IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

U.S. SECURITIES AND EXCHANGE COMMISSION,	)	
Plaintiff,	)	
v.	)	No. 11 C 5223
STEPHEN D. FERRONE, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

The U.S. Securities and Exchange Commission ("SEC") has moved for summary judgment on its claims that Douglas McClain, Sr. ("McClain Sr.") and Douglas McClain, Jr. ("McClain Jr.") (collectively, "Defendants" or "the McClains") engaged in securities fraud. *See* Compl. at Counts I and II. I grant the SEC's motion for the reasons stated below.

I.

Defendants have not disputed the SEC's statement of material facts. Therefore, I accept all of the SEC's properly supported factual assertions as true. *See* N.D. Ill. Local R. 56.1(b)(3)(C). However, at the summary judgment stage, I must view the SEC's undisputed facts and the McClains' statement of additional facts in the light most favorable to the non-movants. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

A.

McClain Jr. and James T. Miceli[1] formed Argyll Biotechnologies, LLC ("Argyll") in 2002. McClain Sr. served as Argyll's chief science officer.

In 2006, Argyll acquired the rights to "SF-1019," a biopharmaceutical drug product derived from goat blood. Physicians in Africa and Europe had administrated a precursor form of SF-1019 known as "BB7075" to patients suffering from AIDS and multiple sclerosis. The underlying chemical structure of SF-1019 has been patented in the United States since 2008. *See* U.S. Patent No. 7,358,044.

Shortly after acquiring the rights to SF-1019, Argyll created a public company called Immunosyn Corp. ("Immunosyn"). In exchange for granting Immunosyn an exclusive worldwide license to market and sell SF-1019, Argyll became Immunosyn's majority shareholder. McClain Jr. served as Chairman of the Board and Chief Financial Officer for Immunosyn. McClain Sr. did not have an operational role at Immunosyn, but acquired 2.8 million shares of Immunosyn stock as compensation for the work he performed on SF-1019 as Argyll's chief science officer. Immunosyn stock began trading publicly in October 2007.

In December 2006, Argyll filed an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration

[1] Miceli was a Defendant in this case. He is now deceased.

("FDA") containing a proposal for "Phase I" clinical trials of SF-1019 on human subjects. On January 27, 2007, the FDA notified Argyll during a conference call that its IND application for SF-1019 was being placed on hold and could not be initiated. *See* Pl.'s Ex. 14. McClain Sr. admits that in January 2007, he was aware of the hold placed on SF-1019 clinical trials. Pl.'s Ex. 8 at 33:9-12. In a follow up letter dated March 15, 2007, the FDA placed the IND application for SF-1019 on a "full clinical hold" based on Argyll's presentation of "insufficient information to assess risk to human subjects." Pl.'s Ex. 14 at 1. McClain Sr. and McClain Jr. received notice of the full clinical hold placed on SF-1019 within hours of its announcement. *See* Pl.'s Ex. 8 at 34:3-6; Pl.'s Ex. 15.

In placing a full hold on SF-1019 clinical trials, the FDA informed Argyll, "Until you have submitted the required information, and we notify you that you may initiate the trial(s), you may not legally conduct clinical studies under this IND." Pl.'s Ex. 14 at 3. The FDA hold barred any use of SF-1019 on humans, including through so-called compassionate use waivers. *See* Dr. Rheinstein Declar. at ¶ 17.[2]

[2] The SEC's expert, Dr. Peter Rheinstein, served as a senior official at the FDA from 1974 to 1999. He explains that "compassionate use" is a lay term that refers to the FDA's practice of facilitating "expanded access" to investigational drug treatments for patients with life threatening diseases or

Immunosyn's public filing with the SEC for the 2007 fiscal year noted that "SF-1019 has not been approved for any human use nor treatment of any particular disease, and such approval may never be obtained." Pl.'s Ex. 7 at 16. However, Immunosyn made no mention of the full FDA hold placed on SF-1019 clinical trials in March 2007. McClain Jr. sold hundreds of thousands of his Immunosyn shares between April 2007 and October 2007 while Argyll's first IND application for SF-1019 remained on a full hold. *See* Pl.'s Exs. 35-37.

In July 2008, McClain Sr. was invited to speak to potential investors at the Holistic Health Care Center in Boerne, Texas ("the Texas clinic"). The founder of the Texas clinic, Michelle Longo O'Donnell ("O'Donnell"), told her patients about SF-1019 and Argyll's efforts to secure FDA approval for the drug before McClain Sr.'s visit. O'Donnell asked McClain Sr. to sell some of his Immunosyn shares to her patients at a discounted price.

The SEC alleges that McClain Sr. made several false statements about SF-1019 during his presentation at the Texas clinic: (1) that the FDA had issued "compassionate use waivers" for Argyll or Immunosyn to treat patients in Minnesota and Texas with SF-1019; (2) that Phase 2 clinical trials for SF-1019 were "ready to start in about 60 days under orphan designation"; (3)

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who lack therapeutic alternatives. *See* Dr. Rheinstein Declar. at ¶¶ 15-17.

that "by the time we start our Phrase 2 trials in sixty to ninety days, a year from then we should have our FDA approval"; and (4) that the U.S. Department of Defense "bought 600,000 vials [of SF-1019] from us last year." Pl.'s Ex. 10 ("Transcript of Presentation by Douglas McClain, Sr.") at 5-6, 15-16, and 25.

In addition to his presentation at the Texas clinic, McClain Sr. appeared in two video presentations posted on Immunosyn's website in 2008. The SEC alleges that McClain Sr. made three false statements during the longer of these two presentations: (1) that "[i]n pre-clinical human studies, [SF-1019] appears to create a therapeutic effective response over a range of demyelinating conditions of [the] peripheral nervous system"; (2) that "[c]ompassionate use waivers have been issued by the institutional review board of the FDA in Houston, Texas for the use of SF-1019" and (3) that "preparations for clinical trials are underway in the United States and Europe." Pl.'s Ex. 28 at 2-3.

McClain Sr. collected over $338,000 from selling his Immunosyn shares to people who attended his presentation at the Texas clinic and other investors. It is undisputed that McClain Sr. never delivered Immunosyn shares to these investors and failed to return their money. The SEC has submitted

declarations from five investors who tried, unsuccessfully, to obtain their Immunosyn shares or a refund from McClain Sr.

In November 2008, Argyll submitted a second IND application proposing "Phase II" clinical trials involving SF-1019. On December 17, 2008, the FDA placed this application on a full clinical hold and memorialized this administrative action in a follow up letter identifying "unreasonable and significant risk[s] of illness or injury to human subjects." Dr. Rheinstein Declar. at ¶ 10.

Although Argyll has not withdrawn either of its IND applications, its proposed clinical trials for SF-1019 remain on full FDA holds.

II.

In August 2011, the SEC filed a civil enforcement action against McClain Sr. and McClain Jr. as well as other defendants alleging, *inter alia*, that they engaged in securities fraud.[3] The SEC seeks summary judgment on these claims. At this stage, I must view the facts in the light most favorable to the non-movants and resolve all evidentiary conflicts in their favor.

[3] These are the SEC's only claims against McClain Sr. In addition to its fraud claims, the SEC alleges that McClain Jr. falsely certified Immunosyn's quarterly and annual SEC filings (Count IV); aided and abetted Immunosyn's violations of SEC filing rules (Count VI); and failed to file with the SEC a timely statement reflecting a change in beneficial ownership (Count VII). The only other live Defendant in this case is Stephen Ferrone, Immunosyn's CEO.

Liberty Lobby, 477 U.S. at 255. Summary judgment is appropriate only when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The SEC has asserted claims against McClain Sr. and McClain Jr. under Section 17(a) of Securities Act of 1933, 15 U.S.C. § 77q(a), in Count I and under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, in Count II. Where, as here, the SEC's claims relate solely to alleged fraud in the sale of a security--namely, Immunosyn stock--the three anti-fraud provisions cited above are "substantially the same" and may be analyzed together under the rubrics of Section 10(b) and Rule 10b-5. *SEC v. Bauer*, 723 F.3d 758, 768 (7th Cir. 2013).[4]

"Section 10(b) of the Securities Exchange Act makes it 'unlawful for any person...[t]o use or employ, in connection with the purchase or sale of any security...any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe.'" *SEC v. Zandford*, 535 U.S. 813, 819 (2002) (quoting 15 U.S.C. § 78j(b)).

[4] Sections 17(a)(2) and (a)(3) are unique among the anti-fraud provisions because they do not contain a *scienter* requirement. *See Aaron v. SEC*, 446 U.S. 680, 697 (1980). The SEC makes a passing reference to these provisions in its motion for summary judgment, *see* Pl.'s Mot. at 9 and 11 n.6, but plainly relies on Section 17(a)(1), Section 10(b), and Rule 10b-5.

"To prove a violation of § 10(b) the SEC must establish that [Defendants]: "(1) made a material misrepresentation or a material omission as to which [they] had a duty to speak, or used a fraudulent device; (2) with *scienter*; (3) in connection with the purchase or sale of securities." *Bauer*, 723 F.3d at 768-69. Unlike private plaintiffs, the SEC is not required to establish reliance, damages, or loss causation in a civil enforcement action. *See McCann v. Hy-Vee, Inc.*, 663 F.3d 926, 931 (7th Cir. 2011) ("[T]he SEC can bring an enforcement action for a violation of federal securities law without anyone having suffered harm, which is to say without anyone having relied on a misrepresentation or misleading omission to his detriment.")

The SEC has advanced three distinct theories of how the McClains violated Section 10(b): (1) McClain Sr. defrauded investors by taking their money and never delivering shares of Immunosyn stock or returning their investments; (2) McClain Sr. made materially false or misleading statements about the FDA clinical trial process and the Department of Defense's alleged purchase of SF-1019; and (3) the McClains sold their Immunosyn stock based on inside information about the FDA holds placed on SF-1019 clinical trials. I must address all three of the SEC's theories of liability because the civil penalties for securities fraud are based, in part, on the number of violations committed. *See* 15 U.S.C. §§ 77t(d), 78u(d)(3).

A.

It is undisputed that McClain Sr. took money from investors and failed to deliver Immunosyn shares or provide a refund. "[A] broker who accepts payment for securities that he never intends to deliver, or who sells customer securities with intent to misappropriate the proceeds, violates § 10(b) and Rule 10b-5." *Zandford*, 535 U.S. at 819 (deferring to SEC's interpretation of § 10(b)); *see also Kurz v. Fidelity Mgmt. & Research Co.*, 556 F.3d 639, 642 (7th Cir. 2009) ("Failure to keep one's promises about the handling of securities can violate federal securities law.").

The only contested issue on the SEC's first theory of liability is whether McClain Sr. acted with the requisite *scienter* when he stated that he would deliver Immunosyn shares to investors or refund their money. The *scienter* requirement is what distinguishes securities fraud from ordinary breach of contract claims. *See Zandford*, 535 U.S. at 823-24. "Under *Ernst & Ernst v. Hochfelder*, 425 U.S. 185 (1976), and *Aaron v. SEC*, 446 U.S. 680 (1980), only persons who act with an intent to deceive or manipulate violate Rule 10b-5." *SEC v. Jakubowski*, 150 F.3d 675, 681 (7th Cir. 1998). "[R]eckless disregard of the truth counts as intent for this purpose." *Id*. (citing *Sundstrand Corp. v. Sun Chemical Corp.*, 553 F.2d 1033, 1044-45

(7th Cir. 1977)); *see also SEC v. Lyttle*, 538 F.3d 601, 603 (7th Cir. 2008).

McClain Sr. contends that the issue of whether he intended to deceive or manipulate investors at the Texas clinic cannot be resolved at the summary judgment stage because doing so would deny him the opportunity to explain his "motives and intentions" to a trier of fact. Dkt. No. 88 ("Defs.' Opp'n") at 7.

The Seventh Circuit has rejected McClain Sr.'s contention that he is automatically entitled to a trial simply because his state of mind is at issue. *See Lyttle*, 538 F.3d at 604 ("Even when a party's subjective beliefs are critical to liability, it is not always true that the case cannot be decided on summary judgment."); *see also Jakubowski*, 150 F.3d at 681-82 (affirming summary judgment for SEC on securities fraud claim where "[d]eliberate ignorance" was the most favorable interpretation of defendant's mental state). In order to avoid summary judgment, McClain Sr. must demonstrate that his state of mind at the time he took money from investors and gave them nothing in return is genuinely in dispute. *See Liberty Lobby,* 477 U.S. at 248 ("[T]he dispute about a material fact is genuine...if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.").

McClain Sr. has submitted a declaration, signed under penalty of perjury, that provides the following explanation for

his failure to deliver Immunosyn shares to investors or refund their money:

> Several patients from the [Texas] clinic expressed an interest in purchasing shares of Immunosyn stock from me. They forwarded payment for the shares, but shortly thereafter Immunosyn's open market stock price fell below the already-discounted price that I had agreed to accept for my shares. I attempted to factor this into the prospective sales, and subsequently offered to refund the purchase funds for shares to any purchasers who were so interested. Since 2008, I have attempted to maintain regular contact with those purchasers, either directly or through my personal attorney, Ken Nunley, and I remain willing to refund these funds.

Dkt. No. 88-2 ("McClain Sr. Declar.") at ¶ 26.

This explanation does not provide a basis upon which a reasonable trier of fact could find that McClain Sr. did not intend to deceive investors at the Texas clinic. The decline in Immunosyn's stock price after McClain Sr.'s presentation at the Texas clinic is not relevant to (1) whether he intended to deceive investors or (2) why he has not delivered on his standing promise to refund their money. The fact remains that McClain Sr. took money from investors and gave them nothing in return. His promises to deliver stock or refund their money were hollow. The only conclusion a reasonable trier of fact could draw from this record is that McClain Sr. intended to deceive investors or showed reckless disregard for the truth in promising to deliver Immunosyn shares or issue refunds.

Accordingly, the SEC is entitled to summary judgment on its first theory of securities fraud liability against McClain Sr.

B.

The SEC's second theory of liability is that McClain Sr. made materially false or misleading statements about SF-1019 during his presentation at the Texas clinic and in two videos posted on Immunosyn's website. McClain Sr.'s statements were indisputably made "in connection with the purchase or sale of securities"--namely, Immunosyn stock. Therefore, my analysis is limited to whether his statements were (1) false or misleading; (2) material; and (3) intended to deceive investors or uttered with reckless disregard for the truth.

1.

Rule 10b-5 makes it unlawful for a seller of securities "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10-b5(b).

McClain Sr. allegedly violated this prohibition during his presentation at the Texas clinic in July 2008. At the time of this presentation, the FDA had placed a full hold on Argyll's application to begin "Phase I" clinical trials of SF-1019 on human subjects. McClain Sr. was aware of the FDA hold, yet he told investors at the Texas clinic that "in the United States,

Phase 2 is getting ready to start in about 60 days under orphan designation." Pl.'s Ex. 10 at 5. He also claimed that "[t]he FDA gave us permission" to treat six terminally ill cancer patients in Minnesota pursuant to "compassionate use waivers." *Id*. McClain Sr. characterized these waivers as "an FDA approval" that Argyll had secured to treat patients in Texas as well. *Id*. at 6. As for full approval beyond the compassionate use waivers, McClain Sr. anticipated that "by the time we start our Phase 2 trials in sixty to ninety days, a year from then we should have our FDA approval." *Id*. at 25. The drug had demonstrated market potential, according to McClain Sr., because the Department of Defense had already purchased 600,000 vials of SF-1019 based on its alleged success in modulating over-reaction of the immune system in people infected with the bird flu virus. *Id*. at 16.

In a video presentation posted on Immunosyn's website, McClain Sr. repeated his claim that an FDA review board in Houston, Texas had issued "compassionate use waivers" for the use of SF-1019 on humans. Pl.'s Ex. 28 at 3. He also stated that "preparations for clinical trials in humans are underway in the United States and Europe." *Id*. Notably, McClain Sr. did not mention in his video presentation that the FDA had placed a full hold on Argyll's application to initiate Phase I clinical trials involving human subjects.

Any reasonable trier of fact would conclude that McClain Sr. made false or misleading statements about SF-1019 at the Texas clinic and in his video presentation. Argyll had not, in fact, secured any form of FDA approval for the use of SF-1019 on humans. Nor were Phase II trials about to start. To the contrary, the FDA had barred Argyll from commencing Phase I trials because of safety concerns. With Phase I trials on an indefinite hold, McClain Sr.'s assertion that Argyll would secure final approval for SF-1019 from the FDA in about one year was highly misleading. His related claim about the Department of Defense's alleged purchase of SF-1019 was outright false. *See* McClain Sr. Dep. at 120:2-6 (admitting that claim about Defense Department order of SF-1019 was a "misstatement"). McClain's Sr.'s belated argument that he merely described "negotiations" between Argyll and the Department of Defense during his presentation finds no support in the record. *See* McClain Sr. Declar. at ¶ 25.

2.

McClain Sr.'s false and misleading statements about SF-1019 violate Section 10(b) only if they were material. *See Basic v. Levinson*, 485 U.S. 224, 238 (1988) ("[I]n order to prevail on a Rule 10b-5 claim, a plaintiff must show that the statements were *misleadin*g as to a *material* fact." (emphasis in original)).

In the context of securities law, a false or misleading statement is "material" if there is "'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *Id*. (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). "[I]t is impossible to determine the extent to which nonpublic information may alter the 'total mix' without first examining the information that was already in the market." *Bauer*, 723 F.3d at 773. "Only if the established omissions are so obviously important to an investor that reasonable minds cannot differ on the question of materiality is the ultimate issue of materiality appropriately resolved as a matter of law." *TSC Indus.*, 426 U.S. at 450 (internal quotation omitted).

Immunosyn's primary asset is its exclusive worldwide license to market and sell SF-1019. The FDA's placement of a full hold on Argyll's new drug applications made this asset less valuable by shutting the door to the U.S. market unless or until the FDA lifts its hold on the proposed clinical trials. Any reasonable investor would view an event that lowers the value of a company's primary asset as "material" in the ordinary sense of the word. Defendants, however, contend that the FDA holds would have been immaterial to investors because Immunosyn disclosed

the "import" of these administrative actions in its public filings. *See* Defs.' Opp'n at 10.

Defendants have not pointed to any language in Immunosyn's public filings that conveys the full import of the FDA holds. Immunosyn's public filing for the 2007 fiscal year stated that "SF-1019 has not been approved for human use in any jurisdiction." Pl.'s Ex. 7 ("SEC Form 10-KSB") at 4. Immunosyn also described the FDA clinical trial process in general terms without disclosing any details about the full hold placed on Argyll's first IND application in March 2007.

> Argyll Biotech must submit the results of preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before any human clinical trials begin in the United States...If the FDA or its foreign equivalent raises questions about an IND within a certain period of time after its submission, that regulatory body may impose a clinical hold. In such a case, the IND sponsor and the regulatory authority must resolve any outstanding concerns before clinical trials can begin.

Id. at 9. Immunosyn's discussion of "clinical holds" as merely an abstract possibility would not have alerted a reasonable investor to the fact that Argyll's proposed clinical trials had already encountered this obstacle.

In its public filing for the 2008 fiscal year, Immunosyn stated that Argyll had submitted an IND application in November 2008 for Phase II clinical trials. *See* Pl.'s Ex. 12 ("SEC Form 10-K") at 12. Immunosyn did not describe the status of this

application, which the FDA had placed on a full hold in January 2009. Nor did Immunosyn disclose that it previously submitted an IND application for Phase I clinical trials, which the FDA had placed on a full hold in March 2007.

Against this backdrop of publicly available information, the FDA's placement of two clinical holds on Argyll's IND applications substantially alters the "total mix" of publicly available information about Immunosyn's primary asset--its exclusive license to market and sell a drug that had not even reached the first phase of clinical testing. Immunosyn publicly acknowledged that clinical trials had not commenced, but remained silent about why this was so. The underlying truth about the FDA holds remained non-public information. Any reasonable investor would want to know that clinical trials had not commenced because Argyll had presented insufficient information for the FDA to assess the risk to human subjects in the proposed trials. Thus, McClain Sr.'s false or misleading statements about the timeframe for clinical trials involving SF-1019 were material.

McClain Sr.'s false statement about the Department of Defense's alleged purchase of SF-1019 is also material. A misrepresentation about an investigational drug's market potential surely alters the total mix of information available to a prospective investor.

3.

McClain Sr. acted with the requisite *scienter* to establish a Rule 10b-5 violation only if he intended to deceive or manipulate investors or recklessly disregarded the truth when making materially false or misleading statements to investors at the Texas clinic. *See Jakubowski*, 150 F.3d at 681; *see also Lyttle*, 538 F.3d at 603.

McClain Sr. argues that he acted in good faith when discussing the FDA clinical trial process at the Texas clinic because (1) Argyll never withdrew its first IND application, which remains pending before the FDA; (2) Argyll submitted a second IND application in November 2008 to begin Phase II clinical trials; (3) Argyll did not learn that the FDA had placed its second IND application on hold "until some time after the response had been issued"; and (4) Argyll "continued its efforts to procure regulatory approval for SF-1019 at least through the first half of 2009." *See* McClain Sr. Declar. at ¶¶ 12, 14-16.

Accepting McClain Sr.'s assertions as true does not change the status quo in July 2008 when he spoke to investors at the Texas clinic. At that time, Argyll had submitted only one IND application, which had been on a full clinical hold since March 2007. Despite knowing about the FDA hold before his presentation at the Texas clinic, McClain Sr. boasted about the

compassionate waiver program as a form of "FDA approval" and made rosy projections about the timetable for Phase II clinical trials of SF-1019 and final FDA approval. In other words, McClain Sr. knowingly misled prospective investors about the FDA approval process for SF-1019. Therefore, he acted with the requisite *scienter* to establish a Rule 10b-5 violation.

The *scienter* analysis is even more straightforward with respect to McClain Sr.'s assertion that the Department of Defense had purchased over half a million vials of SF-1019. In his declaration, McClain Sr. admits that he knew before speaking at the Texas clinic that the Department of Defense had merely inquired about purchasing SF-1019. McClain Sr. Declar. at ¶ 24. Despite knowing that Immunosyn and the Department of Defense were merely engaged in negotiations, McClain Sr. characterized these negotiations as a completed sale during his presentation at the Texas clinic. McClain Sr. knew this assertion was false, which is sufficient to support a finding that he intended to defraud investors. *See In re Chavin*, 150 F.3d 726, 728 (7th Cir. 1998) ("Intent to defraud involves a material representation that you know to be false, or, what amounts to the same thing, an omission that you know will create an erroneous impression.").

4.

In sum, McClain Sr. made false or misleading statements about the FDA approval process for SF-1019 and the alleged sale of this new drug product to the Department of Defense. Any reasonable investor would have viewed these statements as altering the total mix of information about Immunosyn's primary asset. McClain Sr. also acted with the requisite *scienter* for securities fraud because he knowingly misled investors about the FDA approval process for SF-1019 and made a knowingly false statement about Immunosyn's alleged sale of SF-1019 to a large federal agency.

It follows that the SEC is entitled to summary judgment against McClain Sr. on its second theory of liability.

C.

The SEC's final theory of liability is that the McClains engaged in insider trading by selling their Immunosyn stock based on material, non-public information.

The SEC's insider trading claims are based on the "traditional" or "classical" theory that "§ 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." *U.S. v. O'Hagan*, 521 U.S. 642, 651-52 (1997).[5]

[5] The SEC is not relying on Rule 10b5-1, 17 C.F.R. § 240.10b-5(1), "which formally equates possession (or 'awareness') of material nonpublic information with use (save for limited

"Trading on such information qualifies as a 'deceptive device' under § 10(b)...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.'" *Id*. at 652 (quoting *Chiarella v. U.S.*, 445 U.S. 222, 228 (1980)).

I have already determined that the FDA holds placed on Argyll's new drug applications were material, non-public information. *See supra* at § II.B.2. The only contested issue regarding the SEC's insider trading claims is whether Defendants acted with the requisite *scienter* when selling their shares of Immunosyn stock.

1.

The *scienter* requirement for insider trading claims requires the SEC to establish that "inside information...played a causal role in [Defendants'] decision to sell the shares in the amount, and when, [they] did." *Lipson*, 278 F.3d 656, 660 (7th Cir. 2002). This causal connection, when established, shows that an insider "knew or recklessly disregarded the fact that she was unfairly avoiding losses based on her access to nonpublic information." *Bauer*, 723 F.3d at 776.

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exceptions)[.]" *Bauer*, 723 F.3d at 776 n.7 (declining to "comment on the validity of that rule").

A jury may infer that a defendant who possessed material, non-public information about a company at the time he or she sold some of that company's shares traded on the basis of the inside information. *See Lipson*, 278 F.3d at 661. A defendant may rebut this causal inference by showing he "would have sold the shares in the same amounts and on the same dates that he did sell them even if he had not possessed any inside information[.]" *Id*. at 660. "If the defendant can satisfy [this] burden of production, the issue [of causation] must go to the jury[.]" *Bauer*, 723 F.3d at 777.

The SEC has established that the McClains possessed material, non-public information about Immunosyn at the time they sold some of their shares in the company. A jury could therefore infer that they traded on the basis of inside information. Defendants "can avoid judgment as a matter of law on insider trading charges by presenting *some* credible rebuttal evidence of a legitimate purpose for the[ir] trade[s]." *Bauer*, 723 F.3d at 777 (emphasis in original).

The McClains have not even attempted to meet this burden of production. Instead, Defendants argue that the SEC has not presented "evidence of when they came into possession of this [inside] information nor of how soon thereafter they sold Immunosyn stock." Defs.' Opp'n at 11. The jury instruction upheld in *Lipson* did not require temporal proximity between (1)

the date a defendant came into possession of inside information and (2) the date he or she allegedly traded on the basis that information. *See* 278 F.3d at 660 (quoting jury instruction). In other words, the causal inference upon which the SEC relies does not require a showing that the McClains traded on inside information almost as soon as it came into their possession.

To the extent temporal proximity is relevant to the causation analysis, the SEC has presented unrebutted evidence that by March 15, 2007, Defendants knew that the FDA had placed a full hold on Argyll's first application to start clinical trials. *See* Pl.'s Ex. 15. McClain Jr. sold hundreds of thousands of Immunosyn shares between Apr. 26, 2007 and October 24, 2007. *See* Pl.'s Ex. 35-37 (SEC Form 4s submitted by McClain Jr.). In July 2008, while Immunosyn's first new drug application was still on hold, McClain Sr. made knowingly misleading statements about the FDA approval process to an audience of prospective investors at the Texas clinic. The total value of McClain Sr.'s sales of Immunosyn shares to investors in July and August 2008 was approximately $338,000. *See* Dkt. No. 77 at ¶ 8.

The McClains have failed to explain how this timeline meets their burden of showing a "legitimate purpose" for their trades. *Bauer*, 723 F.3d at 777. At best, the timeline shows that they did not trade on inside information as soon as it came into

their possession. What remains missing is a legitimate, non-fraudulent explanation of why they sold their Immuosyn shares when they did. *Cf. Bauer*, 723 F.3d at 777 (holding that defendant rebutted inference of causation by presenting evidence of two legitimate purposes for her trades: (1) the poor performance of the security she sold and (2) her need for cash in advance of an anticipated job change and relocation); *Lipson*, 278 F.3d at 661 (holding that defendant who claimed that his stock sales were motivated solely by his desire to comply with an estate plan had presented sufficient rebuttal evidence to send the issue of causation to a jury).

In sum, the McClains have failed to rebut the inference that inside information about the FDA holds played a causal role in their sales of Immunosyn stock. The SEC is therefore entitled to summary judgment on its insider trading claims.

III.

The SEC's motion for summary judgment is GRANTED for the reasons stated above.

ENTER ORDER:

Elaine E. Bucklo
United States District Judge

Dated: October 10, 2014

General Information

Court	United States District Court for the Northern District of Illinois; United States District Court for the Northern District of Illinois
Federal Nature of Suit	Securities/Commodities/Exchanges[850]
Docket Number	1:11-cv-05223