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Insider Trading and Healthcare: A Potentially Life-Threatening Condition

By Howard A. Fischer, Linda A. Malek, Pralika Jain, and Kiyong Song, Moses & Singer, LLP*

Recent enforcement actions by the U.S. Securities and Exchange Commission ("SEC") highlight the special risks faced by the healthcare and life sciences industry, especially by research companies developing new treatments and products. While advances in research create the potential for new life saving treatments and methods for ameliorating the conditions of disease sufferers, market reaction to news about such advances presents opportunities for financial gain that can be improperly exploited through insider trading. Enforcement actions present both significant legal risks for the bad actors involved as well as reputational and legal risks for the companies at which they occur.

This article explores two recent insider trading enforcement actions brought by the SEC involving research projects, and provides suggestions of steps that healthcare and life sciences companies can take to maximize compliance with applicable securities laws.

The SEC Targets Health Care Companies in Insider Trading Probes

In the last month or so, the SEC has brought several cases involving insiders trading in advance of the release of results of clinical trials. These include cases against (1) Dr. Mohammed A. Bari for insider trading involving the shares of Karuna Therapeutics, Inc. ("Karuna")—a drug company where he was leading a clinical trial on schizophrenia treatment—after learning that the company was on the brink of announcing positive clinical trial results; and (2) a New York-based couple for insider trading of the stock of a pharmaceutical company that was conducting clinical drug trials where one of the defendants worked as a clinical trial project manager.

In *Securities and Exchange Commission v. Mohammed A. Bari* (S.D. Cal. May 26, 2021), the SEC brought charges against Dr. Mohammed Bari, a medical investigator hired by Karuna for the clinical trial of KarXT, a drug being developed by Karuna to treat schizophrenia. Pursuant to his arrangement with Karuna, Bari was subject to a confidentiality agreement that strictly prohibited him from using or disclosing information about the KarXT trial, except for the limited purposes of conducting the trial.

* **Howard Fischer,** a former senior trial counsel at the SEC, is currently a partner at Moses & Singer, where he counsels clients in civil litigation and regulatory enforcement matters. **Linda Malek** is a partner at Moses & Singer LLP and chair of the firm's Healthcare and Privacy and Cybersecurity departments. She concentrates on regulatory, technological and business matters in the healthcare industry. **Pralika Jain** is an associate in Moses & Singer's Healthcare practice, where she advises healthcare and technology companies on matters related to various regulatory, privacy and data laws. **Kiyong Song** is an associate in Moses & Singer's Healthcare practice, where he helps healthcare clients resolve data privacy and protection, and data governance matters.

Bari learned, as part of his employment, that clinical results were positive. He was provided this positive information so that he would be able to act as a liaison with investors and the media about the results. Karuna emphasized then that the information he was receiving was confidential.

Bari then started purchasing Karuna shares before the clinical results could be announced to the general market. When these positive results were announced, Karuna's share price more than quadrupled. Shortly thereafter, Bari sold his shares for a gain of over 300%.

On March 26 of this past year, the SEC filed an action against Bari for insider trading based on material, non-public information. This was predicated on both his confidentiality agreement, which is a key element of many SEC enforcement cases as the foundation upon which a duty of confidentiality is premised, and the terms by which he was provided information about the clinical trial results. He agreed to a penalty of approximately $238,000.

In *Securities and Exchange Commission v. Chad Calice et al.*, (S.D.N.Y. June 7, 2021), the SEC brought charges against Holly Hand, the senior project manager overseeing a clinical drug trial for a company then known as Neuralstem, Inc. and her partner, Chad Calice. Hand had executed a confidentiality agreement with Neuralstem along with annual acknowledgments agreeing to the company's insider trading policy.

The SEC alleged that upon learning of negative results from the trial, which constituted material, nonpublic information belonging to the company (the legal standard for insider trading cases), she did not trade, but tipped her partner Calice, who then sold all of his Neuralstem shares ahead of the public announcement of the negative news. Calice then tipped off his uncle, who sold his entire Neuralstem position that day.

By selling their shares prior to the announcement of the negative news and the resulting drop in share price of around 50%, Calice avoided losses of $103,875, and his uncle avoided losses of $14,434. The settled action required Calice to pay a $222,184 penalty, and Hand to pay a $103,875 penalty.

Key Takeaways from the Two Cases

These recent actions are but the latest iterations of an increasingly common fact pattern, where healthcare insiders receive material non-public information, usually regarding the results of clinical trials, and trade on that information or provide that information to others ("tippees") who then trade on that information. There are several takeaways to be garnered from the two most recent examples of these insider trading cases from the last month or so.

First, regulators are extremely sensitive about and diligent at ferreting out insider trading. At almost every instance where share prices move significantly (either up or down) in response to the release of market-moving news, regulatory authorities will review trading records. Anything out of the ordinary will be flagged, investigated, and if need be, prosecuted—especially if the trader has not previously bought or sold the security at issue. These are among the easiest cases to prosecute. Moreover, in addition to the persons who provide that information, third parties to whom this information is provided are also liable for insider trading if they trade on this material, non-public information. Regulators examine anomalous trading data, and investigate whether any of it could be connected to a company insider. These efforts can only be expected to accelerate, as the SEC has recently announced that it will be taking a renewed look at trading by executives.

Second, as seen in the Hand case, tippers who themselves do not trade can still be found liable and compelled to pay a significant penalty. And tippees—the recipients of material, non-public information – can also be held liable if they trade on material non-nonpublic information.

Third, and most importantly for healthcare and life sciences companies that are seeking to develop and bring new treatments and technologies to market, specific policies to address the risk of insider trading are essential. While all industries are prone to insider trading, healthcare companies that conduct clinical trials are particularly prone to the risk of insider trading, as the public disclosure of the results of those trials is frequently a market-moving event, providing those with advance knowledge of those clinical results before the public has such knowledge an opportunity to engage in illegal insider trading. While there is no way to completely eliminate the risk of insider trading by persons who have access to material non-public information, that risk can be minimized, along with the potential reputational harm that insider trading can cause companies. To do that, certain measures can be taken:

- Companies should develop, implement, and clearly communicate to all employees and contractors policies that explicitly prohibit any communication of material, non-public information. As part of such an effort, specific written policies should be executed by all employees and contractors.
- There should be regular affirmations of the relevant legal standards, both through regular written confirmations, as well as in-person presentations that stress these rules, and the potential adverse consequences of any violations. Personal presentations can, if done correctly, have a greater impact on ensuring compliance than merely the execution of written agreements.
- This communication should include a presentation about the risks of insider trading, which include not only financial penalties but reputational damage as well, likely resulting in not being able to work in the industry again. This could include a description of how trading is tracked, and how various authorities regularly review trading patterns around market-moving announcements. Often, risk-takers are more likely deterred by the certainty of getting caught than by the severity of punishment. Most non-professional traders do not realize how easy it is to track their trades, and sometimes believe that smaller traders can get away with improper trades. Thus, an understanding of how much risk is being assumed might provide a greater level of deterrence than simply executing an agreement.

Conclusion

Developing new treatments and technologies presents opportunity and risk; those risks should not include the risk of enforcement actions for insider trading. Understanding the applicable law, and implementing policies to encourage compliance, can help in minimizing improper activities, and allow healthcare companies to do what they do best: pioneer new treatments and technologies to improve health outcomes.