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THE MATERIALITY STANDARD AFTER *MATRIXX INITIATIVES, INC. V. SIRACUSANO*

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The recent, unanimous decision of the U.S. Supreme Court in Matrixx Initiatives, Inc. v. Siracusano *resolved a circuit split on the materiality standard under Rule 10b-5 of the Securities Exchange Act of 1934. By affirming the Ninth Circuit, the Court re-established the materiality standard set forth twenty-three years ago in* Basic Inc. v. Levinson. *Although the Court relied heavily on this past decision, it did provide some guidance to pharmaceutical companies regarding the disclosure requirements of adverse event reports. With the circuit split now settled, it appears that adverse event reports, standing alone, will generally not be enough to satisfy the materiality standard. However, when in conjunction with affirmative statements concerning the safety and profitability of the drug, these adverse event reports may be material as to not make the statements made misleading. The question remains whether normal advertising of the drug would breach this threshold and require the disclosure of the adverse event reports.*

I. INTRODUCTION

The United States Supreme Court's unanimous decision in *Matrixx Initiatives, Inc. v. Siracusano*[1] on March 22, 2011, resolved a circuit split by affirming the Ninth Circuit's standard of materiality for patient and physician reports under Rule 10b-5 of the Securities Exchange Act of 1934 ("1934 Act").[2] In doing so, the Court rejected the standard established by the First, Second,

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[1] No. 09-1156 (U.S. Mar. 22, 2011).

[2] *See* General Rules and Regulations, Securities Exchange Act of 1934, 17 C.F.R. § 240.10b-5 (2011).

and Third Circuits.[3] The issue arose out of patient and physician reports of adverse effects of using the over-the-counter drug Zicam.[4] The Ninth Circuit held that the materiality of the reports under Rule 10b-5 of the 1934 Act was not dependent on the statistical significance of these complaints,[5] contrary to holdings by the First, Second, and Third Circuit Courts.[6]

Zicam is one of the primary products sold by Matrixx Initiatives, Inc. ("Matrixx").[7] It is sold in numerous forms over-the-counter for use as a cold remedy.[8] Some of these forms are swabs and gel that contain zinc, designed for intranasal application.[9] As early as 1999, users of these Zicam products began to experience the loss of smell.[10] As a publicly traded company, Matrixx is required to comply with certain disclosure requirements of the 1934 Act.[11] Matrixx, as it became aware of these adverse events associated with Zicam use, did not disclose this information on its formal reports to the Securities Exchange Commission ("SEC") and affirmatively denied the validity of these events in press releases.[12] As a result, a group of shareholders brought a class action law suit against Matrixx under the anti-fraud provisions of the 1934 Act, alleging that Matrixx violated Section 10(b) and Rule 10b-5 "by failing to disclose material information regarding Zicam Cold Remedy."[13]

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[3] Matrixx Initiatives, Inc. v. Siracusano, No. 09-1156 (U.S. Mar. 22, 2011).

[4] *Id.*, slip op. at 2–3.

[5] Siracusano v. Matrixx Initiatives, Inc., 585 F.3d 1167, 1178–79 (9th Cir. 2009).

[6] *See* General Rules and Regulations, Securities Exchange Act of 1934, 17 C.F.R. § 240.10b-5 (2011).

[7] *See* Bruce W. Jafek, *Zicam and Loss of Smell*, THE NEWS. OF C. AESCULAPIUM (LDS MED. PROF. COMMUNITY), July 2009, at 1.

[8] *Siracusano*, 585 F.3d at 1170.

[9] Jafek, *supra* note 7, at 1 (explaining further the effects of intranasal application of zinc gluconate).

[10] *See Siracusano*, 585 F.3d at 1169 n.1 (physician reported at least one patient had developed anosmia).

[11] *See generally* 15 U.S.C. § 78 (2006).

[12] *See infra* notes 17 and 19.

[13] *Siracusano,* 585 F.3d at 1169–70.

This Recent Development will first introduce the facts of *Siracusano*. Next, it will discuss the statutes and judicial precedent applicable to this case and continue with a discussion about the District Court's and Ninth Circuit's reasoning in *Siracusano*. Part IV will analyze the recent Supreme Court decision, and this Recent Development will conclude with a discussion of the implications of this decision going forward.

II. *MATRIXX INITIATIVES, INC. V. SIRACUSANO*

Matrixx is a pharmaceutical company and a large distributor of cold medication.[14] Zicam is one of Matrixx's main products and is sold over the counter as a cold remedy.[15] *Siracusano v. Matrixx* is a class action law suit filed by current shareholders against Matrixx for a violation of Rule 10b-5[16] of the Securities Exchange Act of 1934 regarding disclosure of material information concerning the potential adverse effects of using their pharmaceutical products.[17]

The complaint alleged that Matrixx, in failing to disclose the potential link between Zicam and anosmia,[18] violated Section 10(b) of the 1934 Act.[19] Between December 1999 and April 2004, Matrixx received various adverse event reports and became aware of at least one academic study that was conducted by researchers at the University of Colorado about patients suffering from anosmia, allegedly due to Zicam use.[20] During this same period, Matrixx

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[14] Matrixx Initiatives, Inc. v. Siracusano, No. 09-1156, slip op. at 2 (U.S. Mar. 22, 2011).

[15] *Id*; *see also supra* note 7.

[16] 17 C.F.R. § 240.10b-5 (2010).

[17] *Siracusano,* No. 09-1156, slip op. at 3–4 (U.S. Mar. 22, 2011) (alleging Matrixx failed to disclose a number of adverse event reports from physicians and researchers, the fact that there were pending lawsuits stemming from use of Zicam, and research conducted by University of Colorado researchers).

[18] *Id.* at 3.

[19] *Id.* at 7.

[20] *Id.* at 3–4. In December 1999, Matrixx was informed by Dr. Alan Hirsch that at least one patient had developed anosmia, or loss of smell, in conjunction with the use of Zicam, and that studies existed which suggested "potential problems with 'intranasal application of zinc.'" *Sirucausano*, 585 F.3d at 1170. Then, in September 2002, Matrixx executives were informed that studies conducted at the University of Colorado showed a link between the use of zinc

issued several reports in various press releases and filings with the Securities Exchange Commission[21] showing positive profit potential for the Zicam brand and denying any allegations of a connection between Zicam use and anosmia.[22] In February 2004, Good Morning America reported on these potential problems associated with Zicam use and also reported that there were four product liability lawsuits pending against Matrixx alleging that Zicam use caused plaintiffs' anosmia. After this report, the Matrixx common stock price fell 23.8% in one day.[23]

In response to Good Morning America's report, Matrixx issued a press release stating that any link between anosmia and zinc gluconate intranasal gels, such as Zicam, was "completely unfounded and misleading."[24] On February 19, 2004, Matrixx ultimately filed a Form 8-K[25] stating that there was no sufficient

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and anosmia. In September 2003, the University of Colorado researchers were prepared to present data regarding ten patients who developed anosmia after using Zicam. Matrixx refused to allow the researches to use the Zicam name during the presentation. *Id.* By April 2004, University of Colorado researchers reported that there had been approximately 165 cases of anosmia associated with Zicam. *Id.* at 1171.

[21] *See infra* note 22. *See generally* THOMAS LEE HAZEN, TREATISE ON THE LAW OF SECURITIES REGULATION § 9.3[1][A] (6th ed. 2009) (summarizing that annual reports must be filed on a Form 10-K, quarterly reports must be filed on a Form 10-Q, and these reports must be supplemented on a Form 8-K on the occurrences of certain major events which has moved in recent years to a system closer to continuous disclosure).

[22] *Siracusano*, No. 09-1156, slip op. at 4–6 (U.S. Mar. 22, 2011). On October 22, 2003, Matrixx announced a third quarter sales increase and that "[t]he Zicam brand is poised for growth . . . " *Id.* at 4. Further, in a press release dated January 7, 2004, the company announced an expected revenue growth. In the face of a Dow Jones Newswires report stating, "the FDA was 'looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives Inc. (MTXX) may be causing some users to lose their sense of smell,'" Matrixx stated that "[i]n no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function." *Id.* at 5–6. On February 19, 2004 Matrixx filed a Form 8-K with the SEC stating it had conducted a meeting with physicians and scientists and that there was "insufficient scientific evidence . . . to determine if zinc gluconate . . . affects a person's ability to smell." *Id.* at 7.

[23] *Sirucausano*, 585 F.3d at 1174.

[24] *Id.*

[25] *See* HAZEN, *supra* note 21, § 9.3[1][A].

evidence to support a link between Zicam use and anosmia.[26] However, on June 16, 2009, the Food and Drug Administration ("FDA") informed Matrixx that Zicam "may pose a serious risk to consumers."[27]

III. BACKGROUND LAW

A. *The 1934 Act*

The 1934 Act was promulgated mainly as an investor protection statute to prevent any fraud in conjunction with the offering of securities and to increase investor awareness and confidence in securities offerings after the stock market crash of 1929.[28] The anti-fraud provisions of the 1934 Act are stated, in part, in Section 10(b) and further codified by the SEC in Rule 10b-5.[29] Under these anti-fraud provisions, a private right of action exists where the plaintiffs are shareholders and the defendant company is publicly traded and subject to the requirements of the 1934 Act.[30] Further, "[t]o state a claim under Section 10(b) [of the 1934 Act], 15 U.S.C. 78j(b),[31] and Rule 10b-5, 17 C.F.R. § 240.10b5,[32] appellants must allege: (1) a misstatement or omission (2) of material fact (3) made with scienter (4) on which

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[26] *See supra* note 22.

[27] *Siracusano*, No. 09-1156, slip op. at 14 (U.S. Mar. 22, 2011).

[28] *See* HAZEN, *supra* note 21, §§ 9.0–9.1 (stating the 1934 Act has a broad purpose of regulating virtually every aspect of securities transactions; this Act created the Securities Exchange Commission and has broad power to regulate both securities markets and the securities industry).

[29] 17 C.F.R. § 240.10b-5(b) (2010).

[30] *See* HAZEN, *supra* note 21, § 9.2[1][A] (stating all securities traded on a national exchange must be registered pursuant to the 1934 Act's requirements. Additionally, large non-publicly traded companies with assets over ten million dollars and more than 500 shareholders of record must register under the 1934 Act).

[31] 15 U.S.C. § 78j (2006).

[32] 17 C.F.R. § 240.10b-5(b) (stating in part, "[i]t shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange . . . (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading").

Appellants relied (5) which proximately caused their injury."[33] In *Siracusano*, the Supreme Court resolved the issue of what constitutes a material fact under the 1934 Act as applied to pharmaceutical companies.[34]

B. *In the Courts*

1. *U.S. Supreme Court's Materiality Under Section 10(b) of the 1934 Act*

The U.S. Supreme Court first addressed the standard for the materiality element of a Section 10(b) and Rule 10b-5 claim in *Basic, Inc. v. Levinson.*[35] *Basic* involved merger negotiations between two companies, and the plaintiffs in that case alleged material misrepresentations by the target company.[36] The target company, while in the middle of the merger discussions, made three public statements denying the negotiations and stating that they were not aware of any company developments which explained the high trading activity and prices in the company's stock.[37]

In *Basic*, the Court relied on *TSC Industries, Inc. v. Northway, Inc.*[38] to establish the standard for determining materiality under Section 10(b) of the 1934 Act.[39] Although *TSC* involved Section 14(a) of the 1934 Act,[40] the Court explicitly applied the same standard of materiality under Section 10(b).[41] In *TSC*, the Court stated that "[a]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote."[42] The *Basic* Court further

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[33] DSAM Global Value Fund v. Altris Software, Inc., 288 F.3d 385, 388 (2002).

[34] Matrixx Initiatives, Inc. v. Siracusano, No. 09-1156 (U.S. Mar. 22, 2011).

[35] 485 U.S. 224 (1988).

[36] *Id.* at 227–28

[37] *Id.* at 228.

[38] 426 U.S. 438 (1976).

[39] *Basic*, 485 U.S. at 232.

[40] 17 C.F.R. § 240.14a-2 (2010) (relating to the regulation of solicitations of proxies).

[41] *See Basic*, 485 U.S. at 232 ("We now expressly adopt the *TSC Industries* standard of materiality for the § 10(b) and Rule 10b-5 context.").

[42] *TSC Indus.*, 426 U.S. at 449.

clarified that "to fulfill the materiality requirement 'there must be 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.'"[43]

The *Basic* Court acknowledged that in *TSC,* "the Court was careful not to set too low a standard of materiality" because a lower standard could potentially "bring an overabundance of information within its reach."[44] Furthermore, the Court was specifically concerned that an overflow of trivial information into the market could obscure the truth and hinder effective decision-making.[45] Though the Supreme Court's decision in *Basic* was based in the context of merger negotiations, it has been applied in numerous cases and contexts since then.[46] However, because of the unique characteristics of pharmaceutical companies, this standard has been applied differently by the lower courts in these cases.

2. *The Circuit Split: The Circuits' Materiality Standards Under Section 10(b) of the 1934 Act*

When applying the materiality standard to pharmaceutical companies, one must turn first to the *Carter-Wallace, Inc.*[47] line of cases from the U.S. Court of Appeals for the Second Circuit.[48]

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[43] *Basic*, 485 U.S. at 231–32 (quoting *TSC Indus.*, 426 U.S. at 449).

[44] *Id.* at 231.

[45] *See Basic*, 485 U.S. at 231; *see also TSC Indus.*, 426 U.S. at 448–49 (stating that it could result in burying "the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking").

[46] *See e.g.*, Day v. Staples, 555 F.3d 42, 57 (1st Cir. 2009) (citing the *Basic* standard for materiality in conjunction with securities fraud claim).

[47] *In re* Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153 (2d Cir. 1998) ("Carter-Wallace I"); *In re* Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36 (2d Cir. 2000) ("Carter-Wallace II").

[48] *Carter-Wallace I* was heard by the Second Circuit Court of Appeals and reversed and remanded on the grounds that advertisements could be considered in connection with a securities transaction but affirmed on the ground that plaintiff had failed to allege a material misrepresentation. *Carter-Wallace I*, 150 F.3d at 157. *Carter-Wallace II* was heard again on appeal by the Second Circuit and affirmed the district court on the grounds that plaintiff had failed to allege scienter. *Carter-Wallace II*, 220 F.3d at 37–38.

These cases involved the use of an epilepsy drug, Felbatol, and potential side effects from its use.[49] Similar to *Siracusano*, in *Carter-Wallace* the drug manufacturer became aware that some patients developed various illnesses, such as aplastic anemia,[50] while simultaneously running advertisements in medical journals promoting the safety and effectiveness of the medication.[51] During this time, Carter-Wallace was informed by physicians of "at least fifty-seven adverse medical reports relating to Felbatol, including at least six deaths and six cases of aplastic anemia."[52] The next month, Carter-Wallace recommended the discontinuance of Felbatol treatment. Upon disclosure of this information, the company's stock prices fell almost thirty-three percent in one day.[53]

In reaching its decision in *Carter-Wallace II*, the Second Circuit reasoned that since the reports received by Carter-Wallace prior to their withdrawal of the medication "did not demonstrate a statistically significant link between Felbatol and any illness,"[54] plaintiffs had failed to allege facts sufficient to meet the materiality requirement of Section 10(b) of the 1934 Act.[55] The court reasoned that Carter-Wallace had no viable grounds to question the success of Felbatol until the negative reports reached statistical significance.[56] The *Carter-Wallace* court was concerned that randomly associated illnesses could skew the actual potential value of the drug.[57] Specifically, the court reasoned that, "some adverse events may be expected to occur randomly, especially with a drug

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[49] *See Carter-Wallace II*, 220 F.3d at 38.

[50] *Id.; see* Michael C. Mackey, *Unified Hypothesis for the Origin of Aplastic Anemia and Periodic Hematopoiesis*, 51 BLOOD NO. 5, 941, 942 (May 1978) (defining aplastic anemia as a blood condition in which blood cells are not being produced by bone marrow).

[51] *See Carter-Wallace II*, 220 F.3d at 38.

[52] *Id.*

[53] *Id.* ("[F]ollowing disclosure . . . Carter-Wallace's common stock fell $4.875 per share, almost 33 percent, from $15.625 to $10.75 on heavy trading.").

[54] *Id.* at 40.

[55] *Id.*

[56] *Id.* at 41.

[57] *Id.*

designed to treat people that are already ill."[58] As such, the standard set forth by the Second Circuit, as it applies to pharmaceutical companies, is that absent any statistically significant data to support a causal connection between adverse events and the use of the drug, the company is under no obligation to report the adverse events.[59]

Similar to the Second Circuit's decision in *Carter-Wallace*, the Third and First Circuit Courts of Appeals also adopted the statistical significance standard of materiality in Rule 10b-5 cases. In *Oran v. Stafford*,[60] the Third Circuit held that there was no obligation to report information linking two drugs to heart valve disorders unless that information was statistically significant.[61] Similarly, in *N.J. Carpenters Pension and Annuity Funds v. Biogen Idec Inc.*,[62] the First Circuit, referring to a statement that the occurrence of even one adverse event is significant enough to put the drug's safety and marketability in question, the court held that "[i]n the absence of an allegation or inference of proof of any statistical significance of the occurrence . . . the statement is simply not true and is also incorrect as a matter of law."[63] The First Circuit based this ruling, in part, on the Supreme Court's reasoning in *Basic* when it stated, "information is material if a reasonable investor would have viewed it as 'having *significantly* altered the total mix of information made available.'"[64] Thus, the First, Second, and Third Circuit Courts have established a materiality standard which requires an allegation that the claimed adverse event is statistically significant to the use of the drug in question.

However, this standard has not always been so strictly applied. In *In re Pfizer Inc.*,[65] a district court in the Second Circuit refused

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[58] *Id.*

[59] *Id.* at 40.

[60] 226 F.3d 275 (3d Cir. 2000).

[61] *Id.* at 284 (stating "[t]he withheld reports did not provide such statistically significant evidence.").

[62] 537 F.3d 35 (1st Cir. 2008).

[63] *Id.* at 50.

[64] *Id.* at 44 (citing Basic Inc. v. Levinson, 485 U.S. 224, 232 (1988)) (emphasis added)).

[65] 584 F. Supp. 2d 621 (S.D.N.Y. 2008).

to apply the statistical significance standard and instead relied on a strict interpretation of the *Basic* standard. The court in that case, while acknowledging *Carter-Wallace* and *Oran*,[66] held that adverse event reports, even if not statistically significant, may be material.[67] The court, in further distinguishing the statistical significance standard, stated that a 5% threshold for statistical significance could not be used "as a basis for rejecting the significance of complicated medical studies."[68] Based on this court's reasoning, even if statistical significance could be used as a standard for materiality, it is unclear where the line of significance should be drawn. As such, the materiality standard remained somewhat of a mystery prior to the *Siracusano* decision.

3. *The Lower Court Decisions*

Siracusano was first heard in the U.S. District Court for the District of Arizona where the court decided that the plaintiffs had failed to allege facts sufficient to state a valid securities fraud claim.[69] The district court relied on the Second and Third Circuits' reasoning in dismissing the plaintiffs' claims.[70] Following the Second Circuit's standard, the district court found that the omitted information concerning the possible side-effects of Zicam use was not based on statistically significant scientific data.[71] The court reasoned that, not only was there no evidence of the statistical significance of the adverse events reported, but the allegation that Matrixx was aware of only twelve complaints, even if they were reliable, was not enough in itself to meet the statistical significance standard.[72] Thus, the plaintiffs' claim failed because it did not allege that Matrixx had any knowledge of the statistical significance, and they did not present any independent evidence of

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[66] *Id.* at 636 (stating, "the decisions 'do not hold that adverse event reports are always immaterial'" (quoting *In re* Bayer AG Sec. Litig., No. 03 Civ. 1546 WHP, 2004 WL 2190357, at *8 (S.D.N.Y. Sept. 30, 2004))).

[67] *Id.* at 636.

[68] *Id.* at 634.

[69] Siracusano v. Matrixx Initiatives Inc., No. CIV-04-0886-PHX-MHM, 2005 U.S. Dist. LEXIS 41102, at *22 (D. Ariz. Dec. 15, 2005).

[70] *Id.* at *15–20.

[71] *Id.* at *22.

[72] *Id.*

the statistical significance of the adverse events reported.[73] Moreover, Matrixx was not provided with any evidence of the statistical significance, the methodology used, or the peer review status of the University of Colorado study.[74] Therefore, without any allegation that Matrixx knew of or had such evidence, the plaintiffs failed to state a cognizable claim.[75]

On appeal, the Ninth Circuit reversed this decision and rejected the requirement of statistical significance to determine materiality.[76] The Ninth Circuit held instead that the significance of information is a matter of fact and thus should be left to the trier of fact to determine the materiality based on a totality of the circumstances.[77] This court also relied on the Supreme Court's language in *Basic* relating to the expectations of a reasonable shareholder.[78] Thus, the Ninth Circuit rejected a bright line standard based on statistical significance and instead adopted a fact-specific inquiry.[79] As a result of this decision, the court viewed the allegations in the light most favorable to the plaintiff and determined that the plaintiffs had stated a valid claim and remanded the case for a decision on the facts.[80] While the Ninth Circuit based this decision on Supreme Court precedent properly applied in other securities settings,[81] as the Supreme Court later noted, this standard may not provide the precision required by the pharmaceutical industry.

This decision resulted in a circuit split on the materiality standard for Rule 10b-5. As such, the Supreme Court granted a *writ of certiorari* to hear this case and decide whether information concerning potential negative effects of pharmaceutical products

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[73] *Id.*

[74] *Id.*

[75] Siracusano v. Matrixx Initiatives Inc., No. CIV-04-0886-PHX-MHM, 2005 U.S. Dist. LEXIS 41102, at *27 (D. Ariz. Dec. 15, 2005).

[76] Siracusano v. Matrixx Initiatives Inc., 585 F.3d 1167 (9th Cir. 2009), *cert. granted,* 78 U.S.L.W. 3728 (U.S. June 14, 2010) (No. 09-1156).

[77] *Id.* at 1179–80.

[78] *Id.* at 1178 (citing Basic Inc. v. Levinson, 485 U.S. 224, 236 (1988)).

[79] *Id.* at 1179 ("[W]e are to engage in the fact-specific inquiry required by *Basic*.").

[80] *Id.*

[81] *Id.*

must be reported under Rule 10b-5 as material information notwithstanding a lack of statistically significant information to support the causal connection.[82]

IV. THE SUPREME COURT'S DECISION

On March 22, 2011, the Supreme Court affirmed the Ninth Circuit's decision in this case and, in so doing, reaffirmed the materiality standard first established in *Basic*.[83] The Court first noted that Matrixx's argument required the Court "to adopt a bright-line rule that reports of adverse events associated with a pharmaceutical company's products cannot be material absent a sufficient number of such reports to establish a statistically significant risk that the product is in fact causing the events."[84] The Court rejected this argument by restating the Court's language in *Basic* that, "[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 overinclusive or underinclusive."[85] Thus, the Court affirmed the fact-specific inquiry required by the Ninth Circuit.

The Court went on to hold that statistical significance is not the only measure of causation. Medical experts and court-approved expert testimony often rely on many types of evidence other than statistical significance to infer causation.[86] The FDA, the Court noted specifically, considers many factors beyond statistical significance to determine causation.[87] In addition, the FDA may make regulatory decisions based on "evidence that gives rise to only a suspicion of causation."[88]

The Court, after rejecting the bright-line rule, restated the "total mix" standard established in *Basic* and determined that "assessing the materiality of adverse event reports is a 'fact-specific'

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[82] *Id.*

[83] Matrixx Initiatives Inc. v. Siracusano, No. 09-1156, slip op. (U.S. Mar. 22, 2011).

[84] *Id.* at 10–11.

[85] *Id.* at 10 (quoting Basic Inc. v. Levinson, 485 U.S. 224, 236 (1988)).

[86] *Id.* at 12.

[87] *Id.* at 13.

[88] *Id.* at 14.

inquiry."[89] However, the Court also noted that the "mere existence of reports of adverse events . . . will not satisfy this standard."[90] As such, there must be something more. In this case, the Court seems to emphasize that the adverse event reports, combined with the scientific evidence available to Matrixx, was enough to alter the "total mix" of information available. The Court went on to hold that the allegations in this case "suffice to 'raise a reasonable expectation that discovery will reveal evidence' satisfying the materiality requirement."[91]

Moreover, the Court notes "that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all information."[92] In so stating, the Court points to the fact that Matrixx made several affirmative statements concerning the company's potential profits while aware of information that posed a "significant risk to its leading revenue-generating product."[93] The affirmative denial of the reports and scientific evidence created statements which, in the face of this evidence, could be viewed as misleading and could significantly alter the "total mix" of information available. As such, because these affirmative statements were made, the reports and the scientific data became material "in order to make the statements made, in the light of the circumstances under which they were made, not misleading."[94] Unlike the circuit courts, the Supreme Court looked more into the actions of Matrixx and not merely the independent significance of the adverse event reports or scientific studies. This approach provides, not only a more reliable basis of materiality, but conforms more closely to the Courts reasoning in *Basic*.[95]

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[89] *Id.* at 15.

[90] *Id.* at 16.

[91] *Id.* at 18 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007)).

[92] *Id.* at 16.

[93] *Id.* at 19.

[94] *Id.* at 19 (quoting 17 C.F.R. § 240.10b-5(b) (2010)).

[95] *See generally* Basic Inc. v. Levinson, 485 U.S. 224 (1988) (rejecting a bright line rule of agreement-in-principle for merger negotiations and finding that the companies' affirmative denials of engaging in merger negotiations while in the process of negotiating a merger contributed to the materiality of the negotiations regardless of any agreement).

V. IMPLICATIONS OF THE SUPREME COURT'S DECISION

Pharmaceutical companies are in a rare position of vulnerability to securities class action lawsuits.[96] Other industries do not face the uncertainties involved in drug manufacturing or the broad swings in stock prices with which pharmaceutical companies must deal.[97] The high risks and rewards associated with prospective new drugs attract investors and boost stock prices in these companies.[98] But when these promising new drugs turn out to not be the panacea the investing public hoped for, the resulting big losses foster an unusually high number of class action lawsuits.[99] The high costs of litigation, combined with the uncertainty of disclosure requirements pose undue hardship on these companies. As one court stated, "securities laws do not exist to provide down-side investment insurance."[100] This Supreme Court decision does little to clarify the reporting requirements for pharmaceutical companies.

This decision does, however, provide more than the standard explained in the Ninth Circuit's decision. The Court emphasized the fact that Matrixx, in light of the information available, continued to make affirmative statements concerning the profitability of the company and safety of the drug.[101] In making these statements, the Court determined that the adverse events, which may have not been material on their own, became material so as to not make the affirmative statements misleading.[102] Therefore, it seems that pharmaceutical companies have been put on notice to closely monitor the status of the adverse event reports they receive and fully evaluate them prior to any affirmative statements which may be contrary. Specifically, the Court did

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[96] Stuart R. Cohn & Erin M. Swick, *The Sitting Ducks of Securities Class Action Litigation: Bio-Pharmas and the Need for Improved Evaluation of Scientific Data*, 35 DEL. J. CORP. L. 911, 915 (2010).

[97] *Id.* at 912.

[98] *Id.*

[99] *Id.*

[100] *In re* Northfield Labs., Inc. Sec. Litig., 527 F. Supp. 2d 769, 784 (N.D. Ill. 2007).

[101] Matrixx Initiatives Inc. v. Siracusano, No. 09-1156, slip op. at 19 (U.S. Mar. 22, 2011).

[102] *Id.* at 18–19.

recognize that adverse events were common-place in the pharmaceutical industry, and, in an effort to reduce the burden on these companies, the Court held that "[a]pplication of Basic's 'total mix' standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events."[103] Therefore, there is some solace in this opinion for pharmaceutical companies. As the Court states, "companies can control what they have to disclose under these provisions by controlling what they say to the market."[104]

However, this leaves open the question of how much a company can say to the public. For instance, in *Carter-Wallace,* the company, while aware of the adverse events, continued to advertise in medical journals.[105] It is unclear, based on this recent decision, whether the continuation of normal advertising by a pharmaceutical company would qualify as an affirmative statement thus making the adverse event reports material. For example, would a company who is running an advertising campaign on television, the internet, and in medical journals have to cease the advertising when it became aware of certain adverse events?

One potential answer to this question comes from the Securities Act of 1933.[106] Under Section 5(c)[107] of that act, regarding prohibitions related to the offering of securities, a company in the process of a public offering of securities is restricted as to what information it may provide to the public.[108] However, the SEC has stated that normal advertising of products would not be considered a violation of this requirement.[109] The SEC may view normal advertising in the Rule 10b-5 context in the same way as it does in the context of public offerings. If that is the case, it is highly likely that *Carter-Wallace* would be decided the same way under the "total mix" standard today. In any event,

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[103] *Id.* at 15.
[104] *Id.* at 16.
[105] *See supra* note 48.
[106] *See generally* 15 U.S.C. § 77 (2006).
[107] 15 U.S.C. § 77(e)(C) (2006).
[108] *Id.*
[109] *See* HAZEN, *supra* note 21, § 2.3[5] (6th ed. 2009) (stating that issuers should "[c]ontinue to advertise products and services").

pharmaceutical companies should be vigilant in monitoring the adverse events and their advertising endeavors to ensure compliance with the reporting requirements.

In addition, the Court recognizes the limitations of statistical significance on the practical implications of adverse events. The FDA relies on many factors to determine whether a drug warrants certain regulatory action.[110] Increased FDA regulation, the issuance of FDA warnings concerning a drug, or the imposition of additional testing by the FDA all could have a detrimental effect on the drug's profitability.[111] These are regulatory risk considerations that a reasonable investor would consider as having altered the "total mix" of information available.[112] So, not only are the drug's potential negative effects on patients a factor to be considered, but the regulatory implications are also important factors for investors. Since the FDA does not directly base these decisions on statistical significance, the adverse events may be material in the absence of such significance. As such, pharmaceutical companies should consider what effects any adverse event report could have on potential FDA regulatory actions and whether these regulatory risks could potentially make an otherwise accurate statement misleading.

VI. CONCLUSION

The Supreme Court's recent decision resolved the circuit split concerning the materiality standard under Rule 10(b)-5 as it applies to adverse event reports. Even though this decision merely reaffirms the standard set forth in 1988 by the Court in *Basic Inc. v. Levinson,* it provides some additional guidance for pharmaceutical companies concerning the disclosure of adverse event reports while retaining the investor protection features the rule was intended to provide.

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[110] Matrixx Initiatives Inc. v. Siracusano, No. 09-1156, slip op. at 13–14 (U.S. Mar. 22, 2011); *see also id.* at 14 n.9.

[111] *See generally* GAO, M. Crosse et al., Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process, GAO-06-402 (2006).

[112] *See generally* Wielgos v. Commonwealth Edison Co., 892 F.2d 509, 517 (7th Cir. 1989) (suggesting that regulatory risk is an issue of materiality).