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Insider-Trading Case Poses Concern for Researchers

By Thomas W. Durso

The United States Securities and Exchange Commission (SEC) has sent waves of concern through the scientific community by bringing what it calls its first insider-trading case against drug researchers. It is illegal to trade stocks while in possession of information not available to the general public or to inform other traders of such information. Few people believe that such activities are widespread among researchers, but some scientists are responding with fears that the result could be a professional muzzling that prevents them from sharing research results with colleagues.

However, other observers argue the case simply illustrates that researchers are no different from anyone when it comes to the rules of investment. In addition, some say it is yet another aspect of the increasingly discussed issue of industry-funded research (K.Y. Kreeger, *The Scientist*, March 31, 1997, page 1).

In April, SEC officials filed insider-trading suits against Milton Mutchnick, head of the gastroenterology division at Harper Hospital and a faculty member at Wayne State University School of Medicine in Detroit, and his former assistant Rangarao Panguluri, who is now a physician in private practice in Anaheim, Calif. The suits accuse the two of tipping off friends, relatives, and business associates of a drug's poor performance in clinical trials in April 1994. Mutchnick was the chief clinical investigator on a Phase III clinical trial of Thymosin, an anti-hepatitis B drug developed by Alpha 1 Biomedicals Inc. of Bethesda, Md., and licensed to SciClone Pharmaceuticals Inc. of San Mateo, Calif. Mutchnick's wife, Renee Mutchnick, with whom he discussed the results, also was accused in the SEC complaints, along with the 10 people whom SEC claims were told of the results.

The SEC complaint states: "During the early 1990s, prior to the unblinding of the results of the Phase III trial, Mutchnick told several friends and family members that he believed that Thymosin would prove to be efficacious. Thereafter, some or all of the defendants purchased Alpha 1 or SciClone securities based, in whole or in part, upon Mutchnick's optimism that Thymosin would prove to be efficacious."

While Mutchnick and Panguluri owned no shares of either Alpha 1's or SciClone's stock, they were "temporary insiders," according to SEC, and they had "duties not to trade while in possession of the material, nonpublic information [they] obtained concerning the Phase III trial, and to safeguard the confidentiality of that information and not to

misuse it." SEC says that the Mutchnicks and Panguluri "disclosed . . . initial analysis of the Phase III trial results to certain friends and family members whom they knew owned Alpha 1 or SciClone securities. All of these individuals sold all of their Alpha 1 or SciClone securities on April 26, 1994."

A few days later, Alpha 1 announced the results of the clinical trial and prices of the two companies' shares tumbled; Alpha 1 shares fell from $6 to $2, and SciClone shares fell from $13 to $6. But the 10 investors that SEC says were tipped by the Mutchnicks and Panguluri were able to avoid losses of $300,000 because they sold before the bad news was publicized.

The Mutchnicks, along with six of the people with whom they spoke, reached an out-of-court settlement with SEC in which they neither admitted to nor denied the allegations in the complaints. As part of the settlement, the Mutchnicks were required to pay a civil penalty of $163,494.75, an amount equal to the losses avoided by those people SEC claims they tipped. Panguluri and four people with whom he spoke have not settled with SEC; their case is pending.

In a phone interview, Mutchnick says: "I'm just a poor slob who walked into this thing without knowing, then some guys from the government showed up. I told them everything they needed to know. Everything they needed to know is in that complaint."

Mutchnick contends that the complaints filed by SEC make it appear that he was telling secrets only to investors, when instead he was simply sharing his thoughts on the data he had seen so far with colleagues and friends. "When a number of people talked to me about the initial impressions or asked what happened, I said, 'I don't know, I don't have the results, but my initial impressions are I don't see anything,' or something to that effect. They [SEC] say I told five or six people directly. I told more than that. I told everyone who asked me."

In addition, he claims that SEC told him that he was permitted to say only "no comment" in similar situations in the future. "I said, what are you, crazy? I can't walk around for four or five months saying 'no comment.' By saying 'no comment' you're sending a message: that [the results are] negative."

Despite the initial doubts, Mutchnick now says his first interpretations of the results were wrong, and Thymosin could be effective in treating hepatitis. SciClone also conducted its own analysis of Mutchnick's test data, which proved Thymosin's efficacy. The company currently is selling the drug in China and hopes to market it in at least 25 other countries (E. Marshall, *Science*, **276**:671-2, 1996).

While Thymosin may prove successful, Mutchnick worries that his case will result in the silencing of clinical investigators until their results are made public, and he calls this "a very fuzzy area." He asks: "What is considered to be public disclosure? When they publish it? Do they have to come out with a press release? Who can know?"

He is not alone in his concerns. David Blumenthal, chief of the health policy research and development unit at Massachusetts General Hospital and author of a study examining industry support of research (D. Blumenthal et al., *New England Journal of Medicine*, **335**:1734-9, 1996), fears that scientists could end up being held criminally liable because others act upon discussions of

their work.

"It would be very damaging if scientists had to self-censor themselves in conversations about their work because someone else might benefit illicitly from knowing about their work," Blumenthal says. "That would have a tremendous chilling effect on scientific communication."

However, Thomas C. Newkirk, an associate director in SEC's enforcement division, tells The Scientist that the government is not out to get researchers. "We're not focusing on drug trials in particular," he states. "We're focusing on any unusual activity in the markets. . . . Insider-trading rules are the same whether you're on Wall Street or on Main Street or in a science lab. You can't trade while in possession of material that's not public information, and you can't tip others to trade if you're an insider."

Other observers believe that SEC was correct to cite Mutchnick and Panguluri for inappropriate disclosure of the results to others. "This is just absolutely unethical and wrong," declares John D. Siegfried, deputy vice president for science and regulatory affairs for the Pharmaceutical Research and Manufacturers of America (PhRMA), based in Washington, D.C. "If SEC is going after [them], that's totally appropriate. Whether that's an investigator or a V.P. of a company who sees the results and uses them to trade stock, that's just not the way business should be done."

According to Allison Rosenberg, associate executive director of the Government-University-Industry Roundtable, a science policy forum sponsored by the national academies of sciences and engineering and the Institute of Medicine, the situation reflects "an evolution in our basic paradigm governing research, due to an increasing demand for synergy between publicly funded research and national goals of public health and economic vitality." This raises a challenge, she states, between managing "the overlap of interests and expertise in ways that protect public health and ensure the integrity and efficiency of research on one hand, while promoting synergy across sectors-public and private-on the other hand. In short, we need to protect the public while ensuring innovation."

Rosenberg says that "the case at hand presents a really simple problem. This is no different than the question of whether professional publications should have disclosure policies. The answer is simply yes."

Paula Stephan, a professor of economics and associate dean of the School of Policy Studies at Georgia State University, explains that men and women who own a certain amount of stock in a company must register with SEC as "insiders" to the company. In a forthcoming article (P. Stephan, S.S. Everhart, *Small Business Economics*, in press), she examines university scientists who are so registered as "insiders" to more than 50 biotechnology companies that went public in the early 1990s.

"Some made very large sums of money. Obviously, there are many others who don't own quite enough to have to be registered," Stephan reports. "There's a major concern that informal [scientific] communication is breaking down because there are strong incentives to not disclose [information] when this kind of money's on the table" (P. Stephan, *The Scientist*, May 26, 1997, page 8).

She adds that "there's some concern that scientists themselves get so interested in

following the value of their portfolio that they kind of lose touch with their real research." And while Stephan concedes she is not a financial expert, the Mutchnicks' and Panguluri's behavior "is clearly in violation of what the SEC says you can do, as far as I understand."

"It is a problem that needs to be addressed in some way," Siegfried states. "I don't think the solution is to make the whole industry start filing investigator financial statements, or having clinical investigators file a copy of their income-tax returns along with their informed-consent forms."

Rosenberg believes that an easy solution would be for contracts between private companies and clinical investigators to contain a clause making clear "that the rules that govern insider trading on Wall Street also govern the stocks of companies involved in biomedical research. The rules governing the managers, the directors, and all those employed by the company in question are-presumably-made clear in law, and they should be extended to cover explicitly interested investigators both inside and outside the company's corridors."

Still, most observers believe that the Thymosin affair is a relatively isolated case. PhRMA's Siegfried, for example, contends that "this is not a frequent occurrence." Rosenberg adds: "If the SEC allegations are true, I would not like to think that that kind of case would be promoted by the press broadly as representative of something under way at large. I doubt it is." Even SEC official Newkirk comments that while it is difficult to determine the amount of fraud that goes undetected, he is "not comfortable" attributing large numbers of insider trading to "unpublished clinical research results."

Others are not so sure. Leonard Minsky, executive director of the Bethesda, Md.-based National Coalition for Universities in the Public Interest, contends that while no studies have been done, anecdotal evidence indicates that "this is a widespread problem."

Regardless of how extensive the problem is, it plays into issues of industry-funded research, undue influence, and conflicts of interest. "The fact is that these relationships [between researchers and industry] exist, and that there is money as a potential outcome of the relationship," Minsky states. "The money comes in different forms from the way it used to come. It's not only an increase in salary or prestige, or a promotion. We have the potential commercial sale of these products, and if you're working on it, you know in advance if it's going to go or not going to go."

While Mutchnick's case may be the first of its kind, it "doesn't signify anything new with respect to the laws," Newkirk asserts. The message? "Don't do it," he replies. "Part of our enforcement program is to deter fraud, and I think this probably will have an effect. The defendants in our case have firmly but fairly [been] dealt with. Others who care about their reputation and their pocketbooks ought to be cautioned by it."

According to Newkirk, SEC has been contacted by many in the scientific community regarding the case. He sees this as a sign that researchers are getting the message. "These are intelligent people we're dealing with. I expect that [the case] will" have a deterrent effect, he says.

Siegfried wants this to happen, but he is not optimistic, given what he sees as a criminal-justice system that has failed to deter large numbers of other crimes. "What you hope is that this case gets enough notoriety so that if some other poor guy wants to do the same thing, or is too ignorant and doesn't know that it's insider trading, that he'll get the message."

Massachusetts General Hospital's Blumenthal speculates that "a clash of culture and norms" may be at stake between "an agency not used to dealing with universities and scientific norms [and] a set of institutions that are used to open communication." He concludes: "There's a positive societal value to open communication that must be weighted against whatever's on the mind of the SEC in its actions."