

MATRIX INITIATIVES, INC. v. SIRACUSANO: REJECTION OF THE  
STATISTICALLY SIGNIFICANT STANDARD REOPENED THE  
DOOR TO SECURITIES FRAUD STRIKE SUITS

ABSTRACT

*In response to the proliferation of securities fraud strike suits in the 1990s, Congress and the courts sought to impose heightened standards to dispose of frivolous claims at the pleadings stage. To properly plead materiality under Section 10(b) of the 1934 Act and SEC Rule 10b-5, for example, a growing number of circuit courts adopted the 'statistically significant' standard. In sharp contrast, the United States Supreme Court rejected this standard in Matrixx Initiatives, Inc. v. Siracusano.*

*Now, to survive the pleadings stage, plaintiff-investors seeking to assert securities fraud claims based on a pharmaceutical company's failure to disclose adverse event reports are not required to allege that the omitted reports provide statistically significant evidence that the reported events are caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings. As a result of this low threshold for materiality articulated by the Court, this Comment contends that pharmaceutical companies are forced to choose between two equally devastating alternatives: (1) conduct business as usual and risk being the target of securities fraud strike suits; or (2) disclose all adverse event reports and bury investors in an avalanche of trivial information.*

*In addition to highlighting the deficiencies in the Matrixx Court's analysis, this Comment examines the consequences created and explains that these consequences will be felt well beyond the four walls of the courtroom.*

*Moving forward, this Comment suggests, the most efficient remedy is for the SEC and the FDA to cooperatively flex their inherent legislative muscles and proactively promulgate a uniform standard for materiality as it pertains to adverse event reports by developing an industry-specific calculation for determining statistical significance. Such a standard would effectuate protections to both investors and pharmaceutical companies, and at the same time, prevent over-disclosure that results in increased operating costs, artificially depressed stock prices, and uninformed decisionmaking.*

## TABLE OF CONTENTS

I. INTRODUCTION .....	677
II. BACKGROUND: <i>MATRIXx INITIATIVES, INC. v. SIRACUSANO</i> .....	679
III. SECTION 10(b) OF THE 1934 ACT AND SEC RULE 10b-5.....	681
A. <i>Materiality</i> .....	682
B. <i>Scienter</i> .....	683
IV. THE <i>STATISTICALLY SIGNIFICANT</i> STANDARD.....	684
A. <i>The Ninth Circuit's Rejection of the Statistically Significant Standard</i> .....	684
B. <i>The First, Second, and Third Circuits' Application of the Statistically Significant Standard</i> .....	685
C. <i>The United States Supreme Court's Rejection of the Statistically Significant Standard</i> .....	688
1. <i>Materiality: Basic Inc. v. Levinson</i> .....	688
a. <i>Medical Researchers and the FDA</i> .....	689
b. <i>Reasonable Investors</i> .....	691
c. <i>Something More is Needed</i> .....	691
2. <i>Application of Basic's "Total Mix" Standard</i> .....	691
3. <i>Scienter</i> .....	693
V. THE PROPER STANDARD: OMITTED ADVERSE EVENT REPORTS MUST BE STATISTICALLY SIGNIFICANT TO ADEQUATELY PLEAD A SECURITIES FRAUD CLAIM UNDER SEC RULE 10b-5.....	694
A. <i>The United States Supreme Court's Decision is Contrary to Legislative Intent and Modern SEC Rule 10b-5 Jurisprudence</i> .....	694
1. <i>Incorrect Pleading Standard</i> .....	694
2. <i>Misinterpretation of Basic Inc. v. Levinson</i> .....	695
3. <i>Rejection of the Statistically Significant Standard</i> .....	697
4. <i>Adverse Event Reports Are Inherently Unreliable</i> .....	698
5. <i>Reasonable Investor vs. Medical Professional</i> .....	699
6. <i>Scienter</i> .....	700
B. <i>The SEC with the Aid of the FDA, Should Promulgate a Uniform Standard for Materiality by Developing an Industry-Specific Calculation for Determining Statistical Significance</i> .....	702
C. <i>Parties Negatively Affected by the United States Supreme Court's Decision in Matrixx</i> .....	702
1. <i>Pharmaceutical Companies</i> .....	702
2. <i>Investors</i> .....	703
3. <i>Pharmaceutical Users</i> .....	705
4. <i>Biotechnology Sector</i> .....	705
D. <i>Other Negative Ramifications</i> .....	705
1. <i>Siracusano Will Reap Monetary Benefits from its Strike Suit</i> .....	705
2. <i>Strike Suits Will Continue to Ravish the Pharmaceutical Industry</i> .....	706
VI. CONCLUSION .....	706

## I. INTRODUCTION

The complex nature of a securities fraud claim brought against a pharmaceutical company is compounded by deeply rooted policy-based protections afforded to both the investor<sup>1</sup> and the pharmaceutical company.<sup>2</sup> The Securities Exchange Act of 1934 ("1934 Act"), for example, was designed to "protect investors against manipulation of stock prices . . . [by] implementing a 'philosophy of full disclosure.'"<sup>3</sup> If corporate actors fail to comply, the 1934 Act enables investors to seek redress through securities fraud lawsuits.<sup>4</sup> During the 1990s, however, investors abused this protection.<sup>5</sup> As a result, pharmaceutical companies became the target of strike suits that imposed litigation costs so burdensome that defendants were compelled to settle—irrespective of culpability.<sup>6</sup> In response to the proliferation of strike suits, Congress and the courts sought to impose heightened standards to dispose of frivolous claims at the pleadings stage.<sup>7</sup>

In regard to materiality, for example, a growing number of circuit courts adopted the *statistically significant* standard and held that: "Drug companies need not disclose isolated reports of illnesses . . . until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings."<sup>8</sup> In sharp

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<sup>1</sup>Basic Inc. v. Levinson, 485 U.S. 224, 230 (1988) (discussing that the purpose behind the Securities Exchange Act of 1934 was to protect investors).

<sup>2</sup>See Stephen J. Choi, *The Evidence on Securities Class Actions*, 57 VAND. L. REV. 1465, 1468-69 (2004) (explaining that Congress' enactment of the Private Securities Litigation Reform Act of 1995 ("PSLRA") was to deter plaintiff-investors from bringing frivolous securities fraud class action strike suits against non-culpable corporate entities).

<sup>3</sup>*Basic*, 485 U.S. at 230 (quoting *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 478 (1977)).

<sup>4</sup>See *id.* at 230-31 (explaining that the adoption of Section 10(b) of the 1934 Act and Securities Exchange Commission Rule 10b-5 ("SEC Rule 10b-5") removed any doubt that a "private cause of action exists").

<sup>5</sup>Choi, *supra* note 2, at 1468-69 (noting that investors would routinely file strike suits against non-culpable corporate entities: (1) when there was a significant change in an issuer's stock price; (2) to target deep pocket defendants without regard to actual culpability; and (3) to abuse the discovery process to force defendants to settle).

<sup>6</sup>See *id.* at 1469 (discussing reasons why a party would choose to settle).

<sup>7</sup>See *infra* notes 8 and 53 and accompanying text; see also Choi, *supra* note 2, at 1470 ("[The PSLRA requires] [p]laintiffs . . . plead with particularity facts giving rise to a strong inference of the defendants' required state of mind for antifraud actions under the [Securities] Exchange Act . . .").

<sup>8</sup>*N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 58 (1st Cir. 2008) (quoting *In re Carter-Wallace, Inc. Sec. Litig. (Carter-Wallace I)*, 150 F.3d 153, 157 (2d Cir. 1998)); see also *In re Carter-Wallace, Inc. Sec. Litig. (Carter-Wallace II)*, 220 F.3d 36, 40 (2d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d at 157); *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d at 157).

contrast, the Ninth Circuit rejected this standard in *Siracusano v. Matrixx Initiatives, Inc.*,<sup>9</sup> allowing Siracusano's claim to survive the pleadings stage, despite the lack of any allegation that the undisclosed adverse event reports ("AERs") were statistically significant.<sup>10</sup> Defendant Matrixx petitioned and the United States Supreme Court granted a writ of certiorari.<sup>11</sup> The issue before the Court was whether a plaintiff could state a claim under Section 10(b) of the 1934 Act and Securities Exchange Commission Rule 10b-5 ("SEC Rule 10b-5") based on a pharmaceutical company's nondisclosure of AERs, even if the AERs associated with a drug do not amount to a statistically significant number of adverse events.<sup>12</sup> On March 22, 2011, the Court resolved the circuit split by affirming the Ninth Circuit and upholding its rejection of the *statistically significant* standard.<sup>13</sup>

This Comment begins with the background of *Matrixx*, including the events leading up to its filing, as well as its subsequent holdings. Second, to establish context, this Comment examines the fundamental legal concepts at issue in *Matrixx*. Third, it analyzes the Ninth Circuit's reasoning in *Matrixx*, the touchstone cases that adopted the *statistically significant* standard in their respective jurisdictions, and the United States Supreme Court's reasons for affirming the Ninth Circuit and upholding its rejection of the *statistically significant* standard. Fourth, this Comment contends that the Court erred and illustrates numerous deficiencies in its analysis. Fifth, it explains the consequences the Court's decision creates, and explains how these consequences will reverberate well beyond the four walls of the courtroom. This Comment proceeds to argue that the Court's rejection of the *statistically significant* standard manufactured the key to reopen the door to securities fraud strike suits—the same door that Congress and the courts have been determined to shut. Finally, this Comment suggests that the Securities and Exchange Commission ("SEC"), with the aid of the Federal Drug Administration ("FDA"), should proactively promulgate a uniform standard for materiality as it pertains to AERs by developing an industry-specific calculation for determining statistical significance. Proper construction of the *statistically significant* standard and its subsequent application would

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<sup>9</sup>585 F.3d 1167, 1178 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011).

<sup>10</sup>*Id.* at 1183 (reversing the district court's dismissal for failure to state a claim).

<sup>11</sup>*Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009), *cert. granted*, 78 U.S.L.W. 3581 (U.S. June 14, 2010) (No. 09-1156).

<sup>12</sup>*Matrixx Initiatives, Inc. v. Siracusano*, SCOTUSBLOG (Feb. 11, 2011, 12:00 PM), <http://www.scotusblog.com/case-files/cases/matrixx-initiatives-inc-v-siracusano/>. In other words, "Does a drug company violate federal securities laws by failing to disclose reports of patients having adverse reactions to its drugs when the number of incidents was not statistically significant?" *Id.*

<sup>13</sup>*Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324-25 (2011).

effectuate protections to both: (1) investors, by encouraging informed decisionmaking; and (2) pharmaceutical companies, by providing guidance regarding materiality as it pertains to AERs and preventing frivolous claims from surviving the pleadings stage.

## II. BACKGROUND: *MATRIXX INITIATIVES, INC. V. SIRACUSANO*

In April 2004, James Siracusano<sup>14</sup> filed a class action lawsuit against Matrixx Initiatives, Inc.<sup>15</sup> on behalf of investors who purchased Matrixx securities from October 22, 2003, to February 6, 2004 ("class period").<sup>16</sup> Siracusano alleged that Matrixx violated Section 10(b) of the 1934 Act and SEC Rule 10b-5<sup>17</sup> by continuing to advertise the safety and efficacy of its drug, Zicam Cold Remedy ("Zicam"), while failing to disclose material adverse information regarding its drug to investors—specifically, that it caused a loss of smell in its users, a condition called anosmia.<sup>18</sup>

Siracusano alleged that during the class period, Matrixx became aware of the following twelve AERs linking anosmia to the use of Zicam:<sup>19</sup>

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<sup>14</sup>Plaintiff-Appellants are lead plaintiff, NECA-IBEW Pension Fund and James Siracusano ("Siracusano"). *Siracusano*, 585 F.3d at 1169.

<sup>15</sup>Matrixx Initiatives, Inc. is a pharmaceutical company that develops and sells over-the-counter healthcare products within the cold, allergy, sinus, cough, and flu segments in the pharmaceutical market. MATRIXX INITIATIVES, INC., <http://www.matrixxinc.com> (last visited February 16, 2011). At issue in this case is the Zicam Cold Remedy drug sold by Matrixx's wholly-owned subsidiary, Zicam, LLC. *Siracusano*, 585 F.3d at 1169.

<sup>16</sup>*Siracusano*, 585 F.3d at 1170.

<sup>17</sup>*See id.* at 1177. The Ninth Circuit articulated the standard set forth in Section 10(b) of the 1934 Act and SEC Rule 10b-5, stating:

Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), in combination with SEC Rule 10b-5, prohibits any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security. [To properly allege a SEC Rule 10b-5 violation,] a plaintiff must [allege:] (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.

*Id.* (internal quotation marks and citations omitted).

<sup>18</sup>*Id.* at 1169-70.

<sup>19</sup>*Id.* In addition to the twelve undisclosed AERs, Siracusano noted that nine plaintiffs commenced four product liability lawsuits against Matrixx during the class period, alleging a causal link between Zicam and anosmia. *Id.* at 1179. It is unclear, however, whether these nine plaintiffs were the same individuals noted in the twelve undisclosed AERs. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1322 n.11 (2011).

- In December 1999, Dr. Hirsch<sup>20</sup> called Matrixx's customer service line and stated that "at least *one*" of his patients developed anosmia following the use of Zicam.<sup>21</sup>
- In September 2002, Dr. Linschoten<sup>22</sup> spoke on the telephone with Matrixx's Vice President of Research and Development, Timothy Clarot, concerning *one* patient she treated for loss of smell after the use of Zicam.<sup>23</sup> In response, Clarot stated, "Matrixx had received similar complaints from other customers as early as 1999."<sup>24</sup>
- In September 2003, Dr. Jafek<sup>25</sup> notified Matrixx of *ten* patients who developed anosmia following the use of Zicam.<sup>26</sup> Moreover, he notified Matrixx of his plan to present his findings to the American Rhinological Society.<sup>27</sup>

As a result of Matrixx's failure to disclose the AERs, Siracusano alleged that Matrixx securities traded at an artificially inflated price during the class period and dropped significantly upon disclosure of the withheld information.<sup>28</sup>

In December 2005, the United States District Court for the District of Arizona adopted the *statistically significant* standard and granted Matrixx's motion to dismiss.<sup>29</sup> In support of its conclusion, the court reasoned that "Plaintiff's [sic] have failed to present evidence of a statistically significant correlation between the use of Zicam and anosmia so as to make failure to publically [sic] disclose complaints and the [Jafek] study a material omission."<sup>30</sup>

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<sup>20</sup>Dr. Alan Hirsch, M.D., is the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd. *Siracusano*, 585 F.3d at 1170.

<sup>21</sup>*Id.* (emphasis added).

<sup>22</sup>Dr. Miriam Linschoten, Ph.D., was an employee of the University of Colorado Health Sciences Center. *Id.*

<sup>23</sup>*Id.*

<sup>24</sup>*Siracusano*, 585 F.3d at 1170.

<sup>25</sup>Dr. Bruce Jafek was an employee of the University of Colorado School of Medicine. *Id.* at 1171.

<sup>26</sup>*Id.*

<sup>27</sup>*Id.* Upon learning of the presentation, Matrixx officials informed Dr. Jafek that he did not have permission to use the Matrixx brand name or the name of its products in his presentation. *Id.*

<sup>28</sup>*Siracusano*, 585 F.3d at 1176.

<sup>29</sup>*Siracusano v. Matrixx Initiatives, Inc.*, 2005 WL 3970117, at \*9 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011). The district court also granted in part and denied in part Matrixx's Motion to Strike. *Id.*

<sup>30</sup>*Id.* at \*7.

In October 2009, the United States Court of Appeals for the Ninth Circuit reversed the District Court's judgment.<sup>31</sup> The reversal was predicated on the Ninth Circuit's rejection of the *statistically significant* standard.<sup>32</sup> It reasoned that such a standard was "inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact."<sup>33</sup>

In June 2010, the United States Supreme Court granted Matrixx's petition for a writ of certiorari<sup>34</sup> to review whether a plaintiff can state a claim under Section 10(b) of the 1934 Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of AERs, even if the AERs associated with a drug do not amount to a statistically significant number of adverse events.<sup>35</sup>

On March 22, 2011, the Court affirmed the Ninth Circuit and upheld its rejection of the *statistically significant* standard.<sup>36</sup>

### III. SECTION 10(b) OF THE 1934 ACT AND SEC RULE 10b-5

The 1934 Act "provide[s] for regulation and control of [securities] transactions and of practices . . . related thereto."<sup>37</sup> In a broad sense, the 1934 Act's purpose is two-fold: (1) to protect investors against manipulation of stock prices; and (2) to provide redress to those investors who were defrauded by false or misleading statements.<sup>38</sup> Specifically, Section 10(b) of the 1934 Act provides civil redress to individual investors against corporate actors who "engag[e] in manipulative and deceptive practices."<sup>39</sup> The SEC,<sup>40</sup>

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<sup>31</sup>*Siracusano*, 585 F.3d at 1183. The Ninth Circuit applied *de novo* review. *Id.* at 1177 (citing *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009)).

<sup>32</sup>*Id.* at 1178 (concluding that the District Court "erred in relying on the statistical significance standard").

<sup>33</sup>*Id.* at 1183.

<sup>34</sup>*Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009), *cert. granted*, 78 U.S.L.W. 3581 (U.S. June 14, 2010) (No. 09-1156).

<sup>35</sup>*Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1313 (2011).

<sup>36</sup>*Id.* at 1314.

<sup>37</sup>Securities Exchange Act of 1934, 15 U.S.C. § 78b (2006) (outlining reasons to regulate the exchange of securities).

<sup>38</sup>Kevin S. Shmelzer, Comment, *The Door Slammed Shut Needs to Be Reopened: Examining the Pleading Requirements Under the Private Securities Litigation Reform Act*, 78 TEMP. L. REV. 405, 408 (2005) (describing the historical background and context of the 1934 Act). Following the Great Depression, President Franklin D. Roosevelt recognized the "need to safeguard 'the individual who has risked his pay envelope or his meager savings . . . [from corporations] which sought by manipulation to raise or depress market quotations far out of line with reason, all of this resulting in loss to the average investor, who is of necessity personally uninformed.'" *Id.* (quoting S. REP. NO. 73-792, at 1-2 (1934)).

<sup>39</sup>*Id.* at 408 (citing 15 U.S.C. § 78j(b) (2000)).

under Section 10(b) of the 1934 Act, promulgated SEC Rule 10b-5, a vehicle to enforce Section 10(b) violations.<sup>41</sup> To properly plead a violation under SEC Rule 10b-5, a plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation."<sup>42</sup> The two elements at issue in *Matrixx*, materiality and scienter, are discussed below.

### A. Materiality

A securities fraud claim brought under SEC Rule 10b-5 is actionable only if the misrepresentation or omission relates to a *material* fact.<sup>43</sup> To be material, "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."<sup>44</sup> An *insignificant* misrepresentation or omission, therefore, is non-actionable, notwithstanding a statement's falsity or incompleteness.<sup>45</sup> In acknowledging that certain information can be of "dubious significance,"<sup>46</sup> the United States Supreme Court emphasized that the standard for materiality must not be set too low.<sup>47</sup> Setting the standard too low, the Court warned, would cause

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<sup>40</sup>Section 4(a) of the 1934 Act established the SEC, a federal agency, whose principal objective was (and still is) to regulate the federal securities market. Securities Exchange Act of 1934, 15 U.S.C. § 78d (2006).

<sup>41</sup>Shmelzer, *supra* note 38, at 408-09. 17 C.F.R. § 240.10b-5 (2010) states:

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, . . .

- (a) To employ any device, scheme, or artifice to defraud,
- (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, or
- (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

*Id.*

<sup>42</sup>*Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1317-18 (2011) (quoting *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)).

<sup>43</sup>*Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988).

<sup>44</sup>*Id.* at 231-32 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

<sup>45</sup>*Id.* at 238.

<sup>46</sup>*Basic*, 485 U.S. at 231.

<sup>47</sup>*Id.*

management to "bury the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking."<sup>48</sup> Consequently, management is discouraged from disclosing immaterial information.<sup>49</sup>

### B. *Scienter*

To adequately plead a securities fraud claim under SEC Rule 10b-5, a plaintiff must also establish that the defendant acted with the "[requisite degree of] scienter—[a mental state embracing] intent to deceive, manipulate, or defraud."<sup>50</sup> To satisfy this culpability standard, the defendant must engage in "*intentional or willful* conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities"<sup>51</sup>—mere negligence is insufficient.<sup>52</sup> By enacting the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Congress instituted heightened pleading requirements to filter out frivolous claims and quell the profusion of securities fraud strike suits.<sup>53</sup> The PSLRA requires a plaintiff's complaint to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."<sup>54</sup> In determining whether a strong inference exists, "the court must take into account plausible opposing inferences."<sup>55</sup> To survive a motion to dismiss, therefore, a plaintiff alleging securities fraud under SEC Rule 10b-5 "must plead facts rendering

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<sup>48</sup>*Id.* (quoting *TSC Indus.*, 426 U.S. at 448-49).

<sup>49</sup>*See id.*

<sup>50</sup>*Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976) (internal quotation marks omitted).

<sup>51</sup>*Id.* at 199 (emphasis added).

<sup>52</sup>*Id.*

<sup>53</sup>Choi, *supra* note 2, at 1468-69. The PSLRA was enacted to address the following concerns:

(1) the routine filing of lawsuits against issuers of securities . . . whenever there is a significant change in an issuer's stock price, without regard to any underlying culpability of the issuer, and with only a faint hope that the discovery process might lead eventually to some plausible cause of action; (2) the targeting of deep pocket defendants, including accountants, underwriters, and individuals who may be covered by insurance, without regard to their actual culpability; (3) the abuse of the discovery process to impose costs so burdensome that it is often economical for the victimized party to settle; and (4) the manipulation by class action lawyers of the clients whom they purportedly represent.

*Id.* (citing H.R. REP. NO. 369, at 31 (1995)).

<sup>54</sup>*Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1180 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011) (quoting Securities Exchange Act of 1934, 15 U.S.C. § 78u-4(b)(2) (2006)).

<sup>55</sup>*Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007)).

an inference of scienter *at least as likely* as any plausible opposing inference."<sup>56</sup>

#### IV. THE *STATISTICALLY SIGNIFICANT* STANDARD

##### A. *The Ninth Circuit's Rejection of the Statistically Significant Standard*

In October 2009, the Ninth Circuit reversed the District Court's dismissal of Siracusano's complaint against Matrixx.<sup>57</sup> The reversal was predicated on the court's rejection of the *statistically significant* standard employed by the District Court.<sup>58</sup> It found that standard "inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact."<sup>59</sup> The Ninth Circuit noted that materiality should only be resolved as a matter of law where "the omissions are so obviously important to an investor, that reasonable minds cannot differ on the question of materiality."<sup>60</sup>

Regarding materiality, the Ninth Circuit concluded that the District Court erred by relying on the *statistically significant* standard enunciated in *In re Carter-Wallace, Inc. Securities Litigation*.<sup>61</sup> Instead, the Ninth Circuit adopted the Southern District of New York's approach in *In re Pfizer Inc. Securities Litigation*.<sup>62</sup> In *Pfizer*, the court rejected defendant's argument that plaintiffs failed to plead materiality because the reported adverse effects of the company's drug were not statistically significant.<sup>63</sup> The court held that "statistical significance is a question of fact" and should be determined by the trier of fact.<sup>64</sup>

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<sup>56</sup>*Id.*

<sup>57</sup>*Siracusano*, 585 F.3d at 1183.

<sup>58</sup>*Id.*

<sup>59</sup>*Id.* at 1178. The Ninth Circuit noted:

The Supreme Court has rejected the adoption of a bright-line rule to determine materiality because [t]he determination [of materiality] requires delicate assessments of the inferences a reasonable shareholder would draw from a given set of facts and the significance of those inferences to him. Instead, courts should engage in a fact-specific inquiry in assessing materiality. Thus, [d]etermining materiality in securities fraud cases should ordinarily be left to the trier of fact.

*Id.* (internal quotation marks and citations omitted).

<sup>60</sup>*Id.* (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976)) (internal quotation marks omitted).

<sup>61</sup>*Siracusano*, 585 F.3d at 1178; see *Carter-Wallace II*, 220 F.3d 36, 40 (2d Cir. 2000).

<sup>62</sup>*Id.* at 1179; see *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 635-36 (S.D.N.Y. 2008) (explaining that statistical significance is a question of fact).

<sup>63</sup>*Pfizer*, 584 F. Supp. 2d at 635-36.

<sup>64</sup>*Id.*

Regarding scienter, the Ninth Circuit stated, "[W]ithholding [AERs] . . . is an extreme departure from the standards of ordinary care and presents a danger of misleading buyers or sellers."<sup>65</sup> While the Ninth Circuit *acknowledged* the PSLRA by noting, "the inference that [Matrixx] withheld the information intentionally . . . is at least as compelling as the inference that [Matrixx] withheld the information innocently,"<sup>66</sup> the court did not take into account specific opposing inferences.

In reaching its conclusion, the Ninth Circuit was satisfied that Siracusano's allegations<sup>67</sup> sufficiently met the pleading requirements of Federal Rules of Civil Procedure ("FRCP") 8(a)<sup>68</sup> and successfully "nudge[d] [Siracusano's] claims across the line from conceivable to plausible."<sup>69</sup> As a result, the Ninth Circuit allowed Siracusano's case to proceed beyond the pleadings stage despite the lack of any allegation that the undisclosed AERs were statistically significant.

#### B. *The First, Second, and Third Circuits' Application of the Statistically Significant Standard*

The First, Second, and Third Circuits adopted the *statistically significant* standard in contexts analogous to *Matrixx*. In *Carter-Wallace*, the Second Circuit enunciated the *statistically significant* standard and held that: "Drug companies need not disclose isolated reports of illnesses . . . until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings."<sup>70</sup> Plaintiffs alleged that Carter-Wallace violated Section 10(b) of the 1934 Act and SEC Rule 10b-5 by continuing to advertise the "unprecedented safety" of its epilepsy drug after it became aware of AERs indicating a potential link between severe or fatal illness and the use of its

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<sup>65</sup>*Siracusano*, 585 F.3d at 1183 (internal quotation marks and citations omitted).

<sup>66</sup>*Id.*

<sup>67</sup>*See supra* Part II.

<sup>68</sup>FED. R. CIV. P. 8(a). Under FRCP 8(a), a plaintiff's complaint for relief must contain: "(1) a short and plain statement of the grounds for the court's jurisdiction . . . ; (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and (3) a demand for the relief sought, which may include relief in the alternative or different types of relief." *Id.*

<sup>69</sup>*Siracusano*, 585 F.3d at 1180 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also id.* at 1179-80 (discussing the pleading requirements Siracusano satisfied under the PSLRA).

<sup>70</sup>*Carter-Wallace II*, 220 F.3d 36, 40 (2d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d 153, 157 (2d Cir. 1998)).

drug.<sup>71</sup> As a result, plaintiffs alleged that Carter-Wallace securities traded at an artificially inflated price and dropped significantly upon the disclosure of the withheld information.<sup>72</sup>

In support of its dismissal of plaintiffs' complaint, the court opined that AERs are inherently unreliable and do not, without more, establish a causal relationship between the use of a drug and the reported adverse events.<sup>73</sup> Likewise, plaintiffs' allegation that Carter-Wallace received *fifty-seven* AERs, without establishing a causal link, was "statistically unacceptable."<sup>74</sup> The court also noted that random AERs are expected,<sup>75</sup> especially when users of the drug are already ill.<sup>76</sup> Additionally, while AERs may indicate a *potential* problem, until a statistical link is established, the court "would not expect Carter-Wallace [or any other pharmaceutical company for that matter] to abandon its product on what, at the time, would have been speculation."<sup>77</sup>

The Third Circuit adopted *Carter-Wallace's statistically significant* standard in *Oran v. Stafford*.<sup>78</sup> In *Oran*, plaintiffs filed a class action lawsuit against the pharmaceutical company, American Home Products ("AHP").<sup>79</sup> Plaintiffs alleged that AHP made material misrepresentations and omissions concerning the safety of its drug by failing to disclose research findings and AERs linking its weight-loss drug<sup>80</sup> to heart damage.<sup>81</sup> As a result, AHP securities traded at an artificially inflated price and dropped significantly upon the disclosure of the withheld information.<sup>82</sup> Plaintiffs alleged that AHP learned of at least *thirty-one* cases of heart-valve abnormalities in

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<sup>71</sup>*Carter-Wallace II*, 220 F.3d at 37.

<sup>72</sup>*See id.* at 38.

<sup>73</sup>*Id.* at 40-41.

<sup>74</sup>*Id.* at 40.

<sup>75</sup>*Carter-Wallace II*, 220 F.3d at 41. An "adverse drug experience" broadly includes "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related . . ." 21 C.F.R. § 314.80(a) (2010); *see also* 21 C.F.R. § 314.80(k) ("[A] report . . . by an applicant . . . does not necessarily reflect a conclusion . . . that the report . . . constitutes an admission that the drug caused or contributed to an adverse report.").

<sup>76</sup>*Carter-Wallace II*, 220 F.3d at 41.

<sup>77</sup>*Id.* at 42.

<sup>78</sup>226 F.3d 275 (3d Cir. 2000). Justice Alito, writing for the Third Circuit panel, adopted *Carter-Wallace II's statistically significant* standard. *See id.* at 284.

<sup>79</sup>*Id.* at 279. American Home Products Corporation is incorporated in Delaware, headquartered in New Jersey, and "engage[s] in . . . research, development, manufacture and marketing of prescription and over-the-counter medications." *Id.*

<sup>80</sup>*Id.* "AHP marketed the weight-loss drugs Pondimin (fenfluramine) and Redux (dexfenfluramine). Pondimin was marketed together with another drug, phentermine, in a combination popularly known as 'fen-phen.'" *Id.*

<sup>81</sup>*Id.*

<sup>82</sup>*Oran*, 226 F.3d at 279.

European users of its drug and received "hundreds of [other AERs] of patients displaying [similar] symptoms."<sup>83</sup> In addition, AHP failed to immediately release information received from the Mayo Clinic regarding *twenty-four* documented reports of heart abnormalities in the users of its weight-loss drug.<sup>84</sup> During this time, AHP continued to tout the safety and efficacy of its drug, describing it as "one of the most successful drug launches ever."<sup>85</sup>

The *Oran* court stated, "Because the link between the . . . drugs and heart-valve disorders was never definitively established . . . , AHP's failure to disclose [the AERs] cannot render its statements about the inconclusiveness of the relationship materially misleading."<sup>86</sup> In affirming the district court's dismissal of all plaintiffs' claims on the pleadings, the court quoted *Carter-Wallace*: "[D]rug companies need not disclose isolated reports of illnesses . . . until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings."<sup>87</sup>

Likewise, the First Circuit adopted *Carter-Wallace's* statistically significant standard in *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*<sup>88</sup> In *N.J. Carpenters*, plaintiffs filed a class action lawsuit alleging that Biogen IDEC Inc. ("Biogen") violated Section 10(b) of the 1934 Act and SEC Rule 10b-5.<sup>89</sup> Plaintiffs alleged that Biogen intentionally misrepresented the safety and efficacy of its new multiple sclerosis drug after it became aware of AERs that acknowledged a potential link between its drug and opportunistic infections.<sup>90</sup> As a result, plaintiffs alleged that Biogen securities traded at an artificially inflated price and dropped significantly upon the disclosure of the withheld information.<sup>91</sup> Plaintiffs relied heavily upon the testimony of a former data-entry employee at Biogen, who stated that she received *fifty to sixty AERs per day* and "many" were "serious."<sup>92</sup> The court found, however, "[no] connection[] . . . between the

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<sup>83</sup>*Id.* (emphasis added).

<sup>84</sup>*Id.* at 280.

<sup>85</sup>*Id.* In addition, AHP released a press-release noting that "[s]cientific evidence has shown Redux to be safe and effective when used as indicated." *Id.*

<sup>86</sup>*Oran*, 226 F.3d at 284.

<sup>87</sup>*Id.* (quoting *Carter-Wallace I*, 150 F.3d 153, 157 (2d Cir. 1998)).

<sup>88</sup>*See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 58 (1st Cir. 2008).

<sup>89</sup>*See id.* at 37.

<sup>90</sup>*Id.* at 43.

<sup>91</sup>*Id.* at 41.

<sup>92</sup>*N.J. Carpenters*, 537 F.3d at 53.

symptoms being reported and . . . use of [the drug]."<sup>93</sup> Absent a causal connection, the court stated, "[t]here is no basis to conclude that [such] results . . . were statistically significant."<sup>94</sup> In affirming the district court's dismissal of plaintiffs' complaint, the First Circuit—like its Third Circuit counterpart—quoted *Carter-Wallace*: "[D]rug companies need not disclose isolated reports of illnesses . . . until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings."<sup>95</sup>

### C. *The United States Supreme Court's Rejection of the Statistically Significant Standard*

On March 22, 2011, the United States Supreme Court affirmed the Ninth Circuit's decision and upheld its rejection of the *statistically significant* standard, holding that Siracusano sufficiently stated a claim under Section 10(b) of the 1934 Act and SEC Rule 10b-5.<sup>96</sup> The Court concluded that "materiality of [AERs] cannot be reduced to a bright-line rule."<sup>97</sup> It reasoned, "Although in many cases reasonable investors would not consider [AERs] to be material information, [Siracusano] ha[s] alleged facts plausibly suggesting that reasonable investors would have viewed these particular reports as material."<sup>98</sup> Further, the Court determined that the alleged facts gave rise to a strong inference that Matrixx acted with the requisite degree of scienter.<sup>99</sup> As a result of the Court's decision, Siracusano's case survived the pleadings stage despite the lack of any allegation that the undisclosed AERs were statistically significant.

#### 1. Materiality: *Basic Inc. v. Levinson*

The Supreme Court supported its rejection of Matrixx's proposed *statistically significant* standard by examining its decision in *Basic Inc. v.*

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<sup>93</sup>*Id.*

<sup>94</sup>*Id.* at 50. In fact, the court noted, "The receipt of an [AER] does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report." *Id.* (quoting *Carter-Wallace II*, 220 F.3d 36, 41 (2d Cir. 2000)).

<sup>95</sup>*Id.* at 58 (quoting *Carter-Wallace I*, 150 F.3d 153, 157 (2d Cir. 1998)).

<sup>96</sup>*Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1314 (2011).

<sup>97</sup>*Id.* at 1313-14.

<sup>98</sup>*Id.* at 1314.

<sup>99</sup>*Id.*

*Levinson*.<sup>100</sup> It explained that, similar to Matrixx, the defendant in *Basic* advocated for a bright-line rule, insisting that "preliminary merger negotiations are material only once parties to the negotiations reach an agreement in principle."<sup>101</sup> In rejecting that proposed rule, 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 overinclusive or underinclusive."<sup>102</sup>

The Court analogized the bright-line rule advocated in *Basic* to Matrixx's proposed *statistically significant* standard: "[AERs] 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."<sup>103</sup> The Court characterized Matrixx's argument as "flawed,"<sup>104</sup> reasoning that its categorical rule that "rests on the premise that statistical significance is the *only* reliable indication of causation" would "artificially exclud[e] information that would otherwise be considered significant to the trading decision of a reasonable investor."<sup>105</sup> In reaching its conclusion, the Court assumed that a "reasonable investor" relies on the same varied causation determinants considered by medical researchers and the FDA.<sup>106</sup>

a. *Medical Researchers and the FDA*

The Supreme Court noted that medical researchers rely on numerous factors in assessing causation because "statistically significant data [is] not always available."<sup>107</sup> The absence of such data, the Court opined, "does not mean that medical experts have no reliable basis for inferring a causal link

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<sup>100</sup>*Basic Inc. v. Levinson*, 485 U.S. 224 (1988).

<sup>101</sup>*Matrixx Initiatives*, 131 S. Ct. at 1318.

<sup>102</sup>*Id.* (quoting *Basic*, 485 U.S. at 236).

<sup>103</sup>*Id.* at 1318-19.

<sup>104</sup>*Id.* at 1319.

<sup>105</sup>*Matrixx Initiatives*, 131 S. Ct. at 1319 (emphasis added) (internal quotation marks omitted).

<sup>106</sup>*See id.* at 1321. The Court analogized: "Given that medical professionals . . . act on the basis of evidence of causation that is not statistically significant, it stands to reason that . . . reasonable investors would as well." *Id.*

<sup>107</sup>*Id.* at 1319. The Court noted:

[W]hen an adverse event is subtle or rare, an inability to obtain a data set of appropriate quality or quantity may preclude a finding of statistical significance. Moreover, ethical considerations may prohibit researchers from conducting randomized clinical trials to confirm a suspected causal link for the purpose of obtaining statistically significant data.

*Id.* (internal quotation marks and citations omitted).

between a drug and adverse events."<sup>108</sup> Accordingly, medical experts and researchers "do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence."<sup>109</sup> While statistical significance may be relevant, the Court noted, it is not dispositive in every case.<sup>110</sup>

Additionally, the Court relied on the FDA's proclivity to use evidence other than statistically significant data when assessing causation for purposes of taking regulatory action against a pharmaceutical company.<sup>111</sup> The FDA, the Court stated, "does not apply any single metric for determining when additional inquiry or action is necessary, and it certainly does not insist upon statistical significance."<sup>112</sup> Further, the Court noted, the FDA occasionally acts on evidence that merely *suggests* or gives rise to only a *suspicion* of causation.<sup>113</sup>

Critical to its analysis, the Court noted that facts in *Matrixx*, while not alleged to be statistically significant, articulated the requisite degree of suspicion to trigger the FDA to issue a warning letter in 2009.<sup>114</sup> *Surprisingly*, the Court found this letter—issued five years *after* the close of the class period—relevant to its analysis. The warning letter stated, "A significant and growing body of evidence substantiates that [Zicam] intranasal products *may* pose a serious risk to consumers who use them."<sup>115</sup> The warning letter did *not* rely on statistically significant data.<sup>116</sup>

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<sup>108</sup>*Id.* (emphasis added).

<sup>109</sup>*Matrixx Initiatives*, 131 S. Ct. at 1320.

<sup>110</sup>*Id.* at 1321.

<sup>111</sup>*Id.* at 1320. The Court noted the following:

In assessing the safety risk posed by a product, the FDA considers factors such as strength of the association, temporal relationship of product use and the event, consistency of findings across available data sources, evidence of a dose-response for the effect, biological plausibility, seriousness of the event relative to the disease being treated, potential to mitigate the risk in the population, feasibility of further study using observational or controlled clinical study designs, and degree of benefit the product provides, including availability of other therapies.

*Id.* (internal quotation marks and footnote omitted).

<sup>112</sup>*Id.* (internal quotation marks omitted).

<sup>113</sup>*Matrixx Initiatives*, 131 S. Ct. at 1320. The Court provided the following example: "[T]he FDA requires manufacturers of over-the-counter drugs to revise their labeling to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." *Id.* (internal quotation marks and citations omitted).

<sup>114</sup>*Id.* at 1320-21.

<sup>115</sup>*Id.* (emphasis added). The FDA's warning letter cited as evidence "130 reports of anosmia the FDA had received, the fact that the FDA had received few reports of anosmia associated with other intranasal cold remedies, and evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans." *Id.* at 1321 (internal quotation marks omitted).

<sup>116</sup>*Id.* at 1321.

b. *Reasonable Investors*

The issue remains: "[W]hether a *reasonable* investor would have viewed the nondisclosed information as having *significantly* altered the 'total mix' of information made available."<sup>117</sup> The Supreme Court analogized: "Given that medical professionals . . . act on the basis of evidence of causation that is not statistically significant, it stands to reason that . . . reasonable investors would as well."<sup>118</sup> The Court opined that "*Basic's* 'total mix' standard does not mean that pharmaceutical manufacturers must disclose all [AERs]."<sup>119</sup> Additionally, it stated, "the mere existence of [AERs]—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy this standard. *Something more is needed* . . . ."<sup>120</sup>

c. *Something More is Needed*

The Supreme Court eschewed providing preventative guidance to pharmaceutical companies eager to understand how to detect "something more." Instead, it opined that AERs vary in form and pharmaceutical companies should conduct fact-specific "contextual inquiries" because "something more is not limited to statistical significance and can come from the source, content, and context of the [AERs]."<sup>121</sup> Additionally, the Court noted, "This contextual inquiry may reveal in some cases that reasonable investors would have viewed [AERs] as material even though the [AERs] did not provide statistically significant evidence of a causal link."<sup>122</sup>

## 2. Application of *Basic's* "Total Mix" Standard

The Supreme Court concluded that Siracusano adequately pled materiality and that information received by Matrixx revealed a "plausible

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<sup>117</sup>*Matrixx Initiatives*, 131 S. Ct. at 1321 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988)) (emphasis added) (internal quotation marks and citations omitted).

<sup>118</sup>*Id.*

<sup>119</sup>*Id.* The Court also noted that "[AERs] are daily events in the pharmaceutical industry; in 2009, the FDA entered nearly 500,000 such reports into its reporting system." *Id.*

<sup>120</sup>*Id.* (emphasis added).

<sup>121</sup>*Matrixx Initiatives*, 131 S. Ct. at 1321. The Court noted different forms of AERs, including "direct complaints by users to manufacturers, reports by doctors about reported or observed patient reactions, more detailed case reports published by doctors in medical journals, or larger scale published clinical studies." *Id.*

<sup>122</sup>*Id.* (emphasis added) (internal quotation marks omitted).

causal relationship between Zicam and anosmia,<sup>123</sup> posing a potentially significant risk to Matrixx's commercial viability.<sup>124</sup> In addition to the twelve AERs Matrixx received (out of millions of Zicam users), the Court relied on the following allegations<sup>125</sup> as the source of "something more:" (1) four product liability lawsuits;<sup>126</sup> (2) Dr. Jafek's presentation to the American Rhinological Institute; and (3) biological studies linking the intranasal application of zinc (*not* Zicam) and anosmia.<sup>127</sup>

The Court determined that these allegations were "suffic[ient] to raise a reasonable expectation that discovery will reveal evidence satisfying the materiality requirement . . . and to allo[w] the court to draw the reasonable inference that [Matrixx] is liable for the misconduct alleged."<sup>128</sup> Additionally, the Court noted, "Assuming the facts to be true, these were material facts necessary in order to make the statements made,<sup>129</sup> in the light of the circumstances under which they were made, not misleading."<sup>130</sup> To support its holding, the Court stated, "It is substantially likely that a reasonable investor would have viewed this information as having significantly altered the *total mix* of information made available."<sup>131</sup>

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<sup>123</sup>*Id.* at 1323. The Court assumes facts in the complaint's allegations as true. *Id.*

<sup>124</sup>*Id.* The Court notes that "Zicam Cold Remedy allegedly accounted for 70 percent of Matrixx's sales." *Id.*

<sup>125</sup>*See also* Part II.

<sup>126</sup>It is unclear, however, whether these nine plaintiffs were the same individuals noted in the twelve undisclosed AERs. *Matrixx Initiatives*, 131 S. Ct. at 1322 n.11.

<sup>127</sup>*Id.* at 1322-23. Matrixx contends that the studies using zinc sulfate are unreliable because the active ingredient in Zicam is zinc gluconate. *Id.* at 1322 n.13. The Court, however, found the studies probative and stated, "Matrixx had not conducted any research of its own relating to anosmia . . . [so] it can reasonably be inferred . . . that Matrixx had no basis for rejecting Dr. Jafek's findings . . ." *Id.* at 1322-23.

<sup>128</sup>*Id.* at 1323 (internal quotation marks and citations omitted).

<sup>129</sup>In spite of known risks to its leading revenue-generating drug, Zicam, the Court noted that Matrixx continued to tout the safety and efficacy of its drug and told the market it expected revenue growth over 50 percent. *Id.*

<sup>130</sup>*Matrixx Initiatives*, 131 S. Ct. at 1323 (internal quotation marks omitted). The Court noted:

Matrixx had information indicating a significant risk to its leading revenue-generating product. Matrixx also stated that reports indicating that Zicam caused anosmia were completely unfounded and misleading and that the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established. Importantly, however, Matrixx had evidence of a biological link between Zicam's key ingredient and anosmia, and it had not conducted any studies of its own to disprove that link.

*Id.* (internal quotation marks and citations omitted).

<sup>131</sup>*Id.* (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988)) (emphasis added) (internal quotation marks omitted).

### 3. Scierter

The Supreme Court held that Siracusano adequately pled scierter.<sup>132</sup> Acknowledging the PSLRA's heightened pleading standards,<sup>133</sup> the Court stated, "[The allegations] take[n] collectively, give rise to a cogent and compelling inference that Matrixx elected not to disclose the [AERs] not because it believed they were meaningless but because it understood their likely effect on the market."<sup>134</sup> Moreover, the Court noted, "The inference that Matrixx acted recklessly (or intentionally, for that matter) is at least as compelling, if not more compelling, than the inference that it simply thought the [AERs] did not indicate anything meaningful about adverse reactions."<sup>135</sup>

Matrixx argued, albeit unsuccessfully, that Siracusano had "no basis to consider the inference that [Matrixx] acted recklessly or knowingly to be at least as compelling as the alternative inferences" because Siracusano failed to allege Matrixx knew of any "statistically significant evidence of causation."<sup>136</sup> Rather, Matrixx contended, its management did not disclose the AERs based on its belief that out of millions of Zicam users, twelve AERs were "far too few . . . to indicate anything meaningful about adverse reactions to the use of Zicam."<sup>137</sup> The Court found Matrixx's scierter argument "just as flawed as its approach to materiality."<sup>138</sup>

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<sup>132</sup>*Id.* at 1324-25.

<sup>133</sup>*See supra* Part III.B.

<sup>134</sup>*Matrixx Initiatives*, 131 S. Ct. at 1324-25 (internal quotation marks and citations omitted).

<sup>135</sup>The Court supported its evaluation by stating:

Matrixx was sufficiently concerned about the information it received that it informed Linschoten that it had hired a consultant to review the product, asked Linschoten to participate in animal studies, and convened a panel of physicians and scientists in response to Dr. Jafek's presentation. It successfully prevented Dr. Jafek from using Zicam's name in his presentation on the ground that he needed Matrixx's permission to do so. Most significantly, Matrixx issued a press release that suggested that studies had confirmed that Zicam does not cause anosmia when, in fact, it had not conducted any studies relating to anosmia and the scientific evidence at the time, according to the panel of scientists, was insufficient to determine whether Zicam did or did not cause anosmia.

*Id.* at 1324.

<sup>136</sup>*Id.*

<sup>137</sup>*Id.*

<sup>138</sup>*Matrixx Initiatives*, 131 S. Ct. at 1324. The Court, however, also noted, "Whether respondents can ultimately prove their allegations and establish scierter is an altogether different question." *Id.* at 1325. The Court's epilogue seemingly infers that Siracusano will struggle to prove their allegations. Nevertheless, the Court held that respondents sufficiently pled their claims. As discussed throughout this Comment, securities fraud cases rarely proceed beyond the pleadings stage—a fact that the Court disregarded in its opinion.

V. THE PROPER STANDARD: OMITTED ADVERSE EVENT REPORTS MUST BE STATISTICALLY SIGNIFICANT TO ADEQUATELY PLEAD A SECURITIES FRAUD CLAIM UNDER SEC RULE 10b-5

A. *The United States Supreme Court's Decision is Contrary to Legislative Intent and Modern SEC Rule 10b-5 Jurisprudence*

In rejecting the *statistically significant* standard, the Supreme Court abandoned modern SEC Rule 10b-5 jurisprudence and acted in contravention to Congress' intent to combat securities fraud strike suits.<sup>139</sup> In doing so, the Court allowed Siracusano's case to survive the pleadings stage despite the lack of any allegation that the undisclosed AERs were statistically significant. As a result, the *Matrixx* decision manufactured the key to reopen the door to securities fraud strike suits—the same door that Congress and the courts were determined to shut.

1. Incorrect Pleading Standard

The Supreme Court applied the incorrect pleading standard. Siracusano alleged securities fraud under Section 10(b) of the 1934 Act and SEC Rule 10b-5.<sup>140</sup> Pursuant to FRCP 9(b), when a plaintiff alleges fraud, he must "state with particularity the circumstances constituting fraud."<sup>141</sup> The particularity requirement is imposed to protect a defendant's reputation, and at the same time, deter the filing of strike suits.<sup>142</sup> Here, the Court failed

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<sup>139</sup>See *supra* notes 8 and 53 and accompanying text.

<sup>140</sup>*Matrixx Initiatives*, 131 S. Ct. at 1316.

<sup>141</sup>FED. R. CIV. P. 9(b); see also *Siracusano v. Matrixx Initiatives, Inc.*, 2005 WL 3970117, at \*4 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011) (explaining that FRCP 9(b) requires that a plaintiff plead fraud with particularity).

<sup>142</sup>Christopher M. Fairman, *Heightened Pleading*, 81 TEX. L. REV. 551, 563 (2002) (discussing the rationale behind FRCP 9(b)'s particularity requirement). Fairman notes:

There is a broad consensus that the particularity requirement is imposed in fraud cases for four reasons: protection of reputation, deterrence of frivolous [claims] or strike suits, defense of completed transactions, and providing adequate notice. The essence of the protection-of-reputation rationale is that it is a serious matter to charge someone with fraud. Because of the potential damage to a defendant's reputation and the implication of moral turpitude, no one should be allowed to make such an allegation without going on the record as to what specifically constituted the fraud.

Rule 9(b)'s particularity requirement has also been associated with deterrence of strike suits and other frivolous claims. Theoretically, strike suits, designed to maximize the nuisance value and to extort high settlement offers, would be frustrated by enhancing the plaintiff's pleading burden. By requiring more particularized pleading, Rule 9(b) serves to deter or shorten the duration of such

to apply FRCP 9(b) and instead applied the general pleading requirements of FRCP 8(a): "a short and plain statement of the claim showing that pleader is entitled to relief."<sup>143</sup> The Court clearly erred in applying FRCP 8(a) to Siracusano's securities fraud claim.<sup>144</sup>

*Arguendo*, Siracusano's allegations were not even sufficient to state a claim under the general pleading requirements of FRCP 8(a). The Court's decision, in *Bell Atlantic Corp. v. Twombly*,<sup>145</sup> heightened the *general* pleading requirements necessary to survive a motion to dismiss pursuant to FRCP 12(b)(6).<sup>146</sup> As a result, Siracusano's unsubstantiated allegations regarding the materiality and scienter requirement in its SEC Rule 10b-5 claim did not satisfy the facially plausible requirement necessary to survive Matrixx's motion to dismiss.

## 2. Misinterpretation of *Basic Inc. v. Levinson*

The Supreme Court supported its rejection of Matrixx's proposed *statistically significant* standard by examining *Basic Inc. v. Levinson*.<sup>147</sup> The Court, however, misinterpreted its own precedent. In doing so, the *Matrixx* Court ignored the functional role of materiality—to filter out frivolous claims and prevent strike suits.<sup>148</sup> In *Basic*, the Court recognized that information of "dubious significance"<sup>149</sup> need not be disclosed and proceeded to warn corporations not to "bury . . . shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking."<sup>150</sup> To satisfy the materiality requirement, the *Basic* Court stated, "[T]here must be a *substantial likelihood* that the disclosure of the

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actions, thereby reducing their nuisance value.

*Id.* at 563-64 (internal citations omitted).

<sup>143</sup>FED. R. CIV. P. 8(a)(2); *see also Matrixx Initiatives*, 131 S. Ct. at 1322 n.12 (determining that Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) articulated the appropriate pleading standard).

<sup>144</sup>*See* Brief of Sec. Indus. & Fin. Mkts. Ass'n. et al. as Amici Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426274, at \*17 ("The Court should [have held] that materiality is subject to the heightened pleading requirements of [FRCP] 9(b) and [it should have been] . . . addressed through a motion to dismiss.").

<sup>145</sup>550 U.S. 544 (2007).

<sup>146</sup>*Id.* at 570 (holding that under FRCP 12(b)(6), a plaintiff must plead enough "facts to state a claim to relief that is plausible on its face").

<sup>147</sup>*See Matrixx Initiatives*, 131 S. Ct. at 1318-25.

<sup>148</sup>*Basic Inc. v. Levinson*, 485 U.S. 224, 234 (1988) ("The role of the materiality requirement is . . . to filter out essentially useless information that a reasonable investor would not consider significant." (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976))).

<sup>149</sup>*Id.* at 231 (quoting *TSC Indus.*, 426 U.S. at 448).

<sup>150</sup>*Id.* (quoting *TSC Indus.*, 426 U.S. at 448-49).

omitted fact would have been viewed by the reasonable investor as having *significantly* altered the *total mix* of information made available."<sup>151</sup>

Consequently, the *Matrixx* Court's rejection of the *statistically significant* standard compels pharmaceutical companies to act in contravention to *Basic* by disclosing *all* AERs.<sup>152</sup> The Court attempts to dismiss this concern, stating, "Application of *Basic*'s 'total mix' standard does not mean that pharmaceutical manufacturers must disclose all [AERs]."<sup>153</sup> Admittedly, the mere existence of an AER, the Court notes, "will not satisfy th[e] standard [for materiality]. Something more is needed . . . and can come from 'the source, content, and context of the reports.'"<sup>154</sup> Unfortunately, pharmaceutical companies must rely on their own unguided "contextual inquiry." The Court's failure to provide sufficient guidance as to what constitutes "something more" has the same effect as if the mere existence of an AER *will* satisfy the materiality standard. Now, to circumvent a myriad of dire consequences, most notably SEC Rule 10b-5 claims pertaining to material omissions of AERs, pharmaceutical companies are compelled to disclose *all* AERs—burying shareholders with anecdotal and unsubstantiated information. This negatively affects, among other things: operating costs, stock price, investor interest, and informed decisionmaking—specifically what *Basic* warned corporations against.

One reason for this contradiction is that facts and circumstances in *Basic* and *Matrixx* are not similar enough to mechanically apply *Basic*'s holding to *Matrixx*. First, the occurrence of preliminary merger negotiations, as was the case in *Basic*, *is* sufficiently important to alter the "total mix" of information available to investors. On its face, a merger negotiation *is*—regardless if the transaction is completed—direct evidence of a corporation's volatility. In sharp contrast, unsubstantiated AERs "say[] nothing in and of itself about whether the drug is causing the [reported events]."<sup>155</sup> Analogizing the effects of preliminary merger negotiations and unsubstantiated AERs on an investor's "total mix" of information is nonsensical. Furthermore, *Basic*—while still good law—was decided more than a decade before the profusion of strike suits in the pharmaceutical industry (and Congress' and the courts' vehement attempts to combat them).<sup>156</sup>

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<sup>151</sup>*Id.* at 231-32 (quoting *TSC Indus.*, 426 U.S. at 449) (emphasis added) (internal quotation marks omitted).

<sup>152</sup>*Basic*, 485 U.S. at 231.

<sup>153</sup>*Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011).

<sup>154</sup>*Id.*

<sup>155</sup>*Id.*

<sup>156</sup>*See supra* notes 8 and 53 and accompanying text.

### 3. Rejection of the *Statistically Significant* Standard

The Supreme Court erred by rejecting the *statistically significant* standard. Classifying Matrixx's proposed standard regarding materiality of AERs as a "bright-line" rule is simply misplaced.<sup>157</sup> Rather, by its very definition, to be material a fact should have statistical significance.<sup>158</sup> Matrixx's nondisclosure of twelve AERs out of millions of Zicam users (without any evidence of a causal relationship) was appropriate. According to *Basic*, it was the type of information "hardly conducive to informed decisionmaking."<sup>159</sup>

Consequently, as long as a plaintiff's attorney is able to find "something more"—a vague and extremely low threshold—a certified hypochondriac's undisclosed AER could survive the pleadings stage. Why? Pursuant to *Matrixx*, such claims should be decided by a trier of fact and *not* as a matter of law.<sup>160</sup> In *Matrixx*, the circumstances are not too far removed from this seemingly ridiculous hypothetical. The Court allowed the case to proceed beyond the pleadings stage with: (1) the mere existence of twelve AERs out of millions of Zicam users; (2) no evidence of a statistically significant correlation; (3) no data as to the reliability of the AERs; and (4) no evidence as to the reliability of Dr. Jafek's study or the methodology he used.<sup>161</sup> Disclosure of these types of statistically insignificant AERs would only "harm investors and consumers by distorting the information upon which they base critical investment and healthcare decisions."<sup>162</sup>

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<sup>157</sup>*Matrixx Initiatives*, 131 S. Ct. at 1318-19 (2011) (explaining that the *statistically significant* standard is a bright-line rule).

<sup>158</sup>BLACK'S LAW DICTIONARY 1066 (9th ed. 2009) (defining material as "[o]f such a nature that knowledge of the item would affect a person's decision-making; significant; essential").

<sup>159</sup>*Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

<sup>160</sup>*Matrixx Initiatives*, 131 S. Ct. at 1321 ("[A]ssessing the materiality of [AERs] is a fact specific inquiry that requires consideration of the source, content, and context of the reports.") (internal quotation marks and citations omitted). To illustrate the disturbing breadth of the Court's assessment of materiality, Chief Justice Roberts stated the following:

I'm an investor in Matrixx; I worry whether my stock price is going to go down. You can have some psychic come out and say Zicam is going to cause a disease, with no support whatsoever, but if it causes the stock to go down 20 percent, it seems to me that's material.

Transcript of Oral Argument at 8, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156).

<sup>161</sup>*Siracusano v. Matrixx Initiatives, Inc.*, 2005 WL 3970117, at \*7 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011).

<sup>162</sup>Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426275, at \*8.

#### 4. Adverse Event Reports Are Inherently Unreliable

The Supreme Court failed to recognize the impact of the inherently unreliable nature of AERs. Simply put, where no causal relationship is established between the drug used and the AER, its existence is somewhat meaningless.<sup>163</sup> This is due, in part, to the FDA's broad definition of an AER: "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related."<sup>164</sup> Oftentimes, the users are previously ill and suffer from an ailment that, by itself, is a contributing factor—if not the sole cause—of the event reported.<sup>165</sup> Additionally, adverse events are expected to occur randomly.<sup>166</sup>

Though "useful in the aggregate, [AERs] are inherently unreliable."<sup>167</sup> Usually, AERs omit information necessary for a pharmaceutical company to accurately assess whether a causal relationship exists between the drug and the event reported.<sup>168</sup> Moreover, AERs "make no attempt to rule out even obvious alternative causes (let alone mere chance), because the FDA encourages submission of [AERs] even in doubtful situations, such as cases of user error."<sup>169</sup> Consequently, the FDA receives scores of questionable AERs that "preclude[] determinations of cause and effect."<sup>170</sup>

Here, given the unreliable nature of AERs and the fact that the reported adverse event, anosmia, is closely related to the Zicam users' underlying ailment—the common cold<sup>171</sup>—twelve AERs out of millions of Zicam users, were immaterial.<sup>172</sup>

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<sup>163</sup>*Carter-Wallace II*, 220 F.3d 36, 41 (2d Cir. 2000). An *adverse drug experience* broadly includes "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related . . ." 21 C.F.R. § 314.80(a) (2010); *see also* 21 C.F.R. § 314.80(k) ("[A] report . . . by an applicant . . . does not necessarily reflect a conclusion . . . that the report . . . constitutes an admission that the drug caused or contributed to an adverse report.").

<sup>164</sup>21 C.F.R. § 314.80(a) (emphasis added).

<sup>165</sup>*Carter-Wallace II*, 220 F.3d at 41.

<sup>166</sup>*See id.*

<sup>167</sup>Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426275, at \*5.

<sup>168</sup>*Id.* ("[AERs] often omit critical information such as the patient's underlying illnesses, medical history, and concomitant use of other products and therapies.").

<sup>169</sup>*Id.*

<sup>170</sup>*Id.*

<sup>171</sup>*See* Louis Bakay, M.D., *Olfactory Meningiomas: The Missed Diagnosis*, 251 JAMA 53, 55 (1984) ("The most common cause of temporary obstructive anosmia is the common cold.").

<sup>172</sup>*See, e.g.,* Siracusano v. Matrixx Initiatives, Inc., 2005 WL 3970117, at \*7 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011) (dismissing Siracusano's complaint because the twelve reported AERs were not statistically significant).

## 5. Reasonable Investor vs. Medical Professional

The Supreme Court incorrectly assumed that, because a medical professional relies on "evidence of causation that is not statistically significant, it stands to reason that reasonable investors do as well."<sup>173</sup> Regardless, the issue still remains: "[W]hether a *reasonable investor* would have viewed the nondisclosed information as having *significantly* altered the 'total mix' of information made available."<sup>174</sup>

Medical professionals utilize AERs, together with other relevant information, in attempts to ferret out potentially dangerous drugs. Due to the unreliable nature of AERs,<sup>175</sup> a medical professional's investigation *only* becomes material once a causal link is established.<sup>176</sup> Without a causal link, raw AERs merely serve as background noise.<sup>177</sup> Likewise, access to unsubstantiated AERs would not qualitatively improve reasonable investors' decisionmaking because they lack both the time and expertise to conduct prudent analyses. To the contrary, such access would "artificially depress[] stock prices and increase[] volatility, as confused investors [would be forced to] separate true nuggets of value amidst a torrent of unreliable information."<sup>178</sup>

In *Matrixx*, there was a substantial likelihood that a reasonable investor would *not* have viewed the twelve undisclosed AERs as "significantly alter[ing] the 'total mix' of information made available."<sup>179</sup> As a result, the undisclosed AERs were immaterial, and Siracusano's SEC Rule 10b-5 securities fraud claim should have been dismissed.

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<sup>173</sup>Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1321 (2011).

<sup>174</sup>*Id.* (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988)) (internal quotation marks and citations omitted).

<sup>175</sup>*See supra* Part V.A.4.

<sup>176</sup>Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426275, at \*6-\*7.

<sup>177</sup>*Id.* In support of *Matrixx*, the Advanced Medical Technology Association notes:

Unless and until [AERs] reach the level of *statistical significance*, the most plausible inference under *Tellabs* will always be that the defendant reasonably believes that, in the overall context of the product's history and experience in the market, the existence of the [AERs] did *not* call into question the product's safety. The Ninth Circuit's *contrary* decision, equating raw [AERs] with "red flags" about product safety, *misunderstands* that the multifarious, and sometimes conflicting, [AERs] amount to little more than background noise in a much broader setting of product usage, unless and until subjected to statistical analysis.

*Id.* (emphasis added).

<sup>178</sup>*Id.* at \*8.

<sup>179</sup>*Basic*, 485 U.S. at 231-32 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

## 6. Scierter

In regard to scierter, the Supreme Court incorrectly applied the PSLRA's heightened pleadings standard enacted to prevent strike suits from surviving a defendant's motion to dismiss.<sup>180</sup> The PSLRA's focus on eliminating frivolous claims at the pleadings stage is based on Congress' realization that a strike suit's potential for success is at its apex *after* a defendant's motion to dismiss is denied.<sup>181</sup> At that point, a company, such as Matrixx, faces millions of dollars in discovery costs and will likely settle—irrespective of culpability.<sup>182</sup> Allowing Siracusano to proceed beyond the pleadings stage, virtually unchallenged, was contrary to the PSLRA's underlying purpose.

To establish scierter under the PSLRA, Siracusano must allege that Matrixx engaged in "intentional or willful [omission of material AERs] designed to deceive or defraud investors by controlling or artificially affecting the price of [its] securities."<sup>183</sup> In doing so, Siracusano was required to "plead facts rendering an inference of scierter *at least as likely* as any plausible opposing inference."<sup>184</sup> To determine whether a strong inference exists, courts must review all of the allegations and "take into account plausible opposing inferences."<sup>185</sup>

Instead, the Court merely *conceded* that the "inference that Matrixx acted recklessly (or intentionally, for that matter) is at least as compelling, if not more compelling, than the inference that [Matrixx]" withheld the information innocently.<sup>186</sup> It is entirely conceivable, however, that Matrixx's rationale for not disclosing the twelve AERs (out of millions of Zicam users) was due to its belief that the AERs "were far too few, and too caught up with the confounding cold indicator, to indicate anything meaningful about adverse reactions to use of Zicam."<sup>187</sup> Simply put, without knowledge of a causal link, Matrixx sought to "appropriately protect[] Zicam's good name

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<sup>180</sup>See *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324-25 (2011).

<sup>181</sup>See Choi, *supra* note 53 and accompanying text.

<sup>182</sup>*Id.* "[B]y enacting the PSLRA, Congress intended to address the . . . abuse of the discovery process to impose costs so burdensome that it is often economical for the victimized party to settle." *Id.* As further evidence of Congress' intent to avoid unnecessary discovery, all discovery is stayed until after a decision on any motion to dismiss. *Id.* at 1469.

<sup>183</sup>*Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 199 (1976).

<sup>184</sup>*Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 328 (2007).

<sup>185</sup>*Id.* at 336.

<sup>186</sup>*Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324 (2011).

<sup>187</sup>Brief of Pet'r, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3334501, at \*49.

and marketability."<sup>188</sup> This rationale seems more likely in light of: (1) the unreliable nature of AERs; (2) Congress' intent to combat strike suits; (3) the growing number of circuit courts adopting the *statistically significant* standard; and (4) the District Court's finding that Matrixx's nondisclosure of the twelve AERs was appropriate because they were statistically insignificant and immaterial.<sup>189</sup>

Nevertheless, in support of its conclusion, the Court opined that "Matrixx was sufficiently concerned . . . [because] it hired a consultant to review the product [and] asked Linschoten to participate in . . . studies."<sup>190</sup> Imputing scienter onto Matrixx merely for investigating AERs is a dangerous precedent to set. Rather, pharmaceutical companies should be encouraged to troubleshoot drugs that may *potentially* harm their users—not deterred by imputing scienter onto them. Here, Matrixx's decision to "investigate AERs before publicly disclosing them reflects prudence, not the intent to defraud."<sup>191</sup>

Additionally, in support of its conclusion, the Court noted that Zicam triggered the FDA to issue a warning letter in 2009.<sup>192</sup> However, this letter is irrelevant to support a finding of scienter because it was issued more than five years *after* the close of the class period. Notably, one purpose of the PSLRA's "strong inference" standard is "to ward off allegations of fraud by hindsight."<sup>193</sup> Therefore, the fact that Matrixx's previous statements regarding the safety and efficacy of Zicam were inconsistent with subsequent findings does *not* render such statements false or misleading.<sup>194</sup>

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<sup>188</sup>*Siracusano v. Matrixx Initiatives, Inc.*, 2005 WL 3970117, at \*8 (D. Ariz. Dec. 15, 2005), *rev'd*, 585 F.3d 1167 (9th Cir. 2009), *aff'd*, 131 S. Ct. 1309 (2011). Additionally, companies are not "required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident." Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156) 2010 WL 3426275, at \*29 (citing *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994)).

<sup>189</sup>*Siracusano*, 2005 WL 3970117, at \*7.

<sup>190</sup>*Matrixx Initiatives*, 131 S. Ct. at 1324.

<sup>191</sup>Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426275, at \*7.

<sup>192</sup>*Matrixx Initiatives*, 131 S. Ct. at 1320-21. The FDA issued warning letter stated: "[A] significant and growing body of evidence substantiates that the Zicam Cold Remedy intranasal products *may* pose a serious risk to consumers who use them." *Id.* (emphasis added).

<sup>193</sup>Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426275, at \*28 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)) (internal quotation marks omitted).

<sup>194</sup>*Id.* at \*28.

B. *The SEC with the Aid of the FDA, Should Promulgate a Uniform Standard for Materiality by Developing an Industry-Specific Calculation for Determining Statistical Significance*

The Supreme Court's holding in *Matrixx*, unfortunately, has kicked the legs out from under the *statistically significant* standard before its content was ever fully developed or its benefits fully realized. Now, the most efficient remedy is for the SEC and the FDA to cooperatively flex their legislative muscles and proactively promulgate a uniform standard for materiality as it pertains to AERs by developing an industry-specific calculation for determining statistical significance. Although the *statistically significant* standard has been applied in a growing number of circuits, the functionality of it must be carefully constructed and molded to best effectuate protections to both investors and pharmaceutical companies. While beyond the scope of this Comment, the standard should be somewhat malleable in its application—accounting for industry-specific causation determinants—while establishing parameters required to provide much needed guidance to pharmaceutical companies. Such a standard would protect both investors and pharmaceutical companies, and at the same time, prevent over-disclosure that results in increased operating costs, artificially depressed stock prices, and uninformed decisionmaking.

C. *Parties Negatively Affected by the United States Supreme Court's Decision in Matrixx*

1. Pharmaceutical Companies

Pharmaceutical companies are negatively impacted by the precedent set forth in *Matrixx*.<sup>195</sup> First, pharmaceutical companies will be forced to make a choice between two equally devastating alternatives in regard to their disclosure of AERs. One alternative is to assess the materiality of AERs by conducting, as the Court suggests, fact-specific "contextual inquiries." Ultimately, however, intelligent plaintiffs' attorneys will find "something more" in the "source, content, and context" of the AERs<sup>196</sup> in almost every

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<sup>195</sup>See Brief for Advanced Med. Tech. Ass'n as Amicus Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426275, at \*35. "[Biotechnology] companies seeking to comply with the [Supreme Court's] decision – the very companies that our society looks to research, develop and manufacture critical and life-saving medicines and medical devices – face an effectively no-win choice . . . ." *Id.*

<sup>196</sup>See *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011).

case. Consequently, strike suits will continue to ravish the pharmaceutical industry.

Alternatively, pharmaceutical companies could proactively attempt to avoid liability under SEC Rule 10b-5 by disclosing all AERs—including those known to be insignificant and immaterial. In sharp contrast to Justice White's majority opinion in *Basic*, *Matrixx* compels cautious pharmaceutical companies to "bury . . . shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking."<sup>197</sup> While avoiding strike suits, this alternative defeats the very purpose of disclosure: to enable investors to make informed decisions.

Additionally, pharmaceutical companies will be hamstrung regarding their ability to respond to questions relating to immaterial AERs. The extremely low threshold articulated by the Court likely reserves the question of materiality regarding a pharmaceutical company's "misleading" explanation of an AER to the trier of fact. As a result, pharmaceutical companies will not be afforded a fair opportunity to interpret their AERs without opening themselves up to securities fraud claims under SEC Rule 10b-5. Further, a pharmaceutical company's official touting the benefits of its product will be compelled to provide a disclaimer that acknowledges known AERs, even those known to be statistically insignificant and immaterial at the time of such announcements.

## 2. Investors

Investors are negatively impacted by the precedent set forth in *Matrixx*.<sup>198</sup> Investors will be forced to withstand an "avalanche of trivial information—a result that is hardly conducive to informed decisionmaking."<sup>199</sup> The 1934 Act's philosophy of full disclosure was predicated on Congress' recognition of the need "to protect investors against manipulation of stock prices."<sup>200</sup> Therefore, full disclosure pertains only to information reasonably necessary to make an informed decision. The mere exposure to statistically insignificant and immaterial AERs will unnecessarily alarm investors who are not well versed in interpreting such reports. As a result, investors will make *uninformed* decisions. Moreover,

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<sup>197</sup>*Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988).

<sup>198</sup>*See, e.g.*, Brief for Pharm. Research & Mfrs. of Am. et al. as Amici Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426276, at \*3-\*4. "[E]xcessive disclosure of statistically insignificant [AERs] will lead to investor confusion and stock fluctuation, which will harm manufacturers and their investors . . ." *Id.* at \*4.

<sup>199</sup>*Basic*, 485 U.S. at 231.

<sup>200</sup>*Id.* at 230.

potential investors may choose not to invest in the pharmaceutical sector simply because of the difficulty and time associated with interpreting such disclosures.

Furthermore, investors rely on a company's industry-specific expertise to provide snapshots that enable them to make well informed decisions. Compelling over-disclosure of AERs undermines this fundamental aspect of securities trading and places an undue burden onto the investor. In addition, investors oftentimes lack technical expertise and are ill-equipped to deduce what information is material and how such information affects the viability of particular securities.

Suppose that Investor 'A' and Investor 'B' were interested in purchasing drug manufacturer, El-Dor's stock. El-Dor was poised to release a drug, Eye-Que, that was guaranteed to increase the user's I.Q. by 14 percent. Suppose further that before gaining FDA approval on September 4, 2005, El-Dor received 44 AERs. The FDA and El-Dor deemed the AERs statistically insignificant and not causally connected to Eye-Que. In sum, the AERs were rendered immaterial. One month after FDA approval, however, influxes of similar AERs demonstrating a causal relationship between the events reported and Eye-Que's use, posed a direct threat to El-Dor's commercial viability.

El-Dor, in accordance with industry standards, provided Investor 'A' with a four page snapshot: the first three pages contained pertinent financials, the fourth was a summary of the most recent—and only material—AERs. Investor 'A' cautiously passed on the stock. Investor 'B,' however, demanded El-Dor's disclosure of *every* AER dating back to its first clinical trial. After arduously sifting through a four-inch binder distended with AERs, Investor 'B' overlooked the most recent—and only material—AERs. Investor 'B' purchased 4,000 shares of El-Dor. Two months later, Eye-Que was pulled from the shelf and El-Dor's stock price plummeted 44 percent.

Investor 'B' was faced with the challenge of finding a needle in a haystack, whereas Investor 'A' was essentially pricked by the needle. Analogously, the precedent set forth in *Matrixx* creates a "haystack" of information for the investing public to arduously sift through—a result not "conducive to informed decisionmaking."<sup>201</sup>

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<sup>201</sup>*Id.* at 231.

### 3. Pharmaceutical Users

Pharmaceutical users are negatively impacted by the precedent set forth in *Matrixx*.<sup>202</sup> Potentially, one who would reap benefits from consuming a drug may choose not to take it based on AERs that are of little or no relevance. Alternatively, one who chooses to use a drug may do so improperly—overlooking vital warnings that are buried amongst an "avalanche of trivial information."<sup>203</sup>

### 4. Biotechnology Sector

The biotechnology sector is negatively impacted by the precedent set forth in *Matrixx*.<sup>204</sup> This sector will be forced to divert huge sums of money—typically utilized to promote research and development of new drugs—to combat frivolous securities fraud claims. Similarly, the energy expended by pharmaceutical companies in litigating such matters will likewise be diverted. Consequently, large-dollar supporters of biotechnology may no longer be motivated to contribute their wealth because a significant portion of it will be used to pay litigation fees. Logically, those with the ability to make contributions want their money used helping to advance biotechnology, not to defend strike suits.

#### D. Other Negative Ramifications

##### 1. Siracusano Will Reap Monetary Benefits from its Strike Suit

Siracusano successfully outmaneuvered Congress' and the courts' vehement attempts to combat strike suits. Facing the frightening costs associated with post-pleadings securities fraud litigation, *Matrixx* is likely to settle—irrespective of culpability.

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<sup>202</sup>See Brief for Pharm. Research & Mfrs. of Am. et al. as Amici Curiae Supporting Pet'rs, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011) (No. 09-1156), 2010 WL 3426276, at \*27 (explaining that "over-disclosure is disfavored in the public health context for good reason: it can lead patients and health care professionals to avoid or discontinue using beneficial, perhaps life saving, treatments").

<sup>203</sup>*Basic*, 485 U.S. at 231.

<sup>204</sup>See *supra* note 195 and accompanying text.

## 2. Strike Suits Will Continue to Ravish the Pharmaceutical Industry

Future investor-plaintiffs' frivolous securities fraud claims will likely survive the pleadings stage and force defendant-pharmaceutical companies to settle rather than incurring the costs associated with post-pleadings securities fraud litigation. Plaintiffs' attorneys will rely on *Matrixx* to effortlessly bring strike suits—and cash-in on an almost surefire settlement.

## VI. CONCLUSION

In *Matrixx*, the United States Supreme Court allowed Siracusano's case to proceed beyond the pleadings stage despite the lack of any allegation that the AERs were statistically significant. In doing so, the Court resolved a circuit split by rejecting the *statistically significant* standard.

As a result, pharmaceutical companies are forced to choose between two equally devastating alternatives in regard to disclosing AERs. First, pharmaceutical companies may assess the materiality of AERs by conducting, as the Court suggests, fact-specific "contextual inquiries." Plaintiffs' attorneys, however, will effortlessly find "something more" in almost every case. Consequently, strike suits will continue to proliferate throughout the pharmaceutical industry. Alternatively, cautious pharmaceutical companies may disclose *all* AERs—burying shareholders in trivial information. While proactively avoiding strike suits, this defeats the very purpose of disclosure: to enable investors to make informed decisions.

The Court had the opportunity to accomplish what the legislature and lower courts have been unable to do—impose a system that protects investors, and at the same time, shields pharmaceutical companies from strike suits. Admittedly, the *statistically significant* standard is not a magic potion. A nexus could be achieved, however, through cooperated efforts directed at defining materiality as it pertains to AERs. Providing pharmaceutical companies with a baseline to assess materiality would enable them to avoid strike suits, and simultaneously, prevent the crippling effect of compelling over-disclosure of immaterial information.

Now, the most efficient remedy is for the SEC and the FDA to flex their inherent legislative muscles and proactively promulgate a uniform standard for materiality as it pertains to AERs by developing an industry-specific calculation for determining statistical significance. While *Matrixx* manufactured the key to reopen the door to securities fraud strike suits, the SEC and the FDA have both the authority and the expertise to slam the door shut, change the lock, and throw away the key.

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