No. 09-1156

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., *et al.*,
Petitioners,

v.

JAMES SIRACUSANO, *et al.*,
Respondents.

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

BRIEF FOR THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICUS CURIAE* [1]

The Advanced Medical Technology Association ("AdvaMed") is the largest medical technology association in the world, representing more than 300 medical device, diagnostic, and health information system companies. AdvaMed's members manufac-

[1] The parties have filed letters with the Clerk of Court consenting to the filing of all amicus briefs. No counsel for any party to these proceedings authored this brief, in whole or in part. No other entity or person, aside from *amicus* AdvaMed and its counsel, made any monetary contribution for the preparation or submission of this brief.

ture 90 percent of the $75 billion in health care technology purchased annually in the United States and over 50 percent of the $175 billion in global sales in this most vital of markets.

The question presented concerns an issue of fundamental importance to AdvaMed's members and to all healthcare companies subject to the federal requirements for adverse event reporting, as well as investors, health care providers, and patients more generally. AdvaMed has a strong interest in ensuring that the federal securities laws are construed so as to require healthcare companies to disclose publicly meaningful and coherent information, instead of partial and anecdotal information that would more likely mislead and confuse investors, rather than assist them.

In the decision below, the Ninth Circuit rejected the majority view, endorsed by three courts of appeal and numerous district courts, that a company's non-disclosure of adverse event reports to investors will not form the basis for a claim under Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5, unless such reports are statistically significant.

The Ninth Circuit's decision rests on an apparent misconception about the nature of the adverse event reporting system. Left in place, it would require AdvaMed's members to include statistically insignificant and substantively meaningless reports in their public disclosures that would expand the information available to investors and consumers without qualitatively improving it. AdvaMed submits this *amicus curiae* brief to assist the Court in considering (1) the nature and role of federal adverse event reporting; and (2) the proper impact of adverse event reports on scienter in Rule 10b-5 actions.

SUMMARY OF ARGUMENT

The Food and Drug Administration ("FDA") requires healthcare companies, and encourages medical professionals voluntarily, to submit to the agency any and all anecdotal reports tying the use of a medical device or a pharmaceutical product to an adverse event. Although each report is typically meaningless if evaluated on its own—because the reports do not purport to show any actual causal link between the product and the adverse event—the FDA believes that, in the aggregate, the reporting of enough of these events might evidence a statistically significant link between the use of the product and some adverse condition that would merit further investigation.

Prior to the Ninth Circuit's decision below, the lower courts had agreed that plaintiffs proceeding under Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5 could not state a claim based solely on a company's non-disclosure of adverse event reports to investors, absent a statistically significant link between the company's product and the adverse events. Those decisions rested upon an appreciation that the FDA's adverse event reporting system provides far more noise, absent some kind of scientifically valid screen, than the reliable, material information suitable for disclosure to investors under the securities laws.

As explained in Petitioners' opening brief, adverse event reports thus should not be regarded as material, unless they are sufficient to demonstrate a statistically significant link between the product and the adverse event. AdvaMed submits, however, that the requirements for scienter under the securities laws, as elucidated by this Court's decision in

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007), provide an even more compelling reason why the Ninth Circuit's decision was in error.

In *Tellabs*, the Court held that a strong inference of scienter "must be more than merely plausible or reasonable—it must be cogent and ***at least as compelling as any opposing inference*** of nonfraudulent intent." *Id.* at 314 (emphasis added). In view of the nature of the FDA's adverse event reporting system, it is perfectly ordinary as a matter of practice and appropriate as a matter of prudence for a healthcare company to exercise caution in making public disclosures to investors unless or until the data evidences a statistically significant link. Accordingly, as a matter of law, a plaintiff cannot meet his burden of pleading facts giving rise to a strong inference of scienter "as compelling as any opposing inference" by simply pointing to a company's non-disclosure to the market of scientifically meaningless adverse event reports.

In concluding that the mere "[w]ithholding [of] reports of adverse effects" supports a strong inference of scienter, regardless of the reports' statistical significance, the Ninth Circuit misapplied the controlling principles of *Tellabs* and the stiff pleading requirements imposed by Congress for securities fraud claims. A careful examination of the nature and role of adverse event reporting under the relevant federal regulations compellingly exposes the flaws in the Ninth Circuit's reasoning and demonstrates why the decision should be reversed.

1. Federal regulations require companies that manufacture drugs, medical devices, vaccines, and other products to submit adverse event reports—known as Medical Device Reports ("MDRs") in the

medical device industry—to the FDA. MDRs, like all adverse event reports, reflect unverified anecdotal information submitted in various ways to manufacturers by health professionals and product users.

Although potentially useful in the aggregate, adverse event reports are inherently unreliable and subject to numerous biases. *First*, MDRs make no attempt to rule out even obvious alternative causes (let alone mere chance), because the FDA encourages submission of adverse event reports even in doubtful situations, such as cases of user error. The FDA's reporting systems often generate voluminous but questionable information that precludes determinations of cause and effect. *Second*, adverse event reports often omit critical information such as the patient's underlying illnesses, medical history, and concomitant use of other products and therapies. *Third*, adverse publicity, including litigation-generated mass media attention, greatly influences—and often distorts—reporting of adverse events. Indeed, the potential for distortion is greatly magnified under passive surveillance systems, like the FDA's voluntary reporting regime for medical professionals, that are inherently prone to underreporting.

Recognizing the inherent limitations of adverse event reports, the FDA expressly disclaims using them to assess causation. At most, MDRs are individual data points—"signals" in FDA parlance—that can suggest a need for further inquiry. By themselves, they establish no medical or scientific facts. The FDA thus employs sophisticated statistical analyses of adverse events in its databases before drawing any conclusions about their significance, and it expects life sciences companies to do the same.

The FDA's skepticism of raw adverse event reports is shared by courts analyzing causation in civil cases. Numerous courts have held that the inherent flaws of adverse event reporting are too serious to allow their use to prove causation.

2. The nature of the FDA's adverse event system underscores why statistical significance is necessary before a court may draw any inference, much less a "strong" inference, that non-disclosure of adverse event reports to the investing public is probative of scienter. Three well-established principles of securities law demonstrate why statistical significance is an appropriate minimum threshold for scienter in cases involving alleged non-disclosure of adverse events to investors:

First, a court may infer scienter from the defendant's non-disclosure of information only if there is plausible reason to think that the defendant believes he or she has something to hide. A strong inference of scienter therefore may not reasonably be inferred when the defendant regards the undisclosed information as unreliable or inconclusive. *In re Carter-Wallace Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998), and 220 F.3d 36 (2d Cir. 2000), and its progeny among the lower courts, properly hold that the mere receipt of inconclusive adverse event reports does not support a strong inference of scienter. A defendant cannot be deemed to know of, let alone intentionally or recklessly ignore, a causal link between its product and an adverse event where the reports have never established such a connection. Unless and until adverse event reports 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 reports did not call into question the product's safety. The Ninth Circuit's contrary decision, equating raw adverse event reports with "red flags" about product safety, misunderstands that the multifarious, and sometimes conflicting, reports amount to little more than background noise in a much broader setting of product usage, unless and until subjected to statistical analysis.

Second, scienter must turn on a defendant's knowledge at the time of an alleged misstatement. "Fraud-by-hindsight" is not actionable under the securities laws. The subsequent linkage of a product to an adverse event does not demonstrate prior intent to deceive. Abandoning statistical significance as a prerequisite to a securities fraud claim would effectively hold a life sciences company and its officers culpable for not predicting—based on unreliable and inconclusive adverse event reports—the later emergence of a *bona fide* safety issue. The statistical significance standard protects defendants from such *post hoc* critiques. Indeed, the Ninth Circuit's finding of a strong inference of scienter based on nondisclosure of statistically insignificant adverse event reports (and an FDA warning letter issued some five years after the class period), raises the untenable specter of fraud-by-hindsight.

Third, a defendant's decision to investigate adverse event reports before publicly disclosing them reflects prudence, not the intent to defraud. A company cannot determine the scientific implications of a series of adverse event reports without engaging in a sophisticated statistical analysis of these cumulative reports. The FDA recognizes this and thus advises life sciences companies to investigate such reports

carefully before drawing any conclusions. In direct conflict with that direction, the Ninth Circuit actually concluded that Petitioners' investigation supported an inference of scienter, treating such raw reports as indicia of causation. That was error.

3. Adopting the Ninth Circuit's indiscriminate approach to disclosure of unverified adverse event reports would adversely affect life science companies, investors, and patients. If affirmed, the Ninth Circuit's decision would push companies selling pharmaceuticals, biotechnology, and medical technology to disclose publicly every single adverse event report—amounting to potentially hundreds of thousands of reports annually—with little regard to the strength of the causal link. Under such a regime, companies would be forced to give their imprimatur to unverified and unreliable reports about their products, leading in some cases to artificially depressed stock prices and increased volatility, as confused investors seek to separate the true nuggets of value amidst a torrent of unreliable information. Disclosing such statistically insignificant adverse event reports would harm investors and consumers by distorting the information upon which they base critical investment and health care decisions.

While statistical significance alone may not establish the strong inference of scienter that *Tellabs* demands, the failure even to allege it should be grounds for dismissal. The decision below should be reversed.

ARGUMENT

The decision below rests upon a misunderstanding of the significance of adverse event reports for products distributed among tens of thousands, and

sometimes millions, of consumers throughout the country and the world. As discussed below, the FDA has long recognized that adverse event reports do not constitute reliable information upon which companies or consumers should base actual medical decisions until statistical significance suggests a pattern that merits investigation. Yet the Ninth Circuit held that adverse event reports alone, even if statistically insignificant, may create a factual question about liability under the federal securities laws.

Although the lower court misapplied the principles that govern the element of materiality, as explained in Petitioners' opening brief, the Ninth Circuit's holding on scienter is premised upon an even more drastic error. It assumes an inference of ***fraudulent*** intent to be equally appropriate to a benign inference when a healthcare company prudently follows FDA recommendations—and common sense—by evaluating the implications of reported adverse events through the lens of science before making a public statement.

In pleading securities fraud, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," *i.e.*, scienter. 15 U.S.C. § 78u-4(b)(2).[2] "To qualify as 'strong' within the intendment of § 21D(b)(2) . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference." *Tellabs*, 551 U.S. at 314. A court shall deny a motion to dismiss "only if a reasonable person

[2] Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (quotation marks and citation omitted).

would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324.

Even before *Tellabs*, the Second Circuit had long recognized that non-disclosure of statistically insignificant adverse event reports cannot give rise to a strong inference of scienter. *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998) ("*Carter-Wallace I*"); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000) ("*Carter-Wallace II*"). Two other courts of appeals subsequently adopted this standard, *see N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000) (Alito, J.),[3] and numerous district courts agree.[4] These courts recognize that absent statistical significance, the far more plausible inference to be drawn from non-disclosure to the public is that the adverse event reports did not yet evidence a correlation, much less a causal connection, between the product and the events.

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[3] While *Oran* was decided on materiality grounds, the court's analysis would apply equally well to scienter. *Cf. Carter-Wallace II*, 220 F.3d at 41 ("Not only were the financial statements not materially misleading before the link [between the product and an adverse event] could be made, but any inference of scienter was negated as well.").

[4] *See, e.g.*, *Plumbers and Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 673 F. Supp. 2d 718, 742 (S.D. Ind. 2009); *In re Medtronic, Inc. Sec. Litig.*, 618 F. Supp. 2d 1016, 1026 (D. Minn. 2009); *Kairalla v. Advanced Med. Optics, Inc.*, 2008 WL 2879087, at *10-11 (C.D. Cal. June 6, 2008); *In re Intrabiotics Pharm., Inc. Sec. Litig.*, 2006 WL 2192109, at *13-14 (N.D. Cal. Aug. 1, 2006).

In expressly rejecting statistical significance as a prerequisite, the Ninth Circuit considered neither the nature of adverse event reports under the FDA's regulatory scheme nor the importance of statistical analysis in evaluating such reports. Yet statistical significance remains the appropriate threshold for determining whether a defendant's non-disclosure of adverse event reports to investors can support any inference of scienter, much less the strong one required by the securities laws.

I. ADVERSE EVENT REPORTS PROVIDE NO RELIABLE BASIS TO INFER CAUSATION.

A. The FDA Requires Manufacturers To Report All Adverse Events Regardless of Causation.

AdvaMed's members, and all medical device manufacturers, must submit MDRs to the FDA for all suspected adverse incidents. 21 U.S.C. § 360i(a)(1).[5] This reporting requirement, contained in 21 C.F.R. § 803.50(a), extends to more than 20,000 companies and covers almost 100,000 medical devices, from tongue depressors to artificial heart valves.[6]

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[5] This brief focuses on adverse event reporting requirements applicable to medical device companies. Substantially similar requirements apply to virtually all FDA-regulated products, including drugs and vaccines. *See, e.g.*, 21 C.F.R. § 314.80 (drugs); 21 C.F.R. § 600.80 (vaccines).

[6] HHS Office of Inspector General, *Adverse Event Reporting for Medical Devices* ("*Adverse Event Reporting*"), at 1 (Oct. 2009), *available at* http://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf. All Web pages cited herein were last visited no earlier than August 23, 2010.

MDRs must be filed with the FDA without regard to the likelihood of causation. An "MDR Reportable Event" occurs whenever a manufacturer learns of anything "reasonably suggest[ing]" that its device: (1) "[m]ay have caused or contributed to a death or serious injury," or (2) experienced a non-injurious "malfunction" that "would be likely to cause or contribute to a death or serious injury" if it recurred. 21 C.F.R. § 803.50(a).[7] "Caused or contributed" is defined to include unknown and doubtful cases:

> Caused or contributed means that a death or serious injury was or ***may have*** been attributed to a medical device, or a medical device ***may have*** been a factor in the death or serious injury.

21 C.F.R. § 803.3 (emphasis added); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008) (citing 21 C.F.R. § 803.50(a)). MDRs are required even for "user error." 21 C.F.R. § 803.3. Filing an MDR in no way establishes that a device had anything to do with the reported event:

> A report or other information . . . is not necessarily an admission that the device . . . caused or contributed to the reportable event. [Manufacturers] do not have to admit and may deny that the report or information submitted . . . constitutes an admission that the device . . . caused or contributed to the reportable event.

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[7] Malfunction MDRs must be filed whenever "the chance of a death or serious injury . . . is ***not*** remote." FDA, Center for Devices & Radiological Health, *Medical Device Reporting for Manufacturers* ("*Medical Device Reporting*"), 1997 WL 33793806 § 2 (Mar. 1, 1997). For malfunctions, there is "no[] need to assess the likelihood that a malfunction will recur," as recurrence is "presume[d]." *Id.*

21 C.F.R. § 803.16; *see* FDA, *Medical Device Reporting* § 3 (definition of "Disclaimers").[8]

Only two circumstances are exempt from reporting: (1) if the supposed event did not happen at all, and (2) if the event involves another manufacturer's device. FDA, *Medical Device Reporting* § 2.[9]

B. The FDA Recognizes that Adverse Event Reporting Is Subject to Significant Statistical Biases and Lacks Scientific Validity.

Not surprisingly, the FDA has long recognized the limitations of adverse event reporting for medical devices and drugs, and it readily acknowledges that these limitations preclude causation assessment:

> 1. For any given [reported] case, there is no certainty that the suspected drug caused the [adverse event]. This is because physicians and

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[8] The FDA intentionally chose more reports over better ones. As the Tenth Circuit has explained: "FDA reiterated the need for an expansive reporting system and adopted regulations that require manufacturers to file an MDR if they become aware of information suggesting that a device ***may*** have caused or contributed to a death or serious injury rather than the more limited language proposed that would have required manufacturers to file an MDR only in cases where they receive information suggesting that a device ***has*** caused or contributed to a death or serious injury." *TMJ Implants, Inc. v. U.S. Dept. of Health & Human Servs.*, 584 F.3d 1290, 1295 (10th Cir. 2009) (citing FDA regulation).

[9] A similarly broad reporting requirement exists for prescription drugs. Drug manufacturers must make reports to the FDA about "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." *Wyeth v. Levine*, 129 S. Ct. 1187, 1210 (2009) (quoting 21 C.F.R. §§ 314.80(a), (c), (j)).

> consumers are encouraged to report all suspected [adverse events], not just those that are already known to be caused by the drug. The adverse event may have been related to an underlying disease for which the drug was given, to other concomitant drugs, or may have occurred by chance at the same time the suspect drug was administered.
>
> 2. Accumulated [adverse events] may not be used to calculate incidences or estimates of drug risk. Numbers from these data should be carefully interpreted as reporting rates and not occurrence or incidence rates.

FDA, Center for Drug Evaluation and Research, *Annual Adverse Event Drug Experience Report: 1996* 2 (Oct. 30, 1997).[10]

The FDA's current guidance on its Web site candidly advises that adverse event reports lack statistical validity:

> [T]here is no certainty that the reported 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. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, [adverse event reports] can-

[10] *Available at* http://druganddevicelaw.net/Annual%20Adverse%20drug%20experience%20report%201996.pdf.

> not be used to calculate the incidence of an adverse event in the U.S. population.

FDA, *Adverse Event Reporting System* (Aug. 20, 2009).[11] With respect to MDRs, the FDA similarly warns that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices."[12]

The statistical biases in adverse event reports relate to the inconsistent, informal, and anecdotal nature of the FDA's reporting system. Although mandatory for the manufacturers of all medical devices and drugs, adverse event reporting is purely voluntary for healthcare professionals—who may be the primary source for reports, depending upon the device or drug in question. *See In re Medtronic, Inc.*, 184 F.3d 807, 809 (8th Cir. 1999). Through the FDA's "MedWatch" reporting system, physicians, physician assistants, pharmacists, and nurses may submit reports "either directly to the agency or to other entities who report to the agency" (*i.e.*, the manufacturers). *Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules*, 60 Fed. Reg. 16962, 16962 (Apr. 3, 1995); *see* 21 C.F.R. §§ 803.12(d), 803.20(a). Moreover, adverse event reports from healthcare professionals are highly informal; the great majority are made orally to manufacturers. *See* General

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[11] *Available at* http://www.fda.gov/Drugs/Guidance Compliance RegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

[12] MAUDE, which stands for "Manufacturer and User Facility Device Experience," is the FDA's online MDR database. *Available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

Accounting Office, *Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting ("Medical Devices")* 47 (Dec. 1986) (83% are oral reports).

Because the FDA requires manufacturers to submit duplicative adverse event reports for incidents voluntarily reported to them by healthcare providers, MedWatch "generate[s] a deluge of information." Catherine Struve, *The FDA & the Tort System: Postmarketing Surveillance, Compensation, & the Role of Litigation*, 5 Yale J. Health Pol'y, L. & Ethics 587, 604 (2005). For example, the FDA reported receiving 224,197 MDRs during its 2006 fiscal year. FDA, Center for Devices & Radiological Health, *CDRH FY 2006 Annual Report* 29 (2006).[13] A more recent report concluded that this total was even larger:

> This number increased steadily until 2006, when it increased more than fourfold to 443,066 events, and then stayed relatively flat with 449,978 events in 2007.

HHS Office of Inspector General, *Adverse Event Reporting*, at 10. That sharp increase was due to one particular manufacturer's device, *id.*, demonstrating again the volatility of the reporting system.

At the same time, while MDR totals "may seem high, underreporting of adverse events" is a persistent problem. Edward M. Basile & Beverly H. Lorell, *The Food & Drug Administration's Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency's Regula-*

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[13] *Available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129258.pdf.

tory Framework?, 61 Food & Drug L.J. 251, 258 (2006). In 1986 (under earlier regulations), the General Accounting Office ("GAO") estimated that health care providers voluntarily reported only one percent of reportable events to the FDA and only about half to the manufacturers.[14] A decade later, GAO found that systemic underreporting persisted.[15] "Reasons" for underreporting:

> include ignorance of the reporting system, complacency, fear of medicolegal liability, personal or professional guilt about having inadvertently harmed a patient, and uncertainty as to whether the drug or device was actually the cause of the adverse event.

Jeffrey Zigler, et al., *Medical Device Reporting: Issues With Class III Medical Devices*, 62 Food & Drug L.J. 573, 577 (2007).

Chronic underreporting by healthcare providers allows extraneous factors to influence reporting rates. In 2005, the FDA concluded that adverse event reporting is "subject to substantial limitations in interpretation because of the inherent uncertainties in the numerator and denominator." FDA, *Guidance for Industry: Good Pharmacovigilance Practices & Pharmacoepidemiologic Assessment* ("*Good Pharmacovigilance*"), 2005 WL 3628217 § IV(G) (Mar. 2005). Thus:

> [V]oluntary adverse event reporting systems . . . are subject to a variety of reporting biases (*e.g.*,

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[14] GAO, *Medical Devices*, at 50-51.

[15] GAO, *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices* 15-17 (Jan. 1997), *available at* http://www.gao.gov/archive/1997/he97021.pdf.

> some observations could reflect concomitant treatment, not the product itself, and other factors, including the disease being treated, other co-morbidities or unrecorded confounders, may cause the events to be reported). In addition, [the] data may be affected by the submission of incomplete or duplicate reports, underreporting, or reporting stimulated by publicity or litigation.

Id. § IV(E).

In a brief filed with the Court this Term, the Solicitor General similarly acknowledged that voluntary adverse event reporting in the vaccine context is "not sufficient" for "sound" decision making and requires "further investigation":

> Because VAERS [the vaccine adverse event reporting system] depends on self-reporting, however, its data alone are not sufficient for sound public health policy decisions. VAERS data are instead used to trigger further investigation.[16]

To cull true product risk from mere reporting biases, statistical significance—not the number of reported events—is essential. As the FDA recently explained, "[i]nformation from other sources that is neither systematically acquired nor statistically significant can provide only anecdotal information."[17]

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[16] Brief for the United States as *Amicus Curiae* Supporting Respondents, *Bruesewitz v. Wyeth, Inc,* No. 09-152, at 21-22 (U.S. July 23, 2010).

[17] FDA, Center for Devices and Radiological Health, *Guidance for Industry Assessment of Abuse Potential of Drugs* 18 (Discussion Draft Jan. 2010), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf.

The FDA neither acts, nor demands that manufacturers act, upon raw adverse event reports of the sort at issue in the present case. Instead, the FDA employs statistical analysis—precisely what the Ninth Circuit rejected here.[18]

Despite the value of the FDA's adverse event reporting system, the data contained within the database is plagued by significant flaws that prevent the information from being relied upon absent such analysis:

First, no causation requirement means "that the system gets flooded with too many (generally unimportant) reports" and generates so much noise that "[k]ey data regarding new issues can get lost in this sea of irrelevant information." Ralph Hall, *A Proposed Solution to the Notification Problem*, 7 Minn. J.L. Sci. & Tech. 189, 194 (2005).

Second, "underreporting is a recognized problem . . . [p]articularly for low frequency events" where "every report is critical." *Id.*

And *third*, the FDA's "passive systems provide only a raw number of events and not the incident rate"

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[18] The FDA utilizes "trend analyses . . . such as calculating occurrence rate changes for specific events." HHS Office of Inspector General, *Adverse Event Reporting*, at 5. The FDA's latest device guidance recommends sophisticated analysis "to mine large databases of post-market medical reports" in order to "reduce the number of falsely significant associations that are expected." FDA, Center for Devices and Radiological Health, *Guidance for Industry & FDA Staff: Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials*, 2010 WL 545395 § 6 (Feb. 5, 2010). Similar forms of "data mining" are recommended for evaluating adverse drug events. FDA, *Good Pharmacovigilance*, § V.

and "may not provide a valid basis for medical decisions." *Id.*

In other words, the FDA's reporting system results in a database that is both overinclusive and underinclusive, with the biases of underreporting influenced by a variety of confounding factors. Thus, sophisticated statistical analysis is required before the information may be relied upon to draw any meaningful conclusions.

C. Numerous Courts Have Recognized that FDA Adverse Event Reports Are Insufficient for Civil Liability.

Respondents' attempt to rely upon adverse event reports to establish civil liability under the securities laws calls to mind more frequent attempts by plaintiffs in products-liability cases to mine the FDA's adverse event database for evidence of causation. In that context, too, the vast majority of federal courts have concluded that, absent statistical significance, adverse event reports are insufficient to support liability.

In seeking to fulfill its broad mandate to ensure the safety of drugs and medical devices, the FDA seeks to pull together as much information as possible in the adverse event databases, not to assemble a database of reliable reports sufficient to satisfy individual questions of causation. Such administrative analysis involves a much lower standard than necessary in a court of law:

> This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is reasonably

> lower than that appropriate in tort law, which traditionally makes more particularized inquiries into cause and effect.

Allen v. Pa. Eng'g Corp., 102 F.3d 194, 198 (5th Cir. 1996) (citation and internal quotation marks omitted); *see also Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) ("A regulatory agency such as the FDA may choose to err on the side of caution."); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("[M]ethodology employed by a government agency results from the preventive perspective that the agencies adopt.").

For this reason, courts in civil litigation frequently reject the scientific validity of FDA MedWatch reporting when applying scientific reliability standards under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005), for instance, the court recognized that "FDA reports reflect complaints called in by product consumers without any medical controls or scientific assessment." Utilization of such reports to prove causation was unscientific, and admission of this testimony was an abuse of discretion:

> [A]necdotal reports do not prove causation . . . . Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation.

Id. Mere complaints "lack[] the indicia of scientific reliability." *Id.* at 1240. *Accord Glastetter*, 252 F.3d at 989-90 (voluntary reports "make little attempt to screen out alternative causes," "frequently lack analysis," and "often omit relevant facts").

Numerous district courts ruling on *Daubert* and similar evidentiary challenges have reached the same conclusion, dismissing adverse event report data as "uncontrolled anecdotal information," *Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316, 1327 (M.D. Ala. 2006), that "suggest only a potential, untested hypothesis," *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1228 (D. Colo. 1998), that lack any "known or potential rate of error," *In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1041 (D. Minn. 2007), and are simply "not probative of . . . notice." *Smith v. Pfizer Inc.*, 2010 WL 1754443, at *5 (M.D. Tenn. Apr. 30, 2010).[19]

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[19] *Accord In re Accutane Prod. Liab. Litig.*, 2007 WL 1288354, at *3 (M.D. Fla. May 2, 2007) (MedWatch reports "reflect[] nothing more than an assessment of a possible relationship, not an actual relationship"); *Dellinger v. Pfizer Inc.*, 2006 WL 2057654, at *9 (W.D.N.C. July 19, 2006) (reports "are not scientific proof of causation" and "cannot support a causation opinion"); *Ervin v. Johnson & Johnson, Inc.*, 2006 WL 1529582, at *6 (S.D. Ind. May 30, 2006) (reports "do little more than establish a temporal association between an exposure to a drug and a particular occurrence"), *aff'd*, 492 F.3d 901 (7th Cir. 2007); *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 807 (N.D. Ohio 2004) ("[P]roportional reporting rate analyses are incomplete and often misleading because they do not show the total distribution of reports."), *aff'd*, 447 F.3d 861 (6th Cir. 2006); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003) (reports lack "information that would be necessary to determine . . . causation"); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 537 (W.D. Pa. 2003) (reports "are compilations of occurrences" and "do not demonstrate a causal link but instead represent coincidence"); *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1133 (D. Ariz. 2001) (reports "are merely compilations of occurrences, and have been rejected as reliable scientific evidence"); *In re Diet Drugs Prod. Liab. Litig.*, 2001 WL 454586, at *15 (E.D. Pa. Feb. 1, 2001) (reports "are universally recognized as insufficient and unreliable evidence of causation"); *Hollander*

State courts applying similar scientific validity standards concur. In *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997), the court excluded "case reports" because "anecdotal . . . evidence accomplishes no more than a false appearance of direct and actual knowledge of a causal relationship." So too the Iowa Supreme Court, which recently held that FDA "[c]ase reports are merely accounts of medical events. They reflect only reported data, not scientific methodology." *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 693 (Iowa 2010).[20]

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v. Sandoz Pharm. Corp., 95 F. Supp.2d 1230, 1237 (W.D. Okla. 2000) (reports "are not controlled studies and do not eliminate confounding variables"), *aff'd in relevant part*, 289 F.3d 1193 (10th Cir. 2002); *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) (reports "don't isolate and investigate the effects of alternative causation agents," "are compilations of reported phenomena," and "reflect reported data, not scientific methodology"); *In re Norplant Contraceptive Prod. Liab. Litig.*, 1997 WL 80527, at *1 (E.D. Tex. Feb. 19, 1997) (reports excluded because "the FDA requires [defendant] to submit all adverse events reported to it without regard to whether there is any proven causal connection"); *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1164 (S.D. Fla. 1996) (reports "can be used to generate hypotheses" but "scientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies"), *aff'd mem.*, 158 F.3d 588 (11th Cir. 1998); *DeLuca v. Merrell Dow Pharm., Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (reports have "inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions"), *aff'd mem.*, 6 F.3d 778 (3d Cir. 1993).

[20] *Accord Heckstall v. Pincus*, 797 N.Y.S.2d 445, 447 (N.Y. App. Div. 2005) (MedWatch reports are "unverified listings and reporting of adverse reactions" and "are not generally accepted in the scientific community on questions of causation"); *Reynolds v. Warthan*, 896 S.W.2d 823, 828 (Tex. App. 1995) (reports only "create[] a suspicion without any medical proof").

In no other case and in no other area of the law have adverse event reports carried the weight that the Ninth Circuit gave them below.

II. THE INHERENT LIMITATIONS OF ADVERSE EVENT REPORTS PRECLUDE DRAWING ANY INFERENCE OF SCIENTER, ABSENT STATISTICAL SIGNIFICANCE.

Given the inherent limitations and biases of adverse event reports, as acknowledged by the FDA and the courts, such reports are presumptively inconclusive of a correlation—let alone a causal connection—between a product and an adverse event. They are scientifically meaningless until cumulative statistical analysis demonstrates otherwise.

In view of such limitations, there is simply no basis upon which a court could draw an inference that a company's decision not to disclose such isolated reports through a public statement to investors was suspicious in any way, much less that it supports a "strong inference" of fraudulent intent "at least as compelling as any opposing inference." *Tellabs*, 551 U.S. at 314.[21]

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[21] Adverse event reports received by medical device manufacturers are, in fact, publicly available. The FDA has authority to disclose adverse event reports to the public, *see* 21 C.F.R. § 803.9(a), and through the MAUDE online database, *see supra*, n.12, all adverse event reports involving medical devices (MDRs) are made available to the public by the FDA, subject to protection of trade secrets and patients' personal medical information. *See id.* § 803.9(b); *see also Medical Device Reporting* § 3 (explaining disclosure process).

The public availability of MDRs is a separate reason why securities fraud claims against medical device manufacturers cannot be based on the alleged non-disclosure of MDRs. *See,*

A. Non-Disclosure of Unreliable or Speculative Information to the Public Does Not Support an Inference of Scienter.

In assessing scienter in non-disclosure cases, the quality of the undisclosed information is critical. Information need not be disclosed that is inconclusive, speculative, or "of dubious significance." *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448

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e.g., *Santa Fe Indust., Inc. v. Green*, 430 U.S. 462, 474 (1977) (no actionable Rule 10b-5 claim where plaintiffs were "furnished with all relevant information on which to base their decision"); *see also Avon Pension Fund v. GlaxoSmithKline*, *PLC*, 343 Fed. App'x 671, 674 (2d Cir. 2009) (disclosure to the FDA "effectively refutes that the pleaded circumstances support the requisite inference of scienter"); *Fort Worth Empl. Ret. Fund v. Biovail Corp.*, 615 F. Supp.2d 218, 221 (S.D.N.Y. 2009) (no scienter where allegedly undisclosed letter "was publicly available on the FDA's website throughout the putative class period, where it could have been read and assessed by any investor"); *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005) (no scienter where "the MAUDE printouts were available through the FDA"; "the market already had the necessary information"). Unlike medical devices, the product at issue in the present case, Zicam, was an over-the-counter homeopathic product, and the FDA did not require mandatory adverse event reporting for such OTC medications until 2006. *See* Dietary Supplement & Nonprescription Drug Consumer Protection Act, Pub. L. 109-462, 120 Stat. 3469, *codified as* 21 U.S.C. §§ 379aa (OTC drug reporting requirements) and 379aa-1 (same for dietary supplements). The allegations in this case involved the non-disclosure of pre-2006 adverse events reports. But no matter whether a company is obliged to submit adverse event reports to the FDA, the scienter analysis should remain the same. In either case, as discussed below, scienter does not exist where a company has no reason to believe that the reports are statistically significant.

(1976)).[22] Non-disclosure of such information to the market supports no inference, much less a strong inference, of intent to deceive. In these circumstances, "the defendant did not have ***sufficient*** information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." *N.J. Carpenters*, 537 F.3d at 45 (emphasis added). Stated differently, a defendant has no "reason to believe" that non-disclosure of inconclusive or otherwise suspect information creates a danger of misleading investors. *Carter-Wallace I*, 150 F.3d at 157; *see also Schlifke v. Seafirst Corp.*, 866 F.2d 935, 946 (7th Cir. 1989) ("The question is not merely whether the [defendant] had knowledge of the undisclosed facts; rather, it is the ***danger of misleading buyers*** that must be actually known or so obvious that any reasonable man would be legally bound as knowing.") (citation and internal quotation marks omitted).

A company cannot have culpable knowledge of a product safety issue without a sound reason to believe that the product is causally linked to an adverse event. Yet until a statistically significant association is apparent, the company can draw no meaningful inferences from anecdotal reports and thus has no basis "to form an evaluation that there

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[22] *See also Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc*., 531 F.3d 190, 196 (2d Cir. 2008) (no inference of scienter where "[plaintiffs'] broad reference to raw data lacks even an allegation that these data had been collected into reports that demonstrated" their allegations); *In re Healthcare Compare Corp. Sec. Litig.*, 75 F.3d 276, 282-83 (7th Cir. 1996) (no duty to disclose tentative internal estimates subject to revision or verification, even though they conflict with published estimates).

was a need to disclose." *N.J. Carpenters*, 537 F.3d at 45; *see also Avon*, 343 Fed. App'x at 672 ("Reports or test results must yield reliable evidence of a drug's adverse effect to give rise to a duty . . . to disclose those results to potential investors."). Absent statistical significance, the company thus has no reason to view adverse event reports as casting doubt on product safety, and without such a belief, there is no legal basis to infer an intent to deceive the public through non-disclosure.[23] Instead, the most plausible inference is that the company continued to believe that its product—marketed only after FDA review—remained safe.[24]

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[23] It should be emphasized that the statistical significance of adverse event reports is a necessary, but not a sufficient, condition to establish scienter. Scienter requires that the company also know that the reports are "sufficiently serious and frequent to affect future earnings" and threaten the "commercial viability" of the company. *Carter-Wallace I*, 150 F.3d at 157; *see also Masters v. GlaxoSmithKline*, 271 Fed. Appx. 46, 50-51 (2d Cir. 2008) (dismissing non-disclosure complaint because the statistically significant test results were "financially immaterial" as the product represented less than 3% of the company's sales). Moreover, a complaint must plead particularized allegations that support imputing knowledge of non-disclosed adverse events, as well as their significance, to each defendant. *See, e.g.*, *Winer Family Trust v. Queen*, 503 F.3d 319, 335-36 (3d Cir. 2007).

[24] *See, e.g.*, *Carter-Wallace II*, 220 F.3d at 42 ("[U]ntil a connection between [the product] and any illness could be made, we would not expect [defendant] to abandon its product on what, at the time, would have been speculation."); *State Univs. Ret. Sys. of Ill. v. AstraZeneca PLC,* 334 Fed. App'x 404, 407 (2d Cir. 2009) ("[P]laintiffs have not alleged anything to negate the idea that defendants were attempting to develop a drug that they thought [would be] beneficial and were so describing it to the public.") (quotation omitted).

The Ninth Circuit failed to appreciate the inherent inconclusiveness and unreliability of adverse event reports. Instead of viewing unverified adverse event reports with appropriate skepticism, the Ninth Circuit fell victim to their "false appearance of direct and actual knowledge of a causal relationship." *Merrell Dow*, 953 S.W.2d at 720. Nowhere in Respondents' complaint is there any allegation, much less a particularized one, that the non-disclosed adverse event reports at issue here were statistically significant. Absent that critical allegation, there is no scientific basis upon which these adverse event reports may be deemed to support causation, and thus any inference that adverse event reports were withheld with fraudulent intent is not "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314.

B. Statistically Insignificant Adverse Event Reports Can Only Support an Improper Hindsight Inference of Fraud.

This Court has observed that one recognized purpose of the "strong inference" standard for scienter is "to ward off allegations of 'fraud by hindsight.'" *Tellabs*, 551 U.S. at 319 (citations omitted). A plaintiff must allege particularized facts that the defendant's statements were false or misleading when they were made. A classic fraud-by-hindsight scenario assumes that "simply because the alleged misrepresentation conflicts with the current state of the facts, the charged statement must have been false" when made. *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1124 (10th Cir. 1997) (citation and quotation marks omitted). "Corporate officials need not be clairvoyant; they are only responsible for revealing

those material facts that are reasonably available to them." *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000). Nor are they "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." *Shields v. Citytrust Bancorp.*, 25 F.3d 1124, 1129 (2d Cir. 1994).

Securities fraud cases against life sciences companies commonly allege that "a promising drug or medical device is approved by the FDA and then later proves to have health risks which affect the market for the [product]." *N.J. Carpenters*, 537 F.3d at 47. Such suits are rife with fraud-by-hindsight claims.

> But if the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents the marketing of the drug or makes it necessary to take the drug off the market.

In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), *aff'd*, 334 Fed. App'x 404 (2d Cir. 2009).

Carter-Wallace and its progeny cogently recognize that without statistical significance, securities claims based on non-disclosure of adverse event reports to investors inherently allege "fraud by hindsight." *Carter-Wallace II*, 220 F.3d at 42.[25] The defendant is

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[25] *See also* Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. Tort Law 4, 49 (2006) ("Litigation is inherently prone to play into hindsight bias. Early, speculative information—say, from anecdotal experience

blamed for not identifying product safety concerns in advance of the available data. Until scientifically valid methods reveal an association between the product at issue and adverse events, a defendant is entitled to view the reports as they are: unverified anecdotal accounts that may describe events caused by any number of things, from the condition being treated, to a simultaneously used product, to operator error, to mere chance. *See supra* at pp. 11-20. "The eventual linking of [an adverse event] to [a product] cannot relate back to the time of the [allegedly misleading] statements . . . and reflect on [a company's] reasonable belief that the reports were random." *Carter-Wallace II*, 220 F.3d at 41. The statistical significance standard directly protects against such fraud-by-hindsight abuses, such as occurred in the present case.

Indeed, the Ninth Circuit's rejection of any requirement that the non-disclosed adverse event reports be statistically significant virtually guaranteed fraud-by-hindsight. The court itself relied (Pet. App. at 2a n.1) on an FDA warning letter dated June 2009—***more than five years after*** the close of the class period. Such a *post hoc* association plainly can have no legal bearing on Petitioners' conduct during the 2003-2004 class period.

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in the absence of systematic research controls—might seem the first inkling of a drug safety problem only when framed within subsequent scientific developments").

C. It Is Prudent and Sensible for a Company To Investigate Adverse Event Reports for Statistical Significance Before Making A Public Disclosure.

Section 10(b) seeks "to achieve a high standard of business ethics in the securities industry." *SEC v. Zandford*, 535 U.S. 813, 819 (2002) (quotation omitted). "A prudent course of action . . . weakens rather than strengthens an inference of scienter." *Slayton v. Am. Express Co.*, 604 F.3d 758, 777 (2d Cir. 2010) (quoting *Horizon Asset Mgmt. v. H&R Block, Inc.*, 580 F.3d 755, 763 (8th Cir. 2009)).

Because publicly traded companies have a duty to speak accurately when they speak to their investors, "[p]rudent managers conduct inquiries rather than jump the gun with half-formed stories as soon as a problem comes to their attention." *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 760-61 (7th Cir. 2007) (Easterbrook, J.).

Far from reflecting a guilty state of mind, it is prudent and sensible for a publicly traded life sciences company to forego disclosing raw adverse event data to investors unless and until the reports are analyzed both individually and in the aggregate. Only if the reports reveal a statistically significant product safety issue could a disclosure obligation arise. *Carter-Wallace II*, 220 F.3d at 42 ("[U]ntil a connection between [a] product and any illness could be made, we would not expect [a company] to abandon its product."). Making disclosures to investors regarding unverified adverse event reports "on what, at the time, would have been speculation" about their significance, *id.*, is unquestionably irresponsible. *See TSC*, 426 U.S. at 448 (disclosure of "dubious" information "may accomplish more harm than good");

N.J. Carpenters, 537 F.3d at 58 (defendant "would have behaved irresponsibly (and possibly in violation of the securities laws) if it had made a public announcement which was possibly inaccurate because the situation of [adverse event] incidences had not yet been adequately investigated.")[26] The statistical significance standard avoids this no-win dilemma.

Perversely, the Ninth Circuit drew an inference of scienter from Petitioners' decision to investigate the handful of adverse event reports involving Zicam. The court observed that the defendants were "sufficiently concerned" about the customer complaints to "call[] [a doctor] about one of her patients who had complained" and "ask if [the doctor] would participate in studies" of the drug. (Pet. App. at 32a.) But "[k]nowing enough to launch an investigation . . . is a very great distance from convincing proof of intent to deceive." *Higginbotham*, 495 F.3d at 758. Indeed, the far more plausible inference was that Petitioners' investigative efforts reflected compliance with the FDA's guidance simply to investigate the adverse event reports—an inference that must be drawn in Petitioners' favor under *Tellabs*.

Absent statistical significance, the Ninth Circuit's conclusion that non-disclosure of adverse event reports to the public "present[ed] a danger of misleading buyers or sellers" (Pet. App. at 33a) is unwarranted as a matter of law.

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[26] *See also Higginbotham*, 495 F.3d at 761 (defendant "might more plausibly have been accused of deceiving investors had managers called a press conference before completing the steps necessary to determine just what happened"); 17 C.F.R. § 230.175(a) (forecasts made without a reasonable basis are not protected by safe harbor).

III. THE NINTH CIRCUIT'S RULE WOULD HAVE DIRE CONSEQUENCES FOR LIFE SCIENCES COMPANIES, INVESTORS, AND CONSUMERS.

Over the last decade, life sciences companies have assumed that non-disclosure of statistically insignificant adverse event reports (to anyone but the FDA) would not support an actionable securities claim under Rule 10b-5. The Ninth Circuit's contrary decision threatens a dramatic change in the status quo. Absent a statistical significance requirement, life sciences companies will be forced to make difficult decisions whether or not to disclose each and every adverse event report to the market upon receipt, with either choice creating litigation risk. Given the hundreds of thousands of adverse event reports generated annually, that burden and risk cannot be overstated.

The most obvious risk to life sciences companies from any abandonment of the statistical significance standard is present here—a securities lawsuit claiming non-disclosure of statistically insignificant adverse event reports. As all concerned with class action securities litigation are well-aware, the Rule 12(b)(6) stage carries almost "dispositive" significance, as unsuccessful defendants must decide whether to settle based on a multitude of non-merits factors, including the huge cost of protracted discovery. *See Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 80 (2006) ("[L]itigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general . . . Even weak cases brought under the Rule may have substantial settlement value . . . because '[t]he very pendency of the

lawsuit may frustrate or delay normal business activity.'") (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975)); Tom Baker & Sean J. Griffith, *How the Merits Matters: Directors' and Officers' Insurance & Securities Settlements*, 157 U. Penn. L. Rev. 755, 820 (2009) (motions to dismiss are "dispositive" because "essentially all securities class actions that survive a motion to dismiss are [ultimately] settled with a payment to the class"). Under the Ninth Circuit's rule, every decision not to disclose an adverse event report to investors, regardless of statistical significance, could be very costly.

Overcautious companies erring on the side of mass disclosure of adverse event reports expose themselves to different, yet equally troubling, securities litigation risks. The Ninth Circuit's decision will deprive companies of the opportunity to investigate adverse event reports, or to conduct the statistical analyses recommended by the FDA, before making such disclosures. Companies opting for preemptive disclosure would do so on incomplete information. They would be in the precarious position of crafting disclosures that disclaim such events' significance, while simultaneously allowing the possibility that later analysis could reveal a different outcome.[27] Prema-

[27] The food and drug laws, rather than the securities laws, already strike the appropriate balance in disclosing raw adverse event reports. As noted above, *supra* note 21, the FDA makes adverse event reports public for certain products through FDA databases like MAUDE, where medical professionals and any other inquiring minds can seek them out. By contrast, the Ninth Circuit's decision would thrust such raw data on the market by company disclosures that may incorrectly be perceived—no matter how carefully worded—as placing the company's imprimatur on the unverified reports.

ture disclosure could also harm investors by causing an unwarranted decline in stock value (or at a minimum, an increase in volatility) until such time as a complete investigation reveals no statistically significant link.[28]

In short, companies seeking to comply with the Ninth Circuit'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, were the decision below to be affirmed.

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[28] *Cf. In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Where mere disclosure of [an FDA] question might cause the company's stock to decline in value, the eventual answer to the question might cause it to rise once again. Investors who sold that stock when the FDA's question was asked but before the company's answer was given might have legitimate cause for concern."); *accord In re Biogen Sec. Litig.*, 179 F.R.D. 25, 37 (D. Mass. 1997).

CONCLUSION

For the reasons explained, the judgment of the United States Court of Appeals for the Ninth Circuit should be reversed.

Respectfully submitted,

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