No. 09-1156

IN THE
Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

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

BRIEF OF THE NATURAL PRODUCTS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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BRIEF OF NATURAL PRODUCTS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

The Natural Products Association (NPA) respectfully submits this brief as *amicus curiae* in support of Petitioners.

INTEREST OF THE *AMICUS CURIAE*

Founded in 1936, NPA is the nation's largest and oldest non-profit organization dedicated to the natural products industry.[1] NPA represents more than 10,000 retailers, manufacturers, wholesalers, and distributors of natural products, including a wide array of consumer goods that continue to grow in popularity each year. Among these products are natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies, and more. Generally, natural products are considered to be those formulated without artificial ingredients and that are minimally processed.

NPA is recognized for its strong industry presence in Washington, D.C., where it serves as a watchdog on regulatory and legislative issues. As relevant to

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[1] The parties have consented to the filing of this Brief. The written consent of Petitioners to the filing of briefs *amicus curiae* in support of either party or no party was filed with the Court on July 30, 2010. The written consent of Respondents to the filing of briefs *amicus curiae* in support of either party or no party was filed with the Court on July 28, 2010. Pursuant to Supreme Court Rule 37.6, NPA states that no counsel for any party authored this brief in whole or in part, and no counsel for any party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than NPA made such a monetary contribution.

this case, NPA represents members engaged in the business of selling, manufacturing, and distributing dietary supplements, which are regulated under federal law. *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act ("2006 Act"), Pub. L. No. 109-462, 120 Stat. 3469 (2006); Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325.

NPA (then known as the National Nutritional Foods Association) played a key role in the passage of the 2006 Act, which established the Adverse Event Report (AER) system. *See Statements on Introduced Bills and Joint Resolutions*, 152 Cong. Rec. S6285, S6287 (daily ed. June 21, 2006) (statement of Sen. Hatch). This legislation strikes a critical balance between the need for accurate information about "Serious Adverse Events" to be timely reported to the United States Food & Drug Administration (FDA) so that the agency may identify any worrisome signals in the reported data, and the equally important need to protect the industry and its customers from inaccurate, duplicative, or misinterpreted reports. The statute governs when and under what circumstances manufacturers, packers, and distributors of dietary supplements must provide Serious Adverse Event Reports (SAERs) to the FDA. *See* 21 U.S.C. § 379aa-1. Like the reporting law applicable to drug products, this statutory scheme contemplates that the FDA is the proper recipient of such information.

NPA has a direct interest in this litigation because the Ninth Circuit's ruling will undoubtedly extend beyond the pharmaceutical industry to other industries that are similarly required to report on certain adverse events. As such, the ruling poses a

significant threat to the dietary supplement industry and its consumers. The most central flaw in the decision is that it substitutes the judgment of securities fraud plaintiffs and their lawyers for the judgment of FDA scientists, thereby displacing Congress's carefully crafted reporting scheme.

The Ninth Circuit's approach would also vitiate other statutory protections that the 2006 Act provided to the dietary supplement industry, protections that are similar to ones provided to the "over the counter" (OTC) drug industry. In particular, Congress expressly provided that only *Serious* Adverse Events need to be reported to the FDA, and that SAERs "shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event." 21 U.S.C. § 379aa-1(g). By allowing a case to survive a motion to dismiss based on a mere handful of AERs, the decision below overrides these statutory protections and threatens to inundate consumers with useless and potentially misleading information that offers no public-health benefit at all.

SUMMARY OF THE ARGUMENT

In the decision below, the Ninth Circuit held that Petitioner Matrixx Initiatives, Inc. ("Matrixx") had a duty under the securities laws to disclose AERs that it received from users of an OTC drug, Zicam. The court so held even though the AERs at issue were not alleged to constitute statistically significant evidence that the adverse events described were caused by Zicam. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1177-80 (9th Cir. 2009), *cert. granted*, 130 S. Ct. 3411 (2010). As Petitioners establish, the court's holding is erroneous under federal securities laws. In addition, the holding threatens to

undermine the statutory reporting system that Congress has established for manufacturers and distributors of dietary supplements, which in many ways resembles the reporting system for OTC products.

Similar to the requirements for OTC products, federal law requires manufacturers and distributors of dietary supplements to report all SAERs to the FDA. By statute, SAERs address Serious Adverse Events *associated with*, not *caused by*, dietary supplements. *See* 21 U.S.C. § 379aa-1(g). Congress expressly provided that SAERs could not be deemed admissions that a dietary supplement caused the reported Adverse Event. *Id.* § 379aa-1. Thus, the purpose of the statutory scheme is not to identify causation, but to enable the *FDA* to analyze SAERs associated with a particular dietary supplement across time and a number of consumers, in order to identify any signal that a health problem is associated with that supplement.

The Ninth Circuit's decision threatens to undermine Congress's careful scheme by effectively forcing manufacturers and distributors of dietary supplements to publicly disclose *all* AERs, not just SAERs, regardless of their weight or significance, and without the protections provided by Congress. The Ninth Circuit has held that a handful of individual AERs can be sufficient to survive a motion to dismiss and to impose on defendants the massive costs of class-action discovery. Issuers will not know in advance which insignificant AERs (out of the many thousands or more that are received) will be employed by enterprising plaintiffs' attorneys to initiate protracted litigation. As a result, to avoid the massive expense of defending or settling these suits, which are too often filed primarily for their nuisance

value, any entity required to maintain and report AERs will ultimately be compelled to publicly disclose *all* AERs.

In this way, the Ninth Circuit's approach is no better for consumers than it is for the industry. Because manufacturers and distributors of dietary supplements will likely need to publicly disclose all AERs in response to this holding, consumers will be flooded with worthless information. Congress's goal of improving the public health by allowing the FDA to inform the public about statistically significant signals will be all but lost in the confusion of statistically insignificant disclosures. Courts and plaintiffs' lawyers rather than the FDA will be left to determine the significance of such reports, contrary to the will of Congress. The Ninth Circuit's decision should be reversed.

ARGUMENT

I. CONGRESS HAS CRAFTED A CAREFULLY BALANCED SCHEME TO REQUIRE REPORTING OF SERIOUS ADVERSE EVENTS ASSOCIATED WITH DIETARY SUPPLEMENTS.

A. Federal Regulation Of Dietary Supplements.

A "dietary supplement" is defined by statute to include a vitamin, mineral, herb or other botanical, amino acid, "dietary substance for use by man to supplement the diet by increasing the total dietary intake," and a "concentrate, metabolite, constituent, extract, or combination" of any of these. 21 U.S.C. § 321(ff)(1). Prior to 1994, the FDA principally regulated dietary supplements under its general authority over food products. In 1994, however,

Congress created a regulatory regime applicable to dietary supplements as a distinct category of products by enacting DSHEA, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

DSHEA focused both on accurate labeling of dietary supplements, *id.* secs. 5-7, §§ 403B, 403(r), (s), 108 Stat. at 4328-31, and on ensuring the safety of dietary supplements by authorizing the Secretary of Health and Human Services to initiate proceedings to remove a dietary supplement from the marketplace under certain conditions. *Id.* sec. 4, § 402, 108 Stat. at 4328. In particular, a dietary supplement may be removed under DSHEA if it is determined to be adulterated because it "contains any poisonous or deleterious substance which may render it injurious to health," "presents a significant or unreasonable risk of illness or injury," or is declared by the Secretary of the Department of Health and Human Services to "pose an imminent hazard to public health or safety." 21 U.S.C. § 342(a)(1), (f)(1)(A), (C).

In 2006, Congress supplemented this statutory regime through the Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469 (2006), by extending certain Adverse Event reporting requirements, already applicable to drugs and medical devices, to manufacturers of dietary supplements. Specifically, the statute requires manufacturers to file with the FDA SAERs documenting "any report received of a serious adverse event associated with such dietary supplement when used in the United States." *See* 21 U.S.C. § 379aa-1(a)(3), (b)(1). A "Serious Adverse Event" is a "health-related event associated with the use of a dietary supplement that is adverse," *id.* § 379aa-1(a)(1), and that

> (A) results in—(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A),

Id. § 379aa-1(a)(2). These requirements took effect December 22, 2007. 21 U.S.C. § 381 note.

The 2006 Act requires that all those subject to the SAER reporting requirement — called "responsible person[s]" under the statute — must submit to the Secretary any SAER "no later than 15 business days after the report is received." 21 U.S.C. § 379aa-1(c)(1). If a responsible person receives any new medical information related to a submitted SAER within one year of the initial report, that new information must likewise be submitted to the FDA within 15 days. *Id.* § 379aa-1(c)(2). Responsible persons submit required SAERs to the FDA through "MedWatch," FDA's system for post-market monitoring of drugs, food products, and supplements. *See* FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, www.fda.gov/safety/medwatch/default.htm; *see also* 21 U.S.C. § 379aa-1(d); FDA, *Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*, Question 11 (Oct. 2007; revised June 2009), http://www.fda.gov/Food/.GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171383.htm (hereinafter "*Guidance for Industry*"). The FDA also receives SAERs and AERs from third

parties, such as consumers and health care providers, also through the MedWatch system.

In addition to imposing reporting requirements on dietary supplement manufacturers and distributors, the 2006 Act simultaneously created substantial protections for the industry. First, and most significantly, the law explicitly recognizes that such reports are not proof that the adverse event was caused by a dietary supplement: "The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event." 21 U.S.C. § 379aa-1(g); *see also* FDA Form 3500A (MedWatch form, also providing that "[s]ubmission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event"), http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082728.pdf.

Rather, adverse event reporting merely allows the FDA to gather sufficient data to identify potential patterns that warrant more focused study. *See* S. Rep. No. 109-324, at 7 (2006) ("the intent of these new [SAER] systems is to alert officials about emerging problems with a product. … [T]hese new systems are designed to generate signals which require further evaluation."). If the FDA determines, based on its aggregation of information, that a dietary supplement is a cause for significant concern, it issues an alert to inform both the public and the manufacturer of the issue. *See* FDA, Dietary Supplement Alerts and Safety Information, http://www.fda.gov/Food/DietarySupplements/Alerts/default.htm. As such, enforcement is, at least initially, in the hands of a federal agency with

expertise and a congressional mandate, not plaintiffs' attorneys with a strike suit and an economic incentive to impose unnecessary costs on the industry.

Second, in response partly to the concerns raised by the industry that plaintiffs' attorneys would misuse the AER system by bringing meritless litigation, Congress sought to ensure the integrity of the reporting scheme. Congress thus maintained the accuracy of the information submitted in SAERs by expressly prohibiting "[t]he falsification of a report of a serious adverse event submitted to a responsible person." 21 U.S.C. § 331(ii). Congress also made the intentional submission of a false SAER grounds for criminal penalties. *Id.* § 333(a). Finally, Congress granted the FDA authority to "issue guidance" to the industry on what "minimum data elements … should be included in a serious adverse event report" in order to make SAERs complete and accurate for the agency's purposes. *Id.* § 379aa note.

B. The Legislative History Confirms That The AER Reporting Requirements Were Carefully Constructed To Provide Useful Information To FDA Regulators While Protecting Industry Members From Liability And Overly Burdensome Reporting.

The legislative history of the 2006 Act makes clear that Congress, with this legislation, took a measured and science-based approach to the issue of AER reporting by dietary supplement manufacturers and distributors. Citing the FDA's "substantial experience in administering adverse event reporting systems," S. Rep. No. 109-324, at 8, legislators crafted a system by which that agency, in its expertise, would be given authority to receive, review, and act on

SAERs as appropriate. Legislators made clear that the overall purpose of the new reporting requirement was to permit the agency to garner relevant information from across a spectrum of SAERs — that is, to "alert officials about emerging problems with a product" and to "generate signals" informing the agency about which reported events "require further evaluation." *Id.* at 7. In other words, "the intent of the new system is not to determine causality, but rather to provide the government with information about possible problems associated with the use of a supplement." *Id.* at 12.

In order to achieve these goals, legislators emphasized that the Act was deliberately crafted to ensure that only *useful* information would be required to be reported, and that over-disclosure that could prove burdensome and distracting to the industry, agency, and public would be specifically avoided. As the committee report makes clear, the legislation

> limit[s] the reporting requirement to the information FDA really needs: reports of death; a life-threatening experience; hospitalization; a persistent or significant disability or incapacity; a congenital anomaly or birth defect. In limiting the reporting system to serious events only, the committee recognizes that any broader reporting system could overburden manufacturers, consumers and the agency alike, generating information that may not be useful to the public health system at tremendous cost to all involved.

Id. at 6.

Relatedly, legislators described their firm recognition — reflected in the statute as codified, 21 U.S.C. § 379aa-1(g) — that no SAER was proof that

the dietary supplement at issue had caused any sort of harm. "The committee emphasizes that adverse events are communications from consumers regarding events that may be associated with the use of a dietary supplement or nonprescription drug. The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product." S. Rep. No. 109-324, at 6. The Committee Report makes clear that responsible persons were required to submit SAERs to the FDA "whether or not the reporter sought medical care or otherwise had proof of a serious adverse event. Indeed, the committee notes that the MedWatch form, which the reporter must use under [the Act], explicitly directs consumers to 'Report, even if you're not certain the product caused the event' or 'you don't have all the details.'" *Id.* at 7.

Even so, legislators recognized that industry members had

> concerns that possible litigation may ensue from the fact that a report was filed, and that the report could be construed as an admission that the product "caused" the serious event. In response, the committee took great pains to make clear that the mere filing of a report will in no way indicate causation of the serious adverse event. To underscore that point, language is included in [the Act] indicating that the submission of an adverse event report in compliance with the bill's requirements shall not be construed as an admission that the nonprescription drug or dietary supplement involved caused or contributed to the adverse event or otherwise caused or contributed to a death, serious injury or serious illness.

Id. at 12. Legislators also considered, but expressly rejected, "requiring the FDA to prove" that a particular dietary supplement "caused the serious adverse event prior to accepting the report. Even if a system for proving the causality could be determined and agreed upon, proving that causality could be very costly and entail long delays in reporting, depriving public health officials of the valuable sentinel information inherent in a report." *Id.*

Legislators also sought to ensure that the agency would take action based only on accurate information. Although legislators sought "to encourage a broad reporting of all serious adverse events associated with" dietary supplements, they were "also sympathetic to concerns expressed that the potential for multiple reporting of the same event could artificially inflate the numbers of reports associated with a product," and that "incomplete reports could indicate a less-than-serious report is being made." *Id.* at 8-9.

Legislators accordingly "balanced two competing goals — the need to ensure as broad a reporting as possible of any serious adverse events against the cognizance that incomplete, false or duplicative reports could be harmful and costly to manufacturers, the FDA, and the public health." *Id.* at 8. The Act thus explicitly required the agency to "develop systems to ensure consolidation into a single report of both duplicate reports of a serious adverse event, and duplicate reports of additional medical information related to that event." *Id.* at 9. And, noting that the FDA had previously provided Adverse Event reporting guidance to producers of drugs and biological products, the Act thus called on the FDA likewise "to issue guidance on the minimum data elements that should be included in any serious

adverse event reports" in order to improve the accuracy and usefulness of those reports. *Id.* at 8.

Fulfilling that mandate, the FDA has made clear that an SAER is required to be submitted only if the manufacturer or distributor that received the report is able to obtain and include five essential data elements: an identifiable patient, an identifiable initial reporter, identity and contact information for the responsible person submitting the report, a suspect dietary supplement, and a serious adverse event or fatal outcome. *Guidance for Industry*, Question 13. FDA has declared that each of these data elements is necessary "to avoid duplication in its adverse event reports database, interpret the significance of adverse events, facilitate follow-up, and detect fraud." *Id.* In other words, in the agency's view, incomplete SAERs are insufficiently informative to assist the FDA in determining which SAERs indicate that further evaluation is necessary.

Once Congress had crafted the Act with its emphasis on FDA analysis and review of SAERs, and with its many and substantial protections for both consumers and dietary supplement manufacturers and distributors, the legislation found wide-ranging support among consumer groups and industry players alike. *See* 152 Cong. Rec. at S6287 (citing the support of, among others, NPA (then called the National Nutritional Foods Association), the Consumer's Union, the Center for Science in the Public Interest, the Consumer Healthcare Products Association, and the American Herbal Products Association). In the words of Senator Hatch, "[t]hat these groups, not often united — at least on this subject — can rally around our bill today is a testament to good policy, good politics, and a surviving bipartisan spirit." *Id.*

II. AFFIRMING THE NINTH CIRCUIT'S RULING WOULD DISRUPT THE CAREFUL LEGISLATIVE BALANCE EMBODIED IN THE 2006 ACT AND BROADLY THREATEN THE DIETARY SUPPLEMENT INDUSTRY.

The Ninth Circuit's decision, if affirmed, would dismantle the considered approach that Congress took — with the support of both consumer advocates and the dietary supplement industry — in the 2006 Act. The lower court's decision would permit plaintiffs' lawyers, through the vehicle of the securities laws, to allege that a small number of SAERs indicate that a dietary supplement has caused harm to consumers. Such an assertion could be made — and given credence by reviewing courts and juries — even though Congress expressly rejected the notion that SAERs have any such meaning in the 2006 Act. Moreover, such an assertion could be made even when the FDA, with its scientific expertise and its mission to protect the public health, has made no finding that SAERs associated with a particular dietary supplement raise any cause for concern.

Approving such an approach would impose substantial risks on the dietary supplement industry. That industry has been recognized by Congress as contributing extensively both to public health and to the economy. Yet securities law strike suits filed on the basis of insubstantial numbers of unsubstantiated SAERs could create massive costs for dietary supplement manufacturers and distributors — particularly smaller entities, which can ill afford the high costs of litigation — even if entirely meritless. To avoid such costs, manufacturers and distributors would likely be forced broadly to disclose all AERs, to the detriment of the industry, the FDA, consumers,

and the balance carefully calibrated by Congress with the 2006 Act.

A. The Ninth Circuit's Approach Is Inconsistent With The Express Provisions And Purpose Of The 2006 Act.

The 2006 Act expressly anticipates that the FDA will have responsibility for reviewing, and taking action as appropriate on, reports of serious adverse events associated with dietary supplements. It is the FDA to whom SAERs are submitted, and it is the FDA that is tasked with weighing and evaluating SAERs, in recognition that no SAER establishes that the Adverse Event at issue was caused by the identified nutritional supplement. *See* 21 U.S.C. § 379aa. As explained in Part I, *supra*, these fundamental principles are essential to the balanced approach that Congress took with the 2006 Act. And they were essential to securing the support of the dietary supplement industry, which expressed concerns that SAERs would be misinterpreted and would subject industry participants to groundless lawsuits. *See* p. 13, *supra*.

Nonetheless, the approach taken by the Ninth Circuit, if applied in the context of dietary supplements (and there is no reason to suppose it would not), would pay no regard to the expert opinion of the FDA, or to Congress's express limitations on the meaning of SAERs. In its opinion holding that Plaintiffs had stated a claim of securities fraud against Petitioners, the court expressly engaged in its own "fact-specific inquiry" into the Plaintiffs allegations as to the content and nature of AERs related to Zicam. *Siracusano*, 585 F.3d at 1179. The court made no mention of and paid no heed to whether the FDA had reviewed or taken action based on the same AERs, and likewise ignored the meaning

that such AERs would be given by the FDA. *See id.* In doing so, the Ninth Circuit chose to make for itself, rather than allowing the FDA to make, the "difficult policy choices that agencies are better equipped to make than courts." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

Notably, the Ninth Circuit expressly rejected the approach of the Second Circuit, which had, by contrast, taken account of the FDA's role in the AER reporting process:

> FDA regulations require that "all adverse drug experience information" be reported to the FDA. 21 C.F.R. § 314.80(c) (1999). Drug manufacturers receive these reports from several sources, including treating physicians. An "adverse drug experience" is defined broadly to include "[a]ny adverse event associated with the use of a drug in humans, *whether or not considered drug related*." 21 C.F.R. § 314.80(a) (1999) (emphasis added).... Contrary to the appellants' assertions throughout their complaint, the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report.

In re Carter-Wallace, Inc. Secs. Litig., 220 F.3d 36, 40-41 (2d Cir. 2000). By ignoring the context in which such reports are made and submitted to the FDA, and by disregarding the treatment the FDA gives to such reports, the Ninth Circuit's approach distorts the objectives of Adverse Event reporting requirements and vitiates the expert role of the FDA in reviewing and analyzing those reports.

Indeed, that is precisely what happened in the case below. Plaintiffs' claim of securities fraud was based

on Petitioners' alleged failure to disclose AERs from 12 to 23 consumers of Zicam.[2] *Siracusano*, 585 F.3d at 1179; *see also* Pet. 4 & n.1. During the class period at issue in the Complaint, October 2003 through February 2004, the *FDA had taken no action* with regard to Zicam based on AERs received, *see Siracusano*, 585 F.3d at 1169-70 & n.1, although pharmaceuticals manufacturers (like dietary supplement manufacturers and distributors) are required to submit AERs to that agency. *See* 21 C.F.R. § 314.80.

In other words, the AERs submitted to that date were not sufficient to cause the agency to conclude that Zicam was causing adverse events. The FDA did not conclude that action was warranted until it had received "more than 130 reports of anosmia" by users of Zicam — in June 2009. *See* FDA, Warnings on Three Zicam Intranasal Zinc Products, http://www.fda.gov/forconsumers/consumerupdates/ucm166931.htm. Thus, even though the agency most expert in the regulation of such products first concluded that Zicam was associated with adverse events only after receiving some 130 AERs, the Ninth Circuit's approach here allowed Plaintiffs' lawyers to short-

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[2] The uncertainty as to the number of consumers at issue derives from plaintiffs' failure to identify whether the reports relied on in their Complaint include duplicate reports of the same adverse events. *See* Pet. 4 & n.1. Notably, the issue of duplicate reports was a concern explicitly addressed by Congress in its establishment of the SAER system for dietary supplements. *See* S. Rep. No. 109-324, at 9 (discussing "concerns … that the potential for multiple reporting of the same event could artificially inflate the numbers of reports associated with a product"); 21 U.S.C. § 379aa-1(c)(3) ("The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.").

circuit the agency's review process, bringing suit based on the alleged nondisclosure of a mere 12 to 23 statistically insignificant reports.[3]

In short, the Ninth Circuit allowed the agency's judgment to be supplanted by that of the Plaintiffs and their attorneys. Affirming the approach taken by that court could expose participants in all industries subject to similar adverse event reporting requirements to the same result, regardless of the statutory protections conferred on them by Congress.

B. Allowing The Judgment Of The Ninth Circuit To Stand Would Impose Massive Risks On The Dietary Supplement Industry.

In particular, the Ninth Circuit's approach could wreak havoc in the dietary supplement industry. Congress has expressly recognized both the value of dietary supplements to Americans' public health, and the importance of dietary supplements to the national economy. As Congress found, "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies." DSHEA, § 2(2), 108 Stat. at 4325. "[T]here is a link

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[3] As petitioners explain (Br. at 46), the handful of AERs cited by plaintiffs were "received over the course of four years . . . when Matrixx sold literally *millions* of units of Zicam." Moreover, nowhere in the complaint do plaintiffs "compare that trivially miniscule reported incident rate to the known incident rate of anosmia in the population – and in particular, in the population of people who have colds, and thus take remedies like Zicam." *Id* (emphasis omitted). Virtually every (if not, in fact, every) widely marketed over-the-counter drug will be connected with at least some AERs. The complaint does not reflect any analysis showing that the AERs at issue were statistically significant.

between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis," such that "healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty." *Id.* § 2(3)(A), (4), 108 Stat. at 4325-26. Indeed, "preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures." *Id.* § 2(5), 108 Stat. at 4326. Congress found that, as of 1994, "almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition." *Id.* § 2(9), 108 Stat. at 4326.

That level of demand had made "the nutritional supplement industry … an integral part of the economy of the United States," with "the estimated 600 dietary supplement manufacturers in the United States produc[ing] approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000." *Id.* § 2(12)(A), (C), 108 Stat. at 4326. These numbers have dramatically increased in the years since DSHEA's enactment in 1994: as of 2006, the value of the dietary supplement industry was estimated to be approximately $20 billion, 152 Cong. Rec. at S6286, while today it is over $25 billion. *See* NPA, About the Natural Products Association, http://www.npainfo.org/index.php?submenu=About&src=gendocs&ref=AboutNPA&category=About (citing Nutrition Business Journal).

However, many players in that industry face the risk of substantial losses through baseless securities litigation if the Ninth Circuit's decision is upheld. In recognition of the potential costs imposed by such

litigation, this Court has repeatedly emphasized the need for sound rules to govern and constrain private securities-fraud lawsuits. In the absence of such rules, meritless securities litigation can be employed "abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). "[P]laintiffs with weak claims [can] extort settlements from" companies that are innocent, but that nevertheless fear "extensive discovery and the potential for uncertainty and disruption in a lawsuit." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 163 (2008); *see also Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 80-81 (2006).

The risk that such suits will force even innocent companies to settle the litigation is well-recognized. According to one study, almost 100 private securities suits settled for a total value of $3.6 billion in 2008 alone. *See* PriceWaterhouseCoopers, *2008 Securities Litigation Study* 18 (Grace Lamont ed., 2009), *available at* http://10b5.pwc.com/PDF/NY-09-0894%20SECURITIES%20LIT%20STUDY%20FINAL.PDF. Settlement is often a near requirement for defendants in such lawsuits, because of the huge costs of the discovery process when a claim is permitted to proceed beyond a motion to dismiss. *See Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975); *see also Cent. Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 189 (1994) ("uncertainty [in] the governing rules" could prompt companies, "as a business judgment, to abandon substantial defenses and to pay settlements in order to avoid the expense and risk of going to trial").

In light of these "practical consequences" of liberal treatment of securities fraud suits, *see Stoneridge*,

552 U.S. at 156-63, this Court has consistently counseled the application of rules that provide "'certainty and predictability'" in this area. *Cent. Bank*, 511 U.S. at 188 (quoting *Pinter v. Dahl*, 486 U.S. 622, 652 (1988)). The Court has thus rejected "shifting and highly fact-oriented disposition[s]," which do not provide "a satisfactory basis for a rule of liability imposed on the conduct of business transactions." *Id.* (internal quotation marks omitted).

The Ninth Circuit's approach, however, expressly calls for just the sort of "fact-specific inquiry" that this Court has criticized. *See Siracusano*, 585 F.3d at 1179. Indeed, it allows securities fraud plaintiffs to proceed to discovery based on a string of "facts" — that is, individual AERs — that, in the context of dietary supplements, Congress has declared immaterial as a matter of law. In doing so, the Ninth Circuit has exposed all manufacturers and distributors of dietary supplements — as well as participants in other industries subject to AER reporting requirements — to the massive expense and risk of securities litigation. Irrespective of whether the FDA, the agency charged with reviewing SAERs, finds the reports remotely significant, the plaintiffs' bar will be able to shake down the industry with factbound, resource-intensive strike suits.

The risk of harm posed by such strike suits is particularly grave for small and independent producers of dietary supplements. Like all dietary supplement manufacturers and distributors, small firms are required to report Serious Adverse Events. Yet smaller issuers have less capacity to bear the costs of securities litigation, and would face even

more heightened pressure to reach settlement.[4] In the process of enacting the DSHEA, Congress specifically recognized the dire consequences that "baseless lawsuits" pose to small dietary supplement manufacturers: Being forced to face such litigation "subject[s] small manufacturers to the choice of abandoning production and sale of lawful products, or accepting the significant financial burden of defending themselves against baseless lawsuits." S. Rep. No. 103-410, at 21 (1994).

In order to avoid the extensive costs of such litigation, manufacturers and distributors of dietary supplements would likely be forced into the position of over-disclosing. That is, they could manage to avoid a result like that reached by the Ninth Circuit with any certainty only by indiscriminately publicly disclosing every AER that they received. Yet such a result would be highly burdensome, would be to the detriment of both the FDA and the public, and would be directly contrary to the intent of Congress in enacting the 2006 Act. Congress simply did not intend the industry to inundate consumers with useless, immaterial information that is of no value to any purchasing decision.

To the contrary, legislators were highly sensitive to the problems that could be caused by over-disclosure if the SAER reporting requirements established in the 2006 Act were not carefully balanced. First, Congress "limit[ed] the reporting system to serious events only" based on its "recogni[tion] that any broader reporting system could overburden

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[4] Further, to the extent that the Ninth Circuit's flawed materiality analysis made its way into contexts other than securities litigation (for example, products liability), the litigation exposure would increase exponentially.

manufacturers, consumers and the agency alike, *generating information that may not be useful to the public health system at tremendous costs to all involved*." S. Rep. No. 109-324, at 6 (emphasis added). Second, Congress required reporting only to the FDA, which could make a reasonable, scientifically based decision, relying on its expertise and concern for the public interest. Congress did not require disclosure to the SEC, let alone directly to the public and plaintiffs' attorneys who could bring nuisance suits based on erroneous allegations that are costly to disprove.

Unlike the FDA, public consumers of dietary supplements are not well-versed in the limited informational value of individual SAERs. As explained above, p. 6-8, *supra*, an SAER indicates only that an adverse event is *associated with*, not *caused by*, a dietary supplement. *See* 21 U.S.C. § 379aa-1(a)(1). Indeed, consumers are encouraged to report an Adverse Event even if they are "'not certain the product caused the event'" or "'don't have all the details.'" S. Rep. No. 109-324, at 7. Thus, an Adverse Event might be reported based on something completely irrelevant – for example, a traffic fatality that occurred soon after the driver ingested a dietary supplement, even though the accident could have resulted from countless causes.

Unbridled public disclosure of SAERs would provide consumers with no assistance in sorting through and analyzing the disclosures for their significance. In all likelihood, consumers unfamiliar with the limitations on Adverse Event reporting may well take SAERs to have far greater significance than in fact they do. Consumers might thus decline to use a dietary supplement based on statistically insignificant information — even though, as Congress

has found, the use of supplements is highly beneficial to the public health. *See* DSHEA § 2, 108 Stat. at 4325. Such a result would entirely defeat the purpose of the 2006 Act — namely to enable FDA scientists to analyze SAERs in the aggregate in order to identify any statistically significant signals or trends, and to educate the public of the results of their considered and expert review. *See* S. Rep. No. 109-234, at 6-7.

CONCLUSION

For the foregoing reasons, and those stated in Petitioners' Brief, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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