No. 09-1156

In The Supreme Court of the United States

MATRIXX INITIATIVES INC., *et al.*,

Petitioners,

v.

JAMES SIRACUSANO, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR PROFESSORS AT LAW AND BUSINESS SCHOOLS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Will the application of a test of statistical significance to adverse event reports for widely distributed drugs result in a bright-line test for materiality of a kind that is inconsistent with the analytical framework set out in *TSC Indus. v. Northway*, 426 U.S. 438 (1976) and *Basic v. Levinson,* 485 U.S. 224 (1988)?

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INTEREST OF *AMICI CURIAE*[1]

Amici are scholars at American law and business schools whose research and teaching focus on federal securities regulation and the governance of public corporations.[2] Many have written on the antifraud provisions under the federal securities laws and some were cited in *Basic v. Levinson*, 485 U.S. 224 (1988), a seminal case on the subject.[3]

Amici have no financial stake in the outcome of this litigation but are interested in ensuring an accurate interpretation of the standard for materiality under the antifraud provisions of the federal

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[1] This brief was not authored, in whole or in part, by counsel for either party, and no person other than *amici* and their academic institutions contributed monetarily to the preparation or submission of this brief. This amicus brief is filed pursuant to the blanket consent executed by both parties and filed with this Court (by Respondents on July 28, 2010 and by Petitioner on July 30, 2010).

[2] The authors on the cover of this brief also drafted an amicus brief filed in *Merck & Co. v. Reynolds,* 130 S. Ct. 1784 (2010). *See Brief of Amici Curiae Faculty at Law and Business Schools in Support of Respondents, Merck & Co. v. Reynolds*, No. 08-905, Oct. 26, 2009.

[3] *See Basic*, 485 U.S., at 235 n.12 (*citing* Brown, *Corporate Secrecy, the Federal Securities Laws, and the Disclosure of Ongoing Negotiations*, 36 CATH. U. L. REV. 93, 145-155 (1986)); *Id*. at 246 n.24 (*citing* Dennis, *Materiality and the Efficient Capital Market Model: A Recipe for the Total Mix*, 25 WM. & MARY L. REV. 373, 374-381, and n.1 (1984)); *Id*. at 247 n.26 & 256 (*citing* Black*, Fraud on the Market: A Criticism of Dispensing with Reliance, Requirements in Certain Open Market Transactions*, 62 N.C. L. REV. 435 (1984)).

securities laws. It is the view of those on this brief that the application of a test of statistical significance to adverse event reports will result in a bright-line test for materiality that is inconsistent with the analytical framework first set out in *TSC Indus. v. Northway*, 426 U.S. 438 (1976) and directly contradicts this Court's reasoning in *Basic*.[4]

SUMMARY OF ARGUMENT

This case seeks a *sub silentio* reversal of *Basic* and the imposition of a test that is fundamentally inconsistent with the reasoning in *Northway*.

Petitioners challenge the materiality of quantitative data that allegedly shows an association between Zicam Cold Remedy ("Zicam") and anosmia, the loss of smell. They argue for a bright-line test that requires proof of "statistical significance" as a precondition for any determination of materiality. Under the proposed formulation, plaintiffs would need to "at least plead facts establishing that the rate of reported adverse incidents among product users exceeded the relevant background rate by a statistically significant degree." *Brief for Petitioners*, *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156), at 33. The

[4] In addition to those scholars listed on the front page of the brief, a full list of *amici*, who joined this brief as individuals and not representatives of any institutions with which they are affiliated, is set forth in the Appendix.

approach conflicts with the analytical framework for materiality set out by this Court in *Northway* and directly contradicts the reasoning in *Basic*.

Petitioners seek to avoid this conflict by disclaiming the bright-line nature of the test and asserting that it does not artificially exclude information but merely "*defines* the information a reasonable investor would consider relevant. . . ." Pet. Br. 43. The attempted distinction is unavailing. As with the agreement-in-principle test rejected by this Court in *Basic*, Petitioner's formulation would result in the imposition of an underinclusive test that arbitrarily excludes information important to reasonable investors.

Petitioners do not and cannot establish that investors will only find reports important upon a showing of a statistical significance. Moreover, the approach is inconsistent with assumptions underlying this Court's use of a "total mix" analysis. Statistical significance assumes away, at least in the first instance, any contextual examination of the available information and presupposes that the market singularly relies on the presence or absence of a mathematically validated association between the drug and the adverse events at issue. The approach treats investors – whether analysts, institutional owners, or market professionals – as "nitwits unable to appreciate" the importance of any other information that could affect investment decisions. *Basic*, 485 U.S. at 234 (*quoting Flamm v. Eberstadt,* 814 F.2d 1169, 1175 (7th Cir.), *cert. denied*, 484 U.S. 853 (1987)).

Even if investors can be said to require evidence of an association between a drug and adverse health effect, statistical significance is not the only method of establishing the requisite relationship. The quantitative approach proposed by Petitioners does not take into account reports from scientifically valid studies that, while not statistically significant, nonetheless provide evidence of biological significance. The test also would render immaterial reports arising out of, or supported by, observational studies that, while not statistically significant, nonetheless represent reliable methods of demonstrating an association between the drug's administration and serious health effects. Indeed, not even the Food and Drug Administration ("FDA") or manufacturers will always wait for statistical significance before taking action with respect to drug safety.

Nor has the case been made that there is a need for a bright-line test in these circumstances. *Northway* created the analytical template for addressing the materiality of factual misstatements or omissions under the antifraud provisions of the federal securities laws. Information is material if there is a substantial likelihood it would be important to a reasonable investor in making an investment decision or if there is a substantial likelihood that the information would, if disclosed, significantly impact the total mix of available information. The test is fact specific and eschews reliance on bright-line tests.

The materiality standard first set forth in *Northway* has proved sufficiently robust to allow courts to resolve the materiality of quantitative thresholds such as misstatements in earnings or the number of adverse event reports. Quantitative information is typically only a starting point for the analysis of materiality and must be considered in light of all other factors that could render the extant information important to reasonable investors. The Securities and Exchange Commission has likewise rejected numerical cut offs and bright-line tests and instructed that the analysis take into consideration "all the relevant circumstances. . . ." *See* SEC Staff Accounting Bulletin No. 99 (August 12, 1999). Courts have successfully used this approach in resolving the materiality of adverse event reports.

A fact intensive analysis does not impose an unfair burden on manufacturers and will not result in excessive, unfiltered disclosure to investors. *Northway* resolved the concern over an "avalanche of trivial information" by rejecting an approach to materiality that encompassed what "might" be important to a reasonable investor in favor of a "would" and "actual significance" standard. The standard does not, therefore, impose on manufacturers an obligation to disclose all adverse effect reports. In many instances, the reports will be immaterial, either because the health effects are not serious, earnings from the drug are not material, or the reports have no other significance and are merely cumulative.

Rejection of the test of statistical significance will also not provide manufacturers with "a strong incentive simply to disclose all" reports. Pet. Br. 29. Lower courts already routinely apply the *Northway* standard in determining the materiality of adverse event reports. This has not resulted in manufacturers making all such reports available to the public. Reaffirming the longstanding standard set out in *Northway* will leave the law unaltered and not necessitate any change in existing disclosure practices by manufacturers.

Likewise, even if voluntary disclosure of adverse event reports does occur, the case has not been made that this will harm investors. *Northway* did recognize that excessive disclosure could, in some instances, interfere with informed decision making. *See* 426 U.S. at 448-49. But the concern arose in the context of a proxy solicitation. In those circumstances, shareholders are asked to make an informed decision based upon the information included within the materials distributed to them by the company. Including excessive amounts of unrelated information within the proxy materials could make the decision making process more difficult.

This case, however, involves disclosure to the market, not to shareholders. Market disclosure typically occurs through press releases, SEC filings, or postings on the Internet. The information is not sent directly to shareholders but is available to, and filtered by, analysts and other market professionals who have an economic incentive to accurately reflect

the information in share prices. Any safety data revealed by manufacturers will undergo the same filtering process, presumably improving the efficiency of share prices. Consistent with this approach, Congress has encouraged the Securities and Exchange Commission to develop a system of real-time disclosure for public companies.

In any event, the possibility of harm resulting from disclosure is not, as *Basic* reminds, appropriately resolved under the rubric of materiality. This concern is better addressed in the context of the duty to disclose. As this Court has noted often, silence absent a duty to disclose does not violate the antifraud provisions.

The traditional fact intensive approach set out in *Northway* and reiterated in *Basic* provides an appropriate framework for resolving the materiality issue in this case. The FDA and courts have relied on a number of factors in resolving drug safety issues, many present here.

The Complaint contains allegations of reports from health care professionals and lawyers (in the form of lawsuits) received by Matrixx Initiatives Inc. ("Matrixx" or the "Company") of patients suffering from anosmia after the use of Zicam.

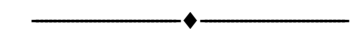
The reports of Zicam's potential threat to health, however, represent only a starting point in assessing the importance of the information to reasonable investors. Other factors that require consideration include: (1) the "rare" nature of the condition; (2) temporal

connections between Zicam and the loss of smell; (3) the fact that, as an over-the-counter homeopathic drug, Zicam was not required to undergo the same rigorous testing required for new drugs approved by the FDA and did not, therefore, have a safety profile approved by the FDA; (4) the existence of scientific studies that link zinc to a loss of smell; (5) the sources of the reports, particularly those submitted by professionals from the University of Colorado Health Sciences Center; (6) awareness of research conducted by health care professionals from the University of Colorado Health Sciences Center raising concerns about the association between Zicam and loss of smell; (7) the response by Matrixx to the reports, including, in 2002, the retention of a consultant to review the product and consideration of animal testing and, in 2004, the convocation of a two-day conference "of physicians and scientists to review current information on smell disorders," Compl. ¶45; and (8) a decline in share prices when an article appeared in the Dow Jones Newswire on Jan. 30, 2004, reporting that the FDA was looking into complaints that "an over-the-counter common-cold medicine manufactured by" Matrixx may cause "some users to lose their sense of smell," Compl., at ¶¶40, 41, and again following a report on Feb. 6, 2004, on *Good Morning America*, about "the connection between Matrixx's zinc gluconate and anosmia." Compl., at ¶¶42, 43.

To impose a requirement that reports must be statistically significant overlooks the central question

in determining materiality: whether it is substantially likely that a reasonable investor would consider the omitted or misstated facts to have significantly altered the total mix of available information. The information need not have produced a different outcome but only have assumed "actual significance" in the deliberative process. The analysis is, as *Northway* rightfully recognized, a subtle one that requires a "delicate assessment of the inferences" in the context of all factors that could render the information important to a reasonable investor. This cannot be done through resort to a single test or factor. It is a standard that has functioned effectively for more than three decades.

To the extent that there is a need for clarity in this area, the matter is better left to the SEC, where the complexities attendant with the adoption of a materiality standard incorporating statistical significance can better be addressed. At least in the first instance, administrative agencies have the expertise to frame the salient issues and clarify the standards for interpreting the statutes that Congress has charged them to enforce. Indeed, here, the administrative agency promulgated the regulation that is the subject of the parties' dispute, Rule 10b-5. 17 C.F.R. § 240.10b-5.



ARGUMENT

I. The Use of Statistical Significance as a Bright-line Test for Determining Materiality Is Inconsistent with the Analytical Framework Set Out By This Court in *Northway* and Conflicts with the Reasoning in *Basic*

This Court developed the standard for materiality under the federal securities laws in two seminal cases, *Northway* and *Basic*. *Northway*, a case brought under the proxy rules, set out the common formula. Information is material if there is a substantial likelihood it would be important to a reasonable investor in making an investment decision or if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Northway*, 426 U.S. at 449. *Northway* emphasized the fact intensive and subtle nature of the analysis. *Id*. at 450 (determination requires "delicate assessments of the inferences" that are to be drawn "from a given set of facts").

More than a decade later, this Court in *Basic* reiterated the fact intensive formulation and extended the approach to actions brought under Rule 10b-5. 17 C.F.R. § 240.10b-5. *Basic* considered and rejected the use of a bright-line test for the disclosure of merger negotiations. As the Court reasoned, "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific

finding such as materiality, must necessarily be over- or underinclusive." *Basic*, 485 U.S. at 236.

Efforts to impose a bright-line test of statistical significance in this case raise the same concerns addressed in *Basic*. Petitioners would require plaintiffs to "at least plead facts establishing that the rate of reported adverse incidents among product users exceeded the relevant background rate by a statistically significant degree." Pet. Br. 33. Under the proposed formulation, statistical significance is a necessary, but not always sufficient, condition for determining materiality.[5] The approach, therefore, replaces a fact intensive analysis with a "single fact or occurrence" that results in an underinclusive test for determining materiality.

Petitioners seek to avoid the conflict with *Northway* and *Basic* by asserting that statistical significance does not artificially exclude information but instead "*defines* the information a reasonable investor would consider relevant . . . " Pet. Br. 44. Petitioners do not and cannot establish that investors will only find reports important upon a showing of a statistical significance.[6] Moreover, the approach is inconsistent

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[5] Petitioners assert that while necessary, statistical significance may not be sufficient. *See* Pet. Br. 33 n.15.

[6] *See* Stephen M. Bainbridge & G. Mitu Gulati, *How do Judges Maximize? (The Same Way Everybody Else Does – Boundedly): Rules of Thumb in Securities Fraud Opinions*, 51 EMORY L.J. 83, 151 n.115 (2000) ("[T]he claim is that investors do not think that information is material until it is statistically

(Continued on following page)

with assumptions underlying this Court's use of a "total mix" analysis. Statistical significance assumes away, at least in the first instance, any contextual examination of the available information and presupposes that the market singularly relies on the presence or absence of a mathematically validated association between the drug and the adverse events at issue. The approach treats investors – whether analysts, institutional owners, or market professionals – as "nitwits unable to appreciate" the importance of any other information that could affect investment decisions. *Basic*, 485 U.S. at 234 (*quoting Flamm v. Eberstadt,* 814 F.2d 1169, 1175 (7th Cir.), *cert. denied*, 484 U.S. 853 (1987)).

Even if investors can be said to require evidence of an association between a drug and adverse health effect, statistical significance is not the only method

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significant. Even if this is correct, how do the courts know of this magical relationship between statistical significance and investor interest. . . ."). Courts in other contexts are moving away from, not toward, reliance on statistical significance as a necessary metric when determining, for example, the admissibility of epidemiological studies. *See, e.g.*, *Cook v. Rockwell Int'l Corp*., 580 F. Supp. 2d 1071, 1102 (D. Colo. 2006) ("there is a considerable dispute in the scientific community about the necessity or even relevance of statistical significance testing to epidemiological studies."). As Judge Posner has noted in criticizing excessive reliance on statistical significance, "[l]itigation generally is not fussy about evidence; much eyewitness and other nonquantitative evidence is subject to significant possibility of error, yet no effort is made to exclude it if it doesn't satisfy some counterpart to the 5 percent significance test." *Kadas v. MCI Systemhouse Corp.*, 255 F.3d 359, 362 (7th Cir. 2001).

of establishing the requisite relationship. The quantitative approach proposed by Petitioners does not take into account reports from scientifically valid studies that, while not statistically significant, nonetheless provide evidence of biological significance.[7] The test also would render immaterial reports arising out of, or supported by, observational studies that, while not statistically significant, nonetheless are reliable methods of demonstrating an association between the drug's administration and serious health effects.[8]

Statistical significance would also impose on investors a standard higher than that used by regulators and manufacturers in resolving drug safety issues. The FDA and manufacturers will not always wait for a statistically significant number of adverse event reports before taking action with respect to drug safety. They may do so, for example, where underreporting makes it difficult if not impossible to determine the number of occurrences in the population of drug

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[7] *See* Erica Beecher-Monas, *The Heuristics of Intellectual Due Process: A Primer for Triers of Science*, 75 N.Y.U. L. REV. 1563, 1603 (2000).

[8] *See Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, GAO-06-402, at 7 n.11 (March 2006) ("*Drug Safety*") ("Observational studies can provide information about the association between certain drug exposures and adverse events."); *see also Reference Manual on Scientific Evidence, Second Edition,* Federal Judicial Center, at 359 (studies "with small sample sizes may find a high relative risk but still not be statistically significant.").

users.[9] Thus, in *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998), Felbatol was taken off the market after the manufacturers learned of ten cases of aplastic anemia. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc.*, 537 F.3d 35 (1st Cir. 2008), the manufacturer withdrew Tysabri, a drug designed to treat autoimmune diseases, from the market after learning that two patients in the clinical trials had contracted progressive multifocal leukoencephalopathy.[10]

Requiring statistical significance as a necessary condition for determining materiality will result in the application of a rigid test that ignores all other

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[9] *See The Adequacy of FDA to Assure the Safety of the Drug Supply: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 110th Cong., 1st Sess. 85, 88 (2007) (statement of Steven E. Nissen, Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic, and President of the American College of Cardiology ("Adverse event reporting is voluntary and studies show that only 1 to 10 percent of serious adverse events are ever reported to the Agency. Accordingly, the actual incidence of serious or life-threatened complications cannot be calculated accurately."); *see also* Barbara A. Noah, *Adverse Drug Reactions in Elderly Patients: Alternative Approaches to Postmarket Surveillance*, Vol. 33, No. 3, J. Health L. 383 (Summer 2000) ("Because the spontaneous reporting numerator represents only a tiny fraction of the actual number of ADRs, it remains difficult to accurately estimate the incidence of safety problems with many prescription drugs.").

[10] *See also In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 210 (S.D. N.Y. 2008) (plaintiffs did not allege that development of progressive multifocal leukoencephalopathy by one to two patients using Tysabri was statistically significant).

information within the "total mix." In the absence of statistical significance, the test would result in the exclusion of medical, biological and observational evidence of an association between a drug and an adverse health effect. The same evidence used by the FDA or manufacturers in resolving drug safety issues would, if not dependent upon a statistically significant number of reports, be treated as if immaterial as a matter of law. Materiality would be reduced to a rote and arbitrary calculation whereby reports of serious health effects, even death, only became material upon receipt of a single or small number of reports that tipped the balance and caused the data to cross the threshold of statistical significance.[11]

II. The Fact Intensive Approach Adopted by This Court in *Northway* Has Proved Sufficiently Robust to Resolve the Materiality of Quantitative Information, Including Adverse Event Reports

In rejecting the use of the bright-line test at issue in *Basic*, this Court left in place a fact intensive analysis for determining materiality. The approach has

[11] *See* Stephen T. Ziliak and Deirdre N. McCloskey, THE CULT OF STATISTICAL SIGNIFICANCE, 28-29 (U. Mich. Press 2008) (five heart attacks by users of Vioxx not statistically significant and therefore treated as having "[no] significance, no risk to the heart" while eight heart attacks met standard of statistical significance).

proved sufficiently robust to resolve the materiality of quantitative data, including adverse event reports. Courts applying the fact intensive approach use the amount of the misstatement or the number of reports as a starting point. They then consider all other factors that have a bearing on the importance of the information to reasonable investors.

A. Quantitative Data Represents at Most a Starting Point for the Analysis of Materiality that Must Be Considered in Light of All Other Factors that Could Render the Information Important to Reasonable Investors

Courts have relied on the fact intensive analysis required by *Northway* and *Basic* to resolve the materiality of quantitative data such as earnings misstatements. Rejecting bright-line tests, they have characterized the amount of the misstatement as merely the starting point for the analysis. The quantitative data must be considered in light of all other factors that bear upon the importance of the information to reasonable investors. *See ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 204 (2d Cir. 2009) (noting that the numerical threshold at issue was "a good starting place for assessing" materiality and that analysis required consideration of "qualitative factors that might contribute to a finding of materiality."); *Ganino v. Citizen Utils. Co.*, 228 F.3d 154, 164 (2d Cir. 2000) (rejecting application of a "bright-line test for

materiality" in context of alleged misstatement of earnings in favor of test requiring consideration of "all relevant circumstances."); *Gebhardt v. ConAgra Foods, Inc.*, 335 F.3d 824, 829 (8th Cir. 2003) (materiality of quantitative information must be considered in light of all "particular circumstances").

Thus, for example, the court in *In re Westinghouse Sec. Litig.*, 90 F.3d 696 (3d Cir. 1996) (Alito, J.), confronted allegations that misstatements concerning loan loss reserves and non-earning loans were immaterial as a matter of law. Although finding the alleged misstatement to be immaterial, the court expressly rebuffed the attempt to impose a bright-line test.

> [W]e also reject defendants' similarly categorical assertion that materiality must be quantified at a specified percentage of income or assets. Although "a 'rule of thumb' of 5-10 percent of net income is widely used as a general materiality criterion" in the accounting profession, . . . the question of materiality must be considered on a case-by-case basis under the standards set forth in *T.S.C. Industries* and our cases.

In re Westinghouse Sec. Litig., 90 F.3d at 714 n.14.

Likewise, the SEC relies on a fact intensive approach in determining materiality in the context of earnings misstatements. In Staff Accounting Bulletin 99 (1999) ("SAB 99"), the staff of the Commission

criticized the use by market professionals of quantitative thresholds for determining materiality.[12] SAB 99 acknowledged the appropriateness of "rules of thumb" as "an initial step in assessing materiality" but concluded that these thresholds cannot "appropriately be used as a substitute for a full analysis of all relevant considerations." *Id.* Instead, materiality requires consideration of other factors, whether, for example, the misstatement shifts a loss to a profit or masks a trend in earnings, that could render the information important to reasonable investors.

Using the fact intensive approach, courts have found small quantitative thresholds to be material when considered in conjunction with other relevant factors. *See United States v. Nacchio*, 519 F.3d 1140, 1162 (10th Cir. 2008), *rev'd on other grounds*, 555 F.3d 1234 (10th Cir. 2009), *cert. denied*, 130 S. Ct. 54 (2009) (jury could find that 4.2% shortfall in revenue was material based on arguments that "the shortfall had particular salience given the state of the economy and the industry"); *SEC v. Thielbar*, 2008 U.S. Dist.

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[12] While SAB 99 represents the views of the staff, the Commission has recognized the need to consider qualitative factors when determining the materiality of quantitative elements. *See In re AIG*, Exchange Act Release No. 48477 (admin. proc. Sept. 11, 2003) ("Materiality judgments involve both quantitative and qualitative considerations."); *see also* Speech by Arthur Levitt, Chairman, U.S. Securities and Exchange Commission, *The Numbers Game* (Sept. 28, 1998) ("Materiality is not a bright line cutoff of three or five percent. It requires consideration of all relevant factors that could impact an investor's decision.").

LEXIS 73906, *20-21 (D. S.D. 2008) (alleged misstatements as low as 1.97% and 1.10% of net income not immaterial as matter of law where company "was closely watched by analysts and investors alike" and net income preceding securities offering "would very likely influence the price at which these shares may sell"); *see also In re MBIA, Inc. Sec. Litig.*, 700 F. Supp. 2d 566, 584-85 (S.D. N.Y. 2010) (financial products were material to portfolio "even though [products] represented one percent of the $ 652 billion insured portfolio" where plaintiffs alleged that losses from these products "could significantly affect MBIA's triple-A ratings and creditworthiness").

Other courts have found similar thresholds to be immaterial in the absence of factors that would otherwise render the information important to reasonable investors. *See Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 547 (8th Cir. 1997) (2% overstatement of assets immaterial because a small increase in risk in a high-risk/high-yield company would not have a significant effect upon investor expectations); *Glassman v. Computervision Corp.*, 90 F.3d 617, 633 n.26 (1st Cir. 1996) (omission of information regarding 3% to 9% difference in backlog from quarter to quarter not material where variable had "minor predictive value" and "disclosure of a rough estimate of that variable's value can obviate the need for more specific disclosure").

The fact intensive framework set out in *Northway* and *Basic* has proved adequate to resolve the materiality of quantitative thresholds. Moreover,

despite the rejection of a bright-line approach, lower courts have acted as effective gatekeepers, eliminating on motions to dismiss those cases involving low quantitative thresholds that were otherwise unsupported by other factors demonstrating their importance to reasonable investors.

B. The Number of Adverse Event Reports Is at Most a Starting Point in Determining Materiality and Requires Consideration of All Other Factors that Could Render the Information Important to a Reasonable Investor

Courts addressing the materiality of drug safety data have applied the same fact intensive analysis set out in *Northway* and *Basic*. As with misstatements in earnings, the number of adverse event reports represents a starting place for analyzing materiality. The reports must be examined in light of all other factors that would render the information important to reasonable investors.

Carter-Wallace and *Oran v. Stafford,* 226 F.3d 275 (3d Cir. 2000), are not to the contrary. In *Carter-Wallace*, plaintiffs asserted that Felbatol, a drug used to treat epilepsy, caused aplastic anemia. The drug had "survived the extensive testing process" required by the FDA. *In re Carter-Wallace, Inc., Sec. Litig*., 220 F.3d 36, 42 (2d Cir. 2000). From October 1993 to July 1994, Carter-Wallace received 57 adverse event reports, only six of which involved aplastic anemia. *See id*. at 38, 40.

The evidence of a connection between Felbatol and aplastic anemia was largely limited to six reports spread out over a nine month period for a thoroughly tested drug. In the absence of other factors suggesting a relationship between the drug and the adverse health condition, the court was left with little more than the quantity of the reports. In those circumstances, the quantitative data could only be material if, standing alone, it demonstrated a sufficient relationship between Felbatol and aplastic anemia. Such a relationship, according to the court, required evidence of statistical significance.

The opinion did not, however, treat statistical significance as the exclusive method of establishing materiality. Indeed, as the court subsequently noted, the issue was not statistical significance per se but whether the alleged facts showed a sufficient "connection" between the drug and the reported health effect. *See id*. at 42. Nothing in the opinion suggested that other factors bearing on the relationship between a drug and adverse effect report were entirely supplanted by a test of statistical significance.[13]

[13] Had the court in *Carter-Wallace* intended to adopt a bright-line standard for materiality, it presumably would have sought to reconcile the approach with the reasoning in *Basic*. The case contains no such discussion or analysis. Moreover, at least one subsequent Second Circuit decision explicitly rejected application of bright-line test for materiality in the context of quantitative information. *See Ganino*, 228 F.3d at 154.

Similarly, in *Oran*, the court did not hold that the materiality of adverse event reports could only be determined through resort to statistical significance. In that case, the manufacturer of fen-phen disclosed reports from cardiologists with the Mayo Clinic and MeritCare Health Systems (Mayo data) that revealed incidents of heart valve abnormalities in users of fen-phen. The manufacturer described the evidence of any causal connection between fen-phen and heart valve abnormalities as "inconclusive." *Oran*, 226 F.3d at 283. The statement informed the market of the possibility of an association, the seriousness of the condition, the source of the reports, and the non-definitive nature of the evidence.

In considering whether the manufacturer also had an obligation to disclose other, earlier reports that contained much of the same information, the court characterized them as merely cumulative, something that had they been disclosed would have "led a reasonable investor to the same conclusion – that the relationship between the two drugs and heart valve disorders was still inconclusive." *Id*. at 284. The undisclosed reports, therefore, merely restated what the market already knew. With the plaintiffs unable to explain how the reports "would have added anything to the disclosures already made," materiality depended entirely on the number of reports. *Id*. at 284. In those circumstances, the court required a showing of statistical significance.

Oran did not restrict the definition of materiality but expanded it. The opinion clarified that adverse

event reports, standing alone, could be material, even absent other factors, upon a showing of statistical significance. What the court did not do was hold that statistical significance was the exclusive test for determining the materiality of adverse event reports. It applied a test of statistical significance only after observing that plaintiffs had presented no other basis for a finding of materiality. Indeed, the opinion did not rely on statistical significance in determining the materiality of other adverse event reports at issue in the case. *Id*. at 283 (Mayo data immaterial not because of lack of statistical significance but because of absence of a "negative effect on the company's stock price").

Both *Carter-Wallace* and *Oran* agree that adverse reports, standing alone, can be material if statistically significant. They do not, and lower courts have not read them to, impose a bright-line test that otherwise dispenses with the fact intensive analysis set out in *Northway* and *Basic*. *See In re Medtronic Inc., Sec. Litig.*, 618 F. Supp. 2d 1016, 1024 (D. Minn. 2009) ("[s]tatistical significance, however, is not a bright-line rule because materiality 'is a flexible, fact-based determination.'") (*quoting In re Bayer AG Sec. Litig*., 2004 U.S. Dist. LEXIS 19593, *27 (S.D. N.Y. Sept. 30, 2004)); *Twinde v. Threshold Pharms., Inc*., 2008 U.S. Dist. LEXIS 58619, *35 (N.D. Cal. 2008) (noting that "statistically significant test results are conclusive" but that "non-statistically significant [serious adverse events] together with other evidence" can be material); *accord*, *In re Elan Corp. Sec. Litig*.,

543 F. Supp. 2d 187, 210 (S.D. N.Y. 2008); *In re Bausch & Lomb, Inc. Sec. Litig*., 592 F. Supp. 2d 323, 350 (W.D. N.Y. 2008); *In re Pfizer, Inc. Sec. Litig*., 584 F. Supp. 2d 621, 636 (S.D. N.Y. 2008).

Courts, then, have applied the fact intensive approach to resolve the materiality of adverse event reports. The number of reports may represent a starting place for the analysis but must be considered in the context of all other factors that render the information important to reasonable investors.

III. Application of the Fact Intensive Analysis Will Not Impose an Excessive Disclosure Burden on Manufacturers or Result in the Inundation of Investors with Excessive and Unfiltered Information

A fact intensive analysis does not impose an unfair burden on manufacturers and will not result in excessive, unfiltered disclosure to investors.

To be sure, *Northway* expressed concern with a standard that could generate an "avalanche of trivial information. . . ." 426 U.S. at 448. The concern, however, arose in the context of a test that sought to extend the definition of materiality to information that "might" be important to a reasonable investor. This Court addressed that matter by rejecting the formulation in favor of a "would" and "actual significance" test. As *Basic* noted, this standard effectively filtered out the "essentially useless information that a reasonable investor would not consider significant,

even as part of a larger 'mix' of factors to consider in making his investment decision." *Basic*, 485 U.S. at 234.

The standard does not, therefore, impose on manufacturers an obligation to disclose all adverse effect reports. Such an assertion conflates the need to inform the market of health risks with the obligation to reveal every report. In many instances, the reports will be immaterial, either because the effects are not serious, earnings from the drug are not material, or the reports have no other significance and are merely cumulative. *See Oran*, 226 F.3d at 284.

Rejection of the test of statistical significance will also not provide manufacturers with "a strong incentive simply to disclose all" reports. Pet. Br. 29. Lower courts already routinely apply the *Northway* standard in determining the materiality of adverse event reports. This has not resulted in manufacturers making all such reports available to the public. Reaffirming the longstanding standard set out in *Northway* will leave the law unaltered and not necessitate any change in existing disclosure practices by manufacturers.

Likewise, even if voluntary disclosure of adverse event reports does occur, the case has not been made that this will harm investors. *Northway* did recognize that excessive disclosure could, in some instances, interfere with informed decision making. *See* 426 U.S. at 448-49. But the concern arose in context of a proxy solicitation. In those circumstances, shareholders are

asked to make an informed decision based upon the information included within the materials distributed to them by the company. *See* J. Robert Brown, Jr., Chapter 5: Materiality, THE REGULATION OF CORPORATE DISCLOSURE, at pp. 5-22.1 – 5-26 (Aspen Business, 3d ed. 2009). Including excessive amounts of unrelated information within the proxy materials could potentially interfere with the decision making process.

This case, however, involves disclosure to the market, not to shareholders. Market disclosure typically occurs through press releases, SEC filings, or postings on the Internet. *See Commission Guidance on the Use of Company Web Sites*, Exchange Act Release No. 58288 (Aug. 7, 2008) (providing guidance on the use of web sites to meet requirements under, among other things, the antifraud provisions of the federal securities laws). The information is not sent directly to shareholders but is available to, and filtered by, analysts and other market professionals who have an economic incentive to accurately reflect the information in share prices. *See* THE REGULATION OF CORPORATE DISCLOSURE, pp. 8-5 – 8-6. The safety data disclosed by manufacturers will undergo the same filtering process, presumably improving the efficiency of share prices. Consistent with this approach, Congress has encouraged the Securities and

Exchange Commission to develop a system of real-time disclosure for public companies.[14]

In any event, the possibility of harm resulting from disclosure is not, as *Basic* reminds, appropriately resolved under the rubric of materiality. This concern is better addressed in the context of the duty to disclose. 485 U.S. at 235. As this Court has noted often, silence absent a duty to disclose does not violate the antifraud provisions. *See Chiarella v. United States*, 445 U.S. 222, 230 (1980); *Basic*, 485 U.S. at 239 n.17; *see also Oran*, 226 F.3d at 285 ("Even non-disclosure of material information, e.g., deaths connected to a drug, will not give rise to liability under Rule 10b-5 unless the defendant had an affirmative duty to disclose that information.").[15]

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[14] *See* Section 409, Corporate and Criminal Fraud Accountability Act of 2002 (Sarbanes-Oxley), Pub. L. No. 107-204, 116 Stat. 745 (July 30, 2002) (amending Section 13 of the Securities Exchange Act to allow SEC to require real time disclosure of "material changes in the financial condition or operations of the issuer"). Indeed, some have called for increased disclosure of adverse health information. *See* James M. Wood & Roxanne M. Gariby, *Hoarding Away Science: Towards a More Transparent View of Health and Online Registries for Independent Postmarket Drug Research*, 60 FOOD & DRUG L.J. 547, 555-556 (2005) ("Online transparency of all results, clinical and post-market, regardless of the source, achieves the goal of not only identifying all information about the safety and efficacy of a prescription medicine, but also would have the additional benefit of preventing unnecessary and costly duplication of research.").

[15] The argument that over-disclosure will occur because of concern about liability under the antifraud provisions of the

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Finally, the test of statistical significance also will not provide the benefits ordinarily associated with a bright-line test. Some courts characterize the test as a factual question. *See Pfizer,* 584 F. Supp. 2d at 635-36 ("[T]he Court cannot determine as a matter of law whether such links were statistically insignificant because statistical significance is a question of fact."); *accord*, *City of Livonia Employees' Ret. Sys. v. Wyeth*, 2010 U.S. Dist. LEXIS 107729, *19 (S.D. N.Y. 2010); *see also Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co*., 2004 U.S. Dist. LEXIS 10730, *21 (D. Del. 2004) ("Statistical significance . . . is a question of fact for the jury as it is an issue of evidentiary weight"), *vacated in part on other grounds*, 425 F.3d 1366 (Fed. Cir. 2005); *Cook v. Rockwell*, 580 F. Supp. 2d 1071, 1102-03 (D. Colo. 2006) ("statistical significance or insignificance of [epidemiologist's] results may affect the weight given to his testimony, but does not determine its admissibility under Rule

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federal securities laws is not supported by the trend in the number of securities class action lawsuits. The number is falling. In 2009, filings dropped to the second lowest number since 1997 when comprehensive statistics were first maintained. *See Securities Class Action Clearinghouse* (168 securities class action lawsuits filed in 2009). This was true despite arguably auspicious circumstances for such suits, including the financial crisis and significant drop in share prices. *See Report of the New York Stock Exchange Commission on Corporate Governance*, September 23, 2010, at 11 ("At its nadir, the Dow Jones Industrial Average hit a 12-year low of approximately 6,600 in March 2009"). Moreover, the decline has continued in 2010. *See Securities Class Action Clearinghouse* (148 securities class action law suits) (last update: Nov. 8, 2010).

702."). Thus, while effectively eliminating information important to reasonable investors, the uncertainty of the test will itself generate legal challenges. *See In re Nuvelo, Inc.*, 668 F. Supp. 2d 1217, 1230 (N.D. Cal. 2009).

Application of a fact intensive analysis in determining the materiality of adverse event reports will not result in untoward harm to investors or manufacturers. Moreover, to the extent manufacturers opt to disclose all such reports to the market, the information will be filtered through analysts and market professionals and presumably result in more efficient share prices.

IV. Application of a Fact Intensive Analysis in this Case Creates a Factual Question as to the Materiality of the Association Between Zicam and Anosmia

In applying a fact intensive analysis to adverse event reports, courts and the FDA have relied on a variety of factors when assessing the importance of the information. A non-exclusive list of factors might include:

1. The nature and rarity of the condition reported;[16]

[16] *Drug Safety, supra* note 8, at 25 n.44.

2. The person or source originating the adverse event reports, with particular weight given to those submitted by health care professionals;[17]

3. The existence of scientific literature supporting the possibility of an association;[18]

4. A temporal association between the administration of the drug and the onset of the adverse event;[19]

5. A significant change in the rate of adverse event reports;[20]

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[17] *Reporting Adverse Drug and Medical Device Events*, Council of Ethical & Judicial Affairs Report B – A-93 (1993) (CEJA Report B – A-93), *reprinted in* American Med. Ass'n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 FOOD & DRUG L.J. 359, 362 (1994) (discussing the importance of reports from physicians and noting that the "impact of physicians' reports is reflected in the observation that although they constitute only a fraction of reports received, physicians' reports account for a much greater proportion of labeling changes.").

[18] *See* Lance L. Shea, Andre Hanson, Tiffany M. Guglielmetti, and Kimberly Levy, *Cause and Effect? Assessing Postmarketing Safety Studies as Evidence of Causation in Products Liability Cases*, 62 FOOD & DRUG L.J. 445, 447 (2007) ("FDA scientists have access to the world's peer-reviewed, published literature, which they review to assess for postmarketing safety issues.") (*Cause and Effect*).

[19] *See Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 932 (8th Cir. 2001) ("Under some circumstances, a strong temporal connection is powerful evidence of causation.").

[20] *See Cause and Effect*, *supra* note 18, at 446 ("FDA evaluates spontaneous reporting data from the AERS to identify

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6. The internal reaction of the manufacturer to the adverse event reports;[21]

7. The number of adverse event reports for other drugs used for the same or similar treatment;[22]

8. The existence of other studies, including observational, epistemological, or controlled studies, that have a bearing on the safety of the drug at issue;[23]

9. The existing safety profile of the drug;[24]

10. Concerns raised by the FDA;[25]

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any serious, rare or unexpected adverse events, or an increased incidence of events.").

[21] *See In re Bayer AG Sec. Litig*., 2004 U.S. Dist. LEXIS 19593, *28-29 (S.D. N.Y. 2004) (adverse reports caused company executives to question viability of drug).

[22] *See* Warning Letter, from Deborah M. Autor, Esq., Director, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, to William J. Hemelt, Acting President, CFO and COO, Matrixx Initiatives, Inc., June 16, 2009 ("By comparison, FDA has received few reports of anosmia associated with other widely-used intranasal products for treatment of the common cold that are marketed subject to approved NDAs or according to an OTC drug monograph.") ("Matrixx Warning Letter").

[23] *See Drug Safety, supra* note 8, at 4, 6-7.

[24] *See In re Carter-Wallace Sec. Litig.*, 220 F.3d at 37 (noting "unprecedented safety profile" of FDA approved drug).

[25] *See In re Connetics Corp. Sec. Litig.,* 542 F. Supp. 2d 996, 1010 (N.D. Cal. 2008) (FDA's statement that drug had "possible carcinogenic effect" characterized as "significant and material").

11. Experiences in foreign markets;[26] and

12. A decline in share prices when the adverse event reports are made public.[27]

Multiple factors may appear in any given case and must be collectively weighed to determine whether the reports would be important to a reasonable investor.

In analyzing the factors in this case, the Complaint contains allegations of somewhere around 20 specific reports involving a loss of smell by users of Zicam. In addition, the Complaint alleges that Timothy L. Clarot, the Company's Vice President, Research and Development, stated that Matrixx had received "complaints from other customers who experienced a loss of smell following use of Zicam nasal gel" and that the complaints had occurred as early as 1999. *See* Compl. ¶26. Aware of these "complaints," Matrixx "hired a consultant to review the product" *id*. and considered undertaking "animal studies." Compl. ¶27.

The number of reports, however, represents only a starting point. The Complaint sets out other factors that must be considered in determining whether the

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[26] Jill D. Jacobson and David Feigal, *Red Sky in the Morning: Modifying Prescription Drug Labels as a Result of Postmarket Surveillance*, 62 FOOD & DRUG L.J. 529 (2007) ("Experiences in foreign countries also provide useful information.").

[27] *See Oran*, 226 F.3d at 283.

information would be important to a reasonable investor.

First, the reported condition, anosmia, is described as "rare." *See* Compl. ¶¶24, 64.

Second, the Complaint contains allegations of a temporal connection between the administration of Zicam and the loss of smell. An abstract for a presentation to the American Rhinologic Society described a patient who, upon the use of the drug, experienced an "immediate, severe burning" followed by a loss of smell. Compl. ¶28. Researchers further reported that there were a number of "other Zicam users with similar symptoms as of September of 2003." *Id*.

Third, Zicam is a homeopathic drug sold over the counter and, as such, was not, during the class period, required to submit to the rigorous safety testing mandated by the FDA for new drug applications. In describing statements that Zicam caused anosmia as "completely unfounded and misleading," Compl. ¶7, therefore, Matrixx was not relying on a determination by the FDA that the drug had an "'acceptable safety profile.'" *Oran*, 226 F.3d at 285. Matrixx did reveal that "the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials . . . " Compl. ¶38. Because clinical trials often have a relatively small number of subjects, they may

not be able to detect "rare" conditions.[28] As the lower court observed, Matrixx did not "state that any tests established that the application of zinc gluconate to the nose is safe." *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1178 n.6 (9th Cir. 2009).[29]

Fourth, the reports were supported by scientific studies linking zinc to a loss of smell. Although the studies involved zinc sulfate (*see* Compl. ¶26) and Zicam contained zinc gluconate (*see* Compl. ¶3), they apparently provided evidence of a possible biological basis for the requisite association.[30]

Fifth, the reports set out in the Complaint came from health care professionals and lawyers (in the form of litigation). One of the professionals, Dr. Alan Hirsch M.D., F.A.C.P., was the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd. Compl. ¶25.

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[28] CEJA Report B – A-93, *supra* note 17 ("in order to detect the difference between an adverse reaction incidence rate of $^1/_{5000}$ and $^1/_{10,000}$, some 306,000 patients would have to be observed, far more than any study could achieve.").

[29] Similarly, the Matrixx Warning Letter revealed that the FDA was "not aware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling." Matrixx Warning Letter, *supra* note 22.

[30] The Matrixx Warning Letter subsequently issued by the FDA acknowledged that "there is evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans." Matrixx Warning Letter, *supra* note 22.

Sixth, Matrixx learned about some of the reports of anosmia through research conducted by Dr. Bruce Jafek, Miriam R. Linschoten and Bruce W. Morrow of the University of Colorado School of Medicine, Department of Otolaryngology. The results were presented at a meeting of the American Rhinologic Society. Compl. ¶29.

Seventh, the internal response by Matrixx suggested an awareness of a possible link between Zicam and anosmia. As early as September 2002, a Matrixx official acknowledged that the Company had hired a consultant "to review the product" and invited Miriam R. Linschoten from the University of Colorado Health Sciences Center to "participate in animal studies that Matrixx was planning to conduct." Compl. ¶¶26, 27. The Company also convened a meeting of scientists and physicians in 2004 "to review current information on smell disorders." Compl. ¶45.

Eighth, share prices declined when an article appeared in the Dow Jones Newswire on Jan. 30, 2004, reporting that the FDA was looking into complaints that "an over-the-counter common-cold medicine manufactured by" Matrixx may cause "some users to lose their sense of smell," Compl. ¶¶40, 41, and again following a report on Feb. 6, 2004, on *Good Morning America*, about "the connection between Matrixx's zinc gluconate and anosmia." Compl. ¶¶42, 43.

* * *

To impose a requirement that reports must be statistically significant overlooks the central question in determining materiality: whether it is substantially likely that a reasonable investor would consider the omitted or misstated facts to have significantly altered the total mix of available information. The information need not have produced a different outcome but only have assumed "actual significance" in the deliberative process. The analysis is, as *Northway* rightfully recognized, a subtle one that requires a "delicate assessment of the inferences" in the context of all factors that could render the information important to a reasonable investor. This cannot be done through resort to a single test or factor.

Section 10(b) is part of a statutory scheme that has as a "fundamental purpose" the reliance on full disclosure. *See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 171 (1994). Disclosure in turn helps "stimulate and stabilize the markets" and "inspire investor confidence in the integrity of the markets." Elizabeth Nowicki, *10(b) or Not 10(b)? Yanking the Security Blanket for Attorneys in Securities Litigation*, 3 COLUM. BUS. L. REV. 637, 690 (2004). *Basic* rejected a rigid and underinclusive test for materiality aware that, without accurate and complete disclosure, investors would "'be less likely to invest, thereby reducing the liquidity of the securities markets to the detriment of investors and issuers alike.'" 485 U.S. at 235 n.12 (*quoting In re Carnation Co.*, Exchange Act Release No. 22214

(1985)). A test of statistical significance raises the same concerns.

The standard in *Northway* has functioned effectively for more than three decades.[31] To the extent that there is a need for intervention in this area, the matter is better left to the SEC, where the complexities attendant with the adoption of a materiality standard incorporating statistical significance can better be addressed.[32] At least in the first instance, administrative agencies have the expertise to frame the salient issues and clarify the standards for interpreting the statutes that Congress has charged them to enforce. *See Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843 (1984). Indeed, here, the administrative agency promulgated the regulation that is the subject of the parties' dispute, Rule 10b-5.

CONCLUSION

The court below applied the correct analysis, examining not only the number of reports but also the other factors that could render the information important to a reasonable investor. *Amici* therefore

[31] *See Jones v. Harris Assocs. L.P.*, 130 S. Ct. 1418, 1430-31 (2010) ("The *Gartenberg* standard . . . may lack sharp analytical clarity, but . . . has provided a workable standard for nearly three decades.").

[32] The SEC has, for example, adopted a rule providing a safe harbor for the disclosure of forward-looking statements. *See* Rule 175, 17 C.F.R. § 230.175.

respectfully urge this Honorable Court to affirm the ruling of the United States Court of Appeals for the Ninth Circuit.

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