Company stock prices before public announcements of oncology trial results

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Prior knowledge of phase III clinical trials of new drugs and Food and Drug Administration (FDA) regulatory decisions may affect the price of a drug company's stock according to a study published September 26 in the *Journal of the National Cancer Institute*.

Regulatory decisions made by the FDA and phase III clinical trials are important for the financial success of new drugs. Investors with information on the trial results and FDA decisions before they are released to the public may profit regardless of the drug's success or failure. This information can also influence the market value of the companies that bring the drugs to market. Trial investigators, company employees, and outside consultants are aware of trials results before they are made public, and investment analysts may go to great lengths to obtain this "insider information" for their clients because the results are not necessarily reflected in the market price of a stock.

To determine what kind of impact prior knowledge of clinical results may have had on a company's market value and stock prices of particular drugs, Allan S. Detsky, M.D., Ph.D., and colleagues did a retrospective analysis of stock prices of publicly traded biotechnology and pharmaceutical companies before and after key public announcements made between January 2000 and January 2009 regarding 23 positive and 36 negative phase III clinical trials in which their cancer drug was tested and from 41 positive and nine negative FDA regulatory decisions. They obtained stock prices from the Center for Research in Security Prices and Bloomberg Professional. The researchers then analyzed each

company's daily closing stock price before and after the date of a public announcement.

The researchers found that the average stock price of a drug 120 days before a phase III clinical trial announcement showed an increase of 13.7% for companies that reported positive trials and a decrease of 0.7% percent for companies that reported negative trials. In a post hoc analysis that compared average stock prices over the period from 120 to 60 days before clinical trial announcements to the average price for the subsequent 60 days, companies reporting positive trial results saw a mean increase in their stock price of 9.4%, while those reporting negative trial results saw a decrease of 4.5% in their stock price, a statistically significant difference. Company stock prices before FDA regulatory decisions, however, didn't differ between companies with positive and negative decisions.

According to the researchers, one possible explanation for these trends is insider trading, where individuals make stock trades based on nonpublic information or by providing nonpublic information to others. The researchers write, "The changes in post-announcement share price that we have demonstrated highlight the potential use of this information by individuals for profit once it becomes public." They add that FDA decisions would not influence stock prices because the information on which they are based is already public. However, the researchers also point out certain limitations of the study, including selection bias, the fact that it was retrospective, and the small number of companies included in the analysis. They also note differences in the companies, namely that those reporting positive phase III study results are likely to be more established and profitable.

Even so, the researchers say they were surprised to see the differences in company stock prices in relation to positive and negative trials, given all the variables affecting a company's stock price. They write, "The results

of this study call for increased awareness by investigators regarding the legal and ethical aspects of divulging nonpublic information regarding clinical trials."

In an accompanying editorial, Adam Feuerstein, a Senior Columnist at TheStreet, and Mark J. Ratain, M.D., of the University of Chicago, write that the suggestion by Dr. Detsky and colleagues that some investigators involved in phase III trials are illegally tipping the results, which is a criminal violation of the Securities Exchange Act, is "of grave concern."

However, the editorialists also maintain that the positive and negative trials were different in other ways. In undertaking their own analysis of the companies studied, they calculated the market capitalization of the companies at 120 days before public announcements. They found that it was 80-fold greater for companies with positive trials compared to those with negative trials, implying that the subsequent negative trials were not a surprise. They write, "The perceived high risk of failure of phase III oncology trials is primarily limited to smaller oncology companies." Furthermore, "The stock market is known to anticipate future events, as opposed to reacting to the past. Thus, it is not surprising that sophisticated investors are able to judge the probability of success, which is reflected in the share price."

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