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No. 09-1156

In the Supreme Court of the United States

MATRIXX INITIATIVES INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

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

BRIEF OF DRI—THE VOICE OF THE DEFENSE BAR AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

James C. Martin
Counsel of Record
Colin E. Wrabley
REED SMITH LLP
225 Fifth Avenue
Suite 1200
Pittsburgh, PA 15222
(412) 288-3546
jcmartin@reedsmith.com

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Counsel for Amicus Curiae

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INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae DRI—The Voice Of The Defense Bar is an international organization of more than 22,000 attorneys who often represent individual and corporate defendants in civil cases carrying significant costs and liability exposure. Because of their adverse business and economic impacts, DRI and its members have a vital interest in the fair, efficient, and consistent functioning of our justice system in such cases.

DRI members regularly defend securities fraud suits brought under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. Plaintiffs in these fraud suits are required to plead and prove that defendants' alleged misrepresentations or omissions concern a "material" fact. Under this Court's precedents, this "materiality" requirement acts as a filter on the information that public companies must disclose and helps ensure informed investment decisions by compelling disclosure only of reliable information related to a company's operations or its products.

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[1] No party or counsel for a party authored any part of this brief, and no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have consented to the filing of this brief.

Here, the Ninth Circuit's decision compelling disclosure of anecdotal adverse event reports by companies that manufacture pharmaceuticals or medical devices conflicts with this Court's materiality precedents, undercuts the materiality requirement's filtering function, and thwarts this Court's expressed interest in ensuring "informed decisionmaking" by investors. *See TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976); *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988).

Moreover, in evaluating the legal sufficiency of respondents' complaint, the Ninth Circuit effectively immunized materiality allegations from the scrutiny demanded by this Court's precedents in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009). That immunization, in turn, severely impedes the district courts' ability to screen meritless securities fraud suits.

Finally, although not apparent from the Ninth Circuit's holding or reasoning, the compelled disclosure of anecdotal adverse event reports also unnecessarily threatens the regulation and use of pharmaceuticals and medical devices. Yet, given the life-enhancing and life-sustaining quality of these products, such threats should be avoided, not fostered, by legal standards implemented under the securities laws.

In short, the Ninth Circuit's decision has a profound effect on companies who must publicly disclose material information under the securities laws and unsettles the existing law governing securities cases in significant and undesirable ways. Those impacts directly affect the fair, efficient, and consistent functioning of our civil justice system and, as such, are of vital interest to DRI and its members. DRI therefore respectfully offers its views on the proper resolution of the issues raised in this case.

SUMMARY OF ARGUMENT

This case requires the Court to interpret the requirement under § 10(b) and Rule 10b-5 that plaintiffs must plead a misrepresentation or omission of "material" fact in order to survive a motion to dismiss. Specifically, this case requires the Court to decide whether a statistically insignificant number of reports of adverse patient reactions *hypothetically* linked to the use of a pharmaceutical or medical device are "material" facts that must be disclosed in order to avoid liability under § 10(b). The Court should conclude that in this case, these random adverse event reports ***cannot*** plausibly be equated with those "material" facts that must be disclosed under § 10(b) and Rule 10b-5.

Congress passed the federal securities laws to "protect investors" in publicly-traded companies. *Basic*, 485 U.S. at 230 (citing S. Rep. No. 792, 73d

Cong., 2d Sess., 1-5 (1934)); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 195 (1976). The securities laws accomplish this goal in part by establishing "materiality" requirements that compel public companies to disclose truthful and reliable information about themselves, their operations, and their products and services that very likely would affect an investor's decision whether to purchase the companies' stock. The disclosure of this truthful and reliable information enables reasonable investors to make "informed investment decisions." *Pinter v. Dahl*, 486 U.S. 622, 638 (1988) (1933 Securities Act) (citing *Securities & Exchange Comm'n v. Ralston Purina Co.*, 346 U.S. 119, 124 (1953)); *Basic*, 485 U.S. at 231 ("informed decisionmaking" ensured by Exchange Act); *cf. United States v. O'Hagan*, 521 U.S. 642, 668 (1997) ("very purpose" of Congress's 1968 amendments to Exchange Act was to ensure "informed decisionmaking" by shareholders) (citation omitted). The failure to make all such material disclosures as required by the securities laws can result in civil and even criminal liability. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 166 (2008); 15 U.S.C. § 78ff, § 32(a).

In this case, the Ninth Circuit held that a public company's failure to disclose a handful of anecdotal adverse event reports involving its pharmaceutical left it open to liability under the federal securities laws. This holding—which

effectively treats all adverse event reports as potentially "material" and thus subject to disclosure—squarely conflicts with this Court's materiality precedents and Congress's avowed purpose to ensure "informed decisionmaking." This Court's precedents direct that a fact is material only if it would "significantly alter[ ] the 'total mix' of information made available" and thus would be "substantial[ly] like[ly]" to influence the investment decision of a "reasonable investor." *TSC*, 426 U.S. at 448-49; *Basic*, 485 U.S. at 231-32. Requiring disclosure of a few anecdotal reports that do not reliably indicate any causal relationship between a product and an adverse event does not further the goal of putting reliable information in the hands of a reasonable investor. In essence and in fact, it accomplishes the opposite result.

There is more. This case involves the legal sufficiency of a pleading and therefore implicates this Court's decisions in *Twombly* and *Iqbal*. Yet, in its analysis of the sufficiency of the complaint's allegations, the Ninth Circuit elided those precedents and effectively shielded materiality allegations from the scrutiny those precedents demand. Here again, the Ninth Circuit erred. *Twombly* and *Iqbal* require a showing of a plausible entitlement to relief at the pleading stage. The kind of speculative information the Ninth Circuit ordered disclosed would not enhance or influence the decisionmaking of a reasonable investor and does not

meet the materiality threshold as a matter of law. The Ninth Circuit's decision accordingly subverts the threshold plausibility analysis, erroneously leaving the assessment of materiality in this instance to the trier of fact.

There is another way. The so-called "statistical significance" standard adopted by the First, Second and Third Circuits—decidedly unlike the Ninth Circuit's compelled blanket disclosure rule—comports more closely with this Court's conception of materiality and offers a more certain and intelligible rule for pharmaceutical and medical device companies in cases like this one. *Amicus* urges the adoption of that standard in this case.

ARGUMENT

A. The Ninth Circuit's Compelled Disclosure Of Anecdotal Adverse Event Reports Undermines The Critical Filtering Role Played By Section 10(b)'s Materiality Requirement.

1. Section 10(b)'s materiality requirement is intended to filter information disclosed by public companies to help ensure informed investment decisions.

At bottom, the federal securities laws are intended to facilitate disclosure of relevant and

reliable information to shareholders and investors. The materiality requirement in § 10(b) is critical to this goal. This requirement "filter[s] out essentially useless information that a reasonable investor would not consider significant." *Basic*, 485 U.S. at 231-32 (1988); *see also* Richard C. Sauer, *The Erosion of the Materiality Standard in the Enforcement of the Federal Securities Laws*, 62 BUS. LAW. 317, 318 (Feb. 2007) ("That all information is not created equal is recognized in the federal securities laws through the concept of 'materiality.'"). As one authoritative commentator has noted, this "filtration function is fully as important to the efficient operation of the capital markets as the elimination of false information . . ." *See* Sauer, *supra*, at 317.

This Court's materiality precedents apply this filtration function by limiting what is "material"—and thus must be disclosed—to reliable information that conceivably can benefit a shareholder or investor. As this Court explained it, "[s]ome information is of such dubious significance that insistence on its disclosure may accomplish more harm than good." *TSC*, 425 U.S. at 448. To avoid this result, in *TSC*, this Court defined materiality—not in the abstract—but in terms of what a reasonable shareholder needs to know:

> "An omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote."

Id. at 449. *See also id.* ("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"). This Court further cautioned that if the materiality threshold is set too "low," management will be inclined to "bury shareholders in an avalanche of trivial information"—"a result that is hardly conducive to informed decisionmaking." *Id.* at 448-49.

The concerns that prompted this Court to steer clear of flooding shareholders with unreliable information in *TSC* prompted it to apply the same "substantial likelihood" materiality standard to § 10(b) investor claims in *Basic*. *See Basic*, 485 U.S. at 231-32. There, the Court again highlighted the adverse consequences of setting the materiality threshold too low:

> "[Setting] too low a standard of materiality . . . might bring an overabundance of information within its reach[,]" thereby inducing management to bombard investors with even "trivial information."

Id. To avoid this result and facilitate informed decisionmaking, the Court reiterated that "[t]he role of the materiality requirement is . . . to filter out essentially useless information that a reasonable

investor would not consider significant. . . " *Id.* at 234.

TSC and *Basic* clearly reflect the Court's view that the materiality requirement serves a critical filtering function. It is intended (1) to help ensure that only reliable information is conveyed to shareholders or investors and (2) to guard against swamping shareholders or investors with trivial or insignificant information that clouds informed decisionmaking.

While this filtering function is a cornerstone of this Court's materiality precedents, under the Ninth Circuit's decision, that function loses its significance. Rather than treating the materiality requirement as a means to facilitate the receipt of reliable information, the Ninth Circuit turns the requirement on its head and compels disclosure of purely anecdotal and random information involving a product. Simply put, that result cannot be squared with this Court's precedents.

2. Compelling public disclosure of anecdotal adverse event reports as "material" will hinder, not help, informed investment decisions.

Respondents here alleged that Matrixx and three of its executives violated § 10(b) and Rule 10b-5 by failing to disclose that the use of Zicam could cause "anosmia," or loss of the sense of smell. *See*

Appendix to the Petition ("App.") 3a. To support the supposed causal link between Zicam and anosmia, respondents alleged that over a four-year period, Matrixx received approximately 12 reports of user anosmia. App. 25a. Indisputably, however, respondents did not allege—because they could not—that the 12 adverse event reports were statistically significant. Nor did respondents allege—again, because they could not—that any one of these reports conclusively established an actual link between Zicam and anosmia or that any definitive medical or scientific study had revealed such a link during the class period.

The Ninth Circuit nonetheless reversed the district court's Rule 12(b)(6) dismissal, concluding that respondents had adequately pleaded materiality. In reaching that result, the court rejected the "statistical significance" standard for assessing the materiality of adverse event reports previously adopted by the First, Second and Third Circuits. The court found the standard to be inconsistent with this Court's supposed rejection of "bright-line" rules for determining materiality. App. 23a. Invoking this Court's reference in *Basic* to the "fact-specific inquiry" for assessing materiality, the court also concluded that materiality should be reserved for the trier of fact. *Id.*

The Ninth Circuit's holding compelling disclosure, without more, of a handful of adverse event reports severely undermines the materiality

requirement's filtering function in a number of ways. If that requirement is intended to compel disclosure of reliable information, then it should not be relied on to compel disclosure of a few anecdotal adverse event reports—particularly in the absence of any credible reasons for concluding that the pharmaceutical or medical device referenced in the reports actually caused the identified adverse event.

Indeed, far from showing such a causal link, the FDA's own regulations make clear that adverse event reports, on their own, show ***no*** causal relationship between a drug or device and the reported event. *See* 21 C.F.R. § 803.16; *see also In re Carter-Wallace, Inc. Securities Litig.*, 220 F.3d 36, 41 (2d Cir. 2000) (*Carter-Wallace II*) ("the receipt of an adverse report does not in and of itself show a causal relationship" between the drug or device and the events reported); S. Rep. No. 109-324, at 6 (2006) ("The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product.").

The FDA makes this point even more explicitly on its website:

> [T]here is no certainty that the reported [adverse] event was actually due to the product. FDA does not require that a causal relationship between a product and

> event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive all adverse event reports that occur with a product. . . . Therefore, AERS cannot be used to calculate the incidence of an adverse event in the U.S. population.

U.S. Food and Drug Administration, Adverse Event Reporting System (last modified Aug. 20, 2009) *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

This kind of speculation has no role to play in a materiality determination. Rather, as noted, the materiality determination turns on whether the information that allegedly must be disclosed would be "substantial[ly] likel[y]" to influence a reasonable investor's decision whether to buy the company's stock. *Basic*, 485 U.S. at 231; *TSC*, 426 U.S. at 449. A disclosure showing nothing more than a hypothetical association between a company's product and a consumer's adverse reaction does not reach that threshold. Put another way, without additional evidence substantiating a possible causal link, no "reasonable investor" would expect the reported events to "'affect [the company's] future earnings.'" *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.) (quoting *In re Carter-Wallace,*

Inc. Securities Litig., 150 F.3d 153, 157 (2d Cir. 1998) (*Carter-Wallace I*)). That is so because "until a connection between [the drug] and any illness could be made, we would not expect [the manufacturer] to abandon its product on what, at the time, would have been speculation." *Carter-Wallace II*, 220 F.3d at 42.

Second, in this context, the unfiltered dissemination of anecdotal adverse event reports plainly would severely impair the "informed decisionmaking" this Court has endeavored to preserve. The sheer volume of information that would have to be disclosed would lead to the sort of information overload that this Court and commentators have recognized can paralyze a decisionmaker.[2] *See Basic*, 485 U.S. at 231-32; *TSC*, 425 U.S. at 448-49; *see also* Susanna Kim Ripken, *The Dangers and Drawbacks of the Disclosure*

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[2] In 2009, the FDA received a total of more than 580,000 adverse event reports for all drugs and "therapeutic biologic products," up from approximately 526,000 in 2008. *See* U.S. Food and Drug Administration, Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year (as of March 31, 2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. The upward trend continued through the first quarter of 2010, when the FDA received nearly 160,000 reports for all drugs. *Id.* This comes as no surprise because "[f]ew if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk." *See United States v. Rutherford*, 442 U.S. 544, 555 (1979).

Antidote: Toward a More Substantive Approach to Securities Regulation, 58 BAYLOR L. REV. 139, 162 (2006) (noting that information "overload" in securities disclosures "can hinder informed decision-making and thereby defeat the very purpose of disclosure requirements"); Troy A. Paredes, *Blinded by the Light: Information Overload and its Consequences for Securities Regulation*, 81 WASH. U.L.Q. 417, 446 (2003) ("Meaningful, effective disclosure does not simply mean more disclosure. Because of information overload, in some cases, more disclosure can mean less effective disclosure."); Donald C. Langevoort, *Toward More Effective Risk Disclosure for Technology-Enhanced Investing*, 75 WASH. U.L.Q. 753, 759 (1997) ("[T]he more information there is, the more each bit of it is diluted. The immediate and salient crowds out the less attention-grabbing.").

Third, the greatest threat to "informed decisionmaking" posed by the Ninth Circuit's holding is the *quality*—or lack thereof—of the information it effectively requires pharmaceutical and medical device companies to convey. It should go without saying that "the higher the quality of information provided about available investment opportunities, the more often investors will put capital to its most productive and profitable uses." Sauer, *supra*, at 317. A handful of anecdotal adverse event reports fall well short of the qualitative standard that ought to govern what a public company must disclose to

the investing public. Until there is much greater substantiation of cause and effect, requiring disclosure of such speculative information promises only to confound investment decisions, not facilitate them.

As a result, it is hard to envision a more abrupt departure from this Court's precedents in *TSC* and *Basic* than the Ninth Circuit's holding that a few anecdotal adverse event reports are "material" and must be disclosed. Consistent with these decisions, the materiality requirement's most basic function is to limit what must be disclosed to reliable information that would influence a reasonable investor's decision. By parity of reasoning, under this Court's precedents, speculative information not only need not be disclosed, it should not be disclosed. The Ninth Circuit's decision, in contrast, sends an entirely different message: it threatens a manufacturer with liability for failing to disclose information that is, at its best, anecdotal and speculative. There is no colorable reason for the securities laws to operate in this fashion. This Court should reject the Ninth Circuit's holding and, in doing so, restore the materiality requirement's role in ensuring the flow of reliable information to the securities markets.

B. The Ninth Circuit's Materiality Analysis Undermines The Gatekeeping Function That Federal Courts Perform In Screening Potentially Abusive Securities Actions.

The Ninth Circuit compounds its failure to adhere to this Court's materiality precedents by all but ignoring this Court's controlling decisions for evaluating the sufficiency of a complaint's allegations: *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009). *See* App. 21a, 26a (citing *Twombly* twice and ignoring *Iqbal* entirely). Under the Ninth Circuit's approach, district courts within its jurisdiction will be unable to weed out securities lawsuits in circumstances where plausible allegations of materiality are not, and cannot, be made.

1. The Ninth Circuit's analysis effectively—and erroneously—immunizes materiality allegations from Rule 12(b)(6) challenges.

The Ninth Circuit applied a decidedly **anti**-*Twombly*/*Iqbal* rule to § 10(b)'s materiality requirement—that Rule 12(b)(6) challenges to the sufficiency of materiality allegations virtually can *never* succeed because materiality belongs solely in the province of the finder of fact. App. 22a ("[q]uestions of materiality . . . involv[e] assessments peculiarly within the province of the trier of fact")

(citations and quotations omitted); App. 23a ("courts should engage in a 'fact-specific inquiry' in assessing materiality [and] '[d]etermining materiality in securities fraud cases should ordinarily be left to the trier of fact'") (citations and quotations omitted). The Ninth Circuit's reasoning significantly diminishes any prospect of dismissing a § 10(b) claim at the pleadings stage based on deficient materiality allegations and, in that fashion, impermissibly conflicts with *Twombly* and *Iqbal*.

Twombly and *Iqbal* require district courts to assess whether a plaintiff's allegations "render [the plaintiff's claim to relief] plausible," that is, whether they contain "enough fact to raise a reasonable expectation that discovery will reveal evidence" of actionable conduct. *Twombly*, 550 U.S. at 556; *see also Iqbal*, 129 S.Ct. at 1949-51. Particularly pertinent to the materiality issues here, the Court has explained that "[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 129 S.Ct. at 1950 (citation omitted). And, there is no doubt that the "plausibility" analysis mandated by *Twombly* and *Iqbal* must be

applied to "all civil actions," including securities fraud claims. *See Iqbal*, 129 S.Ct. at 1953.[3]

Against this backdrop, the Ninth Circuit's exclusion of materiality allegations from the scrutiny envisioned in *Twombly* and *Iqbal* is not sustainable. Even before *Twombly* and *Iqbal*, courts had rejected the "broadly cast" assertion "that it is improper for a court deciding a Rule 12(b)(6) motion to dismiss a complaint on the basis of materiality" and concluded that "a court can determine statements to be immaterial as a matter of law on a motion to dismiss . . ." *See ABC Arbitrage Plaintiffs Grp. v. Tchuruk*, 291 F.3d 336, 359 (5th Cir. 2002) (Higginbotham, J.) (citations omitted).

The Fifth Circuit's pre-*Twombly* observations in *ABC Arbitrage* apply with equal force today and there is nothing unique about the materiality requirement that should spare it from a plausibility analysis *Twombly* and *Iqbal* demand. District courts can apply their recognized "judicial experience and common sense" to determine whether omitted information would have been substantially likely to influence a reasonable investor's decisionmaking, and this Court should encourage them to do so.

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[3] The need for plaintiffs to plead materiality consistent with *Twombly* and *Iqbal* is in addition to the statutory requirement that plaintiffs "specify the reason or reasons why" the alleged omission or misstatement of material fact is misleading. 15 U.S.C. § 78u-4(b)(1)(B).

Fidelity to *Twombly* and *Iqbal* in analyzing materiality allegations is especially vital given the abusive tendencies of securities fraud suits, the inordinate costs of defending them, and the secondary effects of these costs on the capital markets. *See Malack v. BDO Seidman LLP*, 2010 WL 3211088, at *10 (3d Cir. Aug. 16, 2010) ("Rule 10b-5 litigation, by its very nature, is costly. An increase in frivolous litigation drives up the overall costs of issuing securities, ultimately harming everyone involved.").

2. The Ninth Circuit's immunization of materiality allegations from Rule 12(b)(6) challenges facilitates the filing of abusive securities fraud strike suits.

The proliferation of such abusive "strike" suits and the threats they pose has been well-chronicled by this Court and Congress. This Court has recognized that "'litigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general.'" *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 80 (2006) (citation omitted); *see also Stoneridge*, 552 U.S. at 163 (expressing concern "that extensive discovery and the potential for uncertainty and disruption in a lawsuit allow plaintiffs with weak claims to extort settlements from innocent companies"); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313

(2007) ("Private securities fraud actions, however, if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law.").[4]

Congress, too, has perceived the abusiveness in such suits and has legislated with the intent to curb it. Congress passed the Private Securities Litigation Reform Act of 1995 ("PSLRA") "[a]s a check against abusive litigation by private parties[.]" *Tellabs*, 551 U.S. at 313. The Committee Reports for the PSLRA are replete with findings of abusive securities fraud suits and their deleterious impact on public companies, their investors, and the capital markets. *See* S. Rep. No. 104-98, at 8-9 (1995) (finding that securities fraud suits "have added significantly to the cost of raising capital and represent a 'litigation tax' on business"); H.R. Rep. No. 104-369, at 31 (1995) (stating that Congress acted "to protect investors and maintain confidence in our capital markets" in response to "significant

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[4] The fact that § 10(b) claims typically are brought as class actions only magnifies these concerns with abuse and excessive costs. *See, e.g.*, *Gulf Oil Co. v. Bernard*, 452 U.S. 89, 99-100 (1981) (acknowledging that class actions "present . . . opportunities for abuse"); *Reiter v. Sonotone Corp.*, 442 U.S. 330, 345 (1979) (admonishing district courts to be "especially alert to identify frivolous [class] claims brought to extort nuisance settlements"); *Malack*, 2010 WL 3211088, at *11 (recognizing that class certification "'may . . . create unwarranted pressure to settle nonmeritorious claims on the part of defendants'") (citation omitted).

evidence" of abusive litigation tactics). Those Reports also reflect Congress's findings—equally if not more true today—that "[m]ost defendants in securities class action lawsuits choose to settle" and that such "cases are generally settled based not on the merits but on the size of the defendant's pocketbook." S. Rep. No. 104-98, at 8-9 (1995).

Beyond all this, the need for rigorous *Twombly*/*Iqbal* scrutiny of the plausibility of materiality allegations is particularly acute in "omission" securities fraud suits like respondents' here because plaintiffs in such actions generally do not need to plead the element of reliance. *See Stoneridge*, 552 U.S. at 159 (citing *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 154 (1972)). As a result, defendants in these kinds of cases are deprived of a key argument at the pleadings stage, thus amplifying the need to demand plausible materiality allegations in order to weed out abusive "omission" claims under § 10(b).

Nor will the adverse consequences that may follow from the Ninth Circuit's anti-*Twombly*/*Iqbal* rule be restricted to companies located or conduct that occurs within the Ninth Circuit's immense territorial jurisdiction—those consequences will impact pharmaceutical and medical device companies from coast-to-coast that sell their products throughout the fifty states, including the numerous states and territories in the Ninth Circuit. Moreover, the Securities Exchange Act provides for

nationwide service of process and personal jurisdiction in any United States forum based on sufficient contacts by a defendant anywhere in the United States. *See* § 27, 15 U.S.C. § 78aa; *Warfield v. Alaniz*, 569 F.3d 1015, 1029 (9th Cir. 2009). As a result, pharmaceutical and medical device companies face the very real threat of being haled into one of the more than dozen federal district courts in the Ninth Circuit to defend a § 10(b) claim based on undisclosed adverse event reports and being subjected to the decision below as a controlling precedent.

It is unlikely, moreover, that this expansion of liability will be confined to § 10(b) claims. Sections 11 and 12 of the 1933 Securities Act—which create private remedies for misstatements and omissions in registration statements and prospectuses—similarly require that the misstated or omitted fact meet a "materiality" standard. *See* 15 U.S.C. § 77k(a); 15 U.S.C. § 77*l*(a)(2). Thus, courts—including the Ninth Circuit—have concluded "that the standard of materiality is the same under section 10(b) as it is under section 11 . . ." *See, e.g., In re Worlds of Wonder Securities Litig.*, 35 F.3d 1407, 1424 (9th Cir. 1994). Courts in the Ninth Circuit faced with claims under these provisions therefore are likely to

follow the Circuit's decision below in determining the scope of "materiality."[5]

The Ninth Circuit's decision not only looses the materiality requirement from its moorings, but, by failing to bring the pleading analysis in *Twombly* and *Iqbal* to bear, undermines the district courts' recognized screening role as well. In combination, this erroneous analytical approach is certain to increase the number of securities lawsuits that survive the pleading stage, with the enhanced public and private costs that inevitably follow.

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[5] This prospect is all the more troubling because there is evidence of a recent upsurge in § 11 securities fraud claims as compared to § 10(b) suits. *See* David I. Michaels, *An Empirical Study of Securities Litigation After WorldCom*, 40 RUTGERS L. REV. 319, 336-43, 347 (2009). This trend is not surprising because unlike § 10(b), "[n]either [s]ection 11 nor [s]ection 12 (a)(2) requires that plaintiffs allege the scienter or reliance elements of a fraud cause of action." *Rombach v. Chang*, 355 F.3d 164, 169 n.4 (2d Cir. 2004).

C. The Ninth Circuit's Compelled Disclosure Of Adverse Event Reports Unnecessarily Threatens The FDA's Regulatory Role, Including Its Expert Oversight Of Pharmaceutical And Medical Device Labeling.

In the unique confines of a case involving pharmaceuticals or medical devices, particularly given the nature of the information that is being disclosed, declaring adverse event reports material engenders consequences that extend beyond the securities laws, securities litigation, and investors. While certainly not outcome determinative, these consequences at least should be considered where the question concerns—as it does here—the substantive legal standard that ought to be adopted under the securities laws.

Labeling information as "material" under the securities laws carries with it a regulatory directive that the information must be disclosed on penalty of civil or criminal liability. Further, in keeping with the statutory scheme, that disclosure must come from the company itself—in its own public filings with the appropriate regulatory agency.

To be sure, the public otherwise could find out about adverse event reports and those reports could make their way, as they did in this case, into the mainstream media. But in those instances, there is no regulatory compulsion or public company filing

behind the conveyance of the information.[6] And, while the public disclosures required here specifically are aimed at investors or shareholders, it would be naïve to think that their effect will end there. Rather, it is no leap of faith to conclude that the compelled disclosure of adverse event reports would impact the regulation and use of the pharmaceutical and medical devices they relate to.

For example, although not addressed or analyzed in the court's decision, the Ninth Circuit's compelled disclosure rule risks intruding on the FDA's oversight of pharmaceutical and medical device labeling. This intrusion profoundly threatens a critical part of the FDA's regulatory mission.

As this Court well knows, FDA approval of pharmaceuticals and medical devices is a "rigorous" process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (citation and internal quotations omitted). Manufacturers submit "new drug applications," which the FDA subjects to a "strict and demanding" review. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619, 627 (1973); *Riegel*, 552 U.S. at 318 (noting that the "FDA spends an average of

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[6] Indeed, where the securities laws are not involved, the company's First Amendment rights are not circumscribed by those laws and the disclosures they require—in such circumstances, the company can, as Matrixx did here, hold its own press conference or issue its own press release to defend its product and provide an unfettered explanation of why the purported risks should not be associated with its product.

1,200 hours reviewing each application" for premarket device approval). The FDA performs a "comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." *FDA, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). It "must 'weig[h] any probable benefit to health . . . against any probable risk of injury or illness" before approval—"[i]t may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318 (citation and quotations omitted).

A pivotal part of the FDA's review accordingly involves its examination of the drug's proposed labeling (*Riegel*, 552 U.S. at 318)—indeed, approval of an NDA must be based on an FDA finding that the pharmaceutical or medical device is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(b)(1)(F), (d); *see also* 21 U.S.C. § 360c(a)(2)(B).

After approval, the manufacturer must investigate and report to the FDA any adverse events associated with the use of the product in humans, 21 C.F.R. § 314.80, and must periodically submit any new information that may affect the FDA's previous conclusions about safety,

effectiveness, or labeling, 21 C.F.R. § 314.81. The FDA, in turn, "monitors adverse events" from various reports and "uses this information to update drug labeling." *Postmarketing Surveillance Programs* (last modified Aug. 18, 2009) *available at* http://www.fda.gove/cder/regulatory/applications/Postmarketing/surveillancepost.htm. The FDA also "shall" withdraw its approval of an application if it finds, among other things, that the drug is not safe or effective under the conditions of use specified in the drug's labeling. *See* 21 U.S.C. § 355(e); 21 U.S.C. § 360e(e)(1); *Riegel*, 552 U.S. at 319-20.

Whether it relates to the original labeling on the pharmaceutical or device or any subsequent changes prompted by adverse event reports, the FDA's decisions as to what must be disclosed in a product's labeling are fact-based, science-based, and formulated with public health and safety in mind. The FDA's experts are compelled by regulation, and equipped by background, training and experience, to make these health and safety evaluations. The FDA does not require every adverse event or conceivable risk to be disclosed. To the contrary, it requires all labeling to be specifically supported by "reasonable evidence of a causal association" between the product and a particular side-effect. 21 C.F.R. § 201.57(c)(6)(i); *see also* 21 C.F.R. § 201.80(e) (requiring "reasonable evidence of an association of a serious hazard"). As a result, pharmaceutical and device labeling conveys only the information that in

the FDA's considered judgment is essential for the physician prescribing the product and the patient receiving it.

The Ninth Circuit, however, has compelled the disclosure—under the materiality requirement imposed by the securities laws—of adverse event reports without regard for pharmaceutical or device labeling or the FDA's independent evaluation. Plainly, as is true in this case, the Ninth Circuit's holding could compel the company to publicly disclose adverse event reports about a drug or device that the FDA has yet to deem substantial enough to require a change in labeling. In that instance, moreover, the manufacturer could not change its labeling on the one hand (by regulation; *see* 21 C.F.R. § 314.70(b)(2)(v)(A)), but would have to publicly disclose the purported risk in its own public filings on the other. This discrepancy threatens the credibility of the FDA's judgments about safety and effectiveness and disrupts the FDA's recognized roles in crafting and monitoring appropriate product labeling.

Here, the sort of "over-warning" of alleged risks that would follow from the compelled public disclosure increases the likelihood that the most important information about pharmaceuticals and medical devices—the labeling information specifically approved and mandated by the FDA—will be drowned out and overlooked. For instance, "excessive warnings can cause more meaningful risk

information to 'lose its significance.'" Br. *Amicus Curiae* U.S. at *17, *Wyeth v. Levine* (filed U.S. S. Ct. June 2, 2008), *available at* 2008 WL 2308908 ("*Wyeth* Br.") (quoting 44 Fed. Reg. p. 37,447 (1970); citing 71 Fed. Reg. p. 3935 (2006) and 65 Fed. Reg. p. 81,083 (2000)); *see also Robinson v. McNeil Consumer Healthcare*, 2010 WL 3156548, at *11 (7th Cir. Aug. 11, 2010) (Posner, J.) (acknowledging the likelihood of consumer "information overload" from prolix pharmaceutical warning labels); Center for Devices and Radiological Health, FDA, *Write it Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care* 7 (1993) ("Overwarning has the effect of not warning at all. The reader stops paying attention to excess warnings."). This is particularly true of "[w]arnings about dangers with less basis in science or fewer hazards"—*e.g.*, adverse event reports—which "could take attention away from those that present confirmed, higher risks." *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001) (*en banc*).

In addition, such over-warning of alleged risks can motivate consumers to refuse to use a beneficial pharmaceutical or medical device based strictly on the untested and anecdotal information. *See Wyeth* Br., 2010 WL 2308908, at *17 (promoting the need to balance notice of "potential dangers" of drug "and not unnecessarily deterring beneficial uses through overwarning") (citing 71 Fed. Reg. p. 3395 (2006));

id. ("Exaggeration of risk could discourage appropriate use of a beneficial drug,' and thereby harm the public health.") (quoting 71 Fed. Reg. p. 3935 (2006)). This will generate even more costs to society. *See New Medicines Increase Productivity and Decrease Absenteeism*, PhRMA Two-Pager Plus, Winter 2004 (concluding that drugs could prevent nearly $30 billion dollars in lost work time due to treatable depression); *Value of Medicines*, PhRMA (discussing significant beneficial impact of pharmaceuticals) *available at* http://www.phrma.org/ issues /value_of_medicines (last visited Aug. 20, 2010).

Even more problematic, however, is the way in which the compelled disclosures could invade the FDA's expert evaluations on what should be disclosed to the consuming public in the interests of public safety and health. As noted, prescription drug and device labeling is not intended to, and does not, disclose every purported risk that conceivably could be linked to a product. The principal reasons for this regulatory discipline are to help ensure that necessary warnings are heeded and that pharmaceuticals and devices will be utilized when they should be.

FDA regulation does not preempt the securities laws. But the securities laws are not intended to be a *sub rosa* public health disclosure statute either. Yet, that is exactly what those laws will become under the Ninth Circuit's holding, and

the conceptual problems that poses for the FDA's regulatory judgments should not be lightly dismissed in evaluating whether the Ninth Circuit's decision should become controlling law.[7]

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[7] There are other potentially troubling consequences that might follow from the adoption of the Ninth Circuit's reasoning. Under the Ninth Circuit's holding, manufacturers have no genuine choice on whether to disclose adverse event reports in their public securities filings—if they fail to do so, they will confront the almost-certain prospect of a securities fraud suit; if they do disclose, however, their public statements likely will prompt consumer lawsuits based on the discrepancies between the manufacturer's product labeling (as required by the FDA) and the "materiality" of the risks disclosed in its regulatory filings. In the end, therefore, one thing is clear: under the Ninth Circuit's decision, manufacturers face the prospect of escalating costs, with no good options for containing them. *See, e.g., Carlin v. Superior Court*, 920 P.2d 1347, 1361 (Cal. 1996) ("the imposition of excessive liability on prescription drug manufacturers may discourage the development and availability of life-sustaining and lifesaving drugs"); *Brown v. Superior Court*, 751 P.2d 470, 478 (Cal. 1988) ("the consuming public . . . will pay a higher price for the product to reflect the increased expense of insurance to the manufacturer resulting from its greater exposure to liability").

D. The "Statistical Significance" Standard For Disclosing Adverse Event Reports Effectuates The Materiality Requirement's Filtering Function, Furthers The Gatekeeping Function Federal Courts Perform In Screening Securities Lawsuits, And More Closely Comports With The FDA's Paramount Role In Regulating Pharmaceutical And Medical Device Labeling.

The "statistical significance" standard adopted by the First, Second and Third Circuits does not suffer from the same infirmities that plague the Ninth Circuit's decision. Instead, as applied in this case, that standard supports the filtering purpose of the materiality requirement, aligns with the plausibility inquiry required under *Twombly* and *Iqbal*, and comports much more closely with the FDA's recognized regulatory function.

The "statistical significance" standard first emerged in the Second Circuit's decision in *Carter-Wallace I*, 150 F.3d 153. Plaintiffs there asserted a § 10(b) claim based on Carter-Wallace's omission from its public securities filings that its anti-epileptic drug, Felbatol, was associated with patient deaths. The court rejected this claim, concluding that Carter-Wallace had no such duty to disclose under § 10(b) until it "had information that Felbatol had caused a statistically significant number of aplastic-anemia deaths and therefore had reason to

believe that the commercial viability of Felbatol was threatened." *Id.* at 157 (citation omitted). The court explained that "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs 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." *Id.* The Third Circuit and the First Circuit subsequently have endorsed *Carter-Wallace I* and adopted the statistical significance standard as well. *See Oran*, 226 F.3d at 284 (Alito, J.); *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 50 (1st Cir. 2008).

As far as the materiality requirement is concerned, the "statistical significance" standard supports, rather than undermines, the requirement's filtering function. Since it requires that adverse event reports be disclosed only when they collectively demonstrate something more than a mere chance of a causal link between the product and the adverse reaction—the point of "statistical significance"—the "statistical significance" standard spares investors and consumers from a barrage of unverified data about drugs and devices that would only impair the decisionmaking process.[8]

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[8] The "statistical significance" standard adopted by these circuits operatives effectively in cases like this one, where the undisclosed adverse event reports are statistically insignificant

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The "statistical significance" standard also squares with this Court's mandate that only "plausible" claims for relief should be permitted past the pleadings stage and through the gateway to discovery. *Iqbal*, 129 S.Ct. at 1949-50; *Twombly*, 550 U.S. at 555-56, 570. Specific and concrete allegations that undisclosed adverse event reports meet the statistical significance threshold provide a more plausible basis for concluding that a reasonable investor would have been influenced by those reports had they been disclosed. By comparison, given that an adverse event report, without more, reflects nothing more than a random association between the event and a pharmaceutical, something less than allegations of statistical significance in this context falls well short of substantiating the plausibility of a claim that a reasonable investor would have been influenced by that statistically insignificant report. *See In re Carter-Wallace II*, 220 F.3d at 42 (reasoning that "until a connection between [the pharmaceutical] and any illness could be made, we would not expect [the manufacturer] to abandon its

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in number, the association between drug and condition that the reports suggest has not been medically or scientifically substantiated at the time of the alleged non-disclosure, and there is no allegation that the company had reached an internal consensus that its drug's risks could affect the company's future earnings. *Compare In re Pfizer Inc. Securities Litig.*, 584 F. Supp. 2d 621, 633-36 (S.D.N.Y. 2008); *In re Bayer AG Securities Litig.*, 2004 WL 2190357, at *9-10 (S.D.N.Y. Sept. 30, 2004).

product on what, at the time, would have been speculation").

Finally, the "statistical significance" standard threatens far less havoc with the FDA's regulatory role than the Ninth Circuit's compelled disclosure of random adverse event reports. The FDA will not take corrective measures with respect to labeling or withdrawal of a pharmaceutical or medical device based on adverse event reports unless and until the amount of those reports provides "reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.80(e). When the adverse event reports reach a level of statistical significance, therefore, it is much more likely that the FDA will have acted and potential conflicts will be minimized or avoided altogether.

On balance, it is apparent that the "statistical significance" standard responds to this Court's repeated emphasis that securities regulation is "'an area that demands certainty and predictability.'" *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 188 (1994) (quoting *Pinter*, 486 U.S. at 652). "[U]ncertainty" in § 10(b)'s "governing rules," the Court stressed in *Central Bank*, could lead some companies, "as a business judgment, to abandon substantial defenses and to pay settlements in order to avoid the expense and risk of going to trial." *Id.* at 189. A clear, objective rule requiring the disclosure of adverse event reports

only when they have reached a statistically significant number provides the requisite certainty.

CONCLUSION

For the reasons noted, *amicus* respectfully urges this Court to reverse the Ninth Circuit's judgment.

Respectfully submitted,

James C. Martin
Counsel of Record
Colin E. Wrabley
REED SMITH LLP
225 Fifth Avenue, Suite 1200
Pittsburgh, PA 15222
(412) 288-3546
jcmartin@reedsmith.com
cwrabley@reedsmith.com

August 27, 2010 *Counsel for Amicus Curiae*