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

REPLY BRIEF FOR PETITIONERS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

Statutes

Regulations

TABLE OF AUTHORITIES (continued)

Page(s)

Rules

Other Authorities

TABLE OF AUTHORITIES
(continued)

Page(s)

REPLY BRIEF FOR PETITIONERS

It should hardly be controversial that uncorroborated, anecdotal hearsay reports of adverse health events following use of a popular non-prescription drug product do not themselves tell a reasonable investor anything useful about whether to invest in the drug company. But respondents and their amici insist that all such reports—even *one* such report—must be disclosed to investors, because *any* information that "simply suggest[s]" a possible link between a drug and some adverse effect is information *someone* might act on, and thus is information an investor would want to have. U.S. Br. 8.

That argument fundamentally misconceives the materiality standard. It is not a "day trader looking for an edge" standard, requiring companies to disclose anything simply because *some* investors want to know everything. According to the Solicitor General, an investor might even want to know about misleading, unreliable, or even outright false information about a company's product because such information could affect the conduct of ill-informed or irrational consumers and other actors. Human behavior certainly can be driven by rumor and innuendo, as anyone with an e-mail account knows. But materiality under the securities laws has never been based on what ignorant or paranoid people might do with unreliable or inaccurate information. Materiality turns instead on the significance of accurate, reliable information to a *hypothetical*, *reasonable* investor.

In this case, the handful of adverse event reports ("AERs") Matrixx Initiatives, Inc. ("Matrixx") alleg-

edly received before February 6, 2004—12-23 uncorroborated hearsay reports, over a four-year period, out of millions of units sold—did not convey any reliable information about whether Matrixx's product Zicam was causally connected to the reported event, anosmia. If Matrixx was required to disclose those few reports as material information, then materiality has no objective meaning at all, and companies will have no intelligible standard to guide their disclosure determinations. Nor can the mere existence of such reports suffice to establish that petitioners acted with the requisite scienter, i.e., that they knew they were withholding information they were required to disclose.

Respondents defended their complaint below, and in opposing certiorari, on the ground that the few AERs they identified in their complaint were, *in and of themselves*, material information that petitioners knew they were required to disclose to investors. Respondents repeat that flawed argument here, but they also try a different tack, essentially rewriting their complaint to cite various *additional* facts about Zicam that they now say suffice to establish an inference of anosmia causation reliable enough that it should have been disclosed. That argument fails as well: not only are respondents constrained by the allegations they pled, but the facts they now add—most prominently, a 1982 study of the "olfactory mucosa of catfish" (RB7)—still fail to establish any reliable basis for inferring a causal relationship that petitioners should have disclosed.

I. RESPONDENTS' COMPLAINT FAILS TO PLEAD FACTS ESTABLISHING THAT PETITIONERS OMITTED MATERIAL INFORMATION ABOUT ZICAM

Respondents and their amici advance essentially four reasons the complaint adequately pleads materiality:

- Materiality under *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), is a fact-intensive element that cannot be determined at the pleading stage.
- "Practical importance," rather than statistical significance, should be the standard for determining when AERs must be disclosed.
- Investors care about virtually any information concerning a product, not just scientifically reliable information.
- There is evidence in addition to the AERs establishing a causal link between Zicam and anosmia.

Those arguments are meritless.

A. Materiality Is Routinely Adjudicated At The Pleading Stage When The Facts Alleged Are Legally Insufficient

Respondents contend that because materiality is a "totality of the circumstances" inquiry, it is unsuitable for adjudication at the pleading stage. RB25-26; *see* U.S. Br. 28. Respondents also argue that dismissal of their complaint would require adoption of an impermissible "bright line rule." RB41, 54. Neither contention is correct.

1. As a general matter, while materiality in all fraud contexts is a factual matter, "[n]o shortage of cases … make clear that materiality may be resolved by a court as a matter of law." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 657 (4th Cir. 2004); *see, e.g.*, *Shandong Yinguang Chem. Indus. Joint Stock Co. v. Potter*, 607 F.3d 1029, 1033 (5th Cir. 2010); *ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 205-06 (2d Cir. 2009); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376, 378 (4th Cir. 2008); *U.S. ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 389-90 (5th Cir. 2008); *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1053 (9th Cir. 2008); *In re AMDOCS Ltd. Sec. Litig.*, 390 F.3d 542, 548 (8th Cir. 2004); *Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 216 (5th Cir. 2004). If the facts alleged, found to be true by the factfinder, would not suffice to permit a legally sustainable finding of materiality, then the complaint must be dismissed. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-50 (2009).

Respondents thus cannot salvage their complaint by pointing to its pleading-stage status. The complaint fails as a matter of law because it does not identify information upon which a reasonable investor would rely in making investment decisions.

2. Nor does *Basic* prohibit courts from treating raw AERs as generally immaterial absent statistical significance. Courts applying *Basic* have not hesitated to identify categories of information considered immaterial as a matter of law. *See* SIFMA/Chamber Br. 14. The *Basic* Court rejected the bright-line rule proposed *in that case*—not *all* rules or intelligible standards. The rule in *Basic* would have determined

the materiality of information about potential mergers according to the artificial and subjective question—easily manipulated after the fact—whether an "agreement in principle" had been reached. 485 U.S. at 233-36. By contrast, the standard of statistical significance is objective, cannot be manipulated by company executives, and represents an intelligible standard for determining when AERs provide material information.[1]

Matrixx does not seek "a bright-line rule requiring statistical significance for *any* allegation of a failure to disclose information about adverse drug effects to be material under the securities laws." RB21. The point is not that "facts about adverse drug effects are *per se* immaterial absent statistically significant data." U.S. Br. 25. It is, rather, that *AERs themselves* are unreliable indicators of a causal link between the drug and the reported effect, and thus *AERs themselves* are immaterial unless they reveal a statistically significant difference between the rate of reported incidents and the background rate for the relevant population. PB16, 42-44. It is true that *other* information can establish a

[1] Noting that materiality applies both to omissions and misrepresentations, the Solicitor General suggests that applying a statistical-significance standard to AER data would permit a company to falsely deny the existence of "credible" information concerning adverse events "associated with use of its drug." U.S. Br. 24-25. Not so. If the company has knowledge of a "credible" basis for inferring that the drug is actually associated with the adverse event, then it cannot falsely deny the existence of that information. But uncorroborated, anecdotal incident reports are *not* a credible basis for inferring an association.

scientifically reliable inference of causation. PB 44 n.22; PhRMA/BIO Br. 22. But if securities-fraud plaintiffs want to pursue a case based on the proposition that a drug company withheld information meaningfully indicating a problem with a drug, they must plead all the facts necessary to establish that proposition. *See Iqbal*, 129 S. Ct. at 1949-50. This is not such a case, as explained below, *infra* at 12-22.

3. Respondents argue that a statistical-significance standard would diminish the prospect for recovery on valid claims by making it too difficult to plead a claim based on AERs. RB54. But as just explained, the procedural posture in this case is irrelevant: if a handful of AERs out of millions of products purchased would be legally insufficient to permit recovery, then alleging that number of AERs is insufficient at the pleading stage.

In any event, commissioning an epidemiological study (U.S. Br. 23) is not required at the pleading stage. For example, one can draw a reasonable inference about the number of users of a product from SEC filings. PB46. Medical treatises and articles typically will identify the background rate of a health condition. Although ethical issues may complicate randomized studies of adverse health effects (*see* Medical Researchers Br. 11), observational studies are a well-recognized alternative that can be performed using adverse event data. *See* Michael D. Green et al., Reference Guide on Epidemiology, *in* Federal Judicial Center, Reference Manual on Scientific Evidence ("FJC Manual") 339-45 (2d ed. 2000); BayBio Br. 13-14.

To be sure, in some situations the relative rarity of certain adverse effects and the difficulty of collecting large samples of AER data might make proper statistical-significance analysis "an exercise in futility." Statistics Experts Br. 19-21. But if AER data are insufficient to support a reliable inference of causation, it does not follow that plaintiffs should be allowed to plead materiality based on a handful of uncorroborated, anecdotal incident reports. It simply means that in some cases securities-fraud plaintiffs will need other information to make out a plausible claim that the company knowingly withheld reliable information that its product causes a serious adverse event. If plaintiffs cannot plead (on information and belief) facts necessary to establish that essential proposition, the correct response is to *dismiss their case*—not to find ways to permit them to proceed without an adequate factual basis.

B. "Practical Importance" Is Not A Substitute For Statistical Significance

Respondents suggest that "practical importance," rather than statistical significance, should govern materiality determinations. RB38-41; *see* U.S. Br. 13. The argument at least concedes that some objective standard is required, and that materiality is not the one-way disclosure ratchet respondents elsewhere describe it to be.

But practical importance is not a substitute for statistical significance. Indeed, statistical significance is *antecedent* to practical importance for epidemiological data: a study might provide statistically significant evidence that a drug increases the risk of an adverse event by only a practically trivial

amount, or the event might be minor compared to the drug's benefits (e.g., increased acne from an anti-cancer medication). *See* David H. Kaye & David A. Freedman, Reference Guide on Statistics, *in* FJC Manual 124. But a causal connection cannot be practically important if it does not even exist. The point of statistical-significance analysis is to separate potentially causal connections from the *post hoc ergo propter hoc* fallacy that often infects lay, anecdotal observations like those reported in raw AERs.

To illustrate practical importance, respondents hypothesize an anti-nausea drug that appears to increase the risk of cancer by 33%, but only at a p-value of .07 or .12, above the typical .05 or .10 thresholds for statistical significance. RB40; *see* U.S. Br. 14 (similar); *see also* Green et al., Reference Guide on Epidemiology, at 357-59. Respondents say that consumers and investors might nevertheless care given the seemingly enormous consequences. Notably, however, they illustrate their point using p-values close to typical (not required) thresholds of statistical significance. They could not seriously suggest that consumers or investors would be concerned if (to use analogous facts) 12-23 users out of millions reported they contracted cancer after using the anti-nausea medication, given the cancer rate in the general population.[2] Thus, while respondents'

[2] In general, no reasonable scientist would contend that numerical data significant at, for example, a .50 significance level reflect a meaningful possibility that the observed incidence rate was due to an actual correlation. That "would sanction the epidemiological equivalent of garbage." Michael D. Green, *Science Is to Law as the Burden of Proof is to Significance Testing*, 37 Jurimetrics 205, 221-22 (1997).

example may suggest that statistical significance *at .05 or .10 p-values* need not be talismanic in all circumstances (*see* PB35-36), it also confirms the point relevant here: *some* meaningful measure of statistical significance must be applied to determine whether uncorroborated, anecdotal, hearsay incident reports reflect anything more than background noise or confounding by indication.

C. The Materiality Standard Must Facilitate Filtering As Well As Disclosure

Respondents contend that statistical significance should not be required because actual investors rely on all kinds of different information. RB42-43. "Even reports that *simply suggest* causation" must be disclosed, says the Solicitor General, because they might "affect the behavior of consumers, potential litigants, and the FDA." U.S. Br. 8 (emphases added).

These arguments would turn materiality standards into a disclosure free-for-all. Respondents condemn as "paternalistic" (RB42) any role for courts in determining what a *reasonable* investor would deem useful. But the law must exclude *some* information, otherwise materiality has no meaning. Courts therefore must distinguish, in some way, information that would be useful to a reasonable investor from information that would be useful only to an unreasonable investor. Disdaining such line-drawing as paternalism simply avoids the issue.

It is doubtless true that some people could be affected by unverified, unreliable reports that "simply suggest" causation, without regard to their truth or accuracy. For years many consumers would not pur-

chase products from Procter & Gamble because of a ridiculous rumor that the company was Satanic. *See P&G Co. v. Amway Corp.*, 242 F.3d 539, 541 (5th Cir. 2001). But no decision of this Court bases securities-law disclosure obligations on how ignorant or paranoid people might react to unreliable or even false information. On that view materiality again would be a meaningless standard—companies would be required to disclose essentially everything, because it is impossible to *rationally* predict *irrational* reactions.

Because they object to the entire enterprise of drawing materiality lines, respondents largely ignore the critical "filtering" function of materiality that this Court has emphasized. *See Basic*, 485 U.S. at 234; *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976); *Jackvony v. RIHT Fin. Corp.*, 873 F.2d 411, 415 (1st Cir. 1989) (Breyer, J.). Overdisclosure provoked by lax or insufficiently clear materiality standards is just as harmful to investors as underdisclosure. PB30-33. Respondents' observation that raw AER data are already available on the FDA's website (RB57; U.S. Br. 26) overlooks the signaling effect of information provided by the company itself. Investors plainly would assume that a company would report such information only if it established a reliable basis for concern—unless companies actually disclosed all AERs as routinely as the FDA does (U.S. Br. 26), in which case disclosure would be pointless. PB29-30. Moreover, respondents' approach would require manufacturers to disclose AERs for all products and all events, even those not governed by FDA requirements (as here), or serious

enough to trigger FDA-imposed reporting responsibilities. *See*, *e.g.*, 21 U.S.C. § 379aa(c)(1), (e).

Unlike respondents, the Solicitor General concedes that *Basic*'s materiality standard "would sometimes permit a company to withhold adverse drug information." U.S. Br. 29. But the proffered examples—"a single report of an adverse event from an anonymous user," or an event "minor and transient" in nature for a drug with only a trivial impact on company revenues (*id.*)—demonstrate the emptiness of the concession. So does the Solicitor General's position in this very case: if Matrixx was required to disclose to investors 12-23 unverified reports of anosmia out of millions of units sold over four years, among a population already uniquely susceptible to anosmia, then no company could confidently withhold limited, unreliable data without risking exposure to costly and time-consuming securities-fraud strike suits.

The Solicitor General's apparent concession to *Basic*'s "filtering" requirement thus comes to nothing, leaving the contrary proposition he otherwise urges: almost all information *could* matter to *someone*—whether it be professional investors who appreciate nuance, or irrational consumers who elevate rumor over data. That view even more clearly would compel companies to inundate shareholders with uncorroborated, misleading, even utterly false assertions about the company's products, "a result that is hardly conducive to informed decisionmaking." *TSC*, 426 U.S. at 448-49.

Properly conceived, the materiality requirement presupposes a hypothetical, reasonable investor who

wants *accurate* and *reliable* information about a company—not information that is "speculative," overly "contingent," or "unreliable." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 290 (3d Cir. 1999). "To hold otherwise would result in endless and bewildering guesses as to the need for disclosure … and threaten to 'bury the shareholders in an avalanche of trivial information'; the very perils that the … materiality requirement serves to avoid." *Taylor v. First Union Corp. of S.C.*, 857 F.2d 240, 245 (4th Cir. 1988) (quoting *TSC*, 426 U.S. at 448-49).

D. Respondents' Complaint Does Not Plead Other Facts Sufficient To Establish Materiality

The complaint's basic theory of securities fraud is that the raw number of anosmia-related AERs received by Matrixx as of February 6, 2004—a total of 12-23 over a four-year period—was material information. That theory is consistent with the arguments, discussed above, that companies must disclose any fact—even a *single* anecdotal report—that merely "suggests" a causal connection between a consumer product and an adverse event. While still defending that extraordinary theory, respondents also now advance a new fraud theory, which focuses on various asserted facts about Zicam, many not alleged in the complaint. Neither theory justifies reversal of the district court's order of dismissal.

1. The theory of securities fraud actually asserted in the complaint is that petitioners deliberately made material misstatements regarding Zicam that "failed to disclose … numerous users of the Zi-

cam product" had complained of anosmia. *See* J.A. 73a (¶ 32); *see also* J.A. 67a (¶ 24); J.A. 79a (¶ 39(d)). The undisclosed numerical data was allegedly reported to petitioners by, among others, "researchers at the University of Colorado." J.A. 74a (¶ 33).

The district court framed the question as whether petitioners committed securities fraud when they did not inform the markets of "12 user complaints" and "the University of Colorado study." Pet. App. 50a. Given that the user complaints were not "statistically significant," and that respondents had "failed to allege that during the class period, Defendants were presented with any evidence that the University of Colorado study was reliable," the court held that the complaint failed to allege materiality adequately. *Id.*

On appeal to the Ninth Circuit, respondents confirmed that their complaint focused on the *number* of anosmia-related AERs Matrixx had received. The "correct analysis of materiality here," respondents argued, "asks … *only* whether a reasonable shareholder would consider it important that *large numbers* of Zicam users had lost their sense of smell." Plaintiff-Appellants' C.A. Reply Br. at 3 (emphases added; quotation omitted). In opposing certiorari, respondents argued the same: the "specific information" petitioners failed to disclose was the "number of Zicam users" who reported experiencing anosmia after using the product. Opp. to Pet. for Cert. 16; *see id.* at 12, 17, 19; PB44 n.22.

The district court correctly rejected that theory. Simply alleging that a drug manufacturer received a small number of AERs tells one nothing about

whether random chance rather than causation is at work. *See Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (Alito, J.). For this reason, four circuit decisions—including one issued just recently—have held that drug companies have no duty to disclose raw numbers of AERs absent factual allegations establishing that the raw numbers are scientifically meaningful. *See Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 807 (8th Cir. 2010); *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48-50 (1st Cir. 2008); *Oran*, 226 F.3d at 284; *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998).

As these courts recognize, no reasonable investor would find 12-23 AERs out of millions of products sold to be significant to an investment decision. Other than product-liability plaintiffs' lawyers, nobody—including the FDA—believes that AERs by themselves reliably indicate whether there is a causal link between a drug and an adverse event. PB17-25.

The AERs in this case are an especially implausible basis for establishing a material omission given not only the minuscule number of reports compared to the number of products sold, but also because of the common problem of confounding by indication. Because anosmia is mainly caused by the very condition for which consumers use Zicam (PB47 & n.24), "determining the direction of causation is difficult at best." *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 868 (7th Cir. 2010); *see* FDA, Center for Drug Evaluation and Research, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment § IV(E) (Mar. 2005),

2005 WL 3628217. Respondents say the background incidence rate and confounding by indication are matters for discovery and trial (RB33-34), but their own complaint expressly raises the problem of confounding by indication (J.A. 78a (¶ 38)), without alleging any basis on which Matrixx knew or could have known that it was Zicam—not the colds for which Zicam was being used—that caused the few reported anosmia incidents. PB47-48. Respondents are obliged to plead facts that would entitle them to recovery if true, *see Iqbal*, 129 S. Ct. at 1949, and because they do not plead facts distinguishing the incidence rate of anosmia among Zicam users from the rate among cold-sufferers, they have no legal basis for recovery.

The Solicitor General contends that raw AERs are material because the FDA sometimes acts on them before statistical significance is demonstrated, and thus a reasonable investor would want to know about the raw AERs. U.S. Br. 19. But the FDA has broad, subjective discretion in determining when to investigate further or to initiate regulatory activity. The agency is not limited to acting on information accurate and reliable enough to matter to a reasonable investor (or reliable enough for federal courts, *see* PB7 n.2). While the known, concrete fact of imminent FDA action may be material, companies cannot know in the abstract whether particular information creates a sufficient "signal" on which the agency may choose to act. The purely speculative possibility that the FDA might act cannot be the basis for reasonable investment decisions. *See Epstein v. Wash. Energy Co.*, 83 F.3d 1136, 1141 (9th Cir. 1996). This case vividly illustrates the point: the

FDA did not do anything until *more than five years* after the end of the class period, and it acted then only on the basis of accumulated information beyond the facts alleged in the complaint. And even now, the FDA says that the data remain "inconclusive." U.S. Br. 8. The few raw AERs Matrixx had received by February 6, 2004, plainly were nowhere close to triggering an agency response, and thus could not have triggered a disclosure obligation on the basis of imminent agency action.[3]

2. Respondents now offer a new theory of securities fraud, *viz.*, that even if AERs are insufficient as a class, the complaint here nevertheless alleged facts establishing materiality because it asserted additional "detailed and corroborated information" about a causal link between Zicam and anosmia. RB49 n.35. But the supposed additional information respondents cite is nothing more than "the user's loss of sense of smell following Zicam's application into the nose"—information received from "otolaryngology researchers, consumer complaints, and personal-injury lawsuits." RB49 n.35. Virtually everything else respondents now emphasize comes from sources outside the complaint. "It is axiomatic," however, "that the complaint may not be amended by the briefs in opposition to a motion to dismiss," *Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d

[3] The absence of prior FDA analysis of Zicam (U.S. Br. 30-31) does not make a handful of raw AERs a reliable basis for inferring causation. And even AERs concerning an FDA-reviewed drug likely would be material under the Solicitor General's "anything could matter to skittish consumers" view of materiality.

173, 181 (3d Cir. 1988) (quotation omitted), and "[i]t is not … proper to assume that [a plaintiff] can prove facts that it has not alleged." *Assoc. Gen. Contractors, Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983). Accordingly, "in reviewing [a] Rule 12(b)(6) dismissal of [a plaintiff's] claims, [an appellate court] may only look to the factual allegations asserted in the complaint." *Gordon v. Wawa, Inc.*, 388 F.3d 78, 84 (3d Cir. 2004). The district court here invited respondents to amend their complaint and plead more facts establishing materiality, but they refused, electing instead to pursue an appeal based entirely on Matrixx's failure to disclose the "numbers" of AERs it had received by February 6, 2004. This Court in turn granted certiorari to review the question whether AERs alone can be material absent statistical significance, and respondents raised no quarrel with that question in their opposition. S. Ct. Rule 15.2. It is too late now to recharacterize either their complaint or the materiality question it presents. *See Travelers Cas. & Sur. Co. of Am. v. Pac. Gas & Elec. Co.*, 549 U.S. 443, 455 (2007).

3. In any event, respondents' new theory does not salvage their complaint. Respondents contend that the AERs at issue here were material because they (i) were "voluntary [and] unregulated communications from knowledgeable specialists"; (ii) include "corroborating details"; (iii) are consistent with "background medical literature"; and (iv) involve a "serious[]" adverse event.[4] RB33, 55; *see* U.S. Br. 30-

[4] In the absence of reliable evidence of a causal link, the asserted seriousness of anosmia is irrelevant. *See supra* at 7-8.

31. Those facts fall well short of establishing any reliable basis for inferring causation under the detailed, multi-factor tests specialists and courts apply when epidemiological studies are not available. PB44 n.22.

a. Doctors have no special expertise in deducing causation simply because they can diagnose conditions. "The ability to diagnose medical conditions is not remotely the same … as the ability to deduce … in a scientifically reliable manner, the causes of those medical conditions." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 673 (6th Cir. 2010) (quotation omitted; alteration in original); *see* Mary Sue Henifin et al., Reference Guide on Medical Testimony, *in* FJC Manual 471-72 ("[A]n expert's opinion on diagnosis and his or her opinion on external causation should generally be assessed separately[.]"). Respondents confuse the differential *diagnosis* of a treating physician (which identifies the condition that causes symptoms) with differential *etiology* (which identifies the cause of a condition). *See Tamraz*, 620 F.3d at 673-74. A differential etiology is reliable when it *both* "rul[es] out" potential causes (RB49), *and* rules in the suspected cause based on scientifically reliable evidence, which does *not* include doctors' case studies or mere temporal association. *See, e.g.*, *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208-09 (8th Cir. 2000); PB25.[5]

[5] Notably, the "specialist" opinions of Jafek and others now cited by respondents have been consistently *rejected* by courts as unreliable. PB7 n.2.

Indeed, doctor-generated AERs do not by themselves reliably indicate causation even when they meet the FDA's criteria for a complete report—which the telephone calls alleged in respondents' complaint plainly do not. *See* FDA, The Clinical Impact of Adverse Event Reporting 5 (Oct. 1996) ("careful, thoughtful review" of clinical AERs is necessary before reliable determination of causation can be made).[6] "Case studies and clinical experience, used alone and not merely to bolster other evidence, are … insufficient to show general causation." *Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010).

b. Respondents argue the AERs discussed in Jafek's poster presentation were supported by "clinical evidence" in the form of a burning sensation following use of Zicam. RB28, 34. But the poster presentation was not attached to the complaint. And respondents alleged nothing drawing a clinical connection between the asserted burning sensation and anosmia, which involves olfactory tissues that lack pain nerves. *See*, *e.g.*, Michael Tal & Marshall Devor, Anatomy and Neurophysiology of Orofacial Pain, *in* Orofacial Pain & Headache § 2.4.2.1, at 24 (Yair Sharav & Rafael Benoliel, eds. 2008) ("The intense burning sensation that follows sniffing of irritating substances such as ammonia or spicy horse-

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[6] *Available at* http://www.fda.gov/downloads/Safety/MedWatch/UCM168505.pdf. The FDA's criteria for a complete AER include a "succinct clinical description of [the] adverse event, [with] confirmatory/relevant test/laboratory results" and a description of "confounding factors (such as concomitant medical products and medical history)." *Id.* at 5-6.

radish is thought to be due to the activation of trigeminal C-fibre chemo-nociceptors, not olfactory receptors."). Anyone who has had a foreign substance—even water—injected into his or her nose knows that burning and watery eyes can follow. Respondents' assumption that a burning sensation is connected to a subsequent loss of smell is classic *post hoc ergo propter hoc* reasoning. *See, e.g.*, *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005). Respondents also claim that Jafek rejected upper respiratory infections ("URIs") as a cause, but the complaint says no such thing, and his poster cites nothing to support that conclusion. The omission is unsurprising: the scientific literature unambiguously establishes a causal link between anosmia and URIs associated with the common cold. PB47 & n.24.

c. Respondents also insist they alleged facts establishing a "biologically plausible" link between Zicam and anosmia. RB28. But the complaint alleges only a "link between zinc *sulfate* and loss of smell." J.A. 69a (¶ 27) (emphasis added). The active ingredient in Zicam is zinc *gluconate*. The common element of zinc does not establish a common harm: carbon dioxide does not have the same effect on humans as carbon monoxide just because both have a carbon element. Respondents nevertheless contend that the complaint's reference to zinc sulfate suffices to allege a biological link between zinc gluconate and anosmia because a 1982 study of the "olfactory mucosa of catfish" (RB7) supposedly identified a link between zinc ions in *other* zinc salts (not even zinc gluconate) and anosmia in catfish. RB29 n.24. But respondents do not (and could not) explain how stud-

ies of a compound's effect on the olfactory mucosa of a nonmammalian species that lives and breathes only underwater could have any bearing on the effect of a different compound on human beings. *See* Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, *in* FJC Manual 410-11.

4. Respondents offer two additional theories of materiality not tied to AERs as such.

First, they argue that the stock price movement following the *Good Morning America* story indicates the AERs themselves were material. RB30-31; U.S. Br. 31. But the *Good Morning America* broadcast reported that Jafek had reliably concluded that Zicam actually causes anosmia. Investors responded to *that* claim, not to the very different information Matrixx possessed. The fact that the stock price moved in response to a direct public declaration of causation on a major network news broadcast, as opposed to a handful of uncorroborated and unreliable AERs, does nothing to establish materiality. *See ECA*, 553 F.3d at 205 (allegation of actual stock drop is insufficient allegation of materiality); *Koncelik v. Savient Pharms., Inc.*, 2010 WL 3910307, at *10 (S.D.N.Y. Sept. 29, 2010).

Second, respondents argue that a lawsuit filed in October 2003 was material because it was an "early indication that Matrixx's flagship drug was now exposed to litigation." RB29-30 n.25. But a reasonable investor obviously would be aware that pharmaceutical companies are routinely exposed to product-liability litigation. Indeed, the impacts of such litigation are addressed in a distinct disclosure duty not implicated here. *See* Regulation S-K, 17 C.F.R.

§ 229.103. Nor is the October 2003 lawsuit rendered uniquely material by Matrixx's Form 10-Q statement that even frivolous lawsuits "could materially adversely affect" the company. J.A. 178a. A reasonable investor would be interested in a particular lawsuit only if there were an objective basis for believing that *that lawsuit* could affect the company. Respondents allege no such facts concerning the October 2003 lawsuit.

II. RESPONDENTS' ALLEGATIONS DO NOT CREATE A STRONG INFERENCE OF SCIENTER

Respondents' complaint also fails to plead facts sufficient to create a strong inference of scienter, i.e., an inference as "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

The most compelling inference that can be drawn from the facts alleged is that Matrixx did not disclose the handful of AERs because they did not provide a reliable basis for inferring that Zicam causes anosmia. PB49-50. Respondents contend that an inference of fraudulent intent is equally compelling, but many of the facts they cite (RB34-38) appear nowhere in the complaint. Respondents cannot now rely on unalleged facts to challenge the dismissal of their complaint. *Supra* at 17.

For instance, respondents assert that "Matrixx attempted to stop Dr. Jafek from publishing" his findings in a poster presentation (RB35), but the complaint alleges no such thing. Instead the complaint alleges only that Matrixx informed Jafek that

he did not have Matrixx's permission to reference "Zicam" or "Matrixx" in the poster presentation. J.A. 61a (¶ 4). Nothing Matrixx said challenged Jafek's right to publish his "findings" concerning anosmia and "intranasal zinc gluconate," which he published without repercussion. Matrixx's statement related solely to the use of the Zicam brand, and there is nothing nefarious about protecting a brand's reputation from unverified public attack. Indeed, the shareholder class suing Matrixx would expect no less.

Respondents also now assert that Matrixx's attempts to obtain more information from Jafek and Linschoten were not made in good faith, claiming that "[t]he record will not bear that interpretation." RB36; *see* RB37 & n.33. But the relevant inquiry is what the *complaint* alleges, and it alleges nothing to suggest that Matrixx was doing anything other than what the complaint itself says—i.e., seeking more information from Jafek and Linschoten about the user complaints they had received, as respondents themselves concede. RB37 (acknowledging that "Matrixx's Vice President and Director of Research and Development personally followed up on communications with Drs. Linschoten and Jafek"). Contrary to respondents' submission, Matrixx could hardly have concluded that their "findings" were a "real concern for its business" (RB37), inasmuch as they were unwilling to provide information supporting those "findings."

Turning to facts actually alleged in the complaint, there is no merit to respondents' reliance on the findings of the scientific panel Matrixx convened after the close of the class period. RB37-38; *see* U.S.

Br. 32-33. The panel's conclusion—*viz.*, that there was "insufficient scientific evidence … to determine if zinc gluconate, when used as recommended, affects a person's ability to smell," J.A. 82a (¶¶ 45-46), 206a—actually *confirmed* Matrixx's previously stated "belie[f]" that Jafek's affirmative declarations that Zicam causes anosmia were completely unfounded and misleading, J.A. 77a (¶ 38). Contrariwise, the panel's conclusion did *not* show that Matrixx knowingly made false statements about Zicam's safety during the class period. Those statements were based on the solid scientific foundation of two double-blind, placebo-controlled, randomized clinical trials of zinc gluconate, in which there were no reports of anosmia, and "the overall incidence of adverse events associated with zinc gluconate treatment was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets." J.A. 117a; *see also* J.A. 62a, 77a-78a, 80a-82a, 86a, 193a-94a, 201a-02a, 261a. The subsequent panel did not reject those studies or condemn Matrixx's prior statements. It concluded only that the existing scientific evidence provided an insufficient basis for drawing affirmative conclusions one way or the other about Zicam and anosmia.

Matrixx's decision to convene a scientific panel to further examine the issue of anosmia after the *Good Morning America* segment is responsible corporate behavior the law should encourage. Allegations that a company took subsequent measures of this nature cannot support an inference of scienter in securities-fraud cases. *See Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 760 (7th Cir. 2007) (rejecting, in secu-

rities-fraud case, allegation that defendant hired company to "beef up [its] financial controls" as supporting an inference of scienter because "[d]rawing any inference from this would be incompatible with Fed. R. Evid. 407, which provides that subsequent remedial measures may not be used as evidence of liability"); *accord Pugh v. Tribune Co.*, 521 F.3d 686, 695 (7th Cir. 2008).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be reversed.

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