potentially troublesome where employees of the sponsor or a PI own stock of the sponsor, so that an unsuccessful trial may provide an incentive to sell the stock before the negative information becomes public.¹⁰³ Ownership of sponsor stock is *not* generally prohibited, though it must be disclosed.¹⁰⁴

Northwestern, for example, has two conflict policies. One focuses on work outside Northwestern.¹⁰⁵ The second, most directly pertinent here, relates to research conducted under the auspices of Northwestern.¹⁰⁶ Northwestern's policy "promotes objectivity in research and establishes the University's conflict of interest compliance framework."¹⁰⁷ To this end, anyone covered by the policy must report ownership of more than five-thousand dollars of stock of a public company.¹⁰⁸ At Northwestern's Feinberg School of Medicine, however, *any* interest in any public company, no matter how small or when acquired, must be reported.¹⁰⁹

102. See, e.g., Jodi S. Cohen, *University of Illinois at Chicago Missed Warning Signs of Research Going Awry, Letters Show*, PRO PUBLICA (Mar. 20, 2019), <https://www.propublica.org/article/university-of-illinois-chicago-uic-research-misconduct-letters-documents> [<https://perma.cc/MFG5-NNLM>] (reporting that medical institution terminated clinical trial and paid a \$3.1 million penalty to the government because of, among other considerations, misconduct of PI).

103. See *United States v. Kosinski*, 976 F.3d 135, 139, 141, 143 (2d Cir. 2020).

104. See *infra* text accompanying notes 108-109. In the absence of publicly available policies in this regard, it is reasonable to speculate that some institutions do expressly prohibit ownership of sponsor stock, that institutions that do not prohibit it in so many words require internal disclosure to facilitate "managing" the potential conflict such as instituting a prohibition in practice. Too much is at stake to run the risk of a disqualifying interest discovered *ex post*.

105. *Policy on Conflict of Interest and Conflict of Commitment*, NW. UNI. (Jan. 22, 2018), https://www.northwestern.edu/coi/docs/core_coi_policy.pdf [<https://perma.cc/9SQ7-M9V3>].

106. See *Policy on Conflict of Interest in Research*, NW. U. (Aug. 24, 2012), https://www.northwestern.edu/coi/policy/research_policy.pdf [<https://perma.cc/W7S4-SD9S>].

107. *Id.*

108. *Id.* at 4. An important finding in the affirmance of Kosinski's conviction for insider trading was his failure to provide required information about his ownership trial sponsor stock. *Kosinski*, 976 F.3d at 145 ("Kosinski further agreed to disclose if his holding of [the sponsor's] stock exceeded \$50,000, which presumably would have triggered [its] closer oversight of Kosinski (or even his termination) given its significance to the FDA, and which he failed to do.").

109. See *Policy on Conflict of Interest in Research*, *supra* note 106, § 4.1. See also *Conflict of Interest – Significant Financial Interests*, NW. UNI., <https://www.northwestern.edu/coi/>

Noncompliance with these policies may play a role in a finding of insider trading liability. In *Kosinski*, a factor in affirming his conviction for insider trading was his failure to provide required information about his ownership of stock in the trial sponsor.¹¹⁰

V. INSIDER TRADING IN THE CLINICAL TRIAL SETTING—CASES WHERE THE LAW HAS BEEN APPLIED

Since at least 1997, the SEC has charged individuals in the pharmaceutical industry with insider trading based on MNPI regarding clinical trials.¹¹¹ Therefore, it is important to stress that those who trade based on MNPI regarding clinical trials *are sometimes caught* and when they are, they often suffer serious consequences, such as imprisonment, so that anyone involved in any trial should take steps to avoid, or at least reduce the risk of, a violation.

The Appendix is a hand-collected list of twenty-eight SEC insider trading enforcement actions involving pharmaceutical industry clinical trials filed by the SEC between January 1, 2012, and September 30, 2022.¹¹² In eleven of those cases, there was also an indictment; *all* of the persons indicted were either convicted after a trial or pleaded guilty.

Undoubtedly, the overwhelming number of violations in any industry are not detected, and there is no way to determine how much insider trading escapes investigation. Because of the SEC's limited resources, it is "impracticable for the staff to investigate or proceed in more than a small fraction of cases in which unlawful trading has likely occurred."¹¹³ Nevertheless, some *are* caught, and no

disclosing/significant-financial-interests.html [https://perma.cc/8M44-X4EK] (last visited Jan. 19, 2023).

110. *Kosinski*, 976 F.3d at 145 ("Kosinski further agreed to disclose if his holding of [the sponsor's] stock exceeded \$50,000, which presumably would have triggered [its] closer oversight of Kosinski (or even his termination) given its significance to the FDA, and which he failed to do.").

111. See Ferguson, *supra* note 9, at 631 (stating that the first such case was filed in 1997, referring to SEC v. Mutchnick, Litig. Release No. 15322, 1997 WL 169980 (Apr. 10, 1997)).

112. Seven percent of the insider trading cases filed in that period involved clinical trial MNPI. Five cases were filed in just the SEC's fiscal year ending September 30, 2022. See App'x. The Appendix shows that on average three cases filed each year were based on misuse of clinical trial MNPI. The total number of insider trading cases filed each fiscal year ending September 30 by the SEC from 2017 (when the SEC first included this category in its annual reports) to date have ranged from twenty-eight to fifty-one, averaging thirty-eight. See, e.g., S.E.C., DIV. OF ENF'T ANN. REP. 20 (2018), <https://www.sec.gov/files/enforcement-annual-report-2018.pdf> [https://perma.cc/HV85-PWL7] (fifty-one cases in court or at the SEC, involving seventy-four individuals). More recently, see Press Release, S.E.C., SEC Charges Former CEO of Biotech Company CytoDyn with Fraud, Insider Trading (Dec. 20, 2022) (available at <https://www.sec.gov/news/press-release/2022-232> [https://perma.cc/6CP3-97W4]) (reporting action filed alleging insider traded without disclosing negative reaction to company Biologics License Application).

113. See LANGEVOORT, *supra* note 1, § 8:1 (footnote omitted).

one can be sure that *her* trading will not be. Several cases involving clinical trial MNPI were noteworthy in showing how the law can be applied in that context and generally. One was *Kosinski*,¹¹⁴ singled out as important when it was decided.¹¹⁵ The second was the controversial decision in *United States v. Martoma*, where the Second Circuit Court of Appeals affirmed the conviction of Martoma, a hedge fund manager, who paid Gilman, a doctor involved in a clinical trial, for MNPI about the trial.¹¹⁶ *Martoma* presented a controversial approach toward tipping that may be inconsistent with a prior Second Circuit panel opinion.¹¹⁷

Gilman, a member of the safety monitoring committee for the trial, told Martoma that he had identified “two major weaknesses in the data” that called into question the efficacy of the drug as compared to a placebo.¹¹⁸ On behalf of the portfolios he managed, Martoma undertook transactions in securities of the trial sponsors that resulted in substantial profits and avoided losses for those portfolios.¹¹⁹ Martoma’s conviction as a tippee was affirmed.¹²⁰ Though Gilman, a doctor, was not indicted for tipping Martoma, the SEC sued him, and they settled.¹²¹

114. *See supra* text accompanying notes 22-25.

115. *Kosinski* was the only insider trading case included in the ABA Business Law Section discussion of notable securities law cases in 2020. William O. Fisher et al., *Caselaw Developments 2020*, 76 BUS. LAW. 1069, 1117-21 (2021).

116. *United States v. Martoma*, 894 F.3d 64 (2d Cir. 2017) (two to one decision, the second panel decision in the case). *See United States v. Martoma*, 869 F.3d 58 (2d Cir. 2017) (two to one decision, first panel decision). One element of the disagreement among the panel members related to the meaning of the comma in the last sentence of the quote from *Dirks*, *supra* text accompanying note 46. *See Martoma*, 894 F.3d at 74 (majority opinion), 84-85 (dissenting opinion).

117. *Criminal Law—Insider Trading—Second Circuit Redefines Personal Benefit Requirement for Insider Trading—United States v. Martoma*, 894 F.3d 64 (2d Cir. 2018), 132 HARV. L. REV. 1730 (2019) (discussing *Martoma*’s “stealth overruling” of a prior Second Circuit panel decision).

118. *Martoma*, 894 F.3d at 69-70. The practice of securities professionals paying doctors involved in trials to provide nonpublic information had become commonplace. *See* David Heath & Luke Timmerman, *Drug Researchers Leak Secrets To Wall St.*, SEATTLE TIMES (May 12, 2005), <https://special.seattletimes.com/o/html/business/technology/drugsecrets1.html> [<https://perma.cc/Z5R2-HNYF>] (reporting finding at least twenty-six cases in which doctors leaked “confidential and critical details” of their ongoing drug research to Wall Street firms, in twenty-four of which “the firms issued reports to select clients with detailed information obtained from doctors involved in confidential studies” and which advised clients whether to buy or sell a drug stock). This practice continues in the form of “expert networks” which provide what may be MNPI to members of the investment community. *See* LANGEVOORT, *supra* note 1, § 11:5 (discussing legal and unlawful expert networks). Experts can easily be found with a Google search for “medical expert network clinical trial.”

119. *Martoma*, 894 F.3d at 70.

120. *Id.* at 68.

121. *SEC v. CR Intrinsic Inv’s LLC*, Litig. Release No. 22539, 2012 WL 5872931, at *2 (Nov. 20, 2012) (reporting Gilman’s settlement).

The deception theory of insider trading has been invoked in a clinical trial setting. A researcher for a brokerage firm allegedly “sent his brother, a research assistant at the firm, to impersonate him by signing up to participate in the clinical trial of the drug” to learn information about the trial. The firm published a research report five days later recommending the sale of the stock of the manufacturer of the drug, citing a side effect the phony applicant learned about when registering for the trial. After public disclosure of this information, the stock fell by a third. The brokerage firm, the firm’s researcher, and his brother all quickly settled charges by the National Association of Securities Dealers, their principal self-regulator in the securities industry.¹²²

In another deception case, the SEC alleged that a former FDA employee, consulting for an investment advisor at the time, deceived a former FDA colleague still working there to obtain MNPI about the status of the trial that he passed on.¹²³ That defendant settled the case.¹²⁴

Someone working on a clinical trial may learn MNPI about the sponsor that has nothing to do with the drug under investigation. The “insider” who is told about some nonpublic impending development, such as an acquisition, and then trades in the securities of the issuer may have violated the law, such as a consultant on one matter who learns of another development.¹²⁵ If the PI is deemed a temporary insider of the sponsor, and if the PI trades based on the MNPI about the acquisition, he may have exposure to an insider trading claim.¹²⁶ Professor Langevoort, noted that “where a person who is an insider under the [classical theory] overhears fellow insiders talking about a material development . . . because of the insider’s fiduciary status, he is precluded from using the information.”¹²⁷ Any information he hears about the company might be within the scope of any confidentiality agreement he signed in connection with the trial. That agreement may provide the foundation for a misappropriation claim.

In the potentially groundbreaking misappropriation case *SEC v. Panuwat*, the SEC alleged that information about one company in the pharmaceutical field was material to the value of the stock of an “economically linked” company, even one

122. Randall Smith, *Sterling Financial, Employees Are Punished in “Posing” Case NASD Imposes Fine, Suspension on Biotech Analyst, His Brother*, WALL ST. J. (Oct. 29, 2002), <https://www.wsj.com/articles/SB1035843978859763871> [<https://perma.cc/88KF-J3CY>].

123. Press Release, SEC, Hedge Fund Managers and Former Government Official Charged in \$32 Million Insider Trading Scheme (June 15, 2016) (available at <https://www.sec.gov/news/pressrelease/2016-119.html> [<https://perma.cc/QXV3-J8VY>]) (alleging that deception was used to obtain MNPI in Cmpl., at ¶¶ 62, 66, 77).

124. See *SEC v. Valvani*, Litig. Release No. 23688, 2016 WL 9086445 at *1 (Nov. 14, 2016).

125. See, e.g., *SEC v. Glassner*, Litig. Release No. 25398, 2022 WL 1644020 at *1 (May 24, 2022) (reporting filing of action against compensation consultant for pharmaceutical company who “learned about [his client’s] impending acquisition by global biopharmaceutical company Sanofi S.A. in the course of his engagement to provide acquisition-related consulting services to Kadmon” and soon thereafter bought stock of the client).

126. See *infra* Part VI (discussing scenarios).

127. LANGEVOORT, *supra* note 1, § 4.7 n.10.

that was not a counterparty to or otherwise involved with the first company.¹²⁸ The SEC contended that when the defendant learned MNPI that his pharmaceutical employer was going to be acquired at a substantial premium, he purchased the stock of another company in the same “mid-cap oncology-focused biopharmaceutical” field, believing that it would be seen as a target of other buyers on the prowl. The trader was not alleged to have had any MNPI regarding the other company itself. The court held that this stated a plausible misappropriation insider trading claim.¹²⁹

The propensity of the SEC to push the limits of the law should give rise to a clarion call for those who trade securities to be wary of how the SEC will use the current outcome in *Panuwat* to press its agenda. There are important scenarios other than *Panuwat*, not yet the subject of claims by the SEC and much less adjudicated, that must be addressed if one is to appreciate the full range of the potential application of the prohibition on insider trading involving MNPI about a clinical trial. These are addressed in Part VI.

VI. INSIDER TRADING IN THE CLINICAL TRIAL SETTING – APPLYING RECOGNIZED PRINCIPLES

The analysis to this point demonstrates that the PI and the rest of the clinical trial team are likely to violate Rule 10b-5 if they trade in the stock of the sponsor when they know MNPI about the trial. They are exposed as insiders (or temporary insiders) as well as potential mis-appropriators, arising out of a relationship of trust and confidence with the sponsor, if only because—as is generally the case—there is a confidentiality agreement that creates that relationship, as under Rule 10b5-2(b)(1). The net in clinical trial cases has been cast very wide, for example, pursuing an outside investor relations consultant who used MNPI about a clinical trial of a pharmaceutical firm client of his, among others.¹³⁰ Analyses of scenarios not yet the subject of a claim by the SEC

128. SEC v. Panuwat, No. 21-cv-06322, 2022 WL 633306 at *9 (N.D. Cal. Jan. 14, 2022) (denying motion to dismiss). See also *infra* text accompanying note 254 (for a further discussion of *Panuwat*). See, e.g., Celeste Koeleveld, *Shadow Trading – The SEC’s Novel Theory Of Insider Trading To Be Tested*, CLIFFORD CHANCE (Aug. 27, 2021), <https://www.cliffordchance.com/briefings/2021/08/shadow-trading---the-sec-s-novel-theory-of-insider-trading-to-be.html> [<https://perma.cc/6XM4-4DCU>]. (The complaint suggests that the SEC may attempt to expand the scope of insider trading liability to include a theory a recent academic paper dubbed “shadow trading”: where corporate insiders exploit material nonpublic information about their firm, to trade in the securities of an “economically linked” firm, such as a similarly situated competitor.)

129. SEC v. Panuwat, No. 21-cv-06322, 2022 WL 633306, at *1-2 (N.D. Cal. Jan. 14, 2022).

130. See Press Release, SEC Charges Investor Relations Firm Executive with Insider Trading Ahead of News Announcements By Clients (Aug. 26, 2014) (available at <https://www.sec.gov/news/press-release/2014-175> [<https://perma.cc/YJL3-NB7Y>]). The defendant pleaded guilty to a related indictment and was sentenced to two-and-a-half years in prison. See also Press Release, U.S. Attorney’s Office for the Southern District of New York, Former Director of Market Intelligence at Investor Relations Firm Sentenced in Manhattan Federal Court for Insider Trading (Jan. 21,

follow. While there is no current reason to believe some of the claims described here are on the immediate horizon, they could be – the vigilant must take that risk into account.

A. Participant Enrollment Phase

These authors are not the only science and legal professionals concerned about the potential breadth of clinical trial insider trading claims, as more than fifteen years ago, four medical and legal authors asked what “if any, are physician–investigators’ scientific, ethical, and legal responsibilities concerning research subjects who choose to buy stock in the companies sponsoring the clinical trials in which they are participating.”¹³¹

With these concerns in mind, we begin with the protocols that must be followed when persons are recruited and enrolled as “participants” in a clinical trial. PIs must comply with requirements of their institution, the FDA, the IRB of record, and the sponsoring company.¹³² First and foremost, there must be informed consent by anyone enrolled in a clinical trial, evidenced by signing an informed consent form (ICF).¹³³ Complete candor by the investigation team is required.

In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study.

Participants can be identified using hospital diagnostic records, support group membership lists, lab screening records, and physician referrals.¹³⁴ Participants

2015) (available at <https://www.justice.gov/archive/usao/nys/pressreleases/January15/LucarelliMichaelSentencingPR.php?print=1> [<https://perma.cc/2CYJ-CB6R>]).

131. Helft, *supra* note 9, at 656.

132. *See generally* 45 C.F.R. § 46 Protection of Human Subjects, especially Subparts A (Basic HHS Protection of Human Research Subjects); and E (Registration of Institutional Review Boards). The process is described at *Norris Handbook*, *supra* note 73, ch. X.

133. 45 C.F.R. § 46.116(a)(1). Some of the requirements imposed on a medical doctor acting as a PI parallel provision of the AMA ethical principles. *See* AMA, PRINCIPLES OF MED. ETHICS (JUNE 2001), <https://www.ama-assn.org/about/publications-newsletters/ama-principles-medical-ethics> [<https://perma.cc/6MKA-8Z22>], and CODE OF MED. ETHICS, <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview> [<https://perma.cc/ZZ3M-UF3E>] (last visited Jan. 19, 2023) (containing links to the individual chapters and opinions) [hereinafter *AMA Opinions*] (containing links to the individual chapters and opinions). *See also* NORTHWESTERN UNIV., *Permission to Take Part in Human Research Study*, Form HRP-592, *passim* (revised June 27, 2022), <https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/biomedical-social-behavioral-consent-templates/index.html> [<https://perma.cc/3P8V-75CG>]. To the same effect, *see Investigator Manual*, *supra* note 79, at App. A-3, pp. 41, 43.

134. NORRIS, *supra* note 73, at 67. The Privacy Rule under the Health Insurance Portability

can be solicited using general media advertising, posters in waiting rooms or doctor's offices, newsletters to patients, and health fairs.¹³⁵ Initial screening can be done in person or by phone.¹³⁶

While there is limited evidence that anyone enrolls in a trial to obtain MNPI about the sponsor in the recruiting phase,¹³⁷ there could be disclosures to the prospect that could pose an insider trading issue. Is MNPI revealed by the PI to the participant in confidence in the recruiting phase, supplying the potential predicate for a misappropriation claim?

When discussing potential enrollment and obtaining consent the FDA requires that a potential participant “must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information,”¹³⁸ including “a concise and focused presentation of the key information that is most likely to assist a prospective subject . . . in understanding the reasons why one may or may not want to participate in the research.”¹³⁹ One important disclosure – where permitted – is the identity of the sponsoring entity and the name of the drug under investigation.¹⁴⁰

“An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.”¹⁴¹ The potential participant must be informed from whom he can obtain “answers to pertinent questions about the research and research subjects’ rights,”¹⁴² and “whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.”¹⁴³

There are limits on what can be done. “Neither the investigator, nor the trial

and Accountability Act (HIPAA) applies to protect information obtained from and about the trial participant in some clinical trials. See HHS, *Summary of the HIPAA Privacy Rule* (July 26, 2013), [https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#:~:text=The%20Privacy%20Rule%20protects%20all,health%20information%20\(PHI\).%22](https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#:~:text=The%20Privacy%20Rule%20protects%20all,health%20information%20(PHI).%22) [<https://perma.cc/3F8G-A4S7>]; HHS, *Research* (Dec. 18, 2017), <https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html> [<https://perma.cc/FVW7-EW6C>]. The question of the extent to which PAA requirements might have to be complied with in a clinical trial (see *Norris Handbook, supra* note 73, at 53-54; *Investigator Manual, supra* note 79, at 17) is beyond the scope of the analysis here.

135. NORRIS, *supra* note 73, at 67-68.

136. *Id.* at 69.

137. See *supra* text accompanying note 122 (discussing case).

138. 45 C.F.R. § 46.116(a)(4).

139. 45 C.F.R. § 46.116(a)(5)(i).

140. The Northwestern IRB provides that the identity of the drug be disclosed to the participant “whenever appropriate.” *Northwestern Univ. Permission, supra* note 133, at 4, 14.

141. 45 C.F.R. § 46.116(a)(2).

142. 45 C.F.R. § 46.116(b)(7).

143. 45 C.F.R. § 46.116(c)(1), (c)(8).

staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.”¹⁴⁴ The American Medical Association (“AMA”) cautions physicians to “refrain[] from persuading the individual to enroll.”¹⁴⁵ At Northwestern, the potential participant is to be told, “[y]ou can ask all the questions you want before you decide”¹⁴⁶ and be informed who he can talk to if he has any questions, including the IRB.¹⁴⁷ This requires meaningful responses to those inquiries, as no information can be withheld.¹⁴⁸ All questions are to be answered “to the satisfaction of the subject.”¹⁴⁹

Persons involved in face-to-face encounters at the intake phase should be attuned to the risk that someone might be feigning interest in the trial as a means of learning MNPI they would use to trade.¹⁵⁰ While the person who engages in deception to obtain information which is then used to trade may violate Rule 10b-5, the PI who is tricked is not exposed,¹⁵¹ at least so long as he does not know he is providing more information than necessary to be responsive such that he might be a tipper.¹⁵²

One case presents a perspective on how legally mandated clinical trial disclosures that might be material can be reconciled with a potential tipping claim. In *Fifth Third Bancorp v. Dudenhoefer*, the Supreme Court addressed a claim of trustee imprudence in oversight of retirement plan assets covered by the Employee Retirement Income Security Act of 1974 (ERISA).¹⁵³ The Court explained how ERISA and the federal securities laws intersect in making investment decisions affecting ownership of company stock held as a plan asset in an employee stock ownership plan (ESOP), “a retirement plan in which an employer contributes its stock to the plan for the benefit of the company’s employees.”¹⁵⁴ The plaintiffs alleged that MNPI known to the (insider) plan trustees suggested that the company stock was overvalued. They contended that

144. *Investigator Manual*, *supra* note 79, App. A-3, Item 7.c, p. 43. *See also* 45 C.F.R. § 46.116(a)(2) (providing that person obtaining informed consent shall “minimize the possibility of coercion or undue influence” when seeking consent).

145. *See AMA Opinions, Informed Consent in Research*, *supra* note 133, at Opinion E-7.1.2.

146. *Northwestern Univ. Permission*, *supra* note 133, at 2.

147. *Id.* at 3.

148. In the doctor-patient context, see *AMA Opinions*, *supra* note 133, at Opinion 2.1.3 (“Withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated creates a conflict between the physician’s obligations to promote patient welfare and to respect patient autonomy.”).

149. *Investigator Manual*, *supra* note 79, App’x A-3, Item 9(g), p. 44.

150. *See supra* text accompanying notes 122 (describing such a case).

151. *See supra* text accompanying note 122.

152. *See supra* text accompanying notes 42-49.

153. *Fifth Third Bancorp v. Dudenhoefer*, 573 U.S. 409 (2014) (addressing issues under 29 U.S.C. § 1104(a)(1)).

154. SEC, *Employee Stock Ownership Plans ESOPS*, INVESTER.GOV, <https://www.investor.gov/introduction-investing/investing-basics/glossary/employee-stock-ownership-plans-esops> [https://perma.cc/NF7Y-82EB] (last visited Jan. 19, 2023).

the trustees could have used the information by selling the stock held by the ESOP, refraining from buying more stock, or making public disclosure of the MNPI.¹⁵⁵

The Court stated:

To state a claim for breach of the duty of prudence on the basis of inside information, a plaintiff must plausibly allege an alternative action that the defendant could have taken *that would have been consistent with the securities laws* and that a prudent fiduciary in the same circumstances would not have viewed as more likely to harm the fund than to help it.¹⁵⁶

Further, “[T]he duty of prudence . . . does not require a fiduciary to break the law . . . ERISA’s duty of prudence cannot require an ESOP fiduciary to perform an action—such as divesting the fund’s holdings of the employer’s stock on the basis of inside information—that would violate the securities laws.”¹⁵⁷

As explained by Professor Langevoort, “[t]he Court has made clear that ERISA’s fiduciary status affords no license (much less responsibility) to engage in unlawful insider trading.”¹⁵⁸ This principle should apply equally to requirements imposed by the FDA, so that making the disclosures required by the FDA to obtain informed consent cannot be unlawful and thus cannot expose the PI to a tipping claim, even if the PI is seeking to achieve a benefit, such as enrolling the minimum cohort to be able to proceed with the trial.¹⁵⁹

If, however, the person doing the intake makes *more* disclosure than required by FDA rules, consideration should be given to whether he was acting *for an improper purpose* especially if enrollment might produce a benefit for the person making the disclosure, satisfying one crucial element of unlawful tipping. That is, if the PI provides *more* information than is required to be disclosed, to persuade the person to enroll, this might be unlawful tipping because the PI is seeking to benefit himself by enhancing his reputation leading to increased compensation or receiving increased compensation directly.¹⁶⁰ Of course, if he has no expectation that the prospect will trade in sponsor securities, there is no *unlawful disclosure*.

Cash is the paradigm benefit, as Gilman received in *Martoma*.¹⁶¹ Another

155. *Dudenhoefer*, 573 U.S. at 427-28.

156. *Id.* at 428 (emphasis added).

157. *Id.* at 428 (citation omitted).

158. *Langevoort Insider Trading*, *supra* note 1, at § 3:1.

159. This question may implicate complex questions of pre-emption, such as those addressed in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), where the Court held that FDA regulations pre-empted state labeling laws because it was impossible for the drug manufacturers to comply with state law without violating federal law.

160. *See supra* text accompanying note 45. As stated in *Dirks*, it is not mere reputational benefit, but rather a benefit “that will translate into future earnings.” *Dirks*, 463 U.S. at 663.

161. *See Martoma*, 894 F.3d at 71 (discussing cash payments to Gilman in exchange for his tip). More recently, the SEC alleged that tips about a clinical trial were paid for with cash. *See SEC v. Rayapureddy*, 2:22-cv-01592-WSH (W.D. Pa, 2022), <https://www.sec.gov/litigation/complaints/>

concrete benefit to the PI or to his institution is that there are enough enrollees to proceed.¹⁶² There might be monetary rewards to the institution that employs the PI through commercial exploitation of the drug, or even to the PI himself, such as earning patent royalties if the trial drug is successfully marketed.¹⁶³

Enhancement or preservation of reputation might satisfy the “benefit” element of tipping, as noted in *Dirks*, the seminal tipping case, at least when it is expected to enhance the income of the tipper in the long run.¹⁶⁴ If the person to whom the PI-tipper made excess disclosure – the prospective enrollee – then traded based on MNPI, that tippee-trader could be an *unlawful* tippee.¹⁶⁵

The prospective participant herself could *not* be a “temporary insider” *before she is enrolled*.¹⁶⁶ There could be no pre-enrollment relationship of “trust and confidence” between the PI and the prospect, even if the PI were an M.D., though it might evolve to embrace some aspects of the traditional doctor-patient relationship for those who participate.¹⁶⁷ While the Northwestern consent form

2022/comp-pr2002-204.pdf [https://perma.cc/AB77-89G9].

162. *See, e.g.*, NAT’L INST. OF ALLERGY & INFECTIOUS DISEASES, DIV. OF AIDS (DAIDS) SITE CLINICAL OPERATIONS & RESEARCH ESSENTIALS (SCORE) MANUAL: PREMATURE TERMINATION OR SUSPENSION OF A CLINICAL TRIAL, at 2 (Jan. 19, 2021), <https://www.niaid.nih.gov/sites/default/files/score-premature-termination-or-suspension-of-clinical-trial.pdf> [https://perma.cc/695U-GWUX] (listing as a reason for early “fails to enroll participants within a requisite time period”).

163. *See supra* text accompanying notes 101-102 (discussing potential tangible benefits). The FDA requires disclosures of these interests. 21 C.F.R. § 54 (2023). One notable example of the realization of significant royalties in connection with a clinical trial is described by Daniel P. Smith, *The Pregabalin Story: How Northwestern University Transformed A \$681,764 Grant Into A Fortune Of Good*, NORTHWESTERN UNIV. INVO NEWS ARCHIVE (Apr. 1, 2017), <https://www.invo.northwestern.edu/about/news/news-archive/the-pregabalin-story.html> [https://perma.cc/3Q73-JBBD] (describing the royalties received by Northwestern for pregabalin (Lyrica), which had been discovered by a Northwestern chemistry professor and a visiting colleague, and that Pfizer royalties are responsible for about 18 percent of the University’s endowment, “[f]irst spurred by a \$681,764 grant from the National Institutes of Health in 1987”).

164. *See supra* text accompanying note 45 (quoting *Dirks*). *See also* SEC v. Stevens, Litig. Release No. 12813, 48 SEC Docket 841 (1991) (describing complaint alleging that when it appeared that company would report earnings lower than expected defendant called analysts to give them advance notice of the impending announcement “in order to protect and enhance his reputation. The Complaint alleges that that action was seen by [defendant] as having direct, tangible benefit to his status as a corporate manager.”).

165. *See supra* text accompanying notes 42-49 (describing elements of tipping).

166. *See supra* text accompanying note 16 (describing “temporary insider”).

167. The relationship between the PI who is an M.D. and trial participant differs from the relationship with a treating physician. The participant must be informed of “the differences between the physician’s responsibilities as a researcher and as the patient’s treating physician.” *AMA Opinions, supra* note 133, Opinion E-7.1.2(c)(ii). At the same time, the physician should “[d]emonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness

contains many explicit references to maintaining the privacy of the *participant's* information, it makes no reference to the participant maintaining the confidentiality of anything *she learns*.¹⁶⁸ Rather, it expressly permits the potential participant to “discuss this study with another person who is not part of the research team before deciding whether to participate in the research.”¹⁶⁹ Thus, though perhaps unlikely at the recruiting stage, tipping *could* become an issue or something *could* occur to create a relationship of trust and confidence.¹⁷⁰

If there is any potential insider trading exposure for sharing information at this stage, the organization conducting the trial could – before making any but the most basic introductory disclosures to a prospective enrollee – require that the prospect sign a confidentiality agreement covering any information provided in the enrollment process. Consideration of whether to enter into a confidentiality agreement should consider that it would create a relationship of trust and confidence, applying Rule 10b5-2(b)(1). This creates a risk for the participant by creating the foundation for the application of the misappropriation theory if she trades. Is it worth the benefit of obtaining enrollment to expose the eventual participant to liability under that theory, remote though the risk may be?

A confidentiality agreement is neither mandated nor recommended by the FDA,¹⁷¹ nor is it listed on the Northwestern ICF, which, in any event, is signed only upon enrollment, not before.¹⁷² Upfront confidentiality agreements in the nonpublic testing setting are not unheard of, however. One parallel is the confidentiality agreement obtained from a person who does “beta testing” of computer software.¹⁷³ Outsiders are given nonpublic information to provide, with

for patients. *Id.* at E-7.1.1(d). The FDA requires disclosure to the participant of “appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject” when seeking consent. 45 C.F.R. § 46.116(b)(4). To the same effect, see *Investigator Manual*, *supra* note 79, at 45.

168. *Investigator Manual*, *supra* note 79, *passim*.

169. *Id.* at 1. While this reads in the singular, it seems unlikely that a prospect is to be limited to speaking to only one other person.

170. If there is a prolonged period of recruitment efforts between a PI and a potential participant, SEC Rule 10b5-2(b)(2) might come into play. That provides that there is a relationship of trust and confidence if two persons develop “a history, pattern, or practice of sharing confidences, such that the [participant] ... knows or reasonably should know that the [PI] ... expects that the [participant] will maintain [information’s] confidentiality.” 17 C.F.R. § 240.10b5-2(b)(2). Frequent one-on-one discussions, especially face-to-face, may produce the kind of intimate relationship that often arises in the traditional doctor-patient setting over time. See also Complaint at ¶ 24, SEC v. Rayapureddy, 2:22-cv-01592-WSH (W.D. Pa, Nov. 10, 2022), <https://www.sec.gov/litigation/complaints/2022/comp-pr2002-204.pdf> [<https://perma.cc/LX46-J76Y>] (alleging that “close personal relationship is shown by “regularly spoke on the telephone, messaged each other, and socialized in person”).

171. 45 C.F.R. § 46 (2023).

172. Northwestern Univ., *supra* note 133.

173. 1 L. J. KUTTEN, COMPUTER SOFTWARE PROTECTION/LIABILITY/LAW/FORMS § 3:19, at 3-23, 25 (2005) (“Beta testing of software occurs when the software is stable enough so that parties

or without compensation, their analysis or reaction to the product in the development stage. Because there is a confidentiality agreement between the members of the IRB, notably the required non-affiliated member of the IRB, and the university for which it functions, IRB members who receive MNPI cannot trade in the stock of a sponsor.¹⁷⁴

The adverse implications of obtaining a confidentiality agreement are extremely speculative, though before dismissing the topic altogether the issues that could arise should be understood. Obtaining a confidentiality agreement from the participant at any stage of the clinical trial process raises many practical issues. First, requesting an agreement at the outset might have a chilling effect. The participant might ask herself, “What is so secret about this that I can tell only a few persons?” and conclude that the information to be kept secret must be negative. The impact that a request for a confidentiality agreement could have to discourage enrollment when recruiting for clinical trials is counter to the public policy of encouraging and facilitating the development of new drugs. While the focus of the FDA regulations described throughout this Article is the safety of trial participants, the FDA also seeks to foster development of new drugs that are effective.¹⁷⁵ An agreement, at this stage or any time during the trial, might give the relationship an adversarial or at least party-counterparty flavor, potentially undermining the mutual candor desired in the PI-participant relationship, especially if there is a conventional doctor-patient relationship.

This promise of confidentiality could be set forth in the ICF itself, not as a separate document, but included with other prohibitions and cautions. It could expressly cover pre-enrollment disclosures. This is also a good place to include prohibitions on posting on social media.¹⁷⁶ A promise of confidentiality, even if included only somewhere in a lengthy document with many independent provisions, would likely be binding on the participant in the absence of a successful conventional contract defense such as fraud, duress, or unconscionability. Enforceability presents questions of contract law of the jurisdiction whose law applies that are beyond the scope of this Article.

The participant’s failure to read the agreement, standing alone, is not

outside the developing organization may participate in the debugging, testing, and evaluation . . . In setting up a beta-test agreement, the tester must . . . sign a confidentiality agreement . . .”). For a current template including a confidentiality agreement for beta testing, see *Beta Test Agreement* ¶ 2, <https://www.upcounsel.com/beta-test-agreement> [<https://perma.cc/3JX6-XLJG>].

174. See Confidentiality Agreement, *supra* note 97.

175. “FDA is responsible for *advancing the public health by helping to speed innovations that make medical products more effective*, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.” FDA, WHAT WE DO – FDA MISSION (Mar. 28, 2018), <https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20Basics> FDA%20Mission,and%20products%20that%20emit%20radiation [<https://perma.cc/Z57G-FS68>] (emphasis added).

176. See *infra* text accompanying notes 223-224 (discussing chatrooms).

ordinarily a defense.¹⁷⁷ The Seventh Circuit has held that “a software license agreement ‘encoded on the CD-ROM disks as well as printed in the manual, and which appears on a user’s screen every time the software runs’” was valid because the buyer has an opportunity to read the license.¹⁷⁸ The court also found that “[s]hrinkwrap licenses are enforceable unless their terms are objectionable on grounds applicable to contracts in general (for example, if they violate a rule of positive law, or if they are unconscionable).”¹⁷⁹ In the clinical trial enrollment setting, there is to be no pressure on the person to enroll and the keystone of the informed consent process is full disclosure and responsiveness to questions, factors which, if satisfied, should counter any argument of duress, for example.

Another issue is the scope of any agreement. The prospect cannot be expected to agree not to disclose important information about the trial to her primary care physician (PCP),¹⁸⁰ or to her spouse, children, and others she might consult or inform when deciding whether to enroll as well as after enrollment. Moreover, any treating physician *should* be informed of the participant’s involvement in the trial.¹⁸¹ For this reason, the participant should carry a card that states he is in a trial, identifying the trial, so that in an emergency anyone treating the participant can take this information into account.

Under insider trading law trading may be prohibited even if there is no agreement not to trade in addition to an agreement to keep information confidential.¹⁸² The confidentiality agreement is enough to establish the relationship of trust and confidence, at least under Rule 10b5-2(b)(1), to trigger misappropriation. In any event, if the principal concern is that anyone involved in the trial does not trade, rather than a sweeping agreement not to reveal confidential information a middle ground could be an express agreement *only* not to buy or sell any securities of the trial sponsor. Requesting this agreement from a layperson, however, might be like telling her, “Don’t think about elephants,” planting an idea that might never have occurred to her, especially in this non-financial setting. Moreover, it does not address tipping or trading in a stock other than that of the sponsor, as in *Panuwat*, for example. Nor does this narrowly

177. See, e.g., *Ballas v. Virgin Media, Inc.*, 18 Misc.3d 1106(A), 2007 WL 4532509, at *3 (N.Y. Sup. Ct. 2007) (“A party is under an obligation to read a document before accepting its terms and cannot avoid the effect of the document by asserting [that] he or she did not read or understand [its] contents . . .”), *aff’d* 60 A.D.3d 712 (2009) (applying New York law).

178. *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1451-52 (7th Cir. 1996).

179. *Id.* at 1449.

180. At Northwestern, PIs are encouraged, with the participant’s approval, to tell a participant’s PCP about the participant’s involvement. *Investigator Manual*, *supra* note 79, Appendix A-3 at 42.

181. See, e.g., Joan Antoni Schoenenberger-Arnaiz et al., *Informing Primary Care Physicians Of Patients’ Involvement In Clinical Trials Carried Out At A Specialist Care Level*, 9 OPEN ACCESS J. CLINICAL TRIALS 59 (2017).

182. See *O’Hagan*, 521 U.S. at 656 (“[F]raud is consummated, not when the fiduciary gains the confidential information, but when, without disclosure to the principal, he uses the information to purchase or sell securities.”).

tailored approach preclude trading by the prospect's PCP and others to whom the prospect might provide MNPI she has learned in this setting, as they are not parties to the agreement.¹⁸³

Thus, at the pre-enrollment stage, insiders, temporary insiders, and those on the research side of the process who have a relationship of trust and confidence with the sponsor in which they obtained MNPI about the trial will likely violate Rule 10b-5 if they trade. The potential enrollee, however, could violate Rule 10b-5 only if she was tipped by any of those persons and then traded, or something in the process created a relationship of trust and confidence. Measures to avoid or discourage wrongful conduct are addressed in Part VII.

B. Active Trial Phase

Most insider trading cases in the pharmaceutical field have involved an insider of a sponsor, a PI, or other person who learned MNPI about the trial and then traded or tipped based on that information, as in *Kosinski* and *Martoma*. Beyond those scenarios, the devil is in the details.¹⁸⁴

1. Potential Securities Law Liability Arising from Trading Based on or Disclosing MNPI During the Trial and Other Concerns

a. Risk to the trial itself from a securities law violation or other misconduct

Though not a securities law issue *per se*, perhaps first and foremost from the perspective of the trial sponsor, the PI, and the latter's institution, any conduct by a participant that might compromise the trial, even lead to its termination, must be avoided.¹⁸⁵ A trial can be adversely affected, for example, by premature disclosure of nonpublic information on social media. The mother of a boy with Duchenne muscular dystrophy heard through Facebook that the trial her son was participating in had been stopped. To learn this devastating news this way was most unfortunate. Moreover, this causes those in the trial to try, more than usual, to find out which participants received the drug, and which received the placebo. This could lead to unblinding everyone, with some participants leaving the trial, potentially impairing the usefulness of the results of the trial.¹⁸⁶

183. Tipping can be a simple "thumbs up." Where a wife broke a promise to her husband not to reveal MNPI regarding his company, the court found that the SEC sufficiently alleged that she tipped her brother when she called him "and gave him 'a wink and a nod' regarding [the company]. [The brother] interpreted this to mean that he should sell" his stock in the company and did so. SEC v. Rocklage, 470 F.3d 1, 4 (1st Cir. 2006).

184. See, e.g., *supra* note 116 (describing the disagreement between the majority and dissent in *Martoma* regarding the meaning of a comma in *Dirks*).

185. 45 C.F.R. § 46.113.

186. Bibiana Campos Seijo, *Concerns Over Social Media and Clinical Trials*, CHEM. & ENG. NEWS (Nov. 18, 2018), <https://cen.acs.org/pharmaceuticals/drug-development/Concerns-over-social-media-clinical/96/i46> [<https://perma.cc/BP5N-DY2G>].

The Duchenne situation is a paradigm example of what *not* to do. This may become a serious issue with regard to the integrity of trials:

One potential concern is the use of online forums by variously interested persons or organizations with the intent of influencing the outcome of a clinical trial. This can occur when the forum collects information from study participants that is not otherwise publicly available (such as impressions of a study drug's efficacy, or the frequency of certain adverse events). We did not see any clear evidence of this in our searches, although we are aware of cases in which online forum postings by self-identified study participants have been cited as source material by journalists and financial analysts. Potential misuse could theoretically come at the hand of researchers, competing pharmaceutical companies, the financial sector, journalists, or any individual who has a stake in the success (or failure) of a drug in development. For example, parties could enter online forums with the aim of discouraging subjects from participating in trials, to solicit information directly from subjects that is not publicly available, or to post misinformation about study-related issues (such as adverse events).¹⁸⁷

b. Potential Rule 10b-5 liability for (A) classical trading, (B) misappropriating to trade, or (C) tipping

As in *Kosinski*¹⁸⁸ and *Martoma*,¹⁸⁹ as a clinical trial proceeds, those involved on the sponsor/investigator side may cross the line into unlawful territory by trading or tipping. Disclosures may be made to participants.¹⁹⁰ Individual participants will observe not only their own *apparent* response to the drug but possibly that of other trial participants, such as persons with whom they interact in a waiting room, the infusion or treatment area, or a support group.¹⁹¹ Information about a participant's medical status might also be shared with her PCP, who might piece together information about multiple participants among his patients or those of other physicians which was revealed as a doctor-patient

187. Seth W. Glickman et al., *The Potential Influence of Internet-Based Social Networking on the Conduct of Clinical Research Studies*, 7 J. EMP. RSCH. ON HUM. RSCH. ETHICS 71, 77 (2012).

188. See *supra* text accompanying notes 22-25.

189. See *supra* text accompanying notes 118-21.

190. Disclosure to the participant about her situation is not mandated by the FDA. See, e.g., 45 C.F.R. § 46.116(c)(8) (2018) (specifying that the participant be provided “[a] statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions”) (emphasis added). The FDA's rules provide, however, that “[w]hen appropriate” the ICF should include “[A] statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.” 21 C.F.R. § 50.25(b)(5) (2017).

191. See *infra* text accompanying note 202 regarding the materiality of this information.

confidence.¹⁹²

In the active trial stage, a participant is still neither a traditional insider nor a temporary insider of the trial sponsor,¹⁹³ unlike the PI who could be either. The *classical theory* thus does not apply to information the participant learns from the research team or from other participants. This shifts the analysis to the misappropriation theory and to tipping.

Clinical trial protocols include numerous pledges of confidentiality *to the participant*. Applying the misappropriation theory must consider whether there is a relationship of trust and confidence based on the agreements and understandings particular to the specific trial or participant. What the PI tells the participant about the participant's own situation, or any other information about the trial, is *not* ordinarily told in confidence, there is no relationship of trust and confidence *unless* Rule 10b5-2(b)(2) applies to the facts, *i.e.*, depending on the creation of a relationship between the parties during the interactions.

Participants would not ordinarily have a relationship of trust and confidence with their fellow trial participants *unless* (1) a disclosure to the fellow participant is expressly made in confidence, such as when one participant tells someone else, asking her to keep it confidential, and the recipient agrees,¹⁹⁴ or (2) the parties have developed a practice of sharing confidences as they bond during the trial.¹⁹⁵ What one participant simply observes about someone in the next infusion chair is not, without more, confidential.

After the participant is already enrolled, the prospect of obtaining a confidentiality agreement from her, which, applying Rule 10b5-2(b)(1), would create a relationship of trust and confidence, may be remote. Obtaining an agreement, even one that does no more than preclude trading in the stock of the sponsor, has the shortcomings noted earlier.¹⁹⁶ Moreover, if a team were to request a confidentiality agreement for the first-time mid-trial it might provoke a suspicion that something *really important*, likely negative, has happened. She might withdraw from the trial – an option she can exercise at any time.¹⁹⁷ Withdrawals in substantial numbers could jeopardize the completion of the trial.¹⁹⁸ The PI does not want to run that risk.

192. *See supra* text accompanying notes 26-27 (involving psychiatrist-patient confidentiality).

193. *See supra* text accompanying notes 166-67.

194. Whether there has been assent, such as by silence, is a matter of general contract law.

195. *See* Willis, *supra* notes 28-29; *see also, supra* note 170 (discussing SEC Rule 10b5-2(b)(2)).

196. *See supra* text accompanying note 175.

197. 45 C.F.R. § 46.116(b)(8) (2019); *Northwestern Univ.*, *supra* note 133, at p. 4.

198. *See* David B. Fogel, *Factors Associated With Clinical Trials That Fail And Opportunities For Improving The Likelihood Of Success: A Review*, 11 CONTEMP. CLIN. TRIALS COMM. 156 (Sept. 11, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092479/> [<https://perma.cc/6J9R-QU5V>] (discussing reasons for termination of clinical trials); Rebecca J. Williams et al., *Terminated Trials in the ClinicalTrials.gov Results Database: Evaluation of Availability of Primary Outcome Data and Reasons for Termination*, PLOS One (May 15, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4444136/pdf/pone.0127242.pdf>. [<https://perma.cc/Z6Z7-VJKR>].

Suppose the PI meets with the participant and tells her that the trial is being terminated because the results are tending strongly negative or because funding has run out. He may make this disclosure so that the participant knows that she may no longer have access to the drug.¹⁹⁹ Public disclosure of termination often has a dramatic effect on the sponsor's stock price, confirming its materiality.²⁰⁰ Suppose further that the participant acts quickly, before a public announcement, selling any stock she owns in the sponsor or buying a put option on the sponsor's stock, avoiding a loss or profiting on the sale of the puts. This disclosure by the PI may have breached a duty of confidentiality owed by the PI to the institution that employs him or to the trial sponsor. His disclosure may thus have been a breach that was an element of an unlawful tip. The participant's trade would not have been an unlawful tippee trade, however, if she did not know or should not have known that the PI breached a duty in revealing the information.²⁰¹ Trading by the participant also would have been misappropriation *only if* there was a relationship of trust and confidence between the PI and the participant, such as a confidentiality agreement or a newly developed personal relationship within Rule 10b5-2(b)(2).

Alter the facts a bit. The PI tells the participant that he has some information the participant might be interested in, but the PI can reveal it only if the participant agrees to keep it confidential. The participant agrees and the PI then tells her that the research team has unblinded the results and this participant, whose condition has improved during the trial, was one who received the drug, not a placebo. The participant now purchases the sponsor's stock, hoping to profit on a rise in the stock price after this favorable information is made public. Begging the fundamental question whether the information revealed to the participant only about herself is material,²⁰² this trade could trigger the misappropriation theory, because the oral pledge of confidentiality by the participant created a relationship of trust and confidence between the PI and the participant, which the participant has breached by trading.²⁰³

If the participant then told her son the good news, the mother may have unlawfully tipped her son, breaching a duty to the PI – *if* there was a sufficient benefit to satisfy that element of a tipping claim. In any event, applying SEC Rule 10b5-2(b)(3), a trade by the son based on what his mother told him could be a violation of the misappropriation theory unless the son can show that the mother

199. The FDA requires “return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated.” 21 C.F.R. § 312.59 (2017). Northwestern's IRB has a comparable requirement. *Northwestern Manual*, *supra* note 79, at 35. There may be an exception if the drug is a providing benefit for the particular participant. Then the sponsor may continue to provide it to the participant even if the trial is terminated as part of the protocol for termination of a trial.

200. *See supra* text accompanying notes 69-70 (regarding stock price movement as indicative of materiality).

201. *See supra* text accompanying note 42-46.

202. *See infra* text accompanying notes 229-34.

203. *See supra* text accompanying notes 18-30.

did not expect her son to keep the information confidential.²⁰⁴

If these activities come to light, it might embarrass the institution, for having prematurely released some aspect of the trial results or allowed them to be discovered by a participant. Though there might not be any institutional liability under the securities laws, the misconduct by its PI might tarnish its chances, or those of the PI who leaked, of becoming a site for further drug trials, or it could lose future funding or even have to repay funds already spent.²⁰⁵

Potential institutional liability in this context has not been discussed in this Article, and for good reason. The bar is very high for the SEC to prevail on that claim. It is extremely unlikely that the institution, such as a medical school, would be charged as a *direct participant* in the trade which acted with scienter, such as engaging in insider trading in securities held by its endowment, unless the manager of the endowment knew the MNPI.²⁰⁶

Section 21A of the Exchange Act provides for the imposition of a penalty on someone who directly or indirectly controlled the person who committed the insider trading violation.²⁰⁷ There are two barriers to SEC success in asserting that claim against the institution. First, controlling person status here cannot be based solely on the fact that the controlling person, the medical school, employed the inside trader. More must be shown to establish control.²⁰⁸ Second, the burden is

204. That rule provides that a duty of trust and confidence exists, whenever a person receives or obtains material nonpublic information from his or her spouse, parent, child, or sibling; *provided*, however, that the person receiving or obtaining the information may demonstrate that no duty of trust or confidence existed with respect to the information, by establishing that he or she neither knew nor reasonably should have known that the person who was the source of the information expected that the person would keep the information confidential, because of the parties' history, pattern, or practice of sharing and maintaining confidences, and because there was no agreement or understanding to maintain the confidentiality of the information. 17 C.F.R. § 240.10b5-2(b)(3) (emphasis added). Bear in mind, once again, that tippee liability and misappropriation liability on the part of the son who received the information in a relation of trust and confidence, as provided in Rule 10b-5(b)(3), are distinct claims. *See supra* two paragraphs following text at end of note 49.

205. *See* 21 C.F.R. § 16 (“Regulatory Hearing Before the Food And Drug Administration”). For a summary of sanctions, see FDA Guidance Document, *Clinical Investigator Regulatory Sanctions - Information Sheet* (Jan. 1998), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-investigator-regulatory-sanctions-information-sheet>. The FDA explained the process for disqualification of investigators at *Clinical Investigators - Disqualification Proceedings*. *See, e.g.*, 21 C.F.R. § 312.70 (“Disqualification of a clinical investigator”).

206. SEC Rule 10b5-1(c)(2) provides an affirmative defense for an entity that trades securities charged with insider trading if, among other things, the firm “implemented reasonable policies and procedures . . . to ensure that individuals making investment decisions would not violate the laws prohibiting trading on the basis of material nonpublic information. These policies and procedures may include those . . . that prevent such individuals from becoming aware of such information.” Rule 10b5-1(c)(2)(ii), 17 C.F.R. § 240.10b5-1(c)(2)(ii).

207. Exchange Act Section 21A(a)(1)(B), 15 U.S.C. § 78u-1(a)(1)(B).

208. Exchange Act Section 21A(a)(2), 15 U.S.C. § 78u-1(a)(2).

on the SEC to prove that the “controlling person knew or recklessly disregarded the fact that such controlled person was likely to engage in the act or acts constituting the violation and failed to take appropriate steps to prevent such act or acts before they occurred.”²⁰⁹ The onerous nature of these conditions may explain why there are no decided cases assessing a penalty for control person liability outside the context of entities regulated by the SEC, such as a broker-dealer.²¹⁰ Even if an institution concludes that there is nothing to fear here, however, the fact that the institution implemented the suggestions in Part VII should cause the SEC to think more than twice about asserting an institutional claim.

Entering into a confidentiality agreement presents a potential conundrum. If the sponsor or the research institution wants to minimize the risk of disclosure of MNPI, whether or not they are concerned about anyone’s unlawful trading, the prudent thing is to obtain a confidentiality agreement and highlighting it to the participant (where it might be one of many fine print provisions, say in the ICF). Doing so, however, makes the recipient of information vulnerable to violating Rule 10b-5 if she were to trade, an exposure that might not exist *but for* that agreement. This may be seen as boxing in the recipient or, perhaps worse, setting the participant up for a problem were she to trade without fully appreciating the legal risk. Is it appropriate for the sponsor or institution to place the participant it recruited at risk in that manner?

c. Risks of insider trading violation by government personnel

Persons other than PIs, their teams, trial participants, and people they know who lawfully come into possession of MNPI about a clinical trial, most notably FDA personnel, could be impacted by insider trading laws. FDA employees as well as their spouse and minor children are prohibited from holding financial interests, like stock, in certain businesses regulated by FDA. This includes many companies working in the drug, biologic, medical device, food, and tobacco industries, among others.²¹¹ In one case, an FDA chemist was charged with insider trading based on confidential information about at least 27 upcoming FDA announcements of drug approval decisions, positive and negative, generating more than \$3.6 million in illicit profits and avoided losses.²¹² The defendant was

209. Exchange Act Section 21A(b)(1), 15 U.S.C. § 78u-1(b)(1).

210. In that context, the proceeding is commonly based on a failure by the broker to supervise. *See, e.g., In The Matter Of SG Americas Securities, LLC* Exchange Act Release No. 59,401, 95 SEC Docket 580 (Feb. 13, 2009) (sanctioning firm and direct supervisor of employee for failure to supervise what was the other employee’s unlawful trading, including apparent insider trading).

211. FDA, PROHIBITED FINANCIAL INTERESTS FOR FDA EMPLOYEES, *Who are restricted from holding financial interest in SROs?* (July 22, 2020), <https://www.fda.gov/about-fda/ethics/prohibited-financial-interests-fda-employees> [<https://perma.cc/Q83P-5N6K>].

212. SEC Litigation Release, *SEC Charges FDA Chemist With Insider Trading Ahead of Drug Approval Announcements*, Litig. Rel. No 21,907 (Mar. 29, 2011), <https://www.sec.gov/news/press/2011/2011-76.htm> [<https://perma.cc/J2Z6-72NQ>]. The defendant settled the case. SEC

also indicted; he pleaded guilty and received a five-year sentence.²¹³

There had been a question whether any of the doctrines of insider trading developed under Rule 10b-5 applied to government employees. For example, did a government employee owe a duty of trust and confidence to anyone, so that the misappropriation theory could apply to his trading or tipping?²¹⁴ In the complaint against the FDA chemist just described, the SEC alleged that the FDA employee owed a duty of trust and confidence to the FDA.²¹⁵

Congress sought to eliminate any ambiguity in this respect by enacting The Stop Trading on Congressional Knowledge (“STOCK”) Act in 2012.²¹⁶ In pertinent part, Section 21A(h) of the Exchange Act, amended by the STOCK Act, now provides that for purposes of Rule 10b-5 each executive branch employee, each judicial officer, and each judicial employee owes a duty arising from a relationship of trust and confidence to the United States Government and the citizens of the United States with respect to material, nonpublic information derived from such person’s position as an executive branch employee, judicial officer, or judicial employee or gained from the performance of such person’s official responsibilities.²¹⁷

Thus, information learned by an FDA employee “derived from such person’s position as an executive branch employee” provides the predicate for a charge of insider trading.

The potential targets of an enforcement action are many, with two principal theories supplemented by tipper-tippee liability, reaching the sponsor (and its insiders), the clinical trial team (not just someone designated a PI), and advisors to any of them, such as an investor advisor to the sponsor,²¹⁸ a member of the

Litig. Release, *Former FDA Chemist Settles SEC Insider Trading Charges*, Litig. Rel. No. 22, 171 (Nov. 30, 2011), <https://www.sec.gov/litigation/litreleases/2011/lr22171.htm> [<https://perma.cc/JES8-GKUJ>].

213. Press Release, DOJ, *Former FDA Chemist Sentenced to 60 Months in Prison for Insider Trading* (Mar. 5, 2012), <https://www.justice.gov/opa/pr/former-fda-chemist-sentenced-60-months-prison-insider-trading> [<https://perma.cc/7ZJL-7NNR>].

214. See *Bainbridge L&P*, *supra* note 1, at 110-12 (describing pre-STOCK Act debate).

215. See *supra* notes 212-213; Cmpl. at ¶¶ 46-56, SEC v. Liang, No. 8:11-cv-00819 (D. Md. Mar. 29, 2011), <https://www.sec.gov/litigation/complaints/2011/comp21907.pdf> [<https://perma.cc/8KHM-8BUE>].

216. STOCK Act, Pub. L. 112-105, 126 STAT. 291., 112th Cong. (2012). The background of The STOCK Act is described at *Bainbridge L&P*, *supra* note 1, at 109-13.

217. 15 U.S.C. § 78u-1(h). The STOCK Act provides that nothing in the STOCK Act “shall be construed to— (1) impair or limit the construction of the antifraud provisions of the securities laws . . . or (3) be in derogation of existing laws, regulations, or ethical obligations governing Members of Congress, employees of Congress, executive branch employees, judicial officers, or judicial employees.” STOCK Act, Pub. L. 112-105, 126 STAT. 291, 112th Cong. (2012). An “executive branch employee,” as defined in 5 U.S.C. § 2015, includes an employee of the FDA, part of the executive branch of the government.

218. See text accompanying notes 124 (citing case).

sponsor's advisory board,²¹⁹ and government employees.²²⁰

d. Other risks of violating Rule 10b-5 not involving insider trading

Anyone with MNPI about a drug trial should not lose the forest of overall trial integrity for the insider trading tree. In particular, anything nonpublic that the participant learns from any source conducting the trial should not be *publicly* revealed by him because public revelation might compromise the trial.²²¹ One paper recommended that “research teams should also talk to their study subjects about where and how they are obtaining information in order to prevent behaviors and correct misinformation that could put a subject’s safety or *the study objectives* at risk.”²²² For these and other reasons, participants must be requested not to post clinical trial information on investor, disease-related, or drug-specific chatrooms.²²³ Participants asked not to post on chatrooms may, however, perceive this as “a violation of their right to self-expression.”²²⁴

Returning to securities law concerns, a person posting on a chatroom information he knows to be false, or posts recklessly, might violate Rule 10b-5. This could have the characteristics of a classic “pump and dump scheme.” Where insiders inflate demand for a stock by disseminating laudatory information about a company—information that is usually false. If the market reacts favorably, the insiders’ cash in their shares before the market readjusts and the share price collapses.²²⁵

219. SEC Litig. Release, *SEC Charges Pharma Insider and Two Relatives with Insider Trading*, Litig. Rel. No. 25, 458 (July 28, 2022), <https://www.sec.gov/litigation/litreleases/2022/lr25458.htm> [<https://perma.cc/7H6U-WWXR>]. (Reporting complaint filed against member of advisory board of sponsor who allegedly tipped his brother who in turn tipped his son-in-law after he learned the FDA “had concluded that the clinical study for [the sponsor’s] developmental drug . . . was not adequate and well-controlled,” and reporting that the initial tipper had settled the case).

220. *See supra* text accompanying notes 214-15 (citing case and discussing STOCK Act).

221. *See supra* text accompanying note 185 (discussing power of IRB to terminate trial).

222. Glickman, *supra* note 117, at 71 (emphasis added). *See also id.* at 73-74, 77.

223. *See* examples of chatrooms or virtual communities are at Healthful Chat, <https://www.healthfulchat.org/health-chat-rooms.html> [<https://perma.cc/LUD3-TU8E>] (last visited Jan. 19, 2023); *see also* Patient Community Forums, <https://patient.info/forums> [<https://perma.cc/4QWY-G8N2>] (last visited Jan. 19, 2023) (providing list and links to disease-specific chatrooms); Yahoo! Finance, <https://finance.yahoo.com/quote/GSK/community/> [<https://perma.cc/9LGX-RTC6>] (last visited Jan. 19, 2023); London South East, <https://www.lse.co.uk/ShareChat.asp?ShareTicker=GSK&share=Glaxosmithkline> [<https://perma.cc/HV3Q-A66B>] (last visited Jan. 19, 2023) (chatrooms regarding stock of pharmaceutical company GlaxoSmithKline plc); Drugs-Forum, <https://drugs-forum.com/> [<https://perma.cc/8PRB-2ATW>] (last visited Jan. 19, 2023) (chatroom regarding any drug).

224. Glickman, *supra* note 187 at 78.

225. *United States v. Weed*, 873 F.3d 68, 70 n.1 (1st Cir. 2017), *quoting* *Garvey v. Arkoosh*, 354 F. Supp. 2d 73, 76 n.4 (D. Mass. 2005).

The initial purchase of sponsor stock by someone involved in the clinical trial might be entirely innocent. If, however, negative information about the drug emerged during the trial and anyone knowing it then posted *false favorable information* on a chatroom to retard a decline in the price of that stock, he might be liable to public investors under Rule 10b-5 on the price maintenance theory.²²⁶ If the participant later sold the stock before the company released the bad news, insider trading would become an issue.²²⁷

The practical point bears emphasis – one who buys stock may be locked in to retaining that stock once she learns MNPI that is unfavorable, *if* she is an insider or has a relationship of trust and confidence with the source of that information. The participant is frozen until the information becomes public or is no longer material. Stock bought many years ago might have to be held for many more.

C. What Information About a Clinical Trial Is Material?

Materiality is often incontestable, for example where the stock price moves immediately and significantly after release of new information and nothing else is offered to account for that but the new information. The clinical trial insider trading case is one where the SEC's assertion of materiality could reasonably be contested, as where the price movement is not dramatic. If the information is *not* material there is no concern about anyone trading while aware of it.

The fundamental question is whether the reasonable investor would find the information important in making an investment decision regarding the stock of the trial sponsor. Because a clinical trial is an ongoing process, the probability/magnitude test could come into play as events ebb and flow.²²⁸ In many clinical trials, whether the drug succeeds or fails has a potentially dramatic impact on the company, satisfying the magnitude prong.²²⁹ To apply that materiality test a court or jury would also have to determine what the probability was, *at the time of the securities transaction underlying the claim*, that the trial was going to succeed or, in the mirror image, fail. Material information could

226. Posting false information to *maintain* the price when the participant has learned MNPI and wants to dump the stock before the truth becomes public, may violate Rule 10b-5. Under the inflation maintenance theory, “a misrepresentation causes a stock price ‘to *remain* inflated by preventing preexisting inflation from dissipating from the stock price.’” Goldman Sachs Grp., Inc. v. Arkansas Teacher Retirement Sys., 141 S. Ct. 1951, 1959 (2021), *quoting* FindWhat Investor Grp. v. FindWhat.com, 658 F.3d 1282, 1315 (11th Cir. 2011) (emphasis in *FindWhat*).

227. The timing of when a company should disclose new material information is typically properly a matter of discretion for management of the company. *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993) (“a corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact. Rather, an omission is actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts.”)

228. *See supra* text accompanying notes 64-72.

229. *See supra* text accompanying note 70. The question is how significant to the company FDA approval or disapproval would be.

emerge at any stage of the process. This is an inherently fact-intensive question at every point, as the probability of a positive or negative outcome ebbs and flows.

There is another materiality-related factor. The scienter, an intent to deceive necessary for liability, depends on what the alleged trader or tipper knew about the trial – facts – as there is liability only if the person knew or recklessly disregarded that the facts were material. This depends on what *she* knew.²³⁰ The information known to the participant – or what she *thinks* she knows – might be materially *incomplete*, she might be entirely wrong about what she thinks she knows. Information about a single trial participant, such as herself, might not be material. She might misinterpret the information she *thinks* she knows – her perceived improvement of *her own health* or that of others in the trial might be the result of the placebo effect, providing no meaningful information about the efficacy of the drug. What she learns and observes about a few other participants might still not, in the aggregate, be material. The accuracy and materiality of what is known by the participant might depend on whether the trial is double blind, single blind, or open label at the time she trades. On the other hand, *isolated instances* of adverse effects that might be attributable to the drug could be material, as the Court held in *Matrixx*.²³¹

A fact that may seem innocuous may be material. For example, financial institutions maintain a restricted list of companies in which company personnel are prohibited from trading. The list contains no information other than the name of the company whose stock is off limits. There is no explanation why the company is on the list.²³² The single fact that a company is on the list, however, might pose insider trading concerns:

The problem with the restricted list is that the simple fact of placement of a company on the list—which by definition will be available to a wide variety of persons within and without the firm—is then a signal that there is undisclosed material information about the particular issuer, which by itself might operate as a tip.²³³

Demonstrating the level of detail that may come into play in making this determination, consider the putative class action where the court declined to dismiss the complaint where the plaintiff alleged there were materially incomplete disclosures regarding a Phase III trial. Assessing materiality required an understanding of the particulars of an international trial. The court held that the plaintiff “sufficiently pleads that Defendants’ statements characterizing their Phase 3 trials as conducted in ‘Europe’ were misleading” when the European trials were all conducted in “Eastern Europe.” “Given that [plaintiff] alleges differences between Eastern and Western European patient populations and that the FDA treats clinical data from those populations differently, Defendants’

230. *See supra* text accompanying notes 33-38.

231. *See supra* text accompanying notes 67-68.

232. *Langevoort Insider Trading*, *supra* note 1, at § 12:3.

233. *Id.*

statements ‘create[d] an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed].’²³⁴

D. When Does Information About a Clinical Trial Become Public?

Rule 10b-5 is not violated if the trading is based on information that is public. A potential trader has no way to know when an event will occur that constitutes public revelation of material information – this raises questions of both fact and law.²³⁵ Information can become public when it leaks²³⁶ or when it is posted to a chatroom. As noted earlier, if information can be found on the internet it is most likely public, but its absence from internet search results does not mean it is *not* public.²³⁷

There are several ways information about a trial is *lawfully* provided to a *limited* audience, where it is not a tip.²³⁸ Information regarding ongoing clinical trials is presented at medical conferences. A major cancer conference had restricted participation; after repeated leaks, however, the proceedings and written presentations were opened to the public.²³⁹ Many conferences, however, remain

234. *Pardi v. Tricida, Inc.*, No. 21-cv-00076-HSG, 2022 WL 3018144, at *5 (N.D. Cal. July 29, 2022) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).

235. The sponsor in *Kosinski* issued a press release announcing the hold on any further activity in the trial. See Press Release, SEC, *Regado Biosciences Announces Clinical Hold Of Regulate-Pci Trial Following Voluntary Halt of Trial By Regado*, Exhibit 99.1 to Form 8-K of Regado Biosciences, Inc. (July 9, 2014), <https://www.sec.gov/Archives/edgar/data/1311596/000119312514264453/d755202dex991.htm> [<https://perma.cc/GH36-XUT4>].

236. See Adam Feuerstein & Matthew Herper, *Early Peek At Data On Gilead Coronavirus Drug Suggests Patients Are Responding To Treatment*, STAT (Apr. 16, 2020), <https://www.statnews.com/2020/04/16/early-peek-at-data-on-gilead-coronavirus-drug-suggests-patients-are-responding-to-treatment/> [<https://perma.cc/SNW4-4ALL>] (reporting on preliminary clinical trial results, based on comments made by PI within the past week “during a video discussion about the trial results with other University of Chicago faculty members. The discussion was recorded, and STAT obtained a copy of the video.”).

237. See *supra* text accompanying note 63 (discussing *Libera*). *Libera* remains the touchstone. See, e.g., *SEC v. Mayhew*, 121 F.3d 44, 50 (2d Cir. 1997) (applying *Libera* in determining information on which defendant traded was nonpublic).

238. SEC Regulation FD (17 C.F.R. pt. 243) requires a public company to make simultaneous or prompt *public* disclosure when a “senior official” of the company makes a private disclosure to anyone in certain categories of persons, such as a securities research analyst. The nonpublic disclosures discussed in this Article would not likely trigger a disclosure obligation under Regulation FD.

239. The American Society of Clinical Oncology (ASCO) holds an annual conference. There was an “ASCO effect” where stock prices of companies whose clinical trial results were going to be revealed there “would often go up or down based on early word on results that were sent to about 25,000 people 2 weeks ahead of time so people could plan what sessions they wanted to attend at the meeting.” Merrill Goozner, *Stocks’ Study Renews Concerns Over Insider Trading on Oncology Drugs*, 103 NATL. CANCER INST. 1652, 1655 (2011). ASCO now publishes abstracts

closed.²⁴⁰ Whether or not the presentation is open to the general public, attendees could carry a phone, tablet, or even a laptop as they roam the conference rooms, in order to place a trade in the stock of a trial sponsor based on what is revealed there, before the press could even blog about the previously undisclosed information. Whether this event constitutes public disclosure is an open question, likely to depend on the specifics of the event, such as who was invited.

Registrants are generally not required to sign any confidentiality or nondisclosure agreement to attend or to access materials (often posted online before the conference opens). For example, the Terms and Conditions for a September 2022 program sponsored by the National Comprehensive Cancer Network imposed only a very limited restriction on the use of information provided at the program.²⁴¹ Attendees are not insiders, nor temporary insiders. There is no relationship of trust and confidence that would preclude trading. Under these circumstances the attendee is likely free to trade, she need not wait to trade once the information is disclosed to a broader audience.

There may be internal presentations at the institution conducting the trial, such as during grand rounds at a hospital, where personnel who are not part of the clinical trial team learn about the status of the trial before any “broad, non-exclusionary distribution” of the information.²⁴² Disclosure to a large number of persons, especially where – as here – there is typically no express pledge of confidentiality, could be deemed to be public disclosure, even if the event is limited to employees of the institution.

Developments in a clinical trial are often first disclosed intentionally in a

when they are sent to participants. *Id.* Currently the conference is essentially open to the public. 2023 ASCO Annual Meeting, <https://conferences.asco.org/am/attend> [<https://perma.cc/DV8Q-5NNP>] (last visited Jan. 19, 2023).

240. *See, e.g.*, PER, *21st Annual International Congress on the Future of Breast Cancer® East*, https://event.gotoper.com/event/7f23d043-df27-42c6-92ab-609355ae164a/summary?utm_medium=paid&utm_source=google&utm_campaign=ibc_east&utm_term=awareness_breast&utm_content=_&gclid=CjwKCAjw7vuUBhBUEiwAEdu2pLnWL4hjIK5XcrZihKWQ1ygX8DQj3pshrNjMm-591Fue6rLvZ82ABoCsDYQAvD_BwE [<https://perma.cc/3FAG-HKKH>] (regarding 2022 meeting) (last visited Jan. 19, 2023). A non-systematic internet search reveals that many conferences are now open to non-professionals, presumably including trial participants, though often at a very high fee to attend. Webcasting makes it more feasible for non-professionals to attend.

241. *See* NCCN, *Event Terms and Conditions*, ¶ 1.4 (“By registering for NCCN 2023 Congress, you agree not to sell, trade, transfer, or share your access link and/or onsite meeting badge, unless such transfer is granted by the Organizer.”); ¶ 1.7 (No part of the NCCN 2023 Congress, including handout materials and slides, may be recorded, rebroadcasted, reproduced, or transmitted in any other form or by any means, electronic or mechanical, without first obtaining written permission from NCCN, participants are permitted to print a copy of handouts for personal use only.”), <https://web.event.com/event/98f8aeb9-2328-420b-9d38-7f0e08509127/websitePage:9e1112b4-3248-4591-9060-202baee45470> [<https://perma.cc/FKX6-H4EL>] (last visited Jan. 19, 2023).

242. *See supra* text accompanying note 62 (quoting Regulation FD).

medical journal.²⁴³ Publication is typically preceded by a “preprint” of the article before publication in a journal. [A] preprint is defined as a complete written description of a body of scientific work that has yet to be published in a journal. Typically, a preprint is a research article, editorial, review, etc. that is ready to be submitted to a journal for peer review or is under review.²⁴⁴

In one case, an author of a paper traded in advance of the publication of the article, using his knowledge of the impending publication to time his trade.²⁴⁵ Reviewers of a preprint may sign a confidentiality agreement or are subject to the publication’s peer review confidentiality policy.²⁴⁶ Breaching that agreement and trading is misappropriation, not trading on a tip.²⁴⁷

The sponsor might give journalists with special knowledge in the field an advance look at trial results, so that when public disclosure is made, such as through a press release by the sponsor, the reporters will be able to publish a prompt, *informed*, not spur-of-the-moment, analysis. Typically, the contents revealed to the journalist are subject to an embargo, a time-limited confidentiality agreement. The policy of the New England Journal of Medicine, for example, states that it “employs a media embargo system, which allows journalists time to conduct interviews in the days before an article’s publication.”²⁴⁸

This journalistic practice presents two potential opportunities for unlawful

243. See, e.g., *supra* note 235 (noting publication of early-stage trial results in a medical journal).

244. Philip E. Bourne et al., *Ten Simple Rules to Consider Regarding Preprint Submission*, 13 PLOS COMPUT. BIOL. 13(5) (2017), <https://doi.org/10.1371/journal.pcbi.1005473> [<https://perma.cc/T3GS-4H92>].

245. SEC Litigation Release, *SEC v. Changnian Liu*, Litig. Rel. No. 15,783 (June 17, 1998), <https://www.sec.gov/litigation/litreleases/lr15783.txt> [<https://perma.cc/RT56-HM2T>] (reporting that the lead author of paper about drug under study settled case in which SEC alleged he traded before the article was published when he knew the article was to be published in a few days).

246. See, e.g., NATURE, *Editorial Policies – Confidentiality*, <https://www.nature.com/nature-portfolio/editorial-policies/confidentiality#:~:text=Editors%2C%20authors%20and%20reviewers%20are,of%20reviewers%20are%20not%20released> [<https://perma.cc/4D8E-PECN>] (“Unless otherwise declared as a part of open peer review, the peer review process is confidential and conducted anonymously; identities of reviewers are not released. Reviewers must maintain confidentiality of manuscripts. . . Nature Portfolio reserves the right to contact funders, regulatory bodies, journals and the authors’ institutions in cases of suspected research or publishing misconduct.”) (last visited Jan. 19, 2023); THE LANCET, *Peer Review*, <https://www.thelancet.com/peer-review> (last visited Jan. 19, 2023). (“Authors share their work with editors on the principle of confidentiality and the expectation that editors and peer reviewers will not circulate the manuscript outside of the peer review process.”).

247. See *supra* second paragraph of text following note 49.

248. THE NEW ENGLAND J. OF MED., *Editorial Policies Embargo*, <https://www.nejm.org/about-nejm/editorial-policies> [<https://perma.cc/H5CD-B98T>] (last visited Jan. 19, 2023). Earlier practices were discussed in M. Waldholz & E. Wyatt, *Stock Traders Get Early Look at Drug Studies*, WALL ST. J. (Feb. 18, 1988), <https://www.sec.gov/news/press-release/2021-94> [<https://perma.cc/2F8W-UJEF>].

trading. If the journalist accepted the early look under a pledge of confidentiality and then traded based on the information, he is exposed under the misappropriation theory because the journalist breached a duty of confidentiality. A leading case involved persons who obtained and the traded and tipped based on advance information about upcoming market-moving columns in the *Wall Street Journal*.²⁴⁹ The author of some of the columns tipped information about the contents of forthcoming columns by himself and others to stockbrokers.

The Second Circuit found it clear that [the columnist], as an employee of the *Wall Street Journal*, breached a duty of confidentiality to his employer by misappropriating from the *Journal* confidential prepublication information, regarding the timing and content of certain newspaper columns, about which he learned in the course of his employment, which sufficed to establish a violation of Rule 10b-5 in connection with the subsequent trading.²⁵⁰

There are many ways in which clinical trial results may become public, other than by a conventional press release, inclusion in an SEC disclosure document (which often attaches a press release as an exhibit), or in a scientific journal. In all cases it is critical to determine *when* nonpublic information becomes public, as well as whether it is material. This involves the exercise of informed *legal* judgment, often at one's peril.

Assume that an insider learns that clinical trial MNPI is about to be made public, as in a press release or SEC filing. Is it lawful for that insider, sitting at his computer logged into his brokerage account, having completed all of the terms of his order, to click on "place order" as soon as someone else presses "send" to release the news in a way that is "reasonably designed to provide broad, non-exclusionary distribution of the information to the public."²⁵¹ The best practice is to wait until the investment professionals whose trading sets the market price have had some time, however short, to factor in this information, so that the individual trading does not benefit from knowing the inside information as to both the facts to be disclosed *and* the timing of disclosure.²⁵²

249. *United States v. Carpenter*, 791 F.2d 1024 (2d Cir. 1986) (affirming convictions, including under Rule 10b-5 applying a version of the misappropriation theory before the definitive ruling in *O'Hagan*), *aff'd* by equally divided court on Rule 10b-5 claim, 484 U.S. 19 (1987) (affirming convictions for mail and wire fraud).

250. *Carpenter*, 791 F.2d at 1029, 1034.

251. *See supra* text accompanying note 62 (quoting Regulation FD).

252. *See Bainbridge L&P, supra* note 1, at 68-70 (stating it is permissible to trade once "the price should have started rising or falling (as the case may be) to reflect the new information"). *See also, supra* text accompanying note 63, describing the *Libera* test for when information becomes public. This may happen very fast, if the market is driven by algorithmic trading enhanced by artificial intelligence, factoring the content of new information into the process. "Whereas initial algorithmic trading relied on preset electronic instructions to execute trading strategies, new technology is introducing artificially intelligent ('AI') trading algorithms that learn dynamically from data and respond intuitively to market changes." Gine-Fail S. Fletcher, *Deterring Algorithmic Manipulation*, 74 VAND. L. REV. 259, 259 (2021); *Cox, supra* note 72, at 97 (describing algorithmic trading as occurring in milliseconds or microseconds, based on a variety of data, including news

*E. Summary of Types of Insider Trading Claims That Might Arise
in Clinical Trial Setting*

This Article has identified several quite plausible situations where someone involved in or privy to information about a clinical trial might run afoul of the Rule 10b-5 prohibition on insider trading or otherwise violate Rule 10b-5. They include:

Trading by an insider, including a temporary insider, of the trial sponsor, aware of MNPI about the company, including MNPI about the sponsor's clinical trial, but also, in some circumstances, a pending acquisition by or of the company or other material event.

Trading by a participant in the trial if she knows or discerns, from nonpublic sources, MNPI regarding the trial – but only if the information was obtained from one or more persons with whom the participant has a relationship of trust and confidence. Depending on the circumstances – development of a practice of sharing confidences or entering into a confidentiality agreement, which need not be a formal document – the misappropriation theory may apply. Limited but arguably unrestricted disclosure, such as at a medical gathering, even before more conventional disclosure such as a press release, may make the information public, so that those who have the benefit of early information may trade.

Tipping MNPI regarding a trial. This includes tips by an insider of the sponsor, anyone on the trial team at the investigating institution, and – at least in theory – a participant in the trial. The tip is unlawful only if the arguable tipper could not himself have traded because to do so would have violated the classical or misappropriation theory.

Providing information to a journalist to give her an advance look at trial information to facilitate informed publication, where providing early information might take on the trappings of a tip by that member of the trial team, though *not* if the investigator's *sole* purpose in disclosing was to facilitate accurate reporting.

Being deceived into revealing MNPI about the trial. While the person deceived by the wrongdoer would not ordinarily violate the law, that person could become enmeshed in a proceeding against the person who engaged in the deception. A member of the trial team or a participant intentionally or recklessly posting arguable MNPI regarding the trial on any chatroom, all the more so if it is false.

In considering the consequences of trading in the stock of a trial sponsor, or a company “economically linked” to it, any entity or individual must bear in mind the consequences of becoming involved in an SEC investigation, even if no proceeding is ultimately filed by the SEC.

A securities law violation or other misuse of MNPI might compromise the trial itself, because of conflict-of-interest issues on the part of those who traded, such as the PI.

VII. RECOMMENDATIONS FOR PROPHYLACTIC ACTION

Many steps should be taken in connection with clinical trials, including those routinely implemented in the for-profit corporate world, to reduce the risk of unlawful conduct, or even of embarrassment and reputational harm that can arise if an investigation ensues.

Any entity, including a for-profit trial sponsor and a not-for-profit institution conducting the trial, should have written policies prohibiting insider trading, typically more broadly defined than the law reaches today, signed by each appropriate person (erring on the side of inclusion) and re-affirmed periodically. Insider trading policies must be updated to reflect developments in the law. One example is including the “shadow trading” theory in the entity’s insider trading policy if only to demonstrate how unpredictably broad the law may be.²⁵³

Corporate insider trading policies are sometimes filed with the SEC as exhibits to a variety of company reports or are otherwise made public by the company. Some are better than others, and anyone contemplating using one as a model should bear in mind that they are *tailored for the circumstances of the particular company or institution*. Some of the most important components are noted here, by no means everything that should or might be included in the policy for a pharmaceutical company or institution that conducts trials.

The steps suggested here should extend to all employees involved in trials who have access to nonpublic information about the trial.²⁵⁴ There should be periodic training explaining generally the law of insider trading and the prohibition on trading when aware of MNPI about a drug or the sponsor of a drug trial, with ample time for questions and answers.²⁵⁵ What reason could there be *not* to do this training from time to time, save the time it takes to train every so often and the potential legal fees in connection with the presentation? Training could include requiring viewing of a video, where those who must watch it *cannot* fast-forward or click on “Next” to avoid watching or listening to the content. Live training could be done under the aegis of a professional organization or group of institutions to reduce the cost for a single institution. Considering this approach must consider whether the participating entities have different written policies, and that confidential information might be revealed during the typical question and answer session.

The pledge of confidentiality should be required of anyone arguably a temporary insider – to the extent that they can be identified, such as temporary staff hired to do data entry – and of anyone who might learn material information

253. *See supra* text accompanying notes 128-29 (discussing shadow theory as addressed in *Panuwat*).

254. Training and policies that are signed should extend to some persons who are not directly involved in the trial, including senior administrative personnel, such as the dean of a medical school, who might learn MNPI in their general oversight role.

255. This explanation of the law need not, indeed should not, be of the scope presented in this Article. The typical description, which often errs on the side of over-designation of what is prohibited may be just a few pages.

about an ongoing trial, including during a chat over coffee with a colleague not involved in the trial or during an organized internal presentation.

The FDA Form 1572 requires disclosure to the sponsor of certain financial interests of the PI, including others involved in the trial.²⁵⁶ The best practice is to absolutely prohibit *any* trading in the stock of a company, including any derivatives whose value depends on the price of the sponsor's stock, by any person involved in any way in the conduct of a clinical trial sponsored or otherwise supported by that company or institution.²⁵⁷ When the trial results in publication, any conflict of interest must be disclosed by the authors.²⁵⁸ Someone who fails to comply with financial disclosure requirements and traded while aware of MNPI might thereby compound his Rule 10b-5 violation.²⁵⁹

One step, analyzed earlier, is to obtain a signed confidentiality agreement from the PI and the staff involved, and possibly trial participants, as early in the process as possible, even if none is signed by a participant until after the ICF is signed. Alternatively, or in addition, the entire investigation team and the trial participants should agree, in writing, not to trade, or *at the very least, at a bare minimum* be admonished not to trade.

Limits should be imposed on participants telling others about how the trial appears to be going, such as informing family members without running the risk of someone misappropriating MNPI told to them in confidence by the participant.²⁶⁰ To be sure, in the case of the trial participant these are substantial concerns only if the information they know, or perhaps deduce, is MNPI – unless they spread false information, which of course they should be admonished in no uncertain terms not to do. It would be best if participants did not share information among themselves about how they are doing vis-à-vis the purpose of the trial. While that information may provide a false impression of the effects of the drug, the more one knows about the apparent response of others the more likely one might create a meaningful mosaic of information that could actually be material, posing a risk that *any* trading or further disclosure could be unlawful.

256. 21 C.F.R. pt. 54. Disclosures are required of the spouse and each dependent child of the investigator and sub-investigator. 21 C.F.R. pts. 54.2(d), 54.4. The FDA has provided guidance on financial disclosures in *Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators* (Feb. 2013), <https://www.fda.gov/media/85293/download> [<https://perma.cc/MXB6-CGLN>]. The recommendations regarding what financial information is to be provided when submitting a marketing application include disclosing “Any equity interest in any sponsor of the covered clinical study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. *Id.* p. 4, Item B.3.

257. Here consider the FDA's strict policy prohibiting ownership of any stock of a trial sponsor, among others. *See supra* text accompanying note 211 (discussing FDA policy).

258. *See, e.g.,* Jeffrey M. Drazen et al., *Toward More Uniform Conflict Disclosures — The Updated ICMJE Conflict of Interest Reporting Form*, 363 N. ENG. J. MED. 188 (July 8, 2010) (discussing conflict of interest disclosures in medical publications).

259. *See Kosinski*, 976 F.3d at 147.

260. *See supra* note 204 (discussing Rule 10b5-2(b)(3)).

This suggests that some effort should be made to isolate information about each participant from each other – though likely a fool’s errand.

If there is no confidentiality agreement with the participant, participants should be given scripted, low key but clear, cautions about what information they can reveal (and what they should not) and to whom they can reveal it *if the need arises*, explaining that a disclosure could undermine the trial, lead to termination of the trial because it has been compromised in some way, or have other adverse repercussions. They should be told that early termination of the trial might adversely affect their disease population, such as when termination of the trial or of their participation would mean that the drug can no longer be evaluated, at least as part of the current trial.

At the extreme, though likely impractical, measures could be taken to avoid consecutive or overlapping treatment appointments or to isolate participants if the trial entails coming to a hospital for a treatment or tests. This would be comparable to measures taken in the financial services world to separate (A) those doing research on issuers of securities or trading for the account of the firm from (B) those who provide services to those same companies, such as investment or commercial banking, where they invariably learn client MNPI.²⁶¹

The institution should direct trial participants not to post *any* information about *any* aspect of the trial on a chatroom and to reveal information *only* to persons who have a need to know. Best to have an agreement to that effect. This might seem unduly cautious. Nevertheless, better to be conservative to avoid any possible compromise of the trial. The participant ought to be able to respond *in general terms* to a social or community acquaintance who simply wants to know how the person is doing. The inquirer may know of the person’s malady but not that she is in a trial or what the drug is. The participant should be told he can discuss the *fact* of the trial if it comes up but not reveal the name of the drug or manufacturer *unless her participation in this trial* has been disclosed. These instructions and admonitions should be written, providing a copy to each participant, and they should be told to retain it.

One measure to consider, which in the corporate world is often applied only to more senior personnel, is to require prior approval of any trade – purchase or sale – in the securities of an issuer. This requires a robust approval process, which means that the approving person must have real-time access to information sufficient to determine whether there is MNPI which might require rejection of the request.²⁶² If there is such a policy, there must be a prohibition on revealing

261. See SEC Rule 10b5-1(c)(2), quoted *supra* note 206.

262. This practice is not fool proof. A senior attorney at Apple who was privy to draft financial disclosures and responsible for monitoring compliance with the company’s insider trading policy, pleaded guilty to a charge of insider trading. Press Release, United States Attorney’s Office for the District of New Jersey, *Apple’s Former Director of Corporate Law Admits Insider Trading* (June 30, 2022), <https://www.justice.gov/usao-nj/pr/apple-s-former-director-corporate-law-admits-insider-trading#:~:text=Gene%20Levoff%2C%2048%2C%20of%20San,by%20complaint%20in%20February%202019> [https://perma.cc/4SGN-JP3L].

In one SEC case, the defendant claimed that a trade was approved by the company’s general

that a request was declined, as it may imply the presence of MNPI in a specific direction.²⁶³

Given the practical difficulties of implementing some of these steps, trading in the sponsor's stock by anyone involved in the trial should be prohibited for the duration of the trial, including selling a pre-existing holding. For example, an investigator may purchase stock of a pharmaceutical company with which he has no current involvement, basing his purchase entirely on public information. Later he becomes a PI for that company's trial. If he learns MNPI about that company, such as clinical trial data, he may – he is likely to be – constrained from trading for a long time. This restriction could last for years, as more MNPI is learned; often there is no point at which all material information has been made public because new information may be developed on an ongoing basis.

VIII. CONCLUSION

The clinical trial setting can present temptations to engage in insider trading for anyone on the research team. Trial participants might experience the same urge. Many persons – corporate executives, medical professionals, and other team members – have given in to the temptation, with regrettable results. Even though the SEC has not brought cases based on some of the theories posited in this Article, the risk is there, with little or no broadening of existing law. Medical and other scientific professionals, as well as the institutions that employ them, and clinical trial participants should be aware of these risks and take the relatively benign steps recommended here to prevent or at least deter violations.

The easiest, best answer, as always, is – when in doubt, don't trade or tip. No case is too small for the SEC and the consequences can be dire.

counsel, in accordance with company policy. *SEC v. Adler*, 137 F.3d at 1329. “When [the general counsel was] asked why he interposed no objection when told of [defendant's] proposed sale, and whether he believed [defendant] possessed material nonpublic information at the time, [the general counsel, also a member of the board] stated that he ‘really did not think of it in those terms.’” *Id.* at 1329 n.7.

263. See Ari B. Lanin & Daniela L. Stolman, *Building a Better Insider Trading Compliance Program*, 25 INSIGHTS (No. 3) 1, 6 (Mar. 2011), <https://www.gibsondunn.com/wp-content/uploads/documents/publications/Lanin-Stolman-BuildingaBetterInsiderTradingComplianceProgram.pdf> [<https://perma.cc/9GTT-WMNN>].

APPENDIX

No.	FILING DATE	VENUE S = SEC C = COURT I = also indicted	NAME OF FIRST DEF; TOTAL NUMBER SUED	URL FOR SEC RELEASE OR PLEADING (Complaint or Order Instituting Proceedings)	DISPOSITION S = Settled SF = settled when filed
1	7/28/22		Klein/3	https://www.sec.gov/litigation/lit releases/2022/lr25458.htm	SF one defendant
2	7/7/22	S	Sweeney/1	https://www.sec.gov/litigation/admin/2022/33-11079.pdf	SF
3	6/27/22	S	Spector/1	https://www.sec.gov/litigation/admin/2022/33-11078.pdf	SF
4	12/20/21	C, I	Catenacci/1	https://www.sec.gov/litigation/lit releases/2021/lr25291.htm	Pleaded guilty
5	12/2/21	C, I	Malik/2	https://www.sec.gov/news/press-release/2021-249	Wood pleaded guilty https://www.justice.gov/usao-nj/pr/former-head-corporate-communications-21-billion-biopharmaceutical-company-admits-insider
6	9/17/21	C, I	Mallu/1	https://www.sec.gov/news/press-release/2021-181	SF Pleaded guilty
7	6/7/21	C	Calice/2	https://www.sec.gov/news/press-release/2021-94	SF

8	7/21/20	S	Leung/1	https://www.sec.gov/enforce/34-89352-s	SF
9	12/20/19	C, I	Wang (Songjiuang) /1	https://www.sec.gov/litigation/lit releases/2019/lr24697.htm	Convicted, aff'd US v. Chan 981 F.3d 39 (1st Cir. 2021) S (https://www.sec.gov/litigation/lit releases/2021/lr25122.htm)
10	12/20/19	C, I	Chan/1	https://www.sec.gov/litigation/lit releases/2019/lr24697.htm	Convicted, aff'd US v. Chan 981 F.3d 39 (1st Cir. 2021) Summary judgment granted to SEC (https://www.sec.gov/litigation/lit releases/2021/lr25122.htm)
11	2/21/19	C	Vacante/1	https://www.sec.gov/litigation/lit releases/2019/lr24406.htm	SF
12	8/8/18	C, I	Collins/3	https://www.sec.gov/litigation/lit releases/2018/lr24231.htm	All three pleaded guilty S later (https://www.sec.gov/litigation/lit releases/2019/lr24687.htm)
13	8/16/18	S	Wang (Hongian)/1	https://www.sec.gov/litigation/admin/2018/34-83857.pdf	SF

14	7/10/18	C	Shen/1	https://www.sec.gov/litigation/lit releases/2018/lr24194.htm	SF
15	12/7/17	C	Leonard/1	https://www.sec.gov/litigation/lit releases/2017/lr24005.htm	SF
16	9/21/17	S	Zingerman/1		SF
17	6/27/17	C, I	Alvater/3 3 separate complaints Alvater indicted	https://www.sec.gov/litigation/lit releases/2017/lr23868.htm	Alvater convicted Two defendants SF This defendant settled later (https://www.sec.gov/litigation/lit releases/2020/lr24855.htm)
18	12/16/16	S	Myers/2	https://www.sec.gov/litigation/lit releases/2017/lr24005.htm	SF
19	9/29/16	C, I	Gadimian/1	https://www.sec.gov/litigation/lit releases/2016/lr23662.htm	Pleaded guilty Settled with SEC after pleading guilty (https://www.sec.gov/litigation/lit releases/2018/lr24217.htm)

20	8/14/16	C, I	Kosinski/1	https://www.sec.gov/litigation/lit releases/2016/lr23611.htm	Conviction aff'd 976 F.3d 135 (2d Cir. 2020) S (https://www.sec.gov/litigation/lit releases/2021/lr25077.htm)
21	6/15/16	C	Valvani/2	https://www.sec.gov/news/press release/2016-119.html	Case abandoned against Valvani who had died Johnston settled after filing (https://www.sec.gov/litigation/lit releases/2016/lr23688.htm)
22	6/9/15	C, I	Fefferman/3	https://www.sec.gov/litigation/lit releases/2015/lr23279.htm	SF as to all three Wiegand and Eracleous pleaded guilty,
23	7/10/15	S	Boudreault	https://www.sec.gov/litigation/admin/2015/33-9864.pdf	SF
24	8/21/14	C, I	Lucarelli	https://www.sec.gov/news/press-release/2014-175	S https://www.sec.gov/news/press-release/2014-175 Pleaded guilty

25	5/19/14	C	Chu/2	https://www.sec.gov/litigation/lit releases/2011/lr22057.htm	SF
26	4/21/14	C	Itri/2	https://www.sec.gov/news/press-release/2014-80	SF
27	11/20/12	C, I	Martoma/3	https://www.sec.gov/litigation/lit releases/2012/lr22539.htm	<p>SF – Gilman (https://www.sec.gov/litigation/lit releases/2012/lr22539.htm)</p> <p>Conviction of Martoma aff'd 894 F.3d 64 (2d Cir. 2017)</p> <p>S Martoma (https://www.sec.gov/litigation/lit releases/2021/lr25022.htm)</p> <p>S Funds (https://www.sec.gov/litigation/lit releases/2013/lr22647.htm)</p>

28	9/27/12	C, I	Lee/1	https://www.sec.gov/news/press-release/2012-2012-201htm	<p>S</p> <p>https://www.sec.gov/files/Judg12-cv-05031Lee.pdf</p> <p>https://www.sec.gov/files/Judg12-cv-05031Chen.pdf</p> <p>Pleaded guilty</p> <p>https://www.sec.gov/litigation/litrleases/2013/r22678.htm</p> <p>https://www.sec.gov/litigation/litrleases/2013/r22758.htm</p>
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