

No. 09-1156

IN THE
Supreme Court of the United States

MATRIX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

BRIEF OF *AMICI CURIAE* ECONOMISTS ROBERT
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RESPONDENTS

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INTEREST OF AMICI CURIAE¹

Amici are professors and academics who teach and write on financial economics. *Amici* wish to ensure that the Court properly assesses the economic costs and benefits of disclosure rules regarding adverse drug events in *Matrixx Initiatives, Inc. et al. v. James Siracusano and Neca-Ibew Pension Fund*. *Amici* have no stake in the outcome of this case. They are filing this brief solely as individuals and not on behalf of the institutions with which they are affiliated.

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¹ Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amici*, their members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amici* also represent that all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amici* briefs have been filed with the Clerk.

antitrust matters. Dr. Litan also has served in several capacities in the federal government. During 1995 and 1996, he was Associate Director of the Office of Management and Budget (where he was responsible for overseeing budgetary and other policies of six cabinet agencies). From 1993 to 1995, he was Deputy Assistant Attorney General, in charge of civil antitrust litigation and regulatory issues, at the Department of Justice. From 1977 to 1979, he was the regulatory and legal staff specialist at the President's Council of Economic Advisers. In the early 1990s, Dr. Litan was a Member of the Commission on the Causes of the Savings and Loan Crisis. During his career, Dr. Litan has authored or co-authored over 20 books, edited another 14, and authored or co-authored over 200 articles in journals, magazines, and newspapers on a broad range of public policy issues. Dr. Litan received his B.S. in Economics, summa cum laude, from the Wharton School of Finance at the University of Pennsylvania; his J.D. from Yale Law School; and both his M. Phil. and Ph.D. in Economics from Yale University.

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INTRODUCTION

Petitioner Matrixx Initiatives Inc., manufacturers Zicam cold medicines, some of which have been alleged to cause anosmia—that is, loss of the sense of smell. Petitioners have argued that a statistical significance standard should be used to determine whether undisclosed adverse events are materially important in Section 10(b) cases. Under such a standard, a complaint would have to demonstrate that the rate of undisclosed adverse events among users of a drug exceeds, *in a statistically significant sense*, the benchmark rate.² Petitioners support such a standard by arguing that the statistical significance standard would mandate disclosure of any information that would be relevant to the financial marketplace in securities litigation.³ However, adverse events may well be material to investors even when they are not statistically significant. As academic

² Brief for Petitioner at 34, *Matrixx Initiatives Inc., et al., v. James Siracusano and NECA-IBEW Pension Fund U.S.* (No 09-1156).

³ *Id.*

and practicing economists, we therefore disagree with the Petitioners.

SUMMARY OF ARGUMENT

Full and timely disclosure of adverse drug events is likely to benefit investors in financial markets. These benefits can be enjoyed without the imposition of additional reporting burdens on drug companies or the possibility of flooding financial markets with excessive information.

The U.S. Food and Drug Administration (FDA) currently requires drug companies to report all serious, unexpected adverse drug experiences, from both prescription and non-prescription medications as well as dietary supplements, within 15 calendar days of becoming aware of the event. Hence, full disclosure can be achieved without any new reporting burdens for drug manufacturers, as firms already have in place systems to collect and report these data. Moreover, such information would be absorbed by investors, who already respond to immense quantities of data from a variety of public and private sources. Therefore, arguments that full disclosure of adverse events would be either overly burdensome to manufacturers or would flood investors with superfluous information are misguided.

A statistical significance requirement, by altering the incentives facing managers and other corporate insiders, could have unintended consequences. Drug companies could have an incentive to withhold information about adverse drug events to protect the firm's market share or share price. A statistical significance requirement could also lead to increased scrutiny of the behavior of insiders, which could increase speculation and volatility in financial markets.

ARGUMENT

I. Full Disclosure of Adverse Drug Events Is Unlikely to Be Harmful to Markets or Drug Companies

Requiring full disclosure of adverse drug events will not create a significant burden for drug companies, which are already required by law to report adverse events to the FDA in the form of Adverse Event Reports (AERs). Financial markets would not be harmed by any additional disclosures because investors already have access to vast quantities of information from a plethora of sources when making their investment decisions.

A. Drug Companies Are Currently Required to Disclose Adverse Drug Events

Opponents of the disclosure of Adverse Drug Reactions (ADRs) to financial markets might argue that such reporting would be costly and overly burdensome. To understand the flaws in this argument in general and with regard to the particular case at hand, one must first understand current and historic requirements of the disclosure of ADRs. Currently, drugs that are not marketed under new drug applications (NDAs) are subject to 21 C.F.R. § 310.305 for prescription, and 21 U.S.C. §§ 379aa(e) for over-the-counter (OTC), drugs. According to 21 C.F.R. § 310.305, manufacturers, packers and distributors of prescription drugs are required “to establish and maintain records and make reports to FDA of all serious, unexpected adverse drug experiences associated with the use of their drug products” within 15 calendar days of becoming aware of the event. More-

over, records of adverse events must be kept for at least six years.⁴

Public Law 109-462 requires reporting responsibilities for non-prescription medications and dietary supplements that are similar to reporting standards of prescription drugs.⁵ Both prescription and OTC drugs marketed under a new drug application must adhere to stricter reporting guidelines. These standards include periodic filings of any adverse drug events.⁶

The requirements described above concern the *current* reporting standards to which a manufacturer of prescription pharmaceuticals or OTC medicines or supplements must adhere. Because Public Law 109-462—the Law requiring reporting of adverse events for OTC products—was not enacted until 2006, Matrixx was not required to report to the FDA adverse events involving Zicam products that occurred during the relevant period of this case. As such, any argument that public reporting of AERs would be overly burdensome to manufacturers *on a going forward basis* is immaterial to this particular matter. That is, Matrixx did not disclose Zicam-related AERs to the FDA, presumably because it was not required to at the time. Instead, the question here is whether Matrixx (1) attempted to hide material information from

⁴ 21 U.S.C. §§ 379aa(e).

⁵ Regulations governing OTC products and dietary supplements are available via Food and Drug Administration, MedWatch, Reporting Serious Problems to the FDA, OTC Products and Dietary Supplements, available at <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm>. Public Law 109-462 is available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm102797.pdf>.

⁶ *See* 21 C.F.R. § 314.80.

investors, such as reported instances of anosmia and specific, pointed warnings of a Zicam-anosmia link by specialists in the field, and (2) consequently, made misleading statements about Zicam products. Matrixx did not even have to consider the costs (such as clerical costs, for example) of mandatory disclosure of Zicam-related AERs.

Finally, a lack of a bright-line standard of significance for materiality of undisclosed AERs would not result in overly burdensome disclosure costs—for example, the need to incur burdensome costs to disclose AERs in periodic financial statements. As stated above, manufacturers of prescription drugs and OTC medicines and supplements are *currently* required to disclose adverse events to FDA. Therefore, any *additional* disclosure costs that might be borne by drug companies should be minimal, as these firms are already familiar with the practice. Moreover, separate reporting of AERs from what is already mandated by law may be unnecessary in many circumstances, as the FDA releases publicly available quarterly reports through its Adverse Event Reporting System (AERS).⁷ This may further reduce any perceived burdens in timely disclosure of ADRs to the financial marketplace.

⁷ Food and Drug Administration, Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS), Quarterly Reports, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm#QuarterlyReports>.

B. Investors Already Respond to Massive Amounts of Information when Making Investment Decisions

The disclosure of ADRs to financial markets is unlikely to burden investors with excessive data that could cloud decision-making or harm the markets in general. Investors already have access to large quantities of data and information when making their decisions to buy, sell or hold securities. All public companies, foreign and domestic, whose securities are publicly registered for trading in the United States are required to file registration statements, periodic reports, and other forms with the Securities and Exchange Commission (SEC), which makes this information freely available on its website.⁸ Accordingly, investors already have a wide array of financial data, market statements and other information disclosed by publicly traded companies themselves that such investors can use to formulate investment decisions.

Company filings and statements are not the only free source of information available to investors. Considerable information is collected and disseminated on multiple websites that do not charge for content. Examples include *Yahoo!Finance*, *CNN Money*, and *Bloomberg*. These websites allow for the download of historic stock data, market indices and other corporate data. They provide periodic investment reports and columns, sometimes by noted authors.

In addition to the free data and reports readily available to investors, numerous financial reports track specific types of market dynamics and pheno-

⁸ Securities and Exchange Commission, Filings & Forms, <http://www.sec.gov/edgar.shtml>.

mena within virtually any particular industry. These reports are drafted by private analysts and are available for purchase, with individual reports routinely costing hundreds or thousands of dollars.⁹ Such a price premium on information over and above what is already provided freely to investors supports the notion that markets can bear more information. Given the incredible amount of data and analysis that is already available for free, investors would not pay for more data and more analysis unless they were able to use it in whole or in part to formulate more intelligent investment decisions.

Information regarding ADRs is already free and publicly available on the FDA's website. This information, which covers adverse event reports for prescription drugs, is updated quarterly. The FDA has used this reporting method since 1969.¹⁰ Indeed, in the past decade, the FDA has entered 3,183,922 reports into its AERS database (through the first quarter of 2010).¹¹ Presumably, investors and securities

⁹ For an example of the availability of industry reports regarding over-the-counter drugs, see MarketResearch.com, Over-the-Counter Drugs Market Research Reports, available at <http://www.marketresearch.com/browse.asp?categoryid=183>.

¹⁰ The Adverse Event Reporting System (AERS) contains over four million reports of adverse events and reflects data from 1969 to the present. Food and Drug Administration, Adverse Event Reporting System (AERS) Statistics, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>.

¹¹ Data describing the number and type of reports received and entered by the FDA is available at Food and Drug Administration, Reports Received and Reports Entered into AERS by Year, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm>. The FDA notes that "these data are presented at the individual re-

analysts have analyzed these data and have incorporated them into their investment decisions. Therefore, it is untenable to argue that ADR reporting could provide harmful and superfluous data to investors.

Finally, the ultimate determinant of materiality in a securities matter could be whether information or data in question, once disclosed, results in a meaningful decrease in share price. Not only is there legal precedent for this standard,¹² but this is also the basic standard used within the field of finance. That is, if information is material to the stock in question, then the revelation of that information to the market, assuming that the market is efficient, would result in a significant “abnormal return.”¹³ Put simply, the stock price would change in a manner that could

port level; some of the numbers may reflect duplicate reporting due to factors such as follow-up reports received on a case or different persons reporting on the same patient case.”

¹² See, e.g., *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 948 (9th Cir. 2003) (stating that “[s]tock price changes—or lack thereof—are also relevant to the determination of materiality”; adding that “[a]t a minimum, the static or dynamic nature of a stock price after the disclosure of previously withheld information is strong evidence of how reasonable investors view the significance of the information.”); *In re Apple Computer Securities Litigation*, 886 F.2d 1109, 1116 (9th Cir. 1989) (stating that large price movements in response to public statements provide strong indication that the public statements were material).

¹³ Abnormal returns are the returns of a stock price that cannot be explained by movement in a relevant index, be it a market index or a sector/industry index. Put differently, abnormal returns for a stock equal the difference between the actual returns on that stock and the returns predicted by a relevant index. See, e.g., Zvi Bodie, Alex Kane, & Alan J. Marcus, *Investments* 368 (McGraw Hill, 2d ed. 1993).

not be explained away by comparable movements in a portfolio benchmark.

II. Full Disclosure of Adverse Drug Events Is Likely to Benefit Investors

Full disclosure would benefit investors by allowing them to make investment decisions from a more informed standpoint. In his seminal work, Professor Eugene Fama of the University of Chicago Booth School of Business described an efficient market as one in which “prices always ‘fully reflect’ available information.” Eugene Fama, *Efficient capital markets: A review of theory and empirical work*, 25 *Journal of Finance* 383, 383 (1970). Different levels of market efficiency are distinguished by the amount of information that is reflected in the market price. According to the strongest form of efficiency, “prices reflect all the information that can be acquired by painstaking analysis of the company and the economy.” Richard A. Brealy, Steward C. Myers & Franklin Allen, *Principles of Corporate Finance*, 359 (McGraw-Hill 2008). In a strongly efficient market, it would not be possible to consistently out-perform the market. Indeed, evidence on strong-form efficiency “has proved to be sufficiently convincing that many professionally managed funds have given up the pursuit of superior performance.” *Id.* at 362.

The process by which markets determine which information is relevant and how prices should behave in response to relevant information is known as price discovery. The efficient-market hypothesis emphasizes that arbitrage will rapidly eliminate any profit opportunities and drive market prices back to fair value. *Id.* at 372. Markets and investors benefit from this process of price discovery, as capital markets

clear in equilibrium, leading to an efficient price such that market supply equals market demand. One benefit of efficient capital markets is that the market price generally will not deviate very far from this equilibrium price, thus helping to avoid sudden market crashes in the future. Another benefit is increased liquidity resulting from investors' confidence that they are not overpaying for a security. In an efficient market "you can trust prices, for they impound all available information about the value of each security." *Id.* at 373.

The mere presence of potentially irrelevant information does not affect outcomes in an efficient capital market. The market will decide whether an ADR conveys relevant information. For example, an ADR citing a minor headache as a side effect will not have the same effect on prices as an ADR showing that death occurred following consumption of a particular drug. Investors, including institutional investors, individual investors and large brokerage houses alike, are free to dispose of any available information that is not relevant to their investment decision. Investors sift through massive amounts of data from many sources every day, and there will be a natural filtering process, as investors decide what information is and is not relevant. Irrelevant information is discarded and thus does not affect an investor's portfolio choice. Moreover, particularly important information, regardless of whether it meets a specific standard of statistical significance, may be deemed relevant. Through this mechanism, markets will remain unaffected by irrelevant information and instead will focus on those factors determined to be worthy of consideration in making investment decisions.

III. A Statistical Significance Requirement Could Have Unintended Consequences

A potential problem with a statistical significance standard is that the power to perform a test in order to accept or reject unreported AERs as significant could fall into the hands of individuals who have a vested interest in the test's outcome. For example, decision-makers within a drug company may stand to benefit from postponing or under-disclosing adverse drug events. This may impact a drug company's behavior significantly, especially where the disclosure issue is perceived to be a "close-call." Furthermore, disclosure of only statistically significant reports would actually increase a stock's volatility and, thus, become even more potentially perilous to the financial markets.

A. A Statistical Significance Requirement Could Cause Drug Companies to Under-Disclose Adverse Drug Events

Disclosure of adverse drug events can lead to drug recalls, which usually result in significant declines in share prices.¹⁴ For example, when Merck recalled the arthritis drug Vioxx in 2004, the company's stock price fell by more than \$12 per share, reducing the value of the company by more than 25 percent.¹⁵

The potential negative effects of adverse drug events on the stock price and valuation of a firm has implications for the behavior of a firm's managers. This extends throughout the corporate organization,

¹⁴ Share price declines following drug recalls have been observed since the 1960s. See David Dranove and Chris Olsen, *The Economic Side Effects of Dangerous Drug Announcements*, 37 J. L. & Econ. 323, 323 (1994).

¹⁵ See Marc Kauffman, *Merck Withdraws Arthritis Medication*, Wash. Post A01 (Oct. 1, 2004).

even where there is a formal division between the firm's business side and science side.

Managers' salaries are often tied to the short-term performance and profitability of the company. For many large companies, it is difficult to observe and measure the manager's performance. This information asymmetry and the resulting problem of motivating a manager to act in the best interests of the firm is known as the principal-agent problem. Tying the manager's compensation structure to overall company performance is a common solution to the principal-agent problem.¹⁶ Cognizant of the effects of adverse drug effects on share prices, and given their own compensation tied to company performance, managers have an incentive to delay or under-disclose adverse drug events that could adversely affect short-term profits as well as investors' perceptions about future profitability. Each or both of these effects could reduce managers' compensation. A statistical significance standard to measure whether certain AERs are considered material would reinforce managers' incentives not to disclose, and specifically would introduce a bias into the conduct of any such test.

Insiders have a similar incentive to under-disclose adverse drug events, because they stand to lose a significant portion of their investment in the event that the publication of an adverse drug event negatively affects the stock price. With many firms now offering employee stock purchase programs and com-

¹⁶ Solutions to the principal-agent problem, including "piece rates, options, discretionary bonuses, promotions, profit sharing, efficiency wages, deferred compensation", are outlined in Canice Prendergast, *The Provision of Incentives in Firms*, 37 J. Econ. Literature 7 (1999).

pany pension plans that invest in the company's own stock, an increasing number of employees have a vested interest in maintaining their company's stock price. Insiders with the power to influence whether and when to report an AER are likely to be more senior employees, who tend to hold larger volumes of shares. These are the insiders who stand to lose most from a share price decline. Consequently, a statistical significance standard of materiality may tempt these insiders to alter the reporting of AERs to their own financial gain.

B. A Statistical Significance Requirement Could Increase Market Volatility

A statistical significance requirement would provide incentive for insiders to sell their shares before the significance requirement is met. Specifically, a bright-line standard of statistical significance would encourage insiders to use AERs so that they may *predict* when a specific standard of significance will be met. By timing sales before such a standard is met, the insider avoids any loss from the resultant decrease in share price following a disclosure. As a result of this incentive, stock sales by insiders would be monitored more closely by industry analysts. Analysts may be concerned that sales of large quantities of shares by insiders, particularly if the timing coincides with third-party accounts of possible but yet officially unreported AERs, are evidence that a significant AER is imminent. This likely would increase speculation and volatility in the markets.

In any event, where a statistical significance test threshold is met and disclosed, this would likely have a greater market impact than when any particular number of AERs is reported. This impact would result in greater market volatility as investors sudden-

ly become aware that a large set of AERs were disclosed. A significant correction to prices would follow, as the market responded to the new information. By comparison, a gradual release of AER-related information allows investors to periodically adjust their expectations of significance in both a statistical and economic sense.

CONCLUSION

Full disclosure of adverse drug experiences is unlikely to be overly burdensome for drug companies, which already report such experiences to the FDA. Full disclosure is also unlikely to burden investors, who already process considerable quantities of information from a plethora of sources. In contrast, investors would benefit from full disclosure, which would facilitate informed decision-making. A statistical significance requirement could have unintended consequences and should be considered with caution. For these reasons, the judgment of the Court of Appeals for the Ninth Circuit to reverse the judgment of the District Court should be affirmed.

Respectfully submitted,

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