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The Clinical Trial Research Participant As An Inside Trader: A Legal And Policy Analysis

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The Clinical Trial Research Participant As An Insider Trader: A Legal And Policy Analysis

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ABSTRACT: This Article examines whether a participant in a clinical research trial for a drug obtains material nonpublic information about the drug and its manufacturer or licensor and, if so, whether the participant may lawfully trade securities based on that information. This issue has been noted but not examined in depth in several articles in recent years. After an introduction to the federal law of insider trading and a discussion of relevant aspects of a supervised research trial, the Article concludes that, absent an agreement to the contrary, the participant would be free to trade securities based on any material nonpublic information learned in the trial. The author evaluates the extent to which the information is material and nonpublic and then presents the policy issues surrounding whether the participant should be precluded from trading when in possession of material nonpublic information gained as a result of participation in the trial. While not resolving the competing policy considerations, including the value of allowing participants to make disclosure of their experiences in the trial before publication of the results in a peer reviewed journal, the Article presents an approach for preventing the misuse of material nonpublic information gained in the clinical trial context, by obtaining an agreement from the participant, and an agreement from the limited circle of persons to whom the participant should be allowed to make disclosure in any event (such as his personal physician and family members), that would render any trading by them unlawful under the federal law of insider trading.

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This Article addresses whether it is unlawful for a person who learns material nonpublic information as a participant in a medical research project to engage in a securities transaction on the basis of that information and, if the law is not violated, what, *if any*, steps should be taken to impose a prohibition on trading on material nonpublic information by that participant, taking into account policy concerns pertinent to medical research on human subjects.¹

I. The Two Basic Theories Of Unlawful Insider Trading

The Securities and Exchange Commission (SEC or Commission) and the courts have participated in an evolutionary process to delineate under what circumstances it is unlawful to engage in a securities transaction while in possession of material nonpublic information regarding the value of the security that is traded.²

¹ In this Article, “insider trading” means trading on the basis of material nonpublic information, and “unlawful insider trading” means insider trading that is prohibited by law. This Article addresses only transactions in publicly traded securities.

These issues were raised in Paul R. Helft et al., *Inside Information: Financial Conflicts of Interest for Research Subjects in Early Phase Clinical Trials*, 96 J. NAT’L. CANCER INST. 656, 659 (2004). While these authors presented neither a precise analysis of the law of insider trading nor a thorough evaluation of the materiality of information obtained or obtainable by these subjects, they did submit first-hand anecdotal evidence that research subjects “had bought or intended to buy stock in the company sponsoring the clinical trial in which the research subject was enrolled” and report that healthy individuals “have insinuated themselves into clinical trials to obtain access to private information about drugs that are under clinical trial.” *Id.* at 656. At the same time, because of uncertainty about the extent to which information is abused, they expressed misgivings about taking any corrective action. *Id.* at 660.

In response to this last concern, it should be noted that most unlawful insider trading goes undetected; thus, the absence of concrete evidence of abuse of inside information in a particular setting is not sufficient reason to ignore the potential problem. DONALD C. LANGEVOORT, *INSIDER TRADING: REGULATION, ENFORCEMENT, AND PREVENTION* § 1.13 (2005).

² This Article addresses only the federal law of insider trading. This implicates the scope of section 10(b) of the Securities Exchange Act of 1934 (Exchange Act), 15 U.S.C. § 78j(b) (2005), and SEC rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5 (2005). For a discussion of the history of legislative efforts to define unlawful insider trading, see Allan Horwich, *Possession Versus Use: Is There a Causation Element in the Prohibition on Insider Trading?*, 52 BUS. LAW. 1235, 1254–58 (1997).

In providing a partial definition of unlawful insider trading in its regulations, the SEC has defined trading “on the basis of” material nonpublic information about a security or an issuer to mean making the purchase or sale when “aware of the material nonpublic information” at the time of the transaction. 17

There are two federal theories of unlawful insider trading, the classical theory and the misappropriation theory. Under the classical or traditional theory, an insider of a company cannot use material nonpublic information about that company for his own benefit when trading in its securities.³ The classical theory has generally been applied to a corporation's transactions in its own securities, so that a corporation cannot trade in its securities when it is in possession of material nonpublic information regarding itself.⁴ The concept of an "insider," and thus the prohibition, extends not only to directors, officers, and employees of the company, but also to "temporary insiders."⁵ With respect to this last category, "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*."⁶ Under the misappropriation theory, it is unlawful to use material nonpublic information for the purpose of trading in securities "in breach of a duty owed to the source of the information."⁷

C.F.R. § 240.10b5-1(b) (2005). This rule does not purport to define unlawful insider trading, however, which remains a matter for the courts. *Id.* preliminary note.

³ Under the "traditional" or "classical theory" of insider trading liability, § 10(b) and Rule 10b-5 are violated when a corporate insider trades in the securities of his corporation on the basis of material, nonpublic information. Trading on such information qualifies as a "deceptive device" under § 10(b), we have affirmed, 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."

United States v. O'Hagan, 521 U.S. 642, 651–52 (1997) (quoting Chiarella v. United States, 445 U.S. 222, 228 (1980)) (alterations in original).

⁴ See, e.g., Shaw v. Digital Equipment Corp., 82 F.3d 1194, 1204 (1st Cir. 1996) (dictum) ("Just as an individual insider with material nonpublic information about pending merger or license negotiations could not purchase his company's securities without making disclosure, the company itself may not engage in such a *purchase* of its own stock, if it is in possession of such undisclosed information."); see also Jordan v. Duff & Phelps, Inc., 815 F.2d 429, 435 (7th Cir. 1987) (holding that privately held corporation has a duty to disclose material nonpublic information when purchasing its shares). For an analysis supporting the ultimate conclusion that a corporation violates rule 10b-5 when it trades in its own securities while in possession of material nonpublic information, see Mark J. Loewenstein & William K.S. Wang, *The Corporation as Insider Trader*, 30 DEL. J. CORP. L. 45 (2005).

⁵ See *infra* note 68 and accompanying text regarding the origin of the term "temporary insider." Sometimes the term "constructive insider" is used. SEC v. Ingram, 694 F. Supp. 1437, 1440 (C.D. Cal. 1988).

⁶ Dirks v. SEC, 463 U.S. 646, 655 n.14 (1983) (emphasis added).

⁷ O'Hagan, 521 U.S. at 652.

The prohibition under either theory extends only to “material” information. The most straightforward definition of “material information” is information with respect to which there is a substantial likelihood a reasonable shareholder would consider it important in making an investment decision.⁸ The prohibition applies only when the information is nonpublic.⁹ There are at least two schools of thought regarding when information is “public.” Information is nonpublic unless either there has been “broad dissemination [of it] to the investing public generally,” or it is known to enough persons so that their trading “has caused the information to be fully impounded into the price of the particular stock.”¹⁰

As the judicial analysis of these issues has matured, it has become clear that what matters is whether some duty is breached in connection with the trading, with the result that a breach of duty concept has become the underpinning of both of the federal theories of unlawful insider trading. Under the classical theory, the duty to disclose (or to abstain) arises out of the relationship of the securities trader to the corporation whose securities are being traded.¹¹ As stated in *Chiarella v. United States*, there is “a relationship of trust and confidence between the shareholders of a corporation and those insiders who have obtained confidential information by reason of their position with that corporation. This relationship gives

⁸ *TSC Industries v. Northway*, 426 U.S. 438, 449 (1976); see *Basic, Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988).

⁹ See *O’Hagan*, 521 U.S. at 651–52; *Dirks*, 467 U.S. at 654.

¹⁰ *SEC v. Mayhew*, 121 F.3d 44, 50 (2d Cir. 1997). The SEC appears to prefer the former concept. Selective Disclosure and Insider Trading, Securities Act Release No. 7,881, Exchange Act Release No. 43,154, Investment Company Act Release No. 245,999, 65 Fed. Reg. 51,716, 51,721 (Aug. 24, 2000) (codified at 17 C.F.R. pts. 240, 243, 249) [hereinafter *Selective Disclosure and Insider Trading*]. The second of the two approaches presumably is the more difficult to apply in practice. In proposing Regulation FD, the SEC stated:

It is well established that information is nonpublic if it has not been disseminated in a manner making it available to investors generally. In order to make information public, “it must be disseminated in a manner calculated to reach the securities market place in general through recognized channels of distribution”

Selective Disclosure and Insider Trading, Securities Act Release No. 7,787, Exchange Act Release No. 42,259, Investment Company Act Release No. 24,209, 64 Fed. Reg. 72,590, 72,595 (proposed Dec. 28, 1999) (codified at 17 C.F.R. pts. 230, 240, 243, 249) (citation omitted) (quoting *Fabrege, Inc.*, 45 SEC 249, 255 (1973)).

¹¹ See *infra* text accompanying note 24 for a further discussion of the “disclose or abstain” formulation.

rise to a duty to disclose”¹² The duty that is breached by the misappropriator arises out of a relationship of loyalty and confidentiality to the source of the information.¹³ Thus, “if the fiduciary discloses to the source that he plans to trade on the nonpublic information, there is no ‘deceptive device’ and thus no § 10(b) violation—although the fiduciary-turned-trader may remain liable under state law for breach of a duty of loyalty.”¹⁴

It is, however, no easy task to determine the boundaries of the prohibition. One issue is what constitutes unlawful tipping of material nonpublic information to a third party (the tippee) who does not himself have a pre-existing duty that precludes him from trading based on the information supplied by the tipper. Under the classical theory, “some tippees must assume an insider’s duty to the shareholders not because they receive inside information, but rather because it has been made available to them *improperly*.”¹⁵ One must therefore determine whether the disclosure by the insider-tipper to the tippee was made in breach of the insider’s duty. This “depends in large part on the purpose of the disclosure. . . . [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.”¹⁶ Answering this question “requires courts to focus on objective criteria, *i.e.*, whether the insider receives a direct or indirect personal benefit from the disclosure, such as a pecuniary gain or a reputational benefit that will translate into future earnings.”¹⁷ Thus, if an insider discloses information to an outsider for a proper purpose and the recipient of the information then trades based on this information, there is no violation of rule 10b-5 under the classical theory.¹⁸

¹² 445 U.S. 222, 228 (1980) (emphasis added) (citation omitted).

¹³ *United States v. O’Hagan*, 521 U.S. 642, 652 (1997).

¹⁴ *Id.* at 655. Although the two theories are different, both theories could apply to the same facts. This is so, notwithstanding that *O’Hagan* describes the misappropriation theory as targeting “a corporate ‘outsider’ in breach of a duty owed not to a trading party, but to the source of the information.” *Id.* at 652–53. For example, an insider who trades in his company’s stock based on inside information, though liable under the classical theory, would also be liable under the misappropriation theory if he traded without disclosing the intent to trade to appropriate superiors in the corporation. Of course, even if he were to disclose his intent, thereby avoiding a deceptive act actionable under the misappropriation theory, the trading would still be unlawful under the classical theory. See also *infra* text accompanying notes 19–21.

¹⁵ *Dirks v. SEC*, 463 U.S. 646, 660 (1983).

¹⁶ *Id.* at 662.

¹⁷ *Id.* at 663.

¹⁸ This was the result in *Dirks*, where the Court found that an insider had provided material nonpublic information to *Dirks*, a securities analyst, with the ultimate

There is a split of authority, unresolved by the Supreme Court, regarding whether the same elements for tipper liability apply in the misappropriation context. It has been suggested that the personal benefit requirement of *Dirks*, developed in the context of a classical analysis, is not necessary when the tipper has misappropriated the information in providing it to a tippee.¹⁹ The better rule, as explained by the Court of Appeals for the Eleventh Circuit, appears to be that for there to be tipper liability under the misappropriation theory, the tipper must intend to confer a benefit upon the tippee.²⁰ Among other considerations,

the need for an identical approach to determining tipper and tippee liability under the two theories becomes evident when one realizes that nearly all violations under the classical theory of insider trading can be alternatively characterized as misappropriations.²¹

Thus, benefit to the tippee in disclosing the inside information should be a required element of any tipper or tippee liability claim.

II. Not All Trading On The Basis Of Material Nonpublic Information Is Unlawful

The preceding summary of insider trading law correctly reflects that not all trading by one who is aware of material nonpublic information is unlawful. To be sure, some early insider trading cases

goal of exposing a fraud at the issuing company—there was no improper purpose by, or personal gain for, the tipper nor expectation that *Dirks* would hold the information in confidence. *Id.* at 665–67. See also *O’Hagan*, 521 U.S. at 663 (explaining the outcome in *Dirks*).

¹⁹ The cases and the debate on the point are summarized in *SEC v. Yun*, 327 F.3d 1263, 1274–80 (11th Cir. 2003). See also WILLIAM K. S. WANG & MARC I. STEINBERG, *INSIDER TRADING* § 5.4.4 (2005) (summarizing cases).

²⁰ *Yun*, 327 F.3d at 1277–78. For analyses supporting the imposition of the benefit requirement in misappropriation tipper cases, see Craig W. Davis, *Misappropriators, Tippees and the Intent-to-Benefit Rule: What We Can Still Learn from Cady, Roberts*, 35 SETON HALL. L. REV. 263 (2004); Nelson S. Ebaugh, *Insider Trading Liability for Tippees: A Call for the Consistent Application of the Personal Benefit Test*, 39 TEX. J. BUS. L. 265 (2003).

²¹ *Yun*, 327 F.3d at 1279 (citation omitted) (noting that the instant case, pursued by the SEC under the misappropriation theory, “fits the facts of a case typically brought under the classical theory of insider trading” while the SEC sought to eliminate the need to prove that the tipper intended to benefit the tippee by resorting to the misappropriation theory).

contained language that, taken out of context, suggested that the prohibition extended to all trading based on material nonpublic information. For example, in the seminal *SEC v. Texas Gulf Sulphur Co.*, the court stated that rule 10b-5 “is based in policy on the justifiable expectation of the securities marketplace that all investors trading on impersonal exchanges have relatively equal access to material information”²² and that “[t]he core of Rule 10b-5 is the implementation of the Congressional purpose that all investors should have equal access to the rewards of participation in securities transactions.”²³ The court applied the principle of “disclose or abstain,” holding that:

anyone in possession of material inside information must either disclose it to the investing public, or if he is disabled from disclosing it in order to protect a corporate confidence, or he chooses not to do so, must abstain from trading in or recommending the securities concerned while such inside information remains undisclosed.²⁴

Some interpreted *Texas Gulf Sulphur*, and other cases of that era, as imposing a rule that *anyone* with material inside information could not lawfully trade without disclosing that information, regardless of the relationship of the trader to the source of the information or how the person learned the information. This is called the “parity of information” rule.²⁵ In *Chiarella*, however, the Supreme Court dispelled any notion that everyone with material nonpublic information was barred from trading, stating that “neither the Congress nor the [SEC] ever has adopted a parity-of-information rule.”²⁶

²² 401 F.2d 833, 848 (2d Cir. 1968).

²³ *Id.* at 851–52.

²⁴ *Id.* at 848. This principle was articulated earlier by the SEC in *In re Cady, Roberts & Co.*, Exchange Act Release No. 6,668, 40 SEC 907, 911 (Nov. 8, 1961). For further background on the “disclose or abstain” concept, see 7 LOUIS LOSS & JOEL SELIGMAN, *SECURITIES REGULATION* 3,481–94 (3d ed. rev. 2003).

²⁵ *Mitchell v. Texas Gulf Sulphur Co.*, 446 F.2d 90, 101 (10th Cir. 1971) (“[T]he federal courts ceased to look upon the Rule in the narrow context of seller protection and began to see in it a greater purpose, i.e., equalization of bargaining position of the parties on both sides of a transaction.”); *Birdman v. Electro-Catheter Corp.*, 352 F. Supp. 1271, 1274 (E.D. Pa. 1973) (“[T]he basic policy of Rule 10b-5 . . . is that all investors have relatively equal access to material information.”).

²⁶ *Chiarella v. United States*, 445 U.S. 222, 233 (1980). As explained in *SEC v. Ingram*, 694 F. Supp. 1437, 1439 (C.D. Cal. 1988), “*Chiarella* marked a major shift in the law applicable to insider trading. Prior to *Chiarella*, the SEC and some courts’ position was premised merely upon the unfairness of trading while in possession of information not available to the marketplace.”

This framework thus permits trading on the basis of material nonpublic information in some circumstances. For example, an eavesdropper, who has no pre-existing duty of trust and confidence to the careless speaker, is free to trade based on the overheard information.²⁷ In addition, a person is *always* free to trade on information regarding her own circumstances, so long as she does not stand in a fiduciary relationship to the other market participants at the time of her trade. That is, a corporation is not free to engage in a transaction in its own securities when it is in possession of material nonpublic information that those on the other side of the trade do not have, because it has a fiduciary relationship with those persons.²⁸ In the absence of such a relationship, a person is free to trade based on information known only to her, such as her intent in purchasing the stock or information she developed independently of any source to whom a duty of confidentiality is owed.²⁹ As observed by the Supreme Court:

The Court of Appeals for the Second Circuit previously held, in a manner consistent with our analysis here, that a tender offeror does not violate § 10(b) when it makes preannouncement purchases pre-

²⁷ SEC v. Switzer, 590 F. Supp. 756, 766-67 (W.D. Okla. 1984) (holding that a bystander, who overheard exchange of material nonpublic information between executive and his wife and then traded based on that information, did not act unlawfully where there was insufficient proof that executive intended to tip the eavesdropper).

²⁸ See *supra* text accompanying note 4. This concept of a fiduciary duty applies both when the corporation is buying its securities from existing security holders and selling its stock to those who do not yet own any of the stock.

Whatever distinctions may have existed at common law based on the view that an officer or director may stand in a fiduciary relationship to existing stockholders from whom he purchases but not to members of the public to whom he sells, it is clearly not appropriate to introduce these into the broader anti-fraud concepts embodied in the securities acts.

In re Cady, Roberts, 40 SEC at 914. In support, the SEC relied upon the court's observation in *Gratz v. Claughton*, 187 F.2d 46, 49 (2d Cir. 1951) (observing that "it would be a sorry distinction to allow him to use the advantage of his position to induce the buyer into the position of a beneficiary, although he was forbidden to do so, once the buyer had become one."). *In re Cady, Roberts*, 40 SEC at 914 n.23.

²⁹ For example, while a business publication would be free to trade based on information it was going to publish about other companies, its employees could not misappropriate that information and trade for themselves. *United States v. Willis*, 778 F. Supp. 205, 208-09 (S.D.N.Y. 1991) (describing *United States v. Carpenter*, 791 F.2d 1024 (2d Cir. 1986), *aff'd*, 484 U.S. 19 (1987) (equally divided Court)).

cisely because there is no relationship between the offeror and the seller: “We know of no rule of law . . . that a purchaser of stock, who was not an ‘insider’ and had no fiduciary relation to a prospective seller, had any obligation to reveal circumstances that might raise a seller’s demands and thus abort the sale.”³⁰

Thus, here, as in most other contexts, there must be a determination of the source of the information before there can be a comprehensive assessment of the application of the classical theory.

The public transit rider with no duty to the corporation who has the good fortune to find some papers that reveal nonpublic material information about that company, which were inadvertently left behind by an executive, lawyer, accountant, or financial or public relations consultant for the company (the last three of which may qualify as “temporary insiders”), is free to trade based on that information. There has been no unlawful tip—the careless insider did not act with an improper purpose within the meaning of *Dirks*—and because the finder had no duty of loyalty, trust, or confidence, he has not deceived the source of the information by using it.³¹ Rather, the misappropriation theory reaches only an investor’s “informational disadvantage” that “stems from contrivance, not luck.”³²

There are also situations when a person *deliberately* given material nonpublic information—where there is no improper purpose in doing so—may trade using that information without violating either the classical or the misappropriation theory. “Reposing confidential information in another . . . does not by itself create a fiduciary relationship.”³³ In one notable case, shareholders of *Company A* sought to recover profits in that company’s stock reaped by an investment banker that had advised *Company B* in a proposed but abandoned acquisition of *Company A* by *Company B*, where the investment banker had

³⁰ *Chiarella*, 445 U.S. 232 n.14 (quoting *General Time Corp. v. Talley Industries, Inc.*, 403 F.2d 159, 164 (2d Cir. 1968)).

³¹ Thus, there is no violation of rule 10b-5 if the source of the information expressly authorizes the person to trade or if the person discloses in advance the intent to trade. See *United States v. O’Hagan*, 521 U.S. 642, 652 (1997); JAMES D. COX ET AL., *SECURITIES REGULATION CASES AND MATERIALS* 867–68 (4th ed. 2004).

³² *United States v. O’Hagan*, 521 U.S. 642, 658–59 (1997).

³³ *United States v. Chestman*, 947 F.2d 551, 568 (2d Cir. 1991) (en banc) (applying state law concepts for purposes of determining whether rule 10b-5 was violated).

obtained confidential information about *Company A* while working on that project.³⁴ After observing that the investment banker's client was *Company B*, that it dealt at arm's length with *Company A*, and that there was no confidentiality agreement between the investment banker and *Company A*, the court held that the investment banker did not owe a fiduciary duty to *Company A* that precluded him from trading in that company's stock.³⁵

The recent decision in *United States v. Cassese* applied these principles.³⁶ Cassese, chairman and president of Computer Horizons, met with a senior executive of Compuware to discuss the potential acquisition of Computer Horizons by Compuware. Compuware tendered a confidentiality agreement to Cassese, which would have prohibited any Computer Horizons employee from trading in Compuware stock based on information exchanged in the discussions, but the agreement was never signed. Compuware then began negotiating a merger with a third company, DPRC. Compuware informed Cassese that Compuware would not acquire Computer Horizons but instead would acquire DPRC. Cassese then bought DPRC stock without publicly disclosing the nonpublic information he had received from Compuware about the proposed merger and sold the stock at a profit after the public announcement of the proposed acquisition.³⁷

Because the indictment did not allege that Compuware's executives breached any duty to Compuware shareholders in making

³⁴ *Walton v. Morgan Stanley & Co.*, 623 F.2d 796, 799 (2d Cir. 1980). *Walton* was cited with approval in *Dirks v. SEC*, 463 U.S. 646, 662 n.22 (1983) (The Court noted that *Walton* turned on the "court's determination that the disclosure did not impose any fiduciary duties on the recipient of the inside information.").

³⁵ *Walton*, 623 F.2d at 799. The situation that underlay *Walton* is less likely to occur today. Under SEC Regulation FD, an issuer may not disclose material nonpublic information regarding itself or its securities to, among others, a broker-dealer or a "holder of the issuer's securities, under circumstances in which it is reasonably foreseeable that the person will purchase or sell the issuer's securities on the basis of the information," without concurrently, or at the very least promptly after the disclosure, making public disclosure of the information, unless, among other exceptions, there is an express agreement "to maintain the disclosed information in confidence." 17 C.F.R. § 243.100(a), (b)(1)(i), (b)(1)(iv), (b)(2)(ii) (2005). Thus, companies that provide information to investment bankers in the *Walton* situation are likely to be required to enter into confidentiality agreements, which preclude trading as a result of rule 10b5-2, 17 C.F.R. § 240.10b5-2 (2005), discussed *infra* in notes 43-47 and accompanying text, which was promulgated together with Regulation FD in Selective Disclosure and Insider Trading, *supra* note 10.

³⁶ *United States v. Cassese*, 273 F. Supp. 2d 481 (S.D.N.Y. 2003) (granting motion to dismiss rule 10b-5-based count of the indictment).

³⁷ *Id.* at 483-84 (summarizing indictment).

disclosure to Cassese, the charges stood or fell on the application of the misappropriation theory.³⁸ The court dismissed the rule 10b-5 charge, ruling that neither a fiduciary duty nor obligations and duties of a confidential relationship can be imposed *unilaterally* by entrusting a person with confidential information.³⁹ The absence of a confidential relationship was underscored by the fact that Compuware and Computer Horizons were competitors so that instead of being in a fiduciary relationship they were “potential arms-length business partners.”⁴⁰ Moreover, there was no “long-standing relationship” or any regular sharing of confidences between the principals.⁴¹

III. The Delineation of a Duty Of Trust or Confidence

It was thus clear that the event, standing alone, of providing confidential information to someone, even when accompanied by disclosure that the information is confidential, does not create a trading-disabling fiduciary relationship or a relationship of trust and confidence. There must be an express agreement to maintain the confidentiality of the information or, perhaps, an established pattern of mutual confidential treatment by the parties in order to render it unlawful to use the information to trade. Whether there is a relationship of trust and confidence under federal law, for purposes of applying rule 10b-5, is dependent upon the specific facts of the case, especially the nature of the relationships among the parties in the chain of communication. For example, the Second Circuit sitting *en banc* split six to five in reversing a

³⁸ *Id.* at 485.

³⁹ *Id.* at 485–86 (citing *United States v. Chestman*, 947 F.2d 551, 567 (2d Cir. 1991) (*en banc*)). See *United States v. Reed*, 601 F. Supp. 685, 715 (S.D.N.Y.) *rev'd in part on other grounds*, 773 F.2d 477 (2d Cir. 1985).

The mere unilateral investment of confidence by one party in the other ordinarily will not suffice to saddle the parties with the obligations and duties of a confidential relationship. Thus, the mere respect for the judgment of another or generalized trust in his character is usually insufficient grounding for a special relationship of trust and confidence.

Id.

⁴⁰ *Cassese*, 275 F. Supp. 2d at 486.

⁴¹ *Id.* at 486. Apart from the impact of rule 10b5-2, even an express agreement of confidentiality may not be sufficient to create a relationship that triggers the prohibition on trading on the basis of material nonpublic information. See *United States v. Kim*, 184 F. Supp. 1006 (N.D. Cal. 2002) (dismissing rule 10b-5 counts of indictment based on events prior to effective date of rule 10b5-2). *But see* Nathan Heyde, *Can You Keep a Secret? The “Similar Relationship of Trust and Confidence” in Misappropriation Theory: U.S. v. Kim*, 26 WHITTIER L. REV. 653 (2004) (criticizing the decision in *Kim*).

conviction under rule 10b-5 for unlawful insider trading, dividing over whether there had been a relationship of trust and confidence among certain family members.⁴²

In an effort to reduce uncertainty in identifying when a relationship of trust and confidence exists, the SEC promulgated rule 10b5-2.⁴³ Rule 10b5-2 “provides a *non-exclusive* definition of circumstances in which a person has a duty of trust or confidence for purposes of the ‘misappropriation’ theory of insider trading.”⁴⁴ The rule enumerates three categories of “duties of trust or confidence.” The third category is largely irrelevant to research participants themselves, as it is based on familial relationships and patterns of behavior in that context.⁴⁵ The first two categories in the rule are of interest in assessing the situation of the clinical trial participant. Rule 10b5-2(b)(1)-(2) provides 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

⁴² *Chestman*, 947 F.2d 551.

⁴³ 17 C.F.R. § 240.10b5-2 (2005). The SEC expressly referred to the result in *Chestman* as a reason a rule was needed. Selective Disclosure and Insider Trading, *supra* note 10, at 51,730 (promulgating rule 10b5-2). This Article does not address the validity of rule 10b5-2, which was promulgated pursuant to authority granted the SEC by, among other provisions, Sections 10 and 23 of the Exchange Act, 15 U.S.C. §§ 78j, 78w (2000). Selective Disclosure and Insider Trading, *supra* note 10, at 51,737. For critical commentary on rule 10b5-2, see Bach Hang, *The SEC’s Criminal Rulemaking in Rule 10b5-2: Incarceration Should be Made of Sterner Stuff*, 41 WASHBURN L.J. 629 (2002).

⁴⁴ 17 C.F.R. § 240.10b5-2 preliminary note (2005) (emphasis added).

⁴⁵ The third category provides:

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 as the source of the information expected that the person would keep the information confidential, because of the parties’ history, pattern or practices of sharing and maintaining confidences, and because there was no agreement or understanding to maintain the confidentiality of the information.

Id. § 240.10b5-2(b)(3)(emphasis in original). As discussed *infra* in the text accompanying note 131, a family member of a research participant may have a relationship of trust and confidence with the participant, as delineated in rule 10b5-2(b)(3).

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.⁴⁶

The SEC nonetheless recognized that, even under rule 10b5-2, a relationship of trust, and confidence cannot be imposed unilaterally. Under rule 10b5-2(b)(2) “mutuality” of the expectation that the information would be held in confidence is “explicit.”⁴⁷

With this background, we now turn to whether persons who are placed into a setting where they inevitably come into possession of nonpublic information in the nature of experimental activities may lawfully trade based on that information.

IV. An Overview of the Conduct of a Drug Trial⁴⁸

Before a prescription drug may be made available in interstate commerce, it must be approved for a specific use by the United States Food and Drug Administration (FDA).⁴⁹ This approval is conditioned upon presentation of favorable results in a clinical trial of the drug.⁵⁰ The FDA regulates these drug trials.⁵¹

⁴⁶ 17 C.F.R. § 240.10b5-2(b)(1), (2).

⁴⁷ Selective Disclosure and Insider Trading, *supra* note 10, at 51,730.

⁴⁸ A comprehensive discussion of the approval process for a new drug, including protocols for the conduct of clinical trials, is beyond the scope of this Article. For a general description of the regulatory process, see RICK NG, DRUGS FROM DISCOVERY TO APPROVAL chs. 7–8 (2004). For a general discussion of the administration of a clinical trial, see DEBORRAH NORRIS, CLINICAL RESEARCH COORDINATOR HANDBOOK (3d ed. 2004).

⁴⁹ The framework for the approval of new drugs is set forth at 21 U.S.C. § 355 (2005). A “new drug” is defined at Section 321(p). The regulations pertinent to applying for approval to investigate a new drug and to approval of a new drug for marketing are at 21 C.F.R. pts. 312 and 314, respectively.

⁵⁰ A new drug application must include “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.” *Id.* § 355(b)(1)(A). *See also id.* § 314.50(c)(2)(viii) (requiring that new drug application contain a summary of the clinical trial data); *Id.* § 314.50(d)(5) (requiring presentation of detailed clinical trial data). Under § 355(d)(5), a new drug application shall be denied if “there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.”

⁵¹ *See* 21 U.S.C. § 355(i) (2005); 21 C.F.R. § 312 (2005).

There are three phases of a clinical trial before the drug is approved by the FDA.

The trials at each phase have a different purpose and help scientists answer different questions: In Phase I trials, researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. In Phase II trials, the experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety. In Phase III trials, the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.⁵²

In a blind study of a drug, the subject does not know whether she is receiving the drug being tested or a placebo; in a double blind study, neither the subject nor the administering health professional knows whether the subject is receiving the real drug.⁵³ Thus, a patient with a favorable experience may be benefiting from the “placebo effect” and may mistakenly believe it is the drug under study that is producing the positive effect.⁵⁴ In some drug trials, however, the patient knows the experiences of and observes the apparent effects of the drug on at least a meaningful segment of the trial group at the particular site where the patient is undergoing treatment, rather than just the possibly misleading effect on him.⁵⁵

⁵² U.S. Nat'l Insts. of Health, *An Introduction to Clinical Trials* (2005) [hereinafter Nat'l Insts. of Health, *Clinical Trials*], at <http://clinicaltrials.gov/ct/info/whatis> (last visited Dec. 27, 2005). See 21 C.F.R. § 312.21.

⁵³ U. S. Nat'l Insts. of Health, *Glossary of Clinical Trial Terms*, [hereinafter Nat'l Insts. of Health, *Glossary*] <http://clinicaltrials.gov/ct/info/glossary> (last visited Dec. 27, 2005). See NG, *supra* note 48, at 145.

⁵⁴ The “placebo effect” is a “physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.” Nat'l Insts. of Health, *Glossary*, *supra* note 53.

⁵⁵ See *infra* text accompanying notes 98–111. Most Phase II and Phase III trials are multi-site, often with only a score of persons involved at any one site. SHEIN-CHUNG CHOW & JEN-PEI LIU, *DESIGN AND ANALYSIS OF CLINICAL TRIALS, CONCEPTS AND METHODOLOGIES*, 240–45 (2d ed. 2004). Participants at a single site thus can obtain only a limited picture of the outcome of the trial, even apart from considerations such as the placebo effect or other variables that affect the experience of any individual participant.

In a drug trial, the research institution that conducts the trial typically enters into a confidentiality agreement with the pharmaceutical company or other party that is the “sponsor” of the trial.⁵⁶ The “investigator”—the individual who conducts the clinical trial⁵⁷—usually signs a confidentiality agreement with the research institution, such as a medical school.⁵⁸ In any event, as an employee or contractor of the research institution, this person owes a duty of trust and confidence to the institution even if no confidentiality agreement is signed.⁵⁹ Industry

⁵⁶ The “sponsor” is the person who initiates the investigation but does not actually conduct it. 21 C.F.R. § 50.3(e) (2005). *See, e.g.*, University of Washington, *Pre-Clinical Trial Nondisclosure Agreement* § 2, at http://Washington.edu/research/osp/forms/preclinical_nda.doc (last visited Dec. 27, 2005); Duke University, *Clinical Trial Site Agreement* § 9, at www.dcri.duke.edu/ccge/contracts/20030516_Standard_Site_Agreement.doc (last visited Dec. 27, 2005).

⁵⁷ § 50.3(d). A “sponsor-investigator” is “an individual who both initiates and actually conducts, alone or with others, a clinical investigation.” *Id.* § 50.30(f).

⁵⁸ *See, e.g.*, SEC v. Rosenberg, Litigation Release No. 16,113, 69 SEC Docket 1,526 (Apr. 20, 1999) (announcing settlement of insider trading charges with employee of clinical research firm who had signed agreement to keep information of drug trial confidential).

The FDA requires the disclosure of a financial interest of those involved in clinical trials, based on a concern that a financial interest could result in bias in conducting the trial. 21 C.F.R. pt. 54 (2005). Some institutions impose more stringent requirements. *See, e.g.*, Stanford School of Medicine, *Faculty Disclosure of Conflicts of Interest*, at <http://med.stanford.edu/conflict/documents/coi.pdf> (last visited Dec. 19, 2005) (providing that faculty involved in human research may be required to divest any financial interest in the outcome of research in which that person is involved); Bernard Lo et al., *Conflict-of-Interest Policies for Investigators in Clinical Trials*, 343 NEW ENG. J. MED. 1616 (2000).

The American Medical Association (AMA) has taken the position that in order to avoid conflicts of interest in biomedical research,

once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual, cannot ethically buy or sell the company’s stock until the involvement ends and the results of the research are published or otherwise disseminated to the public.

AMA CODE OF MED. ETHICS E-8.031 (2005), *available at* <http://www.ama-assn.org/ama/pub/category/8470.html> (last visited Dec. 27, 2005). *See also* the prohibitions imposed by the National Institutes of Health on financial interests of certain employees in pharmaceutical companies at 5 C.F.R. § 5501.110(c), as amended at 70 Fed. Reg. 51559, 51571. (Aug. 31, 2005).

⁵⁹ *See* the following cases decided before the effective date of rule 10b5-2: United States v. Grossman, 843 F.2d 78, 86 (2d Cir. 1988) (affirming conviction of law firm associate for tipping client information and holding that “the district court was not required to charge the jury on [defendant’s] specific knowledge of the [law firm’s] confidentiality policy.”) (alternative holding); United States v. Carpenter, 791 F.2d 1024 (2d Cir. 1986) (affirming rule 10b-5 misappropriation

protocol allows investigators limited access to the trial results for study-related or scientific purposes.⁶⁰ Nothing suggests that use of this information beyond those purposes is permissible.

V. A Brief Digression from the Principal Inquiry—Is the Investigator Free to Trade?

Because of the confidentiality agreement entered into between the investigator and the research institution, as well as the agreement between the institution and the sponsor, there should be no question that, even if the “investigator” is not an insider covered by the classical theory, she is precluded by the misappropriation theory from using information gained in the drug trial to trade in securities of the sponsor. Use of the information to trade would

theory-based conviction of reporter for the Wall Street Journal, who provided other persons with information about forthcoming articles, in violation of company policy and confidentiality rules), *aff'd*, 484 U.S. 19, 24 (1987) (affirming conviction under rule 10b-5 on equally divided vote, and affirming mail fraud conviction). *See also* United States v. Elliott, 711 F. Supp. 425, 433 (N.D. Ill. 1989) (denying motion to dismiss insider trading indictment of law firm partner, noting that the indictment was sufficient even if the information referred to was not identified as “material” as it is “enough if the misappropriated information is ‘solely for corporate purposes,’ and if a reasonable corporate executive would believe keeping that information confidential was valuable to the corporation.”) (citation omitted) (quoting *Dirks v. SEC*, 463 U.S. 646, 655 (1983)).

⁶⁰ One set of industry standards expresses the principles as follows:

[I]nvestigators will be given access to any data (tables, figures, reports) they need from the study that are related to the hypothesis being tested or explored or which are needed in order to understand the results of the study.

....

[Moreover,] [a] conflict of interest exists, in the research setting, whenever an investigator's professional judgment could be influenced by a secondary interest, such as a potential financial gain, . . . investments

[P]ursuant to these PhRMA Principles, sponsors may not use investigators if investigators or their immediate family have a direct ownership interest in the investigational product, and sponsors may not compensate investigators in company stock or stock options.

PHARM. RES. & MFRS. OF AM., PRINCIPLES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF CLINICAL TRIAL RESULTS 40–41, 49–50 (2004) [hereinafter PHARM. RES. & MFRS. OF AM.], available at <http://phrma.org/publications/publications/2004-06-30.1035.pdf> (last visited Dec 27, 2005).

be a paradigm of wrongful conduct under the misappropriation theory.⁶¹

VI. The Nature of the Relationship between the Participant and the Research Institution or Sponsor

Before applying the parameters of the law of unlawful insider trading to the research subject or participant, it is necessary to understand the nature of the relationship between the research institution or the sponsor of the drug trial, and the study participant.⁶² Each participant must sign an “informed consent” form

⁶¹ See, e.g., SEC v. Mutchnick, Litigation Release No. 15,322, 64 SEC Docket 699 (Apr. 10, 1997) (reporting charges against the lead investigator of a Phase III clinical trial for tipping persons that the initial analysis of clinical data indicated the trial had not proven the drug to be effective). See also Robert Steinbrook, *Wall Street and Clinical Trials*, 353 NEW ENG. J. MED. 1091 (2005) (addressing the effect on the integrity of clinical trials when physicians have financial interests, as well as insider trading issues); Eric J. Topol & David Blumenthal, *Physicians and the Investment Industry*, 293 J. AM. MED. ASS'N 2654, 2656 (2005) (noting that physicians who consult with investment companies and provide information regarding research trials “may not only violate the confidentiality agreement with the trial’s sponsor but potentially also provide insider, proprietary information” which is “illegal activity”); Luke Timmerman & David Heath, *Drug Researchers Leak Secrets to Wall St. Selling Drug Secrets*, SEATTLE TIMES, Aug. 7, 2005, at A1 (“Doctors testing new drugs are sworn to keep their research secret until drug companies announce the final results. But elite Wall Street firms—looking to make quick profits—have found a way to harvest these secrets: They pay doctors to divulge details early.”). Senator Charles Grassley (R. Iowa) reportedly has asked the SEC and the Department of Justice to investigate the information reported by the Seattle Times. See Letter, Sen. Charles Grassley to Alberto R. Gonzales and Christopher Cox, Aug. 8, 2005, at <http://finance.senate.gov/sitepages/grassley.htm> (last visited Dec. 8, 2005).

⁶² In addition to the drug trial, there are several somewhat similar test-type situations where material information could be obtained and abused by being used to trade securities, although these are less likely to involve actionable misconduct and will not be discussed in detail. For example, a person who participates in a focus group for a new marketing campaign for an unreleased product or even an existing product may become aware of material nonpublic information about impending developments at the sponsor of the project, such as release of a new product or a new marketing strategy. A person may attend a screening of a major movie before the final cut, so that the producers and directors can gauge audience reaction and consider changes to create a more successful film. See, e.g., John Horn, *The Science of Comedy; Keeping “Virgin” Funny but with Its Pants on*, LOS ANGELES TIMES, Aug. 14, 2005, at E1 (recounting how the movie *The 40 Year-Old Virgin* was recut several times in response to reactions at test screenings, with a total of seven screenings). If there appears to be a uniform reaction to the film at the screening, and if the film is a major factor in the studio’s projected earnings profile, the information may be material.

before entering the trial.⁶³ The informed consent must describe the extent of the protection of the confidentiality of the records identifying the subject but also disclose that the FDA may inspect the records.⁶⁴

Nothing is prescribed, however, regarding the extent, if any, to which the *participant* is expected to maintain the confidentiality of any aspect of the study. Rather, literature in the field addresses the ownership of confidential information as between the sponsor (such as the pharmaceutical company) and the institution conducting the research without so much as a hint that the participant owes any duty of confidentiality to the research institution or the sponsor.⁶⁵ For example, in one skeletal consent form, there is no mention of any duty or pledge of confidentiality on the part of the participant.⁶⁶ Thus, the participant signs on with many rights and receives information and warnings, but undertakes few obligations to the research institution or sponsor, with no contractual obligation of confidentiality. Indeed, he may even elect to leave the trial at any time.⁶⁷

VII. The Research Participant is not a “Temporary Insider”

Research participants are not employees (nor directors or officers) of the sponsor of the clinical trial or the research institution. Indeed, it is highly unlikely that anyone with a direct relationship with either would be a qualified subject of a properly structured clinical trial, because of a built in bias in reporting subjective re-

⁶³ 21 C.F.R. § 50.20 (2005); 45 C.F.R. § 46.116 (2005). *See, e.g.*, TULANE UNIV. HEALTH SCI. CTR., CONSENT TO PARTICIPATE IN RESEARCH (1996) [hereinafter TULANE CONSENT], available at www.som.tulane.edu/irb/forms/sample_consent.pdf (last visited Jan. 14, 2006); Nat’l Insts. of Health, *Clinical Trials*, supra note 52; PHARM. RES. & MFRS. OF AM., supra note 60, at 8–9.

⁶⁴ 21 C.F.R. § 50.25(a)(5) (2005).

⁶⁵ *See, e.g.*, PHARM. RES. & MFRS. OF AM., supra note 60; IVY BAER ET AL., ASS’N OF AM. MED. COLLS., CLINICAL TRIAL CONTRACTS: A DISCUSSION OF FOUR SELECTED PROVISIONS 2–7 (2004), available at https://services.aamc.org/Publications/showfile.cfm?file=version6.pdf&prd_id=76&prv_id=75&pdf_id=6 (last visited Dec. 27, 2005). The National Institutes is silent on any issue of confidentiality. Nat’l Insts. of Health, *Clinical Trials*, supra note 52. In chapters entitled “Informed Consent in Clinical Trials” and “Confidentiality of Clinical Trials Information” in FAY A. ROZOVSKY & RODNEY K. ADAMS, CLINICAL TRIALS AND HUMAN RESEARCH, A PRACTICAL GUIDE TO REGULATORY COMPLIANCE, chs. 5–6 (2003), there is no mention of an agreement by the participant to maintain confidentiality of information.

⁶⁶ TULANE CONSENT, supra note 63. The only express confidentiality provision relates to protection of the subject’s own information. *Id.* at 5.

⁶⁷ 21 C.F.R. § 50.25(a)(8) (2005); *see also* Nat’l Insts. of Health, *Clinical Trials*, supra note 52; TULANE CONSENT, supra note 63, at 5.

actions to the drug or treatment. Therefore, the classical theory of insider trading would apply to any securities trading by a participant only if the participant is a “temporary insider.” The few cases that have applied the *Dirks* temporary insider concept do not provide a rationale for bringing the research participant within that expanded sphere.

SEC v. Lund appears to have been the earliest application of the concept of the temporary insider; it was in fact the case where the term was coined.⁶⁸ Horowitz was chairman, president, and chief executive officer of P & F Industries, Inc. (P&F). Horowitz and Lund were both members of the board of Verit Industries, of which Lund was chairman, president, and chief executive officer. Lund traded in P&F stock after receiving information from Horowitz about an impending joint venture involving P&F when Horowitz approached Lund to ask if Verit would be interested in joining the venture.⁶⁹ The court held that Lund was not the recipient of an unlawful tip because Horowitz breached no duty to the shareholders of P&F when he invited Verit to join the venture, but held that Lund violated rule 10b-5 as a “temporary insider”.⁷⁰ After noting that Horowitz and Lund were “long time friends and business associates” who “often exchanged information about their corporations,” the court stated:

Horowitz told Verit, through Lund, of the [joint venture] because of this special relationship. The information was made available to Lund solely for corporate purposes. It was not disclosed in idle conversation or for some other purpose. The relationship between Horowitz and Lund was such as to imply that the information was to be kept confidential. Horowitz clearly did not expect Lund to make the information public or to use the information for his personal gain. Lund knew or should have known that the information he received was confidential and that it had been disclosed to him solely for legitimate corporate purposes.⁷¹

⁶⁸ 570 F. Supp. 1397, 1403 (C.D. Cal. 1983). See *SEC v. Tome*, 638 F. Supp. 596, 617 n.39 (S.D.N.Y. 1986) (attributing first use of term “temporary insider” to *Lund*).

A Westlaw search did not reveal any earlier use of the term in this context.

⁶⁹ *Lund*, 570 F. Supp. at 1399–1400.

⁷⁰ *Id.* at 1402.

⁷¹ *Id.* at 1403.

Lund was therefore a temporary insider and his trading violated section 10(b).⁷²

Simon DeBartolo Group, L.P. v. The Richard E. Jacobs Group, Inc., is a recent example of the extent of the temporary insider theory. The court analyzed rule 10b-5 in determining whether to uphold sanctions under FED. R. CIV. P. 11 imposed by the lower court on the ground that the plaintiff's insider trading claim was frivolous.⁷³ A group of investors devised a plan to increase the shareholder value of a privately held real estate investment trust, RPT. To maximize the likelihood that the plan would succeed, the defendants, who were not shareholders of RPT but some of whom were participants in the plan, began buying RPT shares, which they could then vote in favor of the plan. Plaintiff, who was interested in acquiring RPT, sued, alleging, *inter alia*, that defendants' purchases of RPT stock without disclosure of the proposed plan violated rule 10b-5.⁷⁴ Although the defendants' group disbanded and the original plan was abandoned, the district court addressed a motion to dismiss, finding, *inter alia*, that the defendants' purchases did not violate

⁷² *Id.* It is possible that, under the current state of the law, the facts of *Lund* would more easily support liability under the misappropriation theory, especially applying rule 10b5-1, 17 C.F.R. § 240.10b5-1 (2005). Alternatively, notwithstanding the court's conclusion, *Lund* might have been decided on tipping under the classical theory without resort to the temporary insider concept:

Lund and Horowitz had a long and close personal relationship. Based upon that relationship, *Lund* could be considered nothing more than a traditional tipper-tippee case. What the Court seems to be saying in *Lund* is that anytime a person is given information by an issuer with an expectation of confidentiality or limited use, he becomes an insider of the issuer. But under *Dirks*, that is not enough; the individual must have expressly or impliedly entered into a fiduciary relationship with the issuer.

SEC v. Ingram, 694 F. Supp. 1437, 1440 n.3 (C.D. Cal. 1988). In *Ingram*, one who assisted the issuer in finding a merger partner and provided advice was held to be a temporary insider, even though the person received no compensation for the activities. *Id.* at 1438–40 & n.1. He was brought into the inner circle by attending meetings and thus became privy to material nonpublic information. *Id.* at 1438–39.

Finally, one leading text suggests that the holding in *Lund* “may reach too far. The information in *Walton* [see *supra* text accompanying note 34] was also provided with an implicit expectation of confidentiality or limited use, but the Supreme Court approved the exoneration of the outsider in that case.” JOHN C. COFFEE, JR. & JOEL SELIGMAN, *SECURITIES REGULATION CASES AND MATERIALS* 1107 (9th ed. 2003).

⁷³ *Simon DeBartolo Group*, 186 F.3d 157 (2d Cir. 1999), *rev'g* 985 F. Supp. 427 (S.D.N.Y. 1997).

⁷⁴ *Simon DeBartolo Group*, 186 F.3d at 162–64.

rule 10b-5.⁷⁵ With regard to the issue of the defendants' duty to disclose the information that they had about the impending plan, the court of appeals held:

[Plaintiffs], by alleging that RPT provided the defendants and the other [participants in the reorganization plan] with material non-public information to be used confidentially and solely for purposes of formulating [the plan], appear to have placed the defendants squarely within [the] limited category of corporate outsiders subject to the prohibition on insider trading, as outlined in [United States v. Chestman, see supra text accompanying notes 33 and 39] and *Dirks*. [Plaintiffs] therefore at least arguably alleged facts sufficient to establish the requisite duty to disclose or to abstain.⁷⁶

There were written confidentiality agreements between RPT and the defendants which stated that:

“the parties' discussions and negotiations [would] involve matters of a confidential nature which [would] require the parties to repose in one another the highest trust and confidence,” and that the defendants would use the confidential information solely for purposes of the contemplated transaction.⁷⁷

Defendants were provided with nonpublic information regarding RPT.⁷⁸ Thus, the confidential relationship between the RPT itself and the outsiders/temporary insiders—the defendants—was rooted in express contractual terms.⁷⁹

The analyses underlying the application of the “temporary insider” concept in these cases rule out the application of the

⁷⁵ *Simon DeBartolo Group*, 985 F. Supp. at 433.

⁷⁶ *Simon DeBartolo Group*, 186 F.3d at 172.

⁷⁷ *Id.* at 162 (alterations in original).

⁷⁸ *Id.*

⁷⁹ One might argue that the purchase of shares by the defendants was “for purposes of the contemplated transaction” and thus not a breach of the agreement, nor indicative that the information was provided by RPT other than for a proper corporate purpose and thus not an unlawful tip. See also *id.* In that event, neither the classical nor the misappropriation theories would have been implicated.

classical theory to the research participant, because that notion is dependent upon there being a temporary fiduciary relationship between the trader and the issuer of the securities, and the research participant does not assume a role in the research trial that manifests the indicia of insider status applied in the cases. The idea of the temporary insider is grounded in an element of trust and confidence reposed in the person under scrutiny. No such confidence is placed in the drug trial participant. Thus, the classical theory, even in its broadest reach, has no application to the drug trial participant.

VIII. With no Relationship of Trust and Confidence, Trading by the Drug Trial Participant is not Prohibited by the Misappropriation Theory

One who trades based solely on his own information is free to trade, so long as he has no fiduciary relationship with those with whom he trades.⁸⁰ It is, however, by no means clear that the drug trial participant may take advantage of this principle when he purports to trade based solely on self-observation of his own experience during the drug trial. The participant's observation of his own condition—whether it be improving, stable, or deteriorating—cannot be divorced from the fact that this information was obtained as part of the trial, he did not develop or discover the information himself, and the identity of the drug (and its manufacturer or licensor) was obtained from others. The facts that the securities trading participant has not disclosed in that situation, under the disclose or abstain rule, are not his reason for acquiring the stock⁸¹—the paradigm situation where the buyer is free to trade without disclosing his future plans—but a condition, albeit his own, that, presumably, was produced by an agent (the drug) that was provided to him by a third party, together with related medical care. In any event, as discussed later, it is unlikely that one's own medical condition, without reference to the apparent effect of the drug on other participants in the trial, is material to the securities markets,⁸² no matter how important it may be to that individual's health.

Thus far, we have seen that the classical theory does not prohibit trading by the drug trial participant and that the self-generated

⁸⁰ See *supra* text accompanying note 30.

⁸¹ *Id.*

⁸² See *infra* part IX, notes 91-109 and accompanying text.

information/nonfiduciary concept does not likely apply to permit trading. This leaves unresolved whether the remaining potential approach, the misappropriation theory, prohibits trading by the participant. Under the misappropriation theory, liability depends upon there being a relationship of trust and confidence between the participant and the source of the information.⁸³ If the source of the participant's information is his fellow participants, whether the nature of the information is direct reports from them or the participant's observations of them, there is no apparent duty of trust and confidence with the source of the information because there is no such duty owed to them. Even if the source of the information is deemed to be the sponsor or investigator, there is no inherent relationship of trust and confidence owed her healthcare provider or the sponsor, nor is there any express agreement to keep any of the information confidential.⁸⁴

There is a duty of trust and confidence flowing from the medical professional conducting the trial, at least to the extent of information for which the patient has not waived disclosure in order to facilitate the trial. Members of the medical profession in most states are constrained from divulging confidential information obtained in the course of treatment of the patient under the physician-patient privilege.⁸⁵ The privilege generally extends to communications made by the patient to the doctor and information of a medical nature observed by the doctor.⁸⁶ The privilege belongs to

⁸³ As observed above in note 21, most classical cases can fit within the rubric of the misappropriation theory, because a relationship of trust and confidence vis-à-vis the source of the information is an essential element of both theories; in the classical situation, there is simply a better defined relationship, that of the traditional corporate fiduciary.

⁸⁴ See *supra* text accompanying notes 63–67.

⁸⁵ There is no general federal physician-patient privilege by common law or statute. 3 JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN'S FEDERAL EVIDENCE § 514.11 (Joseph M. McLaughlin ed., LexisNexis 2d ed. 2005). Most states, however, have established such a privilege by statute. *Id.* § 514.11. The privilege extends to communications in the presence of "third persons who are reasonably necessary to the patient's diagnosis and treatment by the doctor," and the presence of family members does not vitiate confidentiality. *Id.* § 514.12[6]. Depending upon the terms of the applicable statute, disclosure to third persons in order to further the patient's treatment may not be a breach of the privilege. *Id.* There is, however, a federal common law psychotherapist-patient privilege. *Id.* § 504.03. For a critical commentary urging recognition of a federal physician-patient privilege in parallel with the psychotherapist-patient privilege, see Kenneth S. Broun, *The Medical Privilege in the Federal Courts—Should it Matter Whether Your Ego or Your Elbow Hurts*, 38 LOY. L.A. L. REV. 657 (2004).

⁸⁶ WEINSTEIN & BERGER, *supra* note 85, § 514.12[5][a]–[b]. "The privilege [extends] only to communications intended by patients to be confidential." *Id.* § 514.12[6]

the patient, who alone has the power to waive it, subject to certain defined exceptions.⁸⁷ The sponsor also generally agrees to keep the patient's information confidential.⁸⁸ The patient, however, owes no reciprocal duty of confidence to the physician, so that disclosure of facts learned *from the doctor*—as well as the patient's observations of his own condition or that of fellow subjects—need not be held in confidence *by the patient*.

It bears emphasis that the patient in the drug trial typically does not sign a confidentiality agreement.⁸⁹ One reason there is no such agreement is that complete confidentiality is neither expected nor desirable. In the clinical trial setting, manufacturers or other sponsors of the trials recognize that patients must be free at least to provide information to their other healthcare providers and family members.⁹⁰

Under these circumstances of nonconfidentiality in respect to the participant's obligations, neither the classical theory nor the misappropriation theory applies to any information gained by a participant from involvement in the trial. Therefore, the participant is free to trade based on information that is learned in connection with the trial.

(emphasis added). This ties in to the researcher's/sponsor's pledge of confidentiality to the patient in connection with the patient's informed consent. See *supra* text accompanying note 65.

⁸⁷ *Id.* § 514.12[1]. In *United States v. Willis*, 778 F. Supp. 205 (S.D.N.Y. 1991), the court upheld an indictment against a psychiatrist charged with engaging in unlawful insider trading in breach of his fiduciary relationship with his patient, the source of the information, finding that the relationship between a psychiatrist and patient has "all the characteristics of . . . a 'paradigmatic fiduciary relationship.'" *Id.* at 209 (quoting *United States v. Chestman*, 947 F.2d 551, 569 (2d Cir. 1991) (en banc)).

⁸⁸ See, e.g., PHARM. RES. & MFRS. OF AM., *supra* note 60, at 11.

⁸⁹ See *supra* text accompanying notes 65–67.

⁹⁰ The National Institutes of Health informs participants that they will continue to work with their primary healthcare provider. Not only does the drug trial not provide long term care for the participant's condition, but "by having the health care provider work with the research team, the participant can ensure that other medications or treatments will not conflict with the protocol" of the trial. Nat'l Insts. of Health, *Clinical Trials*, *supra* note 52. Thus, proper protocol includes advising the trial participant that her "participation in a clinical trial will not affect the care [she] is receiving from [her] primary care physician . . . [Her] records during [her] participation in a clinical trial may be shared with [her] physician, or they may remain confidential at [her] request." NORRIS, *supra* note 48, at 95.

IX. Does the Research Participant have *Material Information*?

Trading based on nonpublic information is unlawful only if the information is material.⁹¹ Whether the nonpublic information that a research participant has is “material” must be addressed on a case-by-case basis.⁹² As noted earlier, current factual information is material if there is a substantial likelihood that a reasonable shareholder would consider it important in making an investment decision.⁹³ There are alternative definitions, most notably that “there must be 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.”⁹⁴ In some cases, the information possessed by the research participant relates to what may happen in the future, for example, the efficacy of a drug *after* it is approved by the FDA for general use, beyond the confines of a carefully supervised drug trial, and the resulting impact on the profits of the manufacturer or licensor of the drug.⁹⁵ In that situation, materiality “will depend

⁹¹ See *supra* text accompanying note 8. The issue of whether the information is nonpublic is addressed *infra* in the text accompanying notes 112–17.

⁹² All materiality analyses are fact-specific and require a case-by-case determination. *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976) (“The issue of materiality may be characterized as a mixed question of law and fact, involving as it does the application of a legal standard to a particular set of facts.”); *Basic, Inc. v. Levinson*, 485 U.S. 224, 250 (1988) (“Materiality depends on the facts and thus is to be determined on a case-by-case basis.”).

⁹³ See *supra* text accompanying note 8.

⁹⁴ *TSC Industries v. Northway*, 426 U.S. 438, 449 (1976); see *Basic*, 485 U.S. at 231–32.

⁹⁵ A drug trial result can have a significant effect on the price of the sponsoring company’s stock, especially where the particular drug is a major factor in the company’s future. See, e.g., *SEC v. Potter*, Litigation Release No. 18,255, 80 SEC Docket 2,288 (July 28, 2003) (noting that after the company announced adverse developments in a drug trial, the price of the stock “plummeted”); *Former Air Force General in SEC Inquiry*, N.Y. TIMES, Oct. 1, 2003, at C5 (reporting stock dropped 63% after FDA advisory panel recommended disapproval of medical device); Jan M. Rosen, *DataBank; for a 2nd Week, the Market Pushes Higher*, N.Y. TIMES, Feb. 23, 2003, § 3, at 15 (reporting that stock dropped 78% in a week after the company reported that the drug was not working as well as expected).

The fact that the stock price changes in a perceptible way after disclosure of facts is evidence that the facts were “material.” 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,”

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."⁹⁶ Thus, materiality *during the trial* may depend on the likelihood that the drug will be approved, or disapproved, by the FDA and the anticipated financial impact on the pharmaceutical company in that event. As evidenced by the numerous SEC civil actions and criminal prosecutions for alleged wrongful insider trading by persons affiliated with sponsors or investigators, material information regarding drug trials and related regulatory approvals is a fertile subject for potential abuse.⁹⁷

An ill person who participates in a medical trial to determine the safety or efficacy of a drug that may cure or moderate the effects of that illness may, by virtue of that participation, become aware of material nonpublic information about that drug and thus information about the financial prospects of the sponsoring pharmaceutical company, such as its effect on other participants in the trial. Patients at a single trial site interact; they are not walled off from one another. Indeed, none of the sources consulted for this Article prescribed any prohibition on sharing experiences. These subjects are often seriously ill, and thus they are not only expected

as materiality is a question for the jury to decide); No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 934 (9th Cir. 2003) (holding that failure of market movement after disclosure does not *per se* establish absence of materiality).

⁹⁶ *Basic*, 485 U.S. at 238.

⁹⁷ *See, e.g.*, SEC v. Bucknum, Litigation Release No. 19,528, 2006 SEC LEXIS 46 (Jan. 12, 2006) (reporting settlement of civil action regarding trading based on nonpublic information regarding adverse results experienced during a clinical drug trial, where stock dropped 42% on the announcement of previously undisclosed information); SEC v. Waksal, Litigation Release No. 19,039, 84 SEC Docket 2,489 (Jan. 19, 2005) (reporting settlement of civil action regarding trading based on nonpublic information regarding FDA rejection of request for approval of drug); SEC v. Marks, Litigation Release No. 18,956, 84 SEC Docket 262 (Nov. 2, 2004), and United States v. Marks, Litigation Release No. 18,548, 81 SEC Docket 3,592 (Jan. 21, 2004) (reporting criminal conviction, sentencing, and civil relief for trading on nonpublic information regarding suspension of drug trial); SEC v. Potter, Litigation Release No. 18,255, 80 SEC Docket 2,288 (July 28, 2003) (reporting sentencing after guilty plea based on trading on nonpublic information regarding adverse developments regarding a drug under development); SEC Charges Former Genentech Employee with Insider Trading, Litigation Release No. 17,684, 2002 SEC LEXIS 2119 (Aug. 15, 2002) (reporting settlement of civil action for trading on nonpublic information regarding unsuccessful drug trial); United States v. Wyatt, Litigation Release No. 15,776, 1998 SEC LEXIS 1118 (June 9, 1998) (announcing entry of civil relief for trading based on nonpublic information regarding tests showing that the drug was not effective).

but encouraged to support each other.⁹⁸ Whatever the participant learns, beyond his own situation, comes solely from his fellow participants, because the researchers do not provide trial results to participants.⁹⁹ The information gained by observations or even direct conversations, however, may not be indicative of the results of the trial at the stage when the information is obtained.¹⁰⁰

Several medical professionals offered the following analysis pertaining to the materiality of information available to participants in a drug trial:

[H]aving information on a major objective response (one's own or that of another research subject) for an investigative drug would be important information about a new drug's potential efficacy. Nevertheless, much of the information that could be acquired by a research subject during participation in a clinical trial would probably amount to little more than rumor. That is, such information would often consist of the reports of other patients (because patients commonly meet each other and discuss their experiences), the investigators' subjective reports of both responses and toxic effects, and various other bits and pieces of information gleaned from research nurses, pharmacists, and other members of the treating team.

... A prudent investor would understand the preliminary, uncertain, and incomplete nature of much of the information he or she possessed. *However, in*

⁹⁸ See, e.g., ECRI, SHOULD I ENTER A CLINICAL TRIAL? A PATIENT REFERENCE GUIDE FOR ADULTS WITH A SERIOUS OR LIFE-THREATENING ILLNESS 22 (2002) ("Can I talk to other patients in the same trial about my experience? Certainly. Patients who have participated in a trial have reported receiving support and comfort from being part of a group of patients with the same disease or condition."), available at www.ecri.org/Patient_Information/Patient_Reference_Guide/prg.pdf (last visited Dec. 21, 2005).

⁹⁹ Ann H. Partridge et al., *Offering Participants Results of a Clinical Trial: Sharing Results of a Negative Study*, 365 LANCET 963, 963 (2005) ("Patients are not routinely given information about the aggregate results of trials in which they have participated unless it would affect their future care."). Of course, disclosure to a participant by a researcher without authorization of the sponsor or the research institution may implicate questions of tipping under either the classical or misappropriation theory. The proposal made later in this Article would preclude participant use of tipped information to trade irrespective of the purpose of the tip. See *infra* text accompanying note 127.

¹⁰⁰ See ECRI, *supra* note 98, at 22.

*other cases, a research subject's own objective major response to a novel cancer drug or the knowledge of others' confirmed responses to the same cancer drug might be enough to convince a prudent investor to rationally make trading decisions on the basis of this information.*¹⁰¹

Some years earlier, an attorney addressed the materiality issue in a leading medical journal:

[In analyzing the materiality of information from nonpublic research] the inquiry would focus on the likelihood of a commercial benefit for the corporation and the magnitude of that benefit. The inquiry would therefore take into account such factors as the nature and quality of the research, the prospects for FDA approval of the product, the size of the potential market, and the potential contribution of the product to the corporation's overall profitability.

In this analysis, the nature of the research would be especially important in assessing the likelihood and magnitude of commercial benefit. For example, a major breakthrough in basic research could promise a commercial benefit of great magnitude, but the likelihood of such a benefit would be a matter of speculation in the absence of a developed product. In contrast, a favorable outcome in a clinical trial, which necessarily involves a developed product, would have a high likelihood of benefiting the company if the outcome led to FDA approval of the product. More generally, if the research is sufficiently important to the corporation, a court is likely to view the resulting data as a form of material information, even if the prospects for commercial success are uncertain.¹⁰²

¹⁰¹ Helft et al., *supra* note 1, at 659 (emphasis added).

¹⁰² James R. Ferguson, *Biomedical Research and Insider Trading*, 337 NEW ENG. J. MED. 631, 632 (1997) (focusing on liability for insider trading by investigators, assessing their exposure as "temporary insiders" by reason of having entered into confidentiality agreements with the sponsor). Ferguson also concludes that if an investigator receives funding from a source that does not require confidentiality or otherwise restricts use of the data he is free to trade on advance knowledge of the research findings, with no analysis by the author of the possible application of the misappropriation theory. *Id.*

The evaluation of the materiality of information that is gained by the participant from observing fellow participants at a single site must take into account that the single site may involve only a modest percentage of all participants at all sites.¹⁰³ “Early interim results of clinical trials are often misleading,” even to the researchers.¹⁰⁴ Nevertheless, consistent or comparable results at a single site could accurately reflect information about the trial as a whole.¹⁰⁵ Moreover, in some situations evidence that a drug is only of limited benefit may signal an important pharmaceutical development.¹⁰⁶

The stage of the clinical trial has an impact on whether the information gleaned by the participant is material. Material information that is based on the experiences of participants other than (only) the participant-trader is more likely to be obtained in a Phase II or, more likely, Phase III trial, when the effectiveness of the drug is being evaluated.¹⁰⁷

If an entire study is terminated because of adverse results, the patient may know of the termination before the decision is disclosed to the public, providing the patient with information that may be material, especially if the *potential* success of the drug had earlier had a positive effect on the developer’s stock price in anticipation of the profits from the drug.¹⁰⁸ Similarly, interim analysis may dem-

¹⁰³ See *supra* text accompanying note 55.

¹⁰⁴ Thomas R. Fleming et al., *Monitoring Clinical Trials: Issues and Controversies Regarding Confidentiality*, 21 STAT. MED. 2843, 2844 (2002).

¹⁰⁵ See CHOW & LIU, *supra* note 55, at 240–47.

¹⁰⁶ A drug that extends (the quality of) life only briefly for terminally ill patients is worthwhile even though it is not a miracle cure. See *FDA Backs Cancer Drug*, N.Y. TIMES, NOV. 3, 2005, at C2, and Andrew Pollack, *Panel Backs One Drug, But Not 2nd*, N.Y. TIMES, SEPT. 14, 2005, at C3 (reporting that the FDA advisory panel recommended approval and FDA subsequently approved a drug that extended the life of patients with pancreatic cancer for a median of twelve days longer than without using that drug, notwithstanding no improvement in quality of life and the presence of side effects).

¹⁰⁷ It has, however, been suggested that “the dangers [of insider trading] are especially great in early phase clinical trials that are not performed in a blinded or randomized manner, such as phase I trials” Helft et al., *supra* note 1, at 657. However, this is when the focus is on the safety of the drug, not its efficacy in treating a disease. See *supra* text accompanying note 50. Nevertheless, if a drug were found to be unsafe as a result of a Phase I trial, then it would pose an opportunity for a participant to, for example, sell the manufacturer’s stock short or buy a put option before the outcome becomes public. These commentators also note that in the informed consent process in “early phase trials” the potential subjects will be provided with information regarding the drug’s toxic effects. *Id.* This, too, may be nonpublic information of a material character.

¹⁰⁸ For examples of studies that were terminated because of unfavorable results, see Gina Kolata, *Scientists Debating Future of Hormone Replacement*, N.Y. TIMES,

onstrate a significant clear-cut *beneficial* effect resulting in early termination of the trial.¹⁰⁹ This may be the paradigm of favorable material information.

In summary, not every trial participant will obtain material information during the clinical trial, but it cannot be known in advance which situations will and which situations will not entail that potential. Notwithstanding the variables and uncertainties, in at least some clinical trials, depending at least in part on the outcome—which of course is not known in advance—participation presents the *opportunity* to obtain information material to the stock price of the sponsor. This possibility cannot be ignored, if one cares whether material information that may not be public can lawfully be used to trade in securities. Whether this gives rise to a sufficient concern to merit prophylactic action is addressed in the remaining sections of this Article.

X. Is Material Clinical Trial Information that is Known to the Participant Nonpublic?

In any situation there must also be an assessment whether the information, whether material or immaterial, has become so widely known that it is no longer “nonpublic” for purposes of rule 10b-5.¹¹⁰ It could be argued, for example, that if there are a large number of participants in a drug trial, often numbering in the hundreds in a Phase II trial or even the thousands in a Phase

Oct. 23, 2002, at A20 (reporting that an estrogen therapy study was terminated because increased health risks were not offset by the health benefits); *Biogen Halts Remaining Trials on Drug*, N.Y. TIMES, Nov. 3, 1999, at C26 (reporting on the suspension of studies of drugs because they triggered blood clotting problems); Lawrence M. Fisher, *Trials for Sepsis Drug Stopped After a Review*, N.Y. TIMES, Mar. 16, 1993, at D4 (reporting on the termination of a drug trial for treating sepsis because of high death compared to patients receiving a placebo).

¹⁰⁹ See, e.g., Lawrence M. Fisher, *Shares of Centocor Surge 28% After Two Positive Drug Trials*, N.Y. TIMES, Dec. 22, 1995, at D16 (reporting on the suspension of trials of a blood clot dissolving drug because of “unexpectedly strong results”); Larry Josephs, *Fighting AIDS All the Way*, N.Y. TIMES, Oct. 8, 1989, § 6, at 42 (reporting that a study of AZT as a treatment for AIDS was terminated “because the results had become so dramatically clear.”). Recently, however, further trials of the drug in the article cited first in this note were halted because of adverse results, though it was not known if those affected were taking the drug or a placebo. *Cardiac Drug Trial is Suspended*, WALL ST. J., Oct. 5, 2005, at D13.

¹¹⁰ See *supra* text accompanying note 10.

III trial,¹¹¹ then the information learned by trial participants is “public” for purposes of rule 10b-5. That argument, however, falls short. Investigators are pledged to confidentiality.¹¹² Under the approach urged later in this Article that participants agree not to trade and obtain a pledge of confidentiality from those to whom they make disclosure,¹¹³ the information should not be deemed public under either of the accepted criteria for determining whether information is public. First, there would not have been wide dissemination of the information as that concept is understood by the SEC.¹¹⁴ Second, there will not have been trading activity that will cause the price of the stock to reflect the information. It would be anomalous to find participant trading to be permissible on the ground that the information is public when it is only by virtue of their own privileged access to information that they know the information. Conceptually, this is no different from the situation where hundreds of the employees of a company, under a fiduciary duty of confidentiality, are aware of nonpublic material information, such as a new product under development. The size of the group that knows the information is not dispositive of whether the information is “public” when the members of that group are precluded from *either* disclosing or trading.

There are, nevertheless, situations in which clinical trial information may become widely known before, for example, publication in a professional journal. Presentations by investigators at open forums on a particular disease may result in disclosure of trial results before there has been general publicity of the results because publication in a professional journal has been deferred pending peer review.¹¹⁵ This disclosure, however

¹¹¹ See 21 C.F.R. § 312.21 (2005).

¹¹² See *supra* text accompanying notes 56–60.

¹¹³ See *infra* text accompanying notes 127–37.

¹¹⁴ See *supra* text accompanying note 10.

¹¹⁵ After the SEC brought several insider trading cases against clinical investigators, one commentator observed:

[U]nlike many other types of market-related information, the results of clinical trials are often disclosed to a surprisingly large number of people before the news is released publicly. This is particularly true if the results are published in medical journals or presented at a major conference. In such cases, the news becomes public only after advance copies of the research have already circulated among corporate officers, outside consultants, journal editors, scientific reviewers, professional colleagues and even a select number of reporters.

James R. Ferguson, *Viewpoint: Clinical Trials As Inside Information*, N.Y. TIMES, Oct. 19, 1997, § 3, at 15. It is common for clinical trial information to be disclosed

inadvertent or premature, nevertheless may result in the information becoming “public” for purposes of rule 10b-5 under the established criteria.

XI. As a Matter of Policy, Should Trading by Clinical Trial Participants be Restricted?

Thus, there are situations in which information obtained by the drug trial participant is material and is nonpublic, and under the current state of the law, participants are not prohibited from trading based on that information. This flexibility to trade based on information not available to the general investing public is an undesirable outcome as a matter of securities law policy, as manifested in the cases applying rule 10b-5 in the insider trading context. Participation in a drug trial may be undertaken largely for altruistic purposes, where the participant’s disease is terminal (albeit the participant may be seeking a drug that will alleviate some symptoms even without extending his life or prolong life but not effect a remission or cure), or in order to obtain a therapeutic benefit that would not otherwise be available. While the former motivation is sometimes in large part selfless, neither situation suggests that the participant should reap any potential financial reward beyond any direct compensation for participation.¹¹⁶ Moreover, allowing the participant to trade may be detrimental beyond the concern about the integrity of the financial markets that underlies the prohibition on unlawful insider trading. A financial interest in the outcome of the trial also may influence the participant’s activities in the trial itself, a definite societal detriment.¹¹⁷

to those interested in drug development, including not only researchers but also those with the disease who are eager to learn of pending developments. See, e.g., *Just What the Patient Ordered*, *ECONOMIST TECH. Q.*, Sept. 17, 2005, at 34–35 [hereinafter *Just What the Patient Ordered*] (recounting meeting held by disease-specific support and research-funding foundation where researchers and clinicians presented “some early clinical data”).

¹¹⁶ The Office of Human Subjects Research of The National Institutes of Health recommends that informed consent forms to be signed by trial participants describe any benefits of the study and notes: “Monetary compensation is not a benefit. If compensation is to be provided to research subjects or healthy volunteers, the amount should be stated in the consent document” OFF. OF HUMAN SUBJECT RES., NAT’L INSTS. OF HEALTH, OHSR INFO. SHEET NO. 6: GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS, at <http://ohsr.od.nih.gov/info/info.html> (last visited Jan. 14, 2006).

¹¹⁷ See Helft et al, *supra* note 1, at 657. In light of this separate concern, the proposal made later in this Article that the participant not trade would preclude the participant’s use of rule 10b5-1, 17 C.F.R. § 240.10b5-1 (2005), to permit

If the freedom to trade based on this nonpublic information is undesirable or rejected as a matter of policy, participants themselves could be restricted from trading by requiring them to enter into an agreement that they hold in confidence information they obtain as a participant in the trial. This would satisfy the requirements of rule 10b5-2(b)(1) as a predicate for the application of the misappropriation theory if the participant were then to use the information to trade in securities.¹¹⁸ This form of agreement, however, is manifestly too broad, because the participant cannot reasonably be prohibited from sharing the information with medical professionals providing him care

trades for his account in the relevant security. In summary, this rule permits trades to be made for the account of a person who is aware of material nonpublic information at the time of the trade if, in effect, the timing and terms of the trade were determined before he became aware of material nonpublic information. For a general summary of the operation of rule 10b5-1, see Larry Sprigel, *Rule 10b5-1* (2004), at www.realcorporatelawyer.com/faqs/10b5-1.html (last visited Dec. 21, 2005). If, before entering the trial, the participant were to establish some algorithm for trading in the stock of the drug sponsor later, during the trial, when the participant himself could not direct a trade because he became aware of material nonpublic information during the trial, the participant could—at least in the view of Helft et al.—report the effect (or lack of effect) of the drug on himself in such a way as to make the prescheduled trade more profitable. Irrespective of whether a participant's own subjective account of his experiences could affect the outcome or status of the trial in a material way and whether those accounts would override a clinical assessment based on laboratory or other objective tests (e.g., an MRI), any incentive to provide biased subjective reports should be eliminated to the extent possible in the interests of conducting a scientifically sound trial.

¹¹⁸ This Article does not address whether imposing this or any other condition to participation in a drug trial would significantly reduce the number of willing participants. That seems unlikely, especially in those situations in which the principal reason for participating in a trial is to obtain a personal medical benefit. Several commentators observed that “any regulatory issues should be dealt with after enrollment so that the informed consent process is free from the negative influence that discussions of financial conflicts of interest might have.” Helft et al., *supra* note 1, at 659. This suggestion, however, is not an optimal solution if it affects continued participation once the subject has been enrolled in the trial, because he is always free to leave the trial. See *supra* text accompanying note 67.

A possible parallel to obtaining a confidentiality agreement in this context is the type of confidentiality agreement obtained from persons who do “beta testing” of computer software. 1 L. J. KUTTEN, *COMPUTER SOFTWARE PROTECTION/LIABILITY/LAW/FORMS* § 3:19, at 3-23 to -25 (2005) (“Beta testing of software occurs when the software is stable enough so that parties 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 an example of a confidentiality agreement for beta testing, see onecl, *Sample Business Contracts: Sequenom Beta Test Agreement*, at <http://contracts.onecle.com/sequenom/genzyme.supply.1999.07.15.shtml> (last visited Dec. 21, 2005).

who are not members of the investigation team and with family members, clergy, or possibly even friends or his employer.¹¹⁹

At this point, other public policy considerations come into play. For example, several commentators rejected the solution of withholding from participants the identity of the drug under trial as a means of preventing the misuse of material nonpublic information. Their rationale was that there is much information about specific new drugs on the Internet so that “to withhold the names of these new drugs and their manufacturers (or the sponsoring company) would be to improperly and unnecessarily limit research subjects’ options of obtaining from other sources further information about the treatment they are considering.”¹²⁰ Similarly, participants in clinical trials, as well as investigators, sometimes disclose the progress of the trials to support groups and patients who are not participants in the trial, all of whom have a legitimate interest in being informed of potential therapeutic developments.¹²¹ After learning of developments at such a presentation, one executive of a drug development company took the opportunity then and there to work with those present to develop a trial for the drug that was discussed.¹²² There is thus a benefit to society in sharing information among persons with a common interest in a particular disease, even if the information is preliminary, incomplete, or perhaps even inaccurate in some respects. The information may be shared in this manner before the definitive (or at least vetted) formal scientific results become available through journal

¹¹⁹ See *supra* text accompanying note 90. There is, however, no clear need to identify the drug, or its manufacturer or licensor, to all those with a legitimate interest in the participant’s health. By revealing only that the participant is in a trial but not the identity of the drug or those with a financial interest in the outcome of the trial, those people will probably not be in a position to know *material* nonpublic information on which they could base a trade—unless there is enough information available from other sources to permit the recipient of the incomplete information to discover what the drug is. See INT’L FED’N OF PHARM. MFRS. ASS’NS, IFPMA CLINICAL TRIAL PORTAL, at www.ifpma.org/clinicaltrials.html (last visited Dec. 21, 2005) (Internet portal for accessing clinical trials).

¹²⁰ Helft et al., *supra* note 1, at 658.

¹²¹ Under SEC Regulation FD, disclosure of preliminary research results at a patient forum or support group could present problems if the information is provided by a senior executive of a public company when the information is material to the securities of that company. See *supra* text accompanying note 10. In essence, under that regulation the executive is likely prohibited from making disclosure to the self-selected group at the forum, any of whom might be interested in investing in the company’s stock, without making simultaneous public disclosure of that material information. If the information disclosed is not material, for example, because of its very preliminary nature, then the problem does not arise.

¹²² *Just What the Patient Ordered*, *supra* note 116, at 34–35.

publication or presented at a medical or scientific conference. The understandable hunger for the information is reflected in the overwhelming chat room activity about clinical trials.¹²³

Thus, whether trial participants should be sworn to some degree of secrecy entails making a policy judgment on which reasonable minds may differ. One side may argue that the comfort and hope that results from unfettered disclosure of experiences suggesting that progress is at hand outweighs any conceivable harm to the securities markets, especially when the materiality of the information vis-à-vis the markets is uncertain. Another side may argue that patient (as distinguished from researcher) disclosure of largely anecdotal information presents a significant danger of *misinformation* so that securities law concerns outweigh the value, *if any*, of (premature) disclosure, so that the decision to disclose is left in the hands of the investigators and the sponsors.¹²⁴ This is a subject fraught with emotion, and a policy judgment will have to be made as to which factor—(A) scientific information relayed by lay persons with less than a full picture of the overall clinical trial or (B) a financial detriment to securities market participants who do not have this information even in its raw form—is more important.

If the policy balance is struck in favor of restraining disclosure by the participant in order to maintain the fairness of the securities markets (and to commit decisions about public disclosure of clinical trial results to the discretion of the scientists and those who retain them), while at the same time accommodating the undeniably legitimate need to communicate information to a select group of persons associated directly with the participant, the solution is to obtain a more limited agreement from the participant that entails no more than precluding trading in the security or securities as to which the information might be material.¹²⁵ (As explained later, however, there must also be

¹²³ See, e.g., Planet Cancer Chat Room, at www.planetcancer.org/html/index.php (last visited Dec. 21, 2005); see also Gunther Eysenbach et al., *Health Related Virtual Communities and Electronic Support Groups: Systematic Review of the Effects of Online Peer to Peer Interactions*, 328 BRITISH MED. J. 1166 (2004) (reporting that as of April 2004 there were almost 25,000 electronic support groups in the health and wellness section of www.yahoo.com).

¹²⁴ The investigator may prefer to muzzle the participant insofar as public disclosure is concerned, to avoid the dissemination of misinformation—either unduly positive (raising the hopes of those waiting for drug approval) or unduly negative (thereby discouraging persons from participating in later phases of the trial)—so that the scientists maintain full control of any disclosure.

¹²⁵ A participant who has entered into the agreement proposed here, who then trades in violation of the agreement and is called to account under the misap-

an agreement related to the terms of further disclosure to the participant's inner circle.) This should be sufficient to invoke the application of rule 10b5-2 to prohibit the participant's own trading.¹²⁶ Several commentators have recommended this.¹²⁷

Nevertheless, that limited form of agreement, without more, would not adequately inhibit trading by third parties to whom the participant, without an improper purpose or intending to confer a financial benefit, communicates the results of the experimental treatment where there is a legitimate medical or personal need to share the information.¹²⁸ Whether rule 10b5-

appropriation theory for deception by trading without disclosing that intent to the source of the information, might argue that the agreement not to trade was entered under duress or is unconscionable because the agreement was imposed as a condition to receiving a potential life-saving medication. The current law of duress or unconscionability does not appear to be available, however, as a means of abrogating the underlying agreement and thereby eliminating the predicate for application of the misappropriation theory. *See generally* RESTATEMENT (SECOND) OF CONTRACTS §§ 174–179 (1981). Among other relevant considerations, a host of factors are applied in determining who is admitted into a clinical trial, inasmuch as no person has a right or entitlement to be allowed access to an experimental drug, and an agreement designed to advance the policies of the Exchange Act should not be viewed as against public policy.

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¹²⁶ 17 C.F.R. § 240.10b5-2(b)(1) (2005) refers broadly to agreeing to “maintain information in confidence.” Recognizing that rule 10b5-2 is not an exclusive definition of the duty (Rule 10b5-2, Preliminary Note) even if the rule is interpreted not to encompass this specific agreement, there is no principled basis why a narrower agreement not to trade based on the information would not create a contractual (rather than fiduciary) “duty of trust or confidence” as the concept is used in the misappropriation theory. 17 C.F.R. § 240.10b5-2(a) (2005). That is, while rule 10b5-2(b)(1), 17 C.F.R. § 240.10b5-2(b)(1), refers to an agreement to “maintain information in confidence,” an undisclosed breach of an agreement simply not to use information to trade is equally deceptive within the meaning of rule 10b-5. “[T]he deception essential to the misappropriation theory involves feigning fidelity to the source of [the] information.” *United States v. O’Hagan*, 521 U.S. 642, 655 (1997).

¹²⁷ Helft et al., *supra* note 1, at 660.

[They suggest that *if*] financial conflicts of interest . . . [in this realm prove to be] widespread . . . it would be helpful to have research subjects screened (by the sponsoring companies) for financial conflicts of interest after enrollment in a trial and to require subjects to disclose their holdings and to cease trading the stock of the sponsoring company until material information from the study becomes public.

Id. The authors ignore how the subjects can be *required* to disclose information and to change their behavior *after* they have enrolled in the trial. A subject who refuses would, presumably, be removed from the trial, necessitating the finding of a replacement, which is not a very efficient way to populate a clinical trial.

¹²⁸ This does not permit disclosure at, for example, a support group meeting, at least not without prior consent of the sponsor or investigating institution. If

2(b)(3) will apply when the information is communicated by the participant to a close family member depends on the parties' history of sharing and maintaining confidences.¹²⁹ In the participant's agreement with the research institution or trial sponsor that is proposed here, she should agree to provide the information to third parties *only* upon an express understanding with the recipient of the information that it will be retained in confidence and used only for the purpose for which it is disclosed by the participant. This should be sufficient to invoke the misappropriation theory if the recipient of the information trades based on that information in breach of the disclosure made in confidence. Moreover, this approach avoids the question of the application *vel non* of the still somewhat uncharted territory of tipper liability in the misappropriation context.¹³⁰

If, however, the analysis treats the participant as a tipper and the family member as tippee, and the rule of *Yun* is applied, the patient would not be an unlawful tipper because there was no intent to confer a benefit on the tippee. Correspondingly, the family member-tippee would not be precluded from trading, because the disclosure by the patient/participant was neither for an improper purpose nor intended to confer any trading-based benefit on the family member. The purpose of the disclosure was merely to inform that person of the patient's medical progress for proper medical, family, or other permissible reasons.¹³¹ Even if the *Yun* rule is not applied, and the approach in *Libera* is

the balance discussed *supra* in the text accompanying notes 121–25 is struck against restraining disclosure by participants, then of course none of these agreements would be required.

¹²⁹ 17 C.F.R. § 240.10b5-2(b)(3).

¹³⁰ Avoiding this problem and avoiding anomalous outcomes was one reason the SEC issued rule 10b5-2, especially in the family context:

Case law has produced the following anomalous result. A family member who receives a "tip" (within the meaning of *Dirks*) and then trades violates Rule 10b-5. A family member who trades in breach of an express promise of confidentiality also violates Rule 10b-5. A family member who trades in breach of a reasonable expectation of confidentiality, however, does not necessarily violate Rule 10b-5.

Selective Disclosure and Insider Trading, *supra* note 10, 65 Fed. Reg. at 51,729.

¹³¹ As in many insider trading cases, sorting out the *true* motive may be difficult. This problem was addressed in *Libera* where the court simply presumed that any disclosure was to benefit the recipient, ruling "that the tippee's interest in the information is, in contemporary jargon, not for nothing." *United States v. Libera*, 989 F.2d 596, 600 (2d Cir. 1993). This presumption seems misplaced in the medical trial context.

employed, the family member or other recipient of the information who trades will not be liable (nor, therefore, would the trial participant be an unlawful tipper) because there would have been no breach of any duty owed by the patient to the source of the information to trigger the presumption that the tippee is interested in the information for personal gain. In other words, because the participant's only duty to the research firm or to the sponsor was not to trade, and there was no pledge of nondisclosure to others for a *legitimate* purpose, a legitimate disclosure to the family physician, the spouse, or the clergyman that is then abused by the recipient should protect the trial participant for a claim of unlawful tipping in violation of rule 10b-5. The better, and more direct approach, therefore, is to take steps to invoke rule 10b5-2 with respect to the recipient of the information who, by trading, may breach a duty to *his* source—the drug trial participant.¹³²

A participant's agreement not to trade and the secondary information recipient's agreement to maintain the information in confidence could provide for automatic termination when the information becomes public through no fault of the drug trial participant or those to whom he provided the information consistent with the terms of the agreement.¹³³ Nevertheless,

¹³² This was the analysis in *Reed*, where the indictment was upheld in the face of a motion to dismiss on the ground that the son breached a duty to his father in misappropriating information from the father, not from the original source of the information. The court did not treat the case as one where the father tipped the son. The court stated:

Reed asserts, and the Government agrees, that he cannot properly be charged as a "tippee" who illegally traded on the basis of nonpublic confidential information received from a corporate insider. Pursuant to the recent decision of the Supreme Court in *Dirks* . . . the argument proceeds, an essential element of tippee liability under Rule 10b-5 is proof that the tipping insider disclosed the confidential information with the knowledge or expectation that the tippee would trade on the information, and, thus, with the intent to defraud the securities holders of the insider's company. However, the Indictment does not allege the existence of such a state of mind on the part of Gordon Reed, and the Government has formally acknowledged that it will not endeavor to establish that Reed's father was possessed of such fraudulent intent.

United States v. Reed, 601 F. Supp. 685, 693–94 (S.D.N.Y. 1985). It was, however, the government's burden to prove that there was an understanding of confidentiality that was breached by the son when he used the information to trade. *Id.* at 717–18. Rule 10b5-2 now provides a rebuttable presumption in that context. 17 C.F.R. § 240.10b5-2(b)(3) (2005).

¹³³ This is comparable to many types of confidentiality agreements, where the recipient of the information agrees to keep the information confidential and to use it only for specified purposes, unless the information becomes public other than as a result of the breach of that agreement. *See, e.g.*, *Rutherford v.*

as a matter of medical policy rather than securities law policy, in order to reduce the risk that those who are continuing participants in a trial would provide biased reports of the results of their continuing treatment, it may still be appropriate to prohibit drug trial participants or those with a related financial interest, such as a spouse, from trading in the securities of the sponsor, even after material information about a continuing trial becomes public, for the same reasons as trading restrictions are imposed on investigators.¹³⁴

XII. Conclusion

Absent any express agreement to the contrary, the clinical trial participant is generally able to trade based on any material non-public information gained during the course of the trial without running afoul of rule 10b-5. There are means to preclude his exploitation of this financial informational advantage *if*, on balance, it is deemed important to prevent exploitation of this information to the disadvantage of those not privy to some of the information about the progress of the trial. While the trial participant benefits society by participating in the trial, there is no sound policy reason why that contribution to society should allow the participant to benefit financially by using material information in the securities markets to the detriment of those who do not have the information he does. If this concern outweighs whatever benefit is achieved through allowing trial participants to make unrestricted disclosure of whatever they might learn as a trial participant—and especially if it is determined to be better to allow sponsors and investigators to control the public release of information—then drug trial participants should be required to sign an agreement (A) prohibiting them from using information gained in the trial—including information as to their own response to the drug—for personal financial gain in the securities markets and (B) requiring that any disclosure they in turn make be made only after receiving an express pledge of confidentiality (meaning nondisclosure and no use in trading) from any recipient of the information, with the universe of permitted recipients a limited one. Under this protocol the drug trial participant will remain free to disclose his medical information to

Trim-Tex, Inc., No. 89 C 6306, 1991 WL 222268, at *6–8 (N.D. Ill. Oct. 25, 1991) (approving a protective order in litigation where the restrictions “shall not apply to any such documents or information which both parties agree, or the Court rules, is already public knowledge or becomes public knowledge other than as a result of disclosure by the receiving party or which has come or shall come into possession of the receiving party independently of the supplying party . . .”).

¹³⁴ See *supra* text accompanying note 58.

other doctors, to family, to friends, to clergy and even to employers as necessary, but each of those recipients will be prohibited from exploiting that information for personal gain.