

ARTICLE

Company Stock Prices Before and After Public Announcements Related to Oncology Drugs

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Manuscript received March 15, 2011; revised July 11, 2011; accepted August 2, 2011.

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- Background** Phase III clinical trials and Food and Drug Administration (FDA) regulatory decisions are critical for success of new drugs and can influence a company's market valuation. Knowledge of trial results before they are made public (ie, "inside information") can affect the price of a drug company's stock. We examined the stock prices of companies before and after public announcements regarding experimental anticancer drugs owned by the companies.
- Methods** We identified drugs that were undergoing evaluation in phase III trials or for regulatory approval by the US FDA from January 2000 to January 2009. Stock prices of companies that owned such drugs were analyzed for 120 trading days before and after the first public announcement of 1) results of clinical trials with positive and negative outcomes and 2) positive and negative regulatory decisions. All statistical tests were two-sided.
- Results** We identified public announcements from 23 positive trials and 36 negative trials and from 41 positive and nine negative FDA regulatory decisions. The mean stock price for the 120 trading days before a phase III clinical trial announcement increased by 13.7% (95% confidence interval = -2.2% to 29.6%) for companies that reported positive trials and decreased by 0.7% (95% confidence interval = -13.8% to 12.3%) for companies that reported negative trials ($P = .09$). In a post hoc analysis comparing the stock price averaged over 60 trading days before and after day -60 relative to the clinical trial announcement, the mean stock price increased by 9.4% for companies that reported positive trials and decreased by 4.5% for companies that reported negative trials ($P = .03$). Changes in company stock prices before FDA regulatory decisions did not differ statistically between companies with positive decision and companies with negative decisions.
- Conclusions** Trends in company stock prices before the first public announcement differ for companies that report positive vs negative trials. This finding has important legal and ethical implications for investigators, drug companies, and the investment industry.

J Natl Cancer Inst 2011;103:1507-1512

Phase III clinical trials and regulatory decisions by the US Food and Drug Administration (FDA) are high-profile events that are critical for the financial success of new drugs. These events can also have a substantial impact on the market valuation of the companies that might bring these drugs to market (1). Therefore, these events attract great interest from investors (1,2).

Accurate speculation about the results of key clinical trials can be lucrative. With such foreknowledge, investors can profit regardless of whether a company's product succeeds or fails in a clinical trial (3). Many people, including trial investigators, company employees, and outside consultants, know the results of clinical trials before they are made public. In the period before public disclosure of trial results, such information is considered to be inside information—that is, material nonpublic information that is likely to affect the price of a drug company's stock when it is made public (4). Investment analysts will go to great lengths to

obtain such valuable information for their clients, because it is not widely known and is therefore not already reflected in the market price of a stock (5-7).

A study of biotechnology products undergoing phase III clinical trials between 1990 and 1998 found a statistically significant difference in the change in average stock price between companies with a successful product (trial "winners") and those with an unsuccessful product (trial "losers") in the period before and after the public announcement of trial results (8). In this study, we conducted a similar analysis that focused on oncology drugs, whose number is growing rapidly. We examined retrospectively the stock prices of publicly traded biotechnology and pharmaceutical companies before and after key public announcements regarding phase III clinical trials in which their cancer drug was tested, and before and after FDA regulatory decisions for such cancer drugs, to seek indirect evidence of insider trading.

CONTEXT AND CAVEATS

Prior knowledge

Phase III clinical trials and Food and Drug Administration (FDA) regulatory decisions are critical for success of new drugs and can influence a company's market valuation. Knowledge of trial results before they are made public may affect the price of a drug company's stock.

Study design

A retrospective examination of the stock prices of publicly traded biotechnology and pharmaceutical companies before and after key public announcements regarding 23 positive and 36 negative phase III clinical trials in which their cancer drug was tested, and before and after 41 positive and nine negative FDA regulatory decisions for such cancer drugs.

Contribution

The stock prices of companies that reported positive trials tended to increase before the first public announcement of the results, whereas the stock prices of companies that reported negative trials tended to decrease. Changes in company stock prices before FDA regulatory decisions, however, did not differ between companies with positive decisions and companies with negative decisions, possibly because the clinical trial results that informed the decisions were already in the public domain.

Implications

One explanation for the observed trends is insider trading. Trial investigators, company employees, and outside consultants need greater awareness of the legal and ethical aspects of divulging nonpublic information regarding clinical trials.

Limitations

Other factors that may influence a company's stock price were not taken into account. Selection bias was possible. Intrinsic characteristics of the companies themselves may have determined those with the ability to bring a drug through phase III testing with a positive result.

From the Editors

Our primary hypotheses were 1) that stock prices would increase before public announcement of positive clinical trials and decrease before announcement of negative trials and 2) that there would be no consistent changes in stock price seen before and after announcements of FDA regulatory decisions, because the clinical trial results that informed the decisions were already in the public domain.

Methods

The study population consisted of biotechnology and pharmaceutical companies that issued key public announcements regarding an anticancer drug between January 2000 and January 2009. Public announcements about phase III clinical trials and FDA regulatory decisions were identified by searching the BioCentury Archives (9), which provides information and analysis about the biotechnology sector. We used keywords "phase III" and "cancer" to search clinical trials and "FDA," "ODAC," and "cancer" to identify regulatory decisions. The results were then filtered manually.

We searched Factiva (10) to obtain the company press releases to confirm the date and time of the public announcement. We included the first announcement that signaled a positive or negative result. Public announcements usually took the form of press releases; less commonly, they were press releases from major clinical meetings. Stock prices were obtained from the Center for Research in Security Prices (11) and from Bloomberg Professional (12). Companies were listed predominantly on the National Association of Security Dealers Automated Quotations (NASDAQ) or the New York Stock Exchange; other companies were listed on major Canadian or European exchanges.

The companies were classified into two groups. The first group consisted of companies that had drugs undergoing testing in randomized phase III clinical trials, the results of which were first made public during the period noted above. The second (partly overlapping) group consisted of companies whose products were evaluated for FDA approval during this time interval. If a drug was developed by two companies, the company with the lower market valuation at the time of the public announcement was included in this study.

Anticancer drugs were included in this study if they had been evaluated for the treatment of solid tumors or hematologic malignancies. We included novel targeted agents and traditional cytotoxic chemotherapeutic agents. We excluded agents that were used as adjuncts to treatment (such as bisphosphonates, growth factors, and antiemetics), hormonal therapy, and drugs used predominantly in children.

We classified the outcomes of the phase III trials as either positive or negative. A trial was classified as positive if it was the first randomized phase III clinical trial for a given indication in which there was a statistically significant improvement in either 1) the primary endpoint or 2) a key secondary endpoint (such as overall survival, progression-free survival, or time to progression), and 3) the drug was approved subsequently by the FDA for that indication. A drug could be included more than once in this analysis if it was approved for more than one indication, such as for more than one tumor site or for metastatic and adjuvant settings of a given tumor site. Drugs that received accelerated approval based on phase II data were excluded.

A trial was classified as negative if it was the first randomized phase III trial that failed to show a statistically significant difference between treatment arms in the primary endpoint, and the drug had not received FDA approval for any indication. Trials of drugs that were never approved by the FDA but that met their primary or secondary endpoints were excluded. A drug that was evaluated in a negative trial could only be included once.

For experimental drugs that were evaluated by the FDA during the study period, we included decisions made by the FDA and those made by the Oncologic Drugs Advisory Committee (ODAC), which makes recommendations to the FDA, whichever came first. In general, however, ODAC recommendations predated the FDA decision. An overview of the FDA approval process can be found on the FDA website (13). Historically, when a drug was not ready for approval, the FDA issued a "not approvable" letter when there were major deficiencies in an application and an "approvable" letter when changes in the application could lead to approval. In 2008, the FDA replaced these letters with a "complete response"

letter to adopt a consistent approach to inform sponsors of the required changes with no implication as to the ultimate approvability of the application (14). Because of the inherent ambiguity in some of these messages, we defined “positive” and “negative” regulatory decisions as those that gave clear signals to the market. A positive decision was defined as FDA approval or a recommendation for approval by ODAC. A negative decision was defined as a not approvable letter or a negative ODAC recommendation. All other decisions, including approvable letters and decisions not to file an application, were excluded. Situations in which the ODAC recommendation and the FDA decision were dissimilar were excluded.

We analyzed each company’s daily closing stock price before and after the date of a public announcement by using a methodology similar to that described previously (8). Briefly, the company stock prices were recorded for each of the 120 consecutive trading days before and after a public announcement, excluding weekends and statutory holidays, for an equivalent of six calendar months. We defined day 0 as the day before active trading could take place following a public announcement. If the announcement took place before the stock market closed, the previous day was day 0; if it took place after the market had closed, the announcement day was day 0. If a company had a single drug for which there was overlap of the 120 trading days before the announcement for two sequential trials or regulatory decisions, the latter trial or regulatory decision was omitted. If a company had two different drugs with announcements in overlapping trading periods, only the earlier announcement was included in the analysis.

Statistical Analysis

Our prespecified primary outcome measure was the ratio of a company’s average stock price for day –120 to day –116 (baseline) to its price on day –1. We used a 5-day baseline period to reduce variability in the denominator of the ratio. We used a two-sample *t* test of the logarithmic transformation of this ratio for each stock (to account for skewness) to compare positive trials with negative trials; however, we present the results as the percent change in stock price (rather than logarithmic change) because the untransformed data are easier to interpret. Graphs and subsequent analyses were based on what we refer to as standardized prices, which, for each drug, were the company’s stock prices throughout the trading period expressed as a percentage of the mean value on days –120 to –116. The average values for each day of trading were plotted separately for positive and negative trials and for positive and negative FDA regulatory decisions. Approximate 95% pointwise confidence intervals were constructed by adding ± 1.96 SEs to the mean on each day. Each graph includes a reference line that shows the mean standardized value of the NASDAQ index on the corresponding trading days.

Upon initial analysis of the data, we observed that after day –60 the stock of companies that would later report positive trials usually continued to increase in price, whereas that of companies that would later report negative trials often started to decrease. Therefore, we performed a post hoc analysis to evaluate the differences in stock prices between positive and negative trials over periods before and after day –60. For this analysis, we defined day –120 to day –61 as period 1 and day –60 to day –1 as period 2.

The mean standardized price was computed for each stock over the entire period 1 and over the entire period 2, and the between-period difference was compared between positive and negative trials by using a two-sample *t* test.

In sensitivity analyses, we examined the market-adjusted rate of return for each company’s stock—the difference between a stock’s rate of return and the rate of return for the NASDAQ index over the same 120-day period (15)—from day –120 to day –1 before announcement of trial results or an FDA regulatory decision. The rate of return for an individual stock or the NASDAQ index as a whole was calculated as $V_2 - V_1 / V_1$, where V_1 is the value at the start of a period and V_2 is the value at the end of the period. We used a two-sample *t* test to compare the mean market-adjusted rate of return between stocks of companies with positive and negative announcements. Analyses were done separately for announcements of trial results and FDA regulatory decisions. All *P* values are two-sided.

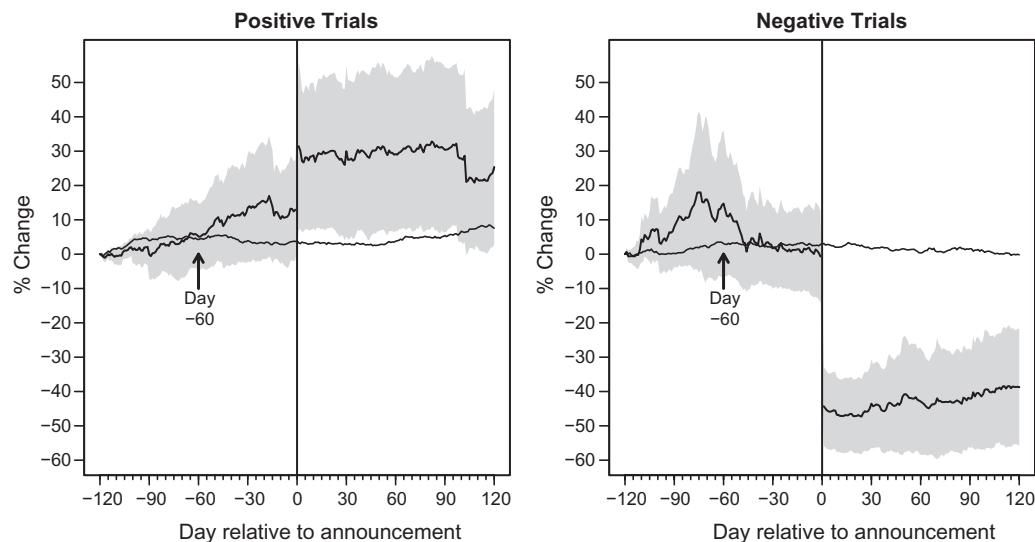
Results

We identified public announcements related to 23 positive and 36 negative trials, and there were 41 positive and nine negative FDA regulatory decisions that met the inclusion criteria for this study (Supplementary Tables 1–6, available online). The 23 positive trials evaluated 20 different drugs; in 13 (56%) of these trials, the drug was being tested for an initial indication. Five drugs that had announcements relating to phase III trials and two drugs with regulatory announcements during the study period were excluded from this analysis because of overlap with other announcements (Supplementary Tables 3 and 6, available online).

Figure 1 depicts the mean percent changes in company stock prices before and after clinical trial announcements for positive and negative trials. After the announcement, the stock prices of companies with positive trials increased, whereas the stock prices of companies with negative trials decreased. This finding confirms that the strategy we used to clearly separate positive trials from negative trials was successful. When we examined the trends in mean percent changes in company stock prices in the time leading up to the announcement, the curves for companies with positive and negative trials appeared to diverge after day –60. The stock prices of companies that would later report positive trials tended to increase after day –60, whereas the stock prices of companies that would later report negative trials tended to decrease (Figure 1). The mean standardized value of the NASDAQ index on the corresponding trading days was relatively constant over the entire study period. The mean percent change in stock price from baseline to day –1 was 13.7% (95% confidence interval [CI] = –2.2% to 29.6%) for companies with positive trials and –0.7% (95% CI = –13.8% to 12.3%) for companies with negative trials (*P* = .09) (Table 1).

In a post hoc analysis, the mean standardized stock price for companies that later reported positive trials was 101.9% of baseline from day –120 to day –61 (period 1) and 111.3% of baseline from day –60 to day –1 (period 2) (net change = 9.4%). The mean standardized stock price for companies that later reported negative trials was 108.1% of baseline in period 1 and 103.6% of baseline in period 2 (net change = –4.5%). The absolute difference in the net

Figure 1. Mean percent change from baseline in company stock prices before and after announcements of positive (n = 23) and negative (n = 36) phase III clinical trials (black line). The shaded area indicates pointwise 95% confidence intervals for this mean. The gray line is the mean standardized value of the National Association of Security Dealers Automated Quotations (NASDAQ) index on corresponding trading days.



change in mean standardized price between companies that reported positive trials and companies that reported negative trials was 13.9% (95% CI = 1.5% to 26.3%, $P = .03$) (Table 2). Analyses based on the ratio of mean costs gave the same results (data not shown).

In the sensitivity analysis that compared market-adjusted rates of return from day -120 to day -1, the mean market-adjusted rate of return was -3.0% for companies that reported negative trials and 8.5% for companies that reported positive trials ($P = .25$, two-sample t test). When we excluded the one negative trial that had a large positive rate of return (119%; Z score = 3.6), the mean market-adjusted rate of return for companies that reported negative trials was -6.4% ($P = .11$ compared with companies that reported positive trials, two-sample t test).

Figure 2 illustrates the percent change in company stock prices before and after announcements of positive and negative regulatory decisions by the FDA. After the announcement, the stock prices of companies that had a positive decision tended to increase, whereas the stock prices of companies that had a negative decision decreased. The differences in mean percent change in stock price between baseline and day 1 before positive and negative FDA regulatory announcements, as well as the changes in the mean stock price between period 1 and period 2, are shown in Tables 1 and 2, respectively, and were not statistically significant.

Discussion

In this study, we found that the stock prices of companies that reported positive trials tended to increase before the first public

announcement of the results, whereas the stock prices of companies that reported negative trials tended to decrease. A post hoc analysis comparing the stock price averaged over 60 trading days before and after day -60 relative to the clinical trial announcement revealed that the absolute difference in price change between companies that reported positive results and those that reported negative results was statistically significant. This finding was consistent with our primary hypothesis. The results of the sensitivity analyses based on market-adjusted rates of return were also consistent with our primary hypothesis, although the P values were not statistically significant. We did not find a difference in the stock price of companies that received positive and negative FDA regulatory announcements, perhaps because at this later stage of drug development, there is less speculative interest, given that the supporting data are already available.

A previous study of biotechnology products undergoing clinical trials in the 1990s demonstrated a statistically significant difference in the change in stock price between companies with a positive announcement vs those with a negative announcement in the time period before the public announcement of trial results (8). Our findings are consistent with those in the previous study; however, our findings are not as statistically strong. In this study, two factors made it more difficult to elucidate the market reaction to public announcements compared with the previous study. First, in the earlier study, most of the companies were small biotechnology firms with a single drug in development. In this study, many of the companies were large and had multidrug portfolios, so that their market valuation was less sensitive to the prospects of a single product. Second, one of the major changes that took place in the biotechnology sector

Table 1. Percent change in company stock price from baseline (average of day -120 to day -116) to day -1 relative to the public announcement of clinical trial results and FDA regulatory decisions*

Public announcement	Mean percent change (95% CI), SD		Pt
	Positive announcement	Negative announcement	
Clinical trial results	13.7 (-2.2 to 29.6), 36.8	-0.7 (-13.8 to 12.3), 38.5	.09
FDA regulatory decisions	18 (3 to 32), 45.5	18 (-25 to 61), 55.6	.87

* CI = confidence interval; FDA = Food and Drug Administration.

† From two-sample t test (two-sided) on the logarithm of the ratio of the stock prices on day -1 and at baseline.

Table 2. Change in standardized company stock price over the period before and after day –60 relative to public announcements of clinical trial results and FDA regulatory decisions*

Public announcement	Percent of baseline				P
	Average standardized price for period 1 (SD)	Average standardized price for period 2 (SD)	Change in average standardized price between period 1 and 2 (SD)	Absolute difference in price change between positive and negative announcements (95% CI)†	
Clinical trial results					
Positive	101.9 (12.3)	111.3 (32.7)	9.4 (23.7)	13.9 (1.5 to 26.3)	.03
Negative	108.1 (34.8)	103.6 (38.0)	–4.5 (22.2)		
FDA regulatory decisions					
Positive	102.7 (10.2)	110.9 (29.5)	8.1 (26.6)	4.6 (–11.0 to 20.2)	.54
Negative	100.0 (10.8)	103.5 (16.7)	3.5 (18.3)		

* Period 1 = day –120 to day –61 relative to announcement; period 2 = day –60 to day –1 relative to announcement. CI = confidence interval; FDA = Food and Drug Administration.

† Two-sample *t* test (two-sided) comparing mean change between stocks with positive and negative announcements.

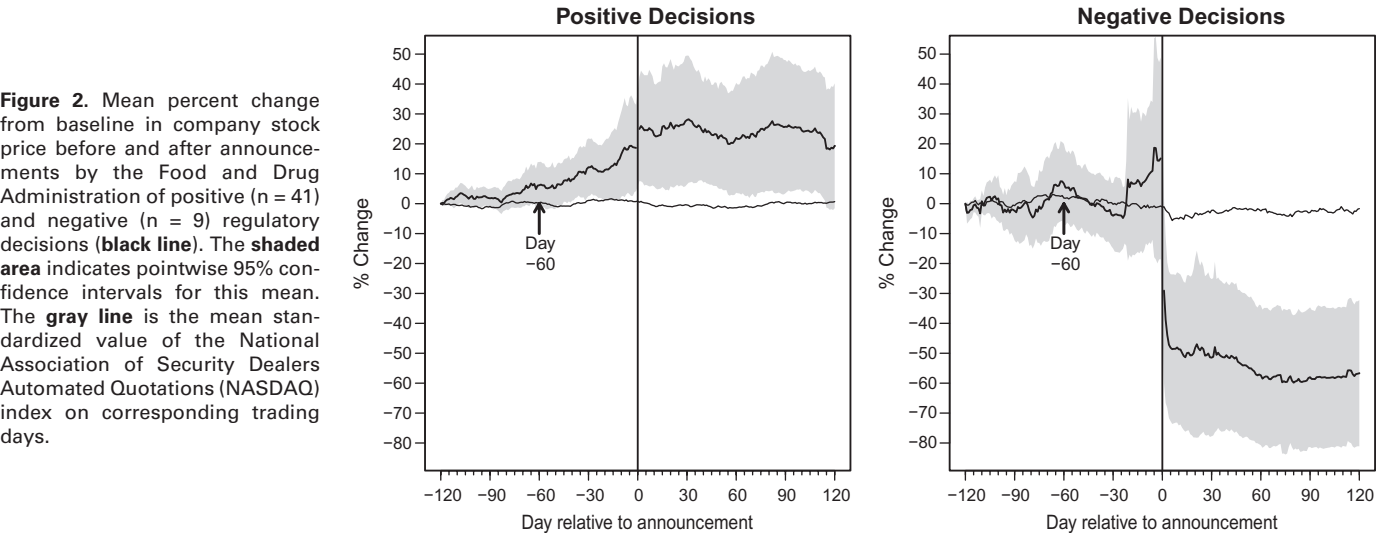
during the period that we analyzed—from 2000 to 2009—was the increasing influence of hedge funds on stock prices (16). The ability of hedge funds to take long and short positions (promises to both buy and sell stock in the future) might have made it more difficult to show an apparent difference between the stock prices of companies that reported positive and negative trials.

One explanation for the trends we observed in this study is insider trading, in which individuals make stock trades based on information before results are public or by providing nonpublic information to others (“tippees”) who act on it in a similar fashion. Before clinical trial results are made public, many people involved in the trial process are likely to have information regarding the outcomes. 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. There are documented examples where information from either a single person or the impressions of multiple investigators led to large effects on a company’s share price (5,6). Sometimes, investigators used the information for personal financial benefit (17); sometimes, the information may have been unwittingly divulged (6). There are even examples of clinical trial subjects themselves disclosing non-public information (18). In this era of widespread use of social media

(eg, Facebook and Twitter), the boundaries of privacy and confidentiality are constantly being challenged. However, for those who do divulge nonpublic information, the electronic trail of information is becoming increasingly more difficult to conceal. Although the pre-announcement trends raise the possibility of insider trading, it is impossible to prove such in this type of study.

This study has several limitations. First, it was retrospective, and we did not account for the many other factors that may influence a company’s stock price. Second, although our selection criteria were designed to include only clear-cut positive and negative announcements, there may be some unknown selection bias. Third, the number of companies included in the analysis was relatively small, and the large 95% confidence intervals seen in the results indicate substantial variability. Fourth, there may be intrinsic differences in the included companies themselves: For example, those with the ability to bring a drug through phase III testing with a positive result may be more established and profitable companies.

Over the past 40 years, there has been increased participation by physicians and scientists in all aspects of the pharmaceutical industry. It has been estimated that up to one in 10 American physicians has a consulting relationship with entities that provide investment advice (19). These relationships may result in the disclosure of nonpublic



confidential information regarding ongoing clinical trials (20). In a recent case, a physician who worked simultaneously as a consultant for a biotechnology firm and a hedge fund provided insider information that allowed the hedge fund to avoid a loss of \$30 million (21).

Some have called for a change in the relationship between physicians and the investment industry to safeguard confidential nonpublic information regarding clinical trials (22). The American Society of Clinical Oncology discourages relationships between clinical investigators and investment advisors and mandates their disclosure (23). In a series of ethics vignettes, Berlin et al. (24) illustrated strategies that may be used by individuals wishing to obtain confidential information from oncologists and the challenges in detecting and resisting such attempts.

Given the complex variables that affect a company's stock price, we are surprised that we were able to see a difference (albeit a subtle one) in company stock prices in relation to positive vs negative trials. The results of this study call for increased awareness by investigators regarding the legal and ethical aspects of divulging nonpublic information regarding clinical trials. Whereas it is common for investigators to sign a financial disclosure form to identify conflicts of interest, the time has come to formally require that investigators and others with access to nonpublic information regarding clinical trials disclose relationships with the investment industry and sign a confidentiality agreement. Investigators with access to nonpublic information regarding a particular drug should never provide investment advice on those products. This is crucial to maintain the public trust and preserve the integrity of both the clinical trial process and the financial markets.

With the growing prevalence of physician involvement in the investment industry, it is important for physician researchers to recognize their legal and ethical responsibilities. In these times of financial turmoil, there is a new emphasis on corporate responsibility and ethical practice. Recent high-profile cases in the media highlight the consequences of white-collar crime for those who ignore this message (21,25).

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Funding

The authors received no external funding for this study.

Notes

We wish to thank Richard van den Broek (HSMR Advisors, LLC, Greenwich, CT) for his helpful advice and Karen Bernstein for providing us with access to the full articles in BioCentury Archives. Neither was compensated for their contribution. The authors had full responsibility for the design of the study; the collection, analysis, and interpretation of the data; the writing of the article; and the decision to submit the article for publication.

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