The SEC's Insider Trading Case Against a Clinical Trial Physician: Lessons For Physicians, Investors, and Public Companies

On November 2, 2010, the Securities and Exchange Commission ("SEC") brought an action for insider trading against a physician involved in an investigational drug clinical trial based on the alleged use of confidential information about the clinical trial disclosed by the physician to a hedge fund portfolio manager. The U. S. Department of Justice ("DOJ") also initiated parallel criminal proceedings for securities fraud based on the same allegations. The charges by the agencies reflect a more aggressive response by the SEC and other federal law enforcement agencies to alleged acts of insider trading as well as a new focus on the growing number of medical professionals that act as consultants to Wall Street investors. As a result, if the SEC and DOJ are successful, the case could have significant implications for: (1) hedge fund managers and other investors working with consultants from the medical community; (2) pharmaceutical and medical device manufacturers testing new products in clinical trials; and (3) physicians and other third parties involved in the conduct of clinical trials. Even if the SEC and DOJ are not ultimately successful, the existence of the case warrants a reconsideration of relationships among investors, manufacturers and third parties involved in clinical trials.

Summary of the Charge and Supporting Allegations

A French physician, Yves M. Benhamou, M.D., was charged with unlawfully providing confidential information regarding disappointing clinical trial results to a hedge-fund portfolio manager. The charge is based on allegations related to the physician's involvement as a consultant and lead investigator for clinical trials conducted by Human Genome Science, Inc. ("HGSI"). The clinical trials involved a new drug then known as Albuferon that HGSI was developing for the treatment of chronic hepatitis C. According to the allegations, Dr. Benhamou was a member of a five person steering committee overseeing the Albuferon clinical trial. The physician was also the "country lead investigator" for France and other parts of Europe. While acting in these capacities, Dr. Benhamou was also retained as a consultant by a portfolio manager, who was managing portfolios of health care hedge funds that, during the relevant period, were collectively long approximately six million shares of HGSI. Dr. Benhamou allegedly alerted the portfolio manager about a setback in the clinical trial. This "tip" occurred several days before HGSI's public announcement of the issues with the trial. In response to the tip, the hedge funds allegedly sold their HGSI positions, avoiding nearly $30 million in losses.

The Case Against the Physician

To prove its insider trading case, the government will need to establish that the physician provided the portfolio manager with material, nonpublic information in breach of a duty of trust or confidence. There are potential issues with the allegations supporting the case. As a preliminary matter, there are questions regarding the confidential nature of the information. First, the SEC suggests that the information was discussed in meetings involving members of the committee charged with monitoring, the clinical trial, steering committee members, HGSI representatives and unidentified others. If attendance included

individuals not subject to confidentiality agreements, the information may no longer have been confidential as a result of those meetings.

Second, the government does not clearly define the duty of trust or confidence that Dr. Benhamou owed HGSI's shareholders. The SEC complaint offers alternative theories on the origins of Dr. Benhamou's alleged duty, stating that the duty is both *implied*, arising [b]y virtue of his role in the clinical trial, and *contractual*, "in accordance with the terms of his contract with HGSI."[1] With respect to the physician's contractual obligations, an affidavit filed in support of the criminal complaint states that the physician signed an agreement in July 2004, years before the events in question, in which he agreed to preserve the confidentiality of any confidential information he received from HGSI. Curiously, two days after HGSI announced the problems encountered in the clinical trial, and after HGSI's stock price declined by approximately 40%, HGSI asked the physician to sign another agreement in which the physician agreed to act as a consultant to HGSI and to preserve the confidentiality of any information received from HGSI. However, according to the affidavit, in a 2009 interview with the government, the physician stated that he always considered himself bound to preserve the confidentiality of all information received from HGSI. If this case is litigated, there will likely be a dispute over whether the physician was in fact contractually obligated to preserve the confidentiality of information he received relating to the clinical trial. If the contractual obligations are deemed insufficient to support insider trading charges, the physician's status on the steering committee will need to be evaluated to determine whether this role imposed a confidentiality obligation on the physician.

While there may be potential issues with the specific allegations in this case, the case nonetheless highlights an overlooked legal risk for physicians and other third parties involved in clinical trials who have access to confidential information. Most notably, physicians and other medical professionals similarly situated to Dr. Benhamou who serve multiple professional roles should be aware of what information may be used when serving as Wall Street consultants and what information should be kept confidential to avoid insider trading liability. To minimize insider trading risk, other third parties involved in clinical trials may want to review their policies and procedures for communicating to personnel, and enforcing compliance with, confidentiality provisions in agreements with manufacturers conducting clinical trials. In particular, if a clinical site contracts with a manufacturer on behalf of an investigator, the site may want specific assurances from the investigator that confidentiality obligations will be satisfied. In the wake of the Dr. Benhamou case, third parties should also be ready to respond to requests from manufacturers for enhanced confidentiality protections and know what they can reasonably accept.

Possible Claims Against the Hedge Funds and Their Advisors

No charges have been filed to date against the hedge funds that allegedly traded based on the physician's tip, the investment advisers to those funds, or the portfolio manager that received the alleged tip. However, the SEC complaint states that the portfolio manager knew or should have known that the doctor was providing him with information in breach of a confidentiality obligation. According to the SEC complaint, the portfolio manager knew or should have known of the breach even though the doctor agreed not to provide the portfolio manager with confidential information. The manager's awareness of the doctor's breach is allegedly based upon his awareness that the doctor "served on the trial's Steering Committee and owed a duty of confidentiality to HGSI."[2]

[1] SEC Compl. ¶ 8.
[2] SEC Compl. ¶ 3.

A 2005 study found that nearly 1 out of 10 U.S. physicians was engaged in some consultancy with the investment industry.[3] Members of the investment community that hire such consultants need to be aware that their retained industry experts could be basing their opinions on confidential information and that simply having a contractual clause with the consultant requiring them not to pass along confidential information may not be enough to escape insider trading liability. This risk is particularly acute when the consultant is in a close relationship to the issuer, including current or former employees of the issuer. Hedge fund advisers and other professional investors may want to consider adopting or reviewing policies regarding the use of industry consultants. Such policies may require, among other things, that portfolio managers and other investment personnel remind consultants of their obligation not to pass along confidential information at the outset of each contact, and that compliance staff monitor conversations between investment personnel and consultants.

Possible Regulation FD Issues

No allegations have been filed against HGSI, nor does either of the government's complaints allege any wrongdoing by HGSI. However, it is of interest that HGSI asked the physician to sign a new confidentiality agreement two days after the announcement of the problems encountered in the clinical trial. This may have occurred because of concerns about Regulation FD, which provides that "[w]henever an issuer, or any person acting on its behalf, discloses any material nonpublic information regarding that issuer or its securities to…[an investor]…, the issuer shall make public disclosure of that information…[s]imultaneously, in the case of an intentional disclosure...and [p]romptly, in the case of a non-intentional disclosure."[4]

As a more general matter, for manufacturers conducting clinical trials, the case highlights the potential need to enhance protection of the confidential information available to the broad range of third parties who assist in the conduct of clinical trials. Manufacturers should catalogue the third parties with likely access to clinical trial information during the course of the clinical trial (e.g., scientific advisors, investigators, clinical sites, independent review board members, data monitoring committee members, clinical research organizations, biostatisticians) and ensure that agreements with each of those third parties have confidentiality provisions or that third parties are otherwise put on notice about the need to preserve confidentiality. Manufacturers may also want to review their standard confidentiality provisions in clinical trial agreements and consider whether those provisions could be strengthened. For example, manufacturers may want to include: (1) an acknowledgement that the other parties (or their directors, officers, employees and agents) involved in the conduct of the clinical trial may be "insiders" who have gained material, nonpublic information about the clinical trial as a result of that involvement; and (2) an agreement by the other parties not to engage in transactions, or advise others to engage in transactions, involving manufacturer stock until the clinical trial results are public. As another example, manufacturers may want to include specific provisions ensuring that any employees, contractors or other agents used by the third parties are subject to, and aware of, the particular confidentiality obligations contained in the agreement. In addition, manufacturers may want to consider specifically requiring third parties involved in clinical trials to disclose any relationships with members of the financial industry to the manufacturer as part of the contracting process and ensure that confidentiality obligations are discussed in investigator meetings.

[3] Topol & Blumental, "Physicians and the Investment Industry," Journal of the American Medical Association, June 1, 2005.
[4] 17 C.F.R. § 243.100(a)(1-2) (2010).

If you would like to discuss these or any other issues pertaining to securities enforcement or health care, please contact one of the attorneys listed below or any member of the Ropes & Gray Government Enforcement, Securities Litigation or Health Care practices.

Richard D. Marshall **Eva Ciko Carman** **Eve M. Brunts**