Whose Game? Whose Rules?

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Research scientists, corporate executives, stock analysts, and regulatory agencies pursue different agendas, and when they clash, the money gets funny.

Golfers, bowlers, and baseball players play different games, with different rules, in different venues. Golfers go for the low scores, bowlers the high scores. Bowlers get as many strikes as they can, baseball batters try not to get any strikes at all. If you tried to mix these games, you would wind up with a real mess.

Played separately, the rules of the various games in the pharmaceutical industry are also clear. However, research scientists, pharmaceutical company executives, and stock analysts have found their playing fields overlapping more and more, with multiple government agencies acting as referees. The results can be as messy as a bowler throwing curve balls on a golf course.

Scientists collect and share data with colleagues to explain a phenomenon or solve a problem, but are wary of publicizing works in progress for fear of having their studies hyped or misinterpreted. Business leaders protect their intellectual capital from their competitors while announcing good news to customers and shareholders. Stock analysts get their clients the information they need to buy low and sell high right now, regardless of how the science turns out in the long run. Prudent public communications in one game can be construed as insider trading in another game. How you classify presentations at scientific meetings and private conversations with colleagues depends to a large extent on which rule book you are using.

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Inside Tips

In April 1997, officials from the U.S. Securities and Exchange Commission (SEC) filed insider-trading suits against Milton Mutchnick, a faculty member at Wayne State University School of Medicine (Detroit) and head of gastroenterology at the University's Harper Hospital (positions he still holds), and his former assistant, Rangarao Panguluri, who now is a physician in private practice in Anaheim, CA (*1, 2*). Mutchnick and Panguluri conducted a well-publicized double-blind Phase III clinical trial of Thymosin alpha 1 (Thymosin), an antihepatitis drug being developed by Alpha 1 Biomedicals (now RegeneRx Biopharmaceuticals, Bethesda, MD) and licensed to SciClone Pharmaceuticals (San Mateo, CA).

According to the lawsuit, Mutchnick and Panguluri unblinded the results of their trial on April 25, 1994, and discovered that patients fared no better using Thymosin than they did with a placebo. That evening, Mutchnick shared his disappointment with friends and family members; Panguluri told a separate group of friends and business associates. Ten of these individuals immediately sold all of their stock in Alpha 1 or SciClone. Alpha 1 announced the results of the clinical trial before the stock market opened on April 28, and that day, the stock prices of Alpha 1 and SciClone declined from $6 to $2 and from $13 to $6, respectively. The 10 people who sold out early avoided total losses of about $300,000.

When the SEC filed suit, Mutchnik and the people he had informed consented to a final judgment against them and agreed to pay $163,495 (the amount of the losses they avoided) plus interest and penalties. The following year, Panguluri and the people to whom he spoke agreed to pay back the $137,256 in losses they avoided, plus interest and penalties. None of the parties involved denied or admitted to being guilty of the SEC's allegations (*3*).

Dueling Regulators

Recently, government regulatory policies instituted to protect investors from insider deals have run head-on into other policies for protecting companies from the premature release of information on drug studies still in progress. The U.S. Food and Drug Administration (FDA) posts approval and tentative approval letters on a publicly accessible website (*www.fda.gov/cder/approval/index.htm*), but does not make public its interim discussions with applicants or its "refusal to file" letters, issued to indicate incomplete or insufficient information in the drug approval application (*4*). Thus, the FDA leaves it to the drug companies to make or withhold announcements on the progress or cancellation of a new drug product.

On the other hand, Regulation Fair Disclosure (Reg FD), adopted by the SEC on August 10, 2001, is aimed at curbing selective disclosure of material information (earnings, mergers and acquisitions, or other information that could affect finances) by stock issuers to analysts, institutional investors, or other privileged groups (*5*). Reg FD tries to level the playing field by mandating that such disclo-

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sures be announced publicly, using Form 8-K filings, webcasts, press releases, or other means. The FDA, as a government agency, is not an "issuer of stock", and so is not bound by the disclosure requirements of the SEC. The resulting conflict in regulations can be manipulated by people wishing to exploit the information flow to their own advantage (*6*).

Abstract, But Material

On April 11, 2002, the stock prices of several biotech firms gyrated wildly, with some firms posting double-digit gains and others posting equally large losses. Researchers from each of these companies had submitted abstracts several months in advance of the May 2002 annual meeting of the American Society of Clinical Oncology (ASCO). ASCO's meeting abstracts were on a protected website, requiring members to log in and click on a confidentiality agreement to view them. The agreement prohibited companies from issuing public comments and reporters from publishing articles based on the abstracts in advance of the meeting. The 18,000 individual clinical oncologists and cancer researchers who make up ASCO's membership were not restricted from speaking as individuals in private settings.

The ASCO webmaster had mistakenly posted some of the abstracts (fewer than 10%) on April 11, four days earlier than scheduled. Someone (or several someones) got an early look at the website and the abstracts made their way into the hands of several stock analysts. Always eager to beat the competition, the stock analysts pounced on these juicy tidbits, including preliminary results of clinical trials for several new cancer treatments.

Adam Feuerstein, a stock analyst for *The Street* (*www.thestreet.com*) who had planned to report on the meeting, was suspected of leaking information in the abstracts before they were cleared for public release, and ASCO withdrew his press credentials (*7*). Feuerstein accused ASCO of selectively distributing financially relevant information, a violation of the spirit, if not the letter of Reg FD. (Reg FD does not apply to nonprofit organizations such as ASCO.)

The scientific community worried about a potential "chilling effect" that these stock price gyrations might have on the future sharing of scientific information in what were intended as purely professional forums. Charles Balch, ASCO's CEO, explained that the ASCO board was concerned that cancer patients might make uninformed decisions regarding their medication based on information they gleaned from the abstracts (*7*). In an interview with Catherine Arnst in *Business Week*, Balch reiterated that his organization's primary concerns were for patient safety and informing the medical community (*8*). Arnst commented: "A noble goal, though cold comfort to those investors without an oncologist for a friend."

The question remains: When researchers discuss results with their colleagues, is it good science or unfair advance notice?

Culture Clash

Perhaps the most famous recent example of this culture clash is the FDA's December 2001 rejection of ImClone Systems's (New York, NY) application for approval of its anticancer drug Erbitux (*9*). ImClone founder and CEO Sam Waksal pleaded guilty on October 15 to criminal securites fraud, among other charges, for selling his shares of ImClone stock shortly before the FDA's rejection was made public. Although lifestyle maven and ImClone investor Martha Stewart received much unfavorable publicity for selling her ImClone stocks at the same time, there are some doubts that a strong insider trading case could be made against her. ImClone stock, which closed at $62.80 on December 24 (914,000 shares traded), was selling for $46.46 on December 31 (18.5 million shares). ImClone continued to develop Erbitux for use with head and neck cancers, and they submitted an abstract for a presentation at the 2002 ASCO meeting. On Friday, April 5, the closing share price was $22.20 (1.2 million shares), but on April 11, the day of the ASCO website leak, the closing price was $23.81 (3.4 million shares). The price had settled to $20.54 (2.2 million shares) by April 15, and it slumped to $7.75 by the end of the second quarter of 2002 (1.6 million shares traded on July 1).

The questions remain: Is selective disclosure an invitation to insider trading or good stewardship of complex information that can easily be misapplied? When researchers discuss results with their colleagues, is it good science or unfair advance notice? When stock analysts issue advice based on information leaks, are they protecting investors' right to know or creating unnecessary instability in the stock market? Whose game are we playing, and who makes the rules? It's becoming more important to know.

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