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 PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Of Counsel:

HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNSEL, INC.
1850 Centennial Park Drive
Suite 510
Reston, Virginia 20191
703-264-5300

August 27, 2010

ANNE E. COHEN
(Counsel of Record)
aecohen@debevoise.com
BETHANY A. DAVIS NOLL
BERGLIND HALLDORSDOTTIR BIRKLAND
DEBEVOISE & PLIMPTON LLP
919 Third Avenue
New York, New York 10022
212-909-6000

Attorneys for Amicus Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

This brief is filed on behalf of the Product Liability Advisory Council, Inc. as *amicus curiae* in support of Petitioners.[1]

INTEREST OF *AMICUS CURIAE*

Amicus Curiae Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association of over 100 corporate members representing a broad cross-section of American and international product manufacturers,[2] who seek to contribute to the improvement and reform of law in the United States and elsewhere, especially that governing the liability of manufacturers of products. Several hundred leading product liability defense attorneys in the country are also sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 850 briefs as *amicus curiae* in both state and federal courts, including more than eighty in this Court, presenting the perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability.

PLAC is well situated to address the issues in this case. Many PLAC members or their related

---

[1] *Amicus* has notified the parties of its intention to file a brief as *amicus curiae*; blanket consent has been granted and filed. No counsel for a party in this case authored this brief in whole or in part, and no person or entity other than *Amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

[2] A list of PLAC 's current corporate membership is included as Appendix A to this brief.

entities are subject to the federal securities laws, including the disclosure requirements outlined in Section 10(b) of the Securities Exchange Act of 1934 and the Securities and Exchange Commission's Rule 10b-5. Many PLAC members are also subject to reporting obligations similar to those at issue here, and so this topic is of substantial interest not only to PLAC's members in the pharmaceutical industry but also those in a wide range of other manufacturing industries. PLAC respectfully submits this brief as *amicus curiae* to describe for the Court some of the other regulatory reporting schemes which could give rise to securities disclosure issues like those presented in this case.

SUMMARY OF ARGUMENT AND INTRODUCTION

In this case, the parties dispute whether Petitioners, Matrixx Industries, Inc., et al., are liable under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Securities Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, for failing to inform investors of certain "adverse event" reports even though there was no statistically significant link between the use of Matrixx's drug, Zicam Cold Remedy, and the undisclosed events.

There is a world of difference between the intended users of information disclosed under the federal securities laws and information reported to regulators, such as the Food and Drug Administration ("FDA"), charged.

For purposes of liability under § 10(b) and Rule 10b-5, "materiality depends on the significance the reasonable investor would place on the withheld

or misrepresented information." *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988). This Court's decisions on materiality recognize that "[s]ome information is of such dubious significance that insistence on its disclosure may accomplish more harm than good." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448 (1975). The role of the materiality requirement is to "filter out essentially useless information that a reasonable investor would not consider significant." *Basic*, 485 U.S. at 234. A low standard of materiality poses risks for issuers and investors alike; in order to avoid liability for "insignificant" omissions or misstatements, corporations and their management may overwhelm investors in "an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking." *TSC Indus.*, 426 U.S. at 448-49.

By contrast, regulatory agencies, such as the FDA, the National Highway Traffic Safety Administration ("NHTSA"), or the Consumer Product Safety Commission ("CPSC"), have statutory mandates to protect the public. Their responsibilities are fulfilled in part by identifying potential patterns and problems from an aggregate of information and are specifically staffed and funded to allow them to analyze and process the information. Adverse event and other forms of regulatory reporting by manufacturers and others is designed to assist this work. By and large, the reporting standards are explicitly broad and over-inclusive. A manufacturer typically will need to make such a report before any causal connection has been hinted at, let alone established, between the event and the use of the manufacturer's product and even before the

manufacturer has had a chance to investigate whether the event actually occurred. *See, e.g.*, 16 C.F.R. § 1115.4(e) ("[S]ubject firms should report [to the CPSC even] if in doubt as to whether a defect exists."). In many cases, agencies also encourage direct reporting by consumers, with little to no oversight of the accuracy of what are essentially anecdotes.

Thus, almost as a rule, isolated adverse event and other regulatory reports are of questionable value to investors, for whom such information will have no intelligible context. "Materiality" acts as a "filter" of such "essentially useless information." *Basic*, 485 U.S. at 234. Regulators, on the other hand, seek out bits and pieces of information which may be premature, marginal, incomplete, or unreliable.

The Courts of Appeals for the First, Second and Third Circuits have recognized the counter-productive impact of requiring disclosure of "adverse events" reported to (or maintained for) regulators where there is no allegation that the undisclosed adverse event reports demonstrated a statistically significant relationship between the product and the alleged event. *See, e.g.*, *New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35 (1st Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000); *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000). As discussed at length in Petitioners' Brief, that rule provides a scientifically intelligible basis for determining when reports become material and can assist investors in understanding which regulatory reports matter and when.

By contrast, the Ninth Circuit's view of materiality in this case would call for disclosure of regulatory reports, even where there is (or can be) no allegation that the events at issue had any meaningful scientific relationship with use of a drug. *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009). The court held that it could not "as a matter of law" determine whether studies or reports were statistically insignificant because "'statistical significance is a question of fact.'" *Id.* at 1179 (quoting *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 635-36 (S.D.N.Y. 2008)). Thus, Ninth Circuit's decision "left to the trier of fact" the question of whether a handful of reports of adverse events could show a "statistically significant link" with a drug used millions of times. *Id.* Not surprisingly, the imposition of such a rule could force manufacturers to disclose regulatory reports without regard to their ultimate scientific value or their intelligibility to investors.

The implications of the Ninth Circuit's decision reach beyond Zicam and over-the-counter medications to a host of industries who are required to report adverse events which may have only a tenuous link to a company's products. Over-disclosure and disclosure of information that cannot be useful to the reasonable investor would be the likely results. As urged by Petitioners, the "statistical significance" standard used in the First, Second, and Third Circuits provides a meaningful guidepost for gauging materiality in this context and should be adopted by the Court.

ARGUMENT

The Ninth Circuit's decision, if allowed to stand, would have implications extending far beyond over-the-counter cold medicines. Manufacturers of products as diverse as hearing aids, infant formula, car batteries, veterinary medicines and motorcycles could conclude that their investors must be informed of "reportable" events, which, by definition, may never have happened.

I. Implications of Ninth Circuit's Decision for Pharmaceuticals and Over-the-Counter Drugs

The reporting requirements at issue in this case apply to pharmaceuticals generally, not just over-the-counter cold medicines, as manufacturers of both prescription and non-prescription drugs have ongoing and periodic obligations to report adverse events to the FDA.

Drug manufacturers, packagers and distributors are required to inform the FDA of "adverse drug experiences" even if they are "not considered drug related." 21 C.F.R. § 314.80(a); *see also* 21 U.S.C. § 379aa(a)-(b); 21 U.S.C. § 355(k). Reportable adverse events expressly include events that may be attributable to "overdose" and "abuse of the drug." 21 U.S.C. § 379aa(1); *see also* 21 C.F.R. § 314.80(a). Experiences which are both "serious"[3]

---

[3] A "serious adverse" drug experience is one that results in death, a life-threatening experience, hospitalization, disability, a congenital anomaly or birth defect or which requires medical intervention to prevent one of these outcome. 21 U.S.C. § 379aa(a)(3); 21 C.F.R. § 314.80(a).

and "unexpected"[4] must be reported within fifteen calendar days. 21 C.F.R. § 314.80(c).[5] All other adverse drug experiences for drugs approved through the new drug application process are to be compiled into periodic reports for the FDA quarterly or annually, based on how long the drug has been approved. 21 C.F.R. § 314.80(c)(2)(i). Records of adverse drug events involving grandfathered products must be maintained for ten years. 21 C.F.R. § 310.305(f). As part of their regulatory obligations, manufacturers are expected to seek out information about their products from various sources, both "foreign and domestic," including from scientific, literature, and unpublished scientific papers. *See* 21 C.F.R. § 314.80(b). This information helps the FDA monitor the safety of all marketed drug products. *See, e.g.*, Final Rule, Adverse Drug Experience Reporting Requirements for Marketed Prescription Drugs Without Approved New Drug or Abbreviated New Drug Applications, 51 Fed. Reg. 24476-01 (July 3, 1986). If manufacturers fall short in their reporting or record-keeping obligations, the FDA may withdraw the approval or prohibit continued marketing of their drug. 21 C.F.R. § 314.80(j).

In addition to reports received from manufacturers in compliance with their regulatory obligations, the FDA receives reports directly from

---

[4] An "unexpected" adverse drug experience is one not currently listed in the drug's labeling. 21 C.F.R. § 314.80(a).

[5] After filing this initial report, manufacturers are expected to continue investigating the event and to file subsequent followup reports. 21 C.F.R. § 314.80(c)(1)(ii).

health care providers and consumers[6] about prescription and over-the-counter drugs and therapeutic biological products.[7] The total volume of adverse event reports each year can be staggering. In 2009 alone, the FDA received over 580,000 reports.[8]

---

[6] These "direct" reports are received "via letters, faxes, telephone calls, emails, or directly over computer modems" and "can include anything from a report of a serious, unexpected [adverse drug reaction] to a report of a well-known, trivial [reaction]." *Drug-Related Adverse Events: Hearing Before the S. Comm. on Health Education Labor & Pensions* (statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration (Feb. 1, 2000), http://www.fda.gov/NewsEvents/Testimony/ucm115007.htm [hereinafter *Woodcock Testimony*].

[7] *See Reports Received and Reports Entered into AERS by Year*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm (last visited Aug. 27, 2010) [hereinafter "*Reports Received and Reports Entered into AERS*"]. Biological products are a subset of drugs and include vaccines and most protein products. *Frequently Asked Questions About Therapeutic Biological Products*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm (last visited Aug. 27, 2010). Like other drugs, they are used "for the treatment, prevention or cure of disease in humans. . . [but] are generally derived from living material—human, animal, or microorganism." *Id.*

[8] *See Reports Received and Reports Entered into AERS*. Of these, 6% were direct reports from consumers and health care providers, 57% were fifteen-day reports of serious adverse events, and 37% were periodic reports. *Id.* There is

The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 2125, 100 Stat. 3743, 3774-78 (1986), requires health professionals and vaccine manufacturers to file adverse event reports ("AERs") with the U.S. Department of Health and Human Services ("HHS") using the Vaccine Adverse Event Reporting System ("VAERS"), which was created in 1990. *See* 42 U.S.C. § 300aa-27(a)(2). As with other reporting systems, VAERS is intended simply to "provid[e] health scientists with signals about possible adverse events" to be followed by controlled epidemiological studies before action is taken.[9] The agencies encourage the reporting of "*any* clinically significant medical event that occurs after vaccination, even if the reporter cannot be certain that the event was caused by the vaccine."[10]

About 30,000 reports regarding vaccines are received each year. While some involve serious side effects, about eighty-five to ninety percent describe "mild adverse events such as fever, local reactions,

---

some duplication in these numbers "due to factors such as follow-up reports received on a case or different persons reporting on the same patient case." *Adverse Event Reporting System (AERS) Statistics*, FOOD AND DRUG ADMINISTRATION (Mar. 31, 2010) http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm [hereinafter *Adverse Event Reporting System*].

9 *About the VAERS Program*, VACCINE ADVERSE EVENT REPORTING SYSTEM, http://vaers.hhs.gov/index/about/index (last visited Aug. 27, 2010).

10 *Id.*

and episodes of crying or mild irritability."[11] The agencies that established and use the system—the FDA, the HHS, and the Centers for Disease Control and Prevention—recognize that while VAERS "enables the early detection of signals that can then be more rigorously investigated," the reports in themselves "can rarely provide definitive evidence of causal associations."[12]

The FDA plainly seeks over-inclusive data to satisfy its broad regulatory role and to stay informed of potential and even remote product hazards. *See* Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938); 21 U.S.C. § 393(b)(2) (defining the FDA's "[m]ission" to include "protect[ing] the public health by ensuring that . . . drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use").[13] Towards this end, for example, an adverse event involving grandfathered products is reportable as long as it was somehow "associated with the use of the drug in humans." 21 C.F.R. § 310.305(a)-(b);

---

[11] *Id.*

[12] *Id.*

[13] Over-inclusiveness is sensible in light of the fact that these reports are assessed by trained professionals who, unlike the lay investor, can sift the wheat from the chaff. *See Adverse Event Reporting System*, *supra* note 8 (explaining that AERs are "evaluated by clinical reviewers" who are able to identify "potential safety concern[s]" that require "further evaluation"); *see also Woodcock Testimony*, *supra* note 6.

see also 21 C.F.R. § 314.80(a).[14] The FDA's analysis of the AERs forms an integral part of its "routine safety monitoring" and provides it with a baseline of data from which it can identify "potential safety issues" that require further monitoring.[15] An "adverse event" has no "cause-and-effect implication" but "simply describes some sort of harm that occurs during healthcare."[16]

---

[14] *See also* 21 U.S.C. § 379aa(g) ("The submission of any adverse event report in compliance with this section shall not be construed as an admission that the nonprescription drug involved caused or contributed to the adverse event."); 21 C.F.R. § 314.80(k) ("A report or information submitted by an applicant . . . does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect."); *Adverse Event Reporting System*, *supra* note 8 (noting that "there is no certainty that the reported event was actually due to the product" because the agency "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").

[15] *See Potential Signals of Serious Risks*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm (last visited Aug. 27, 2010).

[16] *Woodcock Testimony*, *supra* note 6; *see also Adverse Event Reporting System*, *supra* note 8 (noting that the adverse event reporting system is a useful tool because it helps the FDA "look[] for new safety concerns that might be related to a marketed product, evaluat[e] a manufacturer's compliance [with] reporting regulations and respond[] to outside requests for information").

Courts have, as Petitioners have demonstrated, accorded limited probative value to AERs in establishing legal causation,[17] while recognizing their importance to the FDA's regulatory mandate.[18] This reporting standard does not and is not intended to serve as a proxy for the materiality standard.

II. Implications of Ninth Circuit's Decision for Other FDA-Regulated Products

Such reporting requirements are not limited to prescription and over-the-counter drugs. The FDA

---

[17] *See, e.g.*, *Pauley v. Bayer Corp.*, No. 2729, 2006 WL 463866, at *2 (Pa. Com. Pl. Jan. 26, 2006) ("AERS data has not been scientifically or otherwise verified; it is not the product of laboratory research or any type of controlled study. It is merely the compilation of experiential reports submitted by those in the field."); *Swallow v. Emergency Medicine*, 67 P.3d 68, 73 (Idaho 2003) (affirming decision to exclude expert testimony based on AERs because "there was no showing . . . [that they] were statistically significant"); *Ryman v. Sec'y of Dep't. of Health & Human Servs.*, 65 Fed. Cl. 35, 39-40 (2005) (VAERS evidence "is not reliable" because "reports can be filed by anyone," and "[t]he information provided is often insufficient to make an assessment.").

[18] *See, e.g.*, *Hagaman v. Merrell Dow Pharm., Inc.*, No. 84-2202-S, 1987 WL 342949, at *8 (D. Kan. June 26, 1987) (noting that while "the technical completeness of [AERs] leaves much to be desired" and the FDA "does not place much faith in [their] usefulness . . . as an aid in determining causation," they are nonetheless useful "as a red flag mechanism that could, in certain instances, tip off the drug manufacturers and the medical community that a certain drug may have some contraindications").

regulates a wide range of products such as food, radiation-emitting products, infant formula veterinary medicines, medical devices, and animal feed[19] which are, to a lesser or greater extent, subject to adverse event reporting requirements.

For example, the FDA receives AERs from manufacturers concerning "medical devices," a category which runs from "simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices," and includes products for professional and home care use, such as syringes, stents, catheters, defibrillators, hearing aids, glucose meters, wheel chairs, and heating pads.[20] Medical devices manufacturers are required to report within thirty

---

[19] *See* 21 U.S.C. § 393(b) (The FDA shall "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."); *What Does FDA Regulate?*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (last visited Aug. 27, 2010). *See also* ARTHUR N. LEVINE, FDA ENFORCEMENT MANUAL 3-4 (2006) ("The FDA regulates approximately 114,700 establishments engaged in manufacturing, processing, repacking, relabeling, and wholesale warehousing of foods, drugs, medical devices and cosmetics. The agency is responsible for monitoring the integrity of research submitted to it by approximately 25,000-30,000 clinical investigators.").

[20] *Products and Medical Procedures*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm (last visited Aug. 27, 2010).

days[21] any information suggesting that one of their products has "caused or contributed to a death or a serious injury" or has malfunctioned in a way that could have caused death or serious injury. 21 C.F.R. § 803.50(a). Reporting obligations are also imposed on user facilities, including hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities. *See* 21 C.F.R. §§ 803.30, 803.3.

As with the "reportability" standards for drugs, medical device reports are intentionally over-inclusive. *See, e.g.*, 21 C.F.R. § 803.16 (explaining that a medical device AER "is not necessarily an admission that the device . . . caused or contributed to the reportable event"). A manufacturer's obligation to report arises as long as the device "*may* have been a factor in the death or injury" and even if it is due to "[u]ser error." Medical Devices; Medical Device Reporting, 70 Fed. Reg. 9,516, 9,520 (Feb. 28, 2005) (emphasis added). In 2009 alone, the FDA received over 200,000 AERs from manufacturers, importers, distributors, and health care providers.[22]

---

[21] The obligation arises as soon as "an employee of the entity . . . has acquired information that reasonably suggests a reportable adverse event has occurred." Medical Devices; Medical Device Reporting, 70 Fed. Reg. 9,516, 9,519 (Feb. 28, 2005). If the reportable event is one that requires remedial action, a report must be filed within five work days. *Id.* at 9,522.

[22] Manufacturer and User Facility Device Experience Database, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm (last visited Aug. 27, 2010).

Manufacturers of dietary supplements, such as vitamins, or other products intended to "supplement the diet" containing a mineral, an herb or other botanical, or an amino acid,[23] are also subject to reporting requirements. 21 U.S.C. § 379aa-1(b)(1). Manufacturers, packers, and distributors of dietary supplements must forward "serious adverse event reports"[24] to the FDA, 21 U.S.C. § 379aa-1(b)(1), and keep records of any other AER received, 21 U.S.C. § 379aa-1(e)(1).

Again these reporting requirements are designed to be over-inclusive, and it is questionable how many reports are actually attributable to defects in the supplements involved. *See* Ashish R. Talati & Abhishek K. Gurnani, *Dietary Supplement Adverse Event Reports: Review and Analysis*, 64 FOOD & DRUG L.J. 503, 510-11 (2009) (noting large proportion of reports may be attributable to patients' "extensive medical histories and diseases," "age-related health problems," "the combination of dietary supplement products with other various medications," and failure to properly heed warnings

---

[23] 21 U.S.C. § 321(ff).

[24] An "adverse event" is "any health-related event associated with the use of a dietary supplement that is adverse." 21 U.S.C. § 379aa-1(a)(1). A "serious adverse event" is an adverse event that either (1) results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect or (2) requires medical or surgical intervention to prevent such results. 21 U.S.C. § 379aa-1(a)(2). These definitions mirror those for drugs. *See* 21 U.S.C. § 379aa(a)(1) & (2).

on product labels). Thus, in *McClain v. Metabolife Intern., Inc.*—a products liability action involving an herbal weight-loss supplement—the Eleventh Circuit excluded expert testimony that was substantially based on adverse events reports submitted to the FDA. 401 F.3d 1233, 1236 (11th Cir. 2005).[25]

The potential unreliability of this information does not necessarily lessen its value for the FDA's regulatory efforts, as such reports are only one aspect of its broader regulatory strategy that includes analyzing information from such sources as "inspections of dietary supplement manufacturers and distributors . . . consumer and trade complaints . . . laboratory analyses of product samples, and monitor[ing of] retail outlets, including the Internet."[26]

When promulgating the dietary supplements rule, the FDA estimated that it would affect about 1,460 manufacturers. *See* Current Good

---

[25] The court explained that the testimony was inadmissible because the expert's reliance on the reports demonstrated "more of a federal agency risk analysis approach. . . than a courtroom causation analysis" and because "he relied on data that lacks the indicia of scientific reliability"; the court also noted that "[u]ncontrolled anecdotal information [such as the AERs] offers one of the least reliable sources to justify opinions about both general and individual causation." *McClain*, 401 F.3d at 1236.

[26] *Oversight of Dietary Supplements: Hearing Before the S. Special Comm. of Aging* (statement of Joshua M. Sharfstein Principal Deputy Commissioner, Food and Drug Administration), (May 26, 2010) http://www.fda.gov/NewsEvents/Testimony/ucm213531.htm.

Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752, 34,920 (June 25, 2007). A total of 1,107 reports were filed in 2008 and 1,275 in 2009. [27] These numbers are likely to rise; the reporting system only applies to supplements labeled on or after December 22, 2007; and the FDA allowed companies an initial two-year grace period before enforcing the requirements.[28]

Manufacturers of radiation-emitting products, which include, among other things, heavy-duty X-ray machines for hospitals and airports, microwave ovens, and laser light shows,[29] also have to report to the FDA whenever they have "reasonable grounds"[30]

---

[27] *Id.*

[28] Talati & Gurnani, at 504 ("While the Act applies to all supplements labeled on or after December 22, 2007, FDA is allowing an additional two-year period for dietary supplement companies to comply with the new requirements. FDA intends to begin enforcing these requirements for dietary supplements labeled on or after January 1, 2010.").

[29] *Radiation-Emitting Products and Procedures* , FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/default.htm (last visited Aug. 27, 2010). *See also A-Z List of Regulated Products & Procedures*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Radiation-Emitting Products/RadiationEmittingProductsandProcedures/ucm135878.htm (last visited Aug. 27, 2010).

[30] "Reasonable grounds" include "professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred." 21 C.F.R. § 1002.20(a).

for suspecting an "accidental radiation occurrence." 21 C.F.R. § 1002.20. Manufacturers are also required to report any product they "produced, assembled, or imported" that has a defect[31] or fails to comply with applicable federal standards. 21 C.F.R. § 1003.10. Since there is overlap between the definitions of medical devices and radiation-emitting products, some manufacturers are subject to reporting obligations under both regulatory schemes.[32] Once again, these reporting obligations arise *before* causation has been established or the occurrence of an incident has actually been confirmed. *See* 21 C.F.R. § 1002.20(a) (Manufacturers must report as soon as they have any "reasonable grounds for *suspecting* that an incident has occurred." (emphasis added)).

Veterinary medicines are also the subject of adverse event reports, which are to be made even if an incident does not appear to be "drug related" or the drug was not used "in accordance with the approved labeling." *See* 21 C.F.R. § 514.3; *see also* 21 C.F.R. § 514.80.[33] These reports may originate from

---

[31] To be reportable, the defect should "relate[] to the safety of use of such product by reason of the emission of electronic product radiation." 21 U.S.C. § 360*ll*.

[32] *See Overlap of FDA Enforcement Authorities for Radiation-Emitting Products*, FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/downloads/RadiationEmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/UCM133545.pdf (last visited Aug. 27, 2010).

[33] Adverse events may occur "in the course of the use of an animal drug product" or involve a failure of the product "to produce its expected pharmacological or clinical effect." 21

"anyone directly involved with the purported adverse event."[34]

Most food manufactures are required to file electronically with the recently-established Reportable Food Registry ("the Registry") within twenty-four hours of determining that an article of food has a "reasonable probability" of "caus[ing] serious adverse health consequences or death to humans or animals." 21 U.S.C. §§ 350f (a) and (d).[35] Approximately 161,000 domestic and 244,000 foreign facilities are subject to the Registry's jurisdiction

---

C.F.R. § 514.3(1). The definition also includes adverse events "occurring in humans from exposure during manufacture, testing, handling, or use of a new animal drug." *Id.* § 514.3(3).

[34] CENTER FOR VETERINARY MEDICINE, PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: MANAGEMENT OF ADVERSE EVENT REPORTS, HHS 8 (May 1, 2006), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052657.pdf.

[35] The Registry is a tool the regulator uses to identify potential problems early on, not a means for the determination of causation or liability. *See, e.g.*, Report: A New Approach to Targeting Inspection Resources, 75 Fed. Reg. 44,793-01, 44,794 (July 30, 2010) (explaining that the Registry provides "early warning to [the] FDA about potential public health risks" and "increase[s] the speed with which the agency and its partners at the State and local levels can investigate the reports and take appropriate followup action"). Thus, "[a] report or notification . . . shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness." 21 U.S.C. § 350f (j).

which covers products as diverse as dairy, seafood, baked goods, candy, eggs, frozen foods, seasoning, and sweeteners.[36]

Infant formula, while a subset of "food"[37] as defined by the regulation, is excluded from the Registry[38] and subject instead to independent reporting requirements. Manufacturers are required to "promptly notify" the FDA whenever they have knowledge that "reasonably supports the conclusion" that the formula "*may* not provide the nutrients required" or "*may* be otherwise adulterated or misbranded." 21 U.S.C. § 350a(e)(1) (emphasis added).

---

[36] *See* A NEW APPROACH TO TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION: THE REPORTABLE FOOD REGISTRY, FOOD AND DRUG ADMINISTRATION 9-10, 12 (July 28, 2010), *available at* http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM220280.pdf. The FDA's reporting requirements apply to "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States." 21 U.S.C. § 350d(a). The definition of "facility" excludes farms, restaurants, other retail food establishments, nonprofit food establishments and fishing vessels. 21 U.S.C. § 350d(b)(1). The Registry also does not cover products under the exclusive jurisdiction of the Department of Agriculture. 75 Fed. Reg. at 44,973-01.

[37] Infant formula is defined as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." 21 U.S.C. § 321(z).

[38] *See* 21 U.S.C. § 350f(a)(2) (excluding infant formula from definition of "reportable food").

III. Implications of Ninth Circuit's Decision for Products Outside of the FDA's Jurisdiction

The potential impact of the Court's decision in this case goes beyond industries regulated by the FDA. Additional examples are provided by such products as motor vehicles, aircraft, and consumer products in general. All are subject to regimes that are designed to provide the regulator with an over-inclusive array of information about potential safety trends.[39]

1. Motor vehicles, such as passenger cars, trucks, motorcycles and buses, and motor vehicle equipment, such as tires and child restraint systems,[40] are regulated by the National Highway

---

[39] These are just a sample of requirements related to federal agencies. Specific reporting requirements exist for many other products both at the federal and state level. *See, e.g.*, 46 U.S.C. § 4310 and 33 C.F.R. § 179 (requiring recreational vessel manufacturers to notify the Coast Guard of any "defect related to safety" in their vessels); Ga. Code Ann. § 26-2-27.1 (requiring "food processing plants"—defined as "commercial operation[s] that manufacture[] food for human consumption"—to report to the Georgia Department of Agriculture all food that contains "any poisonous or deleterious substance which may render it injurious to health").

[40] Motor vehicles include any vehicle "driven or drawn by mechanical power or manufactured primarily for use on public streets, roads, and highways" such as passenger cars, trucks, motorcycles and buses, while motor vehicle equipment includes "any system, part, or component of a motor vehicle as originally manufactured; . . . or sold for replacement or improvement . . . or as an accessory or addition to a motor vehicle; or, any device or an article or apparel . . . that is not a system, part, or component of a

Traffic Safety Administration ("NHTSA"). Manufacturers of these products are subject to a variety of reporting requirements, including those set forth in the Transportation Recall Enhancement, Accountability, and Documentation Act ("TREAD Act"), Pub. L. No. 106-414, 114 Stat. 1800 (2000).

Under the TREAD Act's "Early Warning" requirements, manufacturers are to report information related to "potential defects," and reports of injury or death related to their products, as well as other relevant data. With some variation depending on company size, manufacturers of vehicles, tires, and child restraint systems must submit quarterly reports on, *inter alia*, (1) every incident involving at least one death or injury identified in a claim against the manufacturer and alleged to have been caused by a possible defect in its vehicle and (2) the "[n]umbers of property damage claims, consumer complaints, warranty claims, and field reports" that they receive regarding their products. 49 C.F.R. § 579.21-27. NHTSA also collects and monitors vehicle owner complaints through its website.[41]

---

motor vehicle and is manufactured, sold, delivered, offered, or intended to be used only to safeguard motor vehicles and highway users against risk of accident, injury, or death." 49 U.S.C. § 30102(a)(6)-(7).

41 *Defects & Recalls: File a Safety Complaint*, OFFICE OF DEFECTS INVESTIGATION, http://www-odi.nhtsa.dot.gov/ivoq/index.cfm (last visited Aug. 27, 2010). *See also* Reporting of Information and Documents About Potential Defects, 67 Fed. Reg. 45,822, 45,823 (July 10, 2002) (explaining that the reports are intended to "help NHTSA

The reporting procedures established under the TREAD Act are designed to capture any information that "*may help* identify defects related to motor vehicle safety and noncompliances with Federal motor vehicle safety standards." 49 C.F.R. § 579.1 (emphasis added). The regulation is designed to capture information about "*possible* safety-related defects and noncompliances." *Id.* at § 579.2 (emphasis added). As explained by the NHTSA's Office of Defects Investigation:

> Manufacturers must report any claim against and received by the manufacturer. Claims are merely requests or demands for relief related to a crash, the failure of a component or system, or a fire originating in or from a vehicle. These claims are unverified allegations. They may help NHTSA identify a possible defect, but in and of themselves the claims are not evidence of a defect.[42]

In addition to the "Early Warning" reports, manufacturers of motor vehicles and certain motor vehicle equipment must report any defect that relates to motor vehicle safety to NHTSA within five days of determining that it exists. *See* 49 U.S.C. § 30118(c)(1); 49 C.F.R. § 573.6(b).

While these reports are essential to the agency's ability to fulfill its mission, many of them

---

identify trends that could indicate potential safety problems").

[42] *Public Release of EWR Data*, OFFICE OF DEFECTS INVESTIGATION, (Sept. 10, 2008), http://www-odi.nhtsa.dot.gov/ewr/qb/documents/NHTSA-ODI-EWR-Facts.pdf.

have limited probative value for other purposes. Consumer complaints on their own, for example, are not generally sufficient to show that a vehicle was defective. *U.S. v. Gen. Motors Corp.*, 841 F.2d 400, 412-13 (D.C. Cir. 1988). Courts have also excluded vehicle owner complaints and accident reports as hearsay, as being irrelevant, or because their prejudicial effect far outweighs their minimal probative value. *See e.g., Jones v. Ford Motor Co.*, 204 Fed. App'x. 280, 286-87 (4th Cir. 2006); *Cole v. Gen. Motors*, No. 87-5966, 1988 WL 76522, at *7 (6th Cir. July 21, 1988).

2. The aviation industry is also subject to significant reporting requirements. The Federal Aviation Administration ("FAA") imposes requirements on certain manufacturers[43] to report aircraft[44] failures, malfunctions and defects it determines have resulted in one of an enumerated list of occurrences, including exhaust or brake system failure, engine failure, abnormal vibration or buffeting, fire or flammable fluid leakage. 14 C.F.R. § 21.3(a) & (c).

Similarly, operators of airplanes with a seating configuration of twenty or more passengers

---

[43] Reporting requirements are imposed on manufacturers who hold a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval, a Technical Standard Orders authorization, or the licensee of a Type of Certificate. 14 C.F.R. § 21.3(a); *see also* 14 C.F.R. §§ 21.113; 21.21-29; 21.303; 21.601.

[44] "Aircraft" is defined as "a device that is used or intended to be used for flight in the air," and includes airplanes and rotorcrafts. 14 C.F.R. § 1.1.

or a maximum payload capacity of 6,000 pounds must file a "service difficulty report" on "the occurrence or detection of each failure, malfunction, or defect." 14 C.F.R. § 125.409(a).[45] Air carriers and operators are also required to file "service difficulty reports" concerning seventeen enumerated types of failures, malfunctions and defects, including fires during flight, false fire warning during flight and damage caused during flight by the engine exhaust system. 14 C.F.R. § 121.703. The FAA collects these reports to track repair problems with private, commercial and military aircraft and aircraft components. The reports are largely made by the aircraft owners and thousands are filed every month. These reports are loaded on a publicly accessible database.[46] A query of the database reveals that more than a thousand such reports were filed just for the first week of January 2010. Manufacturers have the ability to view these reports, and the FAA uses the reports to publish monthly *Aviation Maintenance Alerts*.[47]

In addition, certificated domestic aviation repair stations—which are repair stations certified

---

[45] "Each report of occurrences during a 24-hour period shall be submitted to the collection point within the next 96 hours." 14 C.F.R § 125.409(b).

[46] *See Service Difficulty Reporting Site*, FEDERAL AVIATION ADMINISTRATION, http://av-info.faa.gov/sdrx/Query.aspx (last visited Aug. 27, 2010).

[47] *Aviation Maintenance Alerts*, FEDERAL AVIATION ADMINISTRATION, http://www.faa.gov/aircraft/safety/alerts/aviation_maintenance (last visited Aug. 27, 2010).

by the FAA according to procedures laid out in 14 C.F.R. § 145.51—are required to report within ninety-six hours from the time of discovery, any serious failure, malfunction, or defect they discover in an aircraft component. 14 C.F.R. § 145.221(a). The regulations outline the information that the service difficulty report should provide, including the defective article, the nature of the defect, and the defect's apparent cause. 14 C.F.R. § 145.221(b).

While these reports assist the agency in fulfilling its mission, they have limited probative value for other purposes. For example, the reports are based largely on witness accounts and other hearsay which courts ordinarily exclude from trial. *See generally In re Cessna 208 Series Aircraft Prod. Liab. Litig.*, MDL No. 1721, 2009 WL 2780223 (D. Kan. Sept. 1, 2009) (holding that an FAA Notice of Proposed Rulemaking, which was based largely upon reports of witnesses and other hearsay, was inadmissible under Fed. R. Evid 403, because it was not issued to determine the "legal liability of a particular party or the mechanical soundness of a particular airplane model").

3. Manufacturers of thousands of consumer products are subject to reporting obligations under the Consumer Product Safety Act, which charges the United States Consumer Product Safety Commission ("CPSC") with the task of protecting the public against "unreasonable risks of injury associated with consumer products." Consumer Product Safety Act ("CPSA"), Pub. L. No. 92-573, § 2(a), 86 Stat. 1207, 1207 (1972). The CPSC has jurisdiction over

approximately 15,000 types of consumer products.[48] The CPSA "gave the Commission broad powers to gather, analyze, and disseminate vast amounts of private information." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 111, (1980) ("'If the Commission is to act responsibly and with adequate basis, it must have complete and full access to information relevant to its statutory responsibilities. Accordingly, the committee has built into this bill broad information-gathering powers.'" (quoting H.R. Rep. No.92-1153, at 31 (1972)).

Manufacturers must report "a broad spectrum of safety related information" to the CPSC. 16 C.F.R.

---

[48] The Consumer Product Safety Act defines "consumer product" as:

> [A]ny article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.

15 U.S.C. § 2052(a)(5). Courts have held that this definition should be "liberally construed" in furtherance of "the protection of consumers from injury due to unsafe products." *U.S. v. One Hazardous Prod. Consisting of a Refuse Bin*, 487 F. Supp. 581, 584 (D.N.J. 1980) (citing *Consumer Prod. Safety Comm'n v. Chance Mfg. Co.*, 441 F. Supp. 228, 231-34 (D.D.C. 1977)). *See also Who We Are - What We Do*, CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/pr/whoweare.html (last visited Aug. 23, 2010) (describing scope of agency's jurisdiction).

§ 1115.2(b).[49] They must report all failures to comply with applicable rules and regulations. 15 U.S.C. § 2064(b)(1)-(2). They must file reports of all products that contain defects,[50] which "could create a substantial product hazard," 15 U.S.C. § 2064(b)(3), and all products that "create[] an unreasonable risk of serious injury or death." 15 U.S.C. § 2064(b)(4). They must also report whenever a product is subject to three or more civil actions in a two-year period that result in settlement or judgment in favor of a plaintiff. 15 U.S.C. § 2084(a); 16 C.F.R. § 1116.3(d).[51] Manufacturers of marbles, small balls, latex balloons, and games and toys containing small parts are subject to additional requirements under the Child Safety Protection Act to report all choking incidents. Pub. L. No. 103-267, 108 Stat. 722 (1994). *See also* 16 C.F.R. § 1117.

As the statutes and regulations show, these reports are meant to be over-inclusive. For example, firms are not supposed to "await complete or

---

[49] These reporting obligations also apply to manufacturers regulated under the Refrigerator Safety Act, the Flammable Fabrics Act, the Federal Hazardous Substances Act and the Poison Prevention Packaging Act. 16 C.F.R. § 1115.2(d); *see also* 15 U.S.C. § 2051, *et seq*.

[50] "Defects" include "[a]t a minimum. . . the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure or inadequacy in form or function." 16 C.F.R. § 1115.4.

[51] "The manufacturer's opinion as to the validity of the allegation is irrelevant," 16 C.F.R. § 1116.7(b), but manufacturers "may specifically deny that the information [submitted] reasonably supports [liability]." *Id*.

accurate risk estimates before reporting," 16 C.F.R. § 1115.14(c), but instead to err on the side of reporting. 16 C.F.R. § 1115.4(e) ("[S]ubject firms are *urged to report if in doubt* as to whether a defect could present a substantial product hazard."). The obligation to report arises as soon as the manufacturer "receive[s] the first information regarding a potential hazard, noncompliance or risk," 16 C.F.R. § 1115.12(a), and reporting should not be delayed "in order to determine to a certainty" the existence of a problem. *Id.* The obligation to report applies "even when no final determination of the risk is possible." 16 C.F.R. § 1115.6(a). In the case of choking hazards, manufacturer "*must not wait* until they have investigated the incident or conclusively resolved whether the information is accurate or whether their product was involved in the incident." 16 C.F.R. § 1117.3. Rather the existence of an "allegation . . . is sufficient to require a report." *Id.*

The CPSC recognizes that these reports have limited value in terms of establishing causation. The regulations specifically state that the filing of a report "does not automatically indicate the presence of a substantial product hazard," 16 C.F.R. § 1115.2(c), and that the reports "shall not be interpreted, for any purpose, as an admission of liability or of the truth of the information contained [therein]." 16 C.F.R. § 1117.8. Congress expressly recognized that reporting requirements are not equivalent to liability and should not be used "as the basis for criminal prosecution of the reporting person . . . except for offenses which require a showing of intent to defraud or mislead." 15 U.S.C. § 2064(b).

These reports are, instead, part of the CPSC's broader regulatory mandate and are designed to serve at most as initial indicators of a potential problem. The CPSC, for example, encourages consumers themselves to file reports and sets no threshold for such reporting.[52] It receives over 10,000 reports a year from consumers and industry, which it analyzes in order to "identify patterns of injuries and hazards associated with particular products."[53]

CONCLUSION

The Ninth Circuit's treatment of AERs provides no meaningful guidance to manufacturers and will result in investors receiving "essentially useless" information, not only as to over-the-counter cold medications, but across a wide range of industries. The appropriate standard is that of statistical significance adopted by the First, Second, and Third Circuits, and urged by Petitioners.

For the foregoing reasons, this Court should reverse the decision of the Ninth Circuit.

---

52 *See e.g.*, *Frequently Asked Questions*, CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/about/faq.html (last visited Aug. 27, 2010) (explaining that the CPSC "welcomes" reports from consumers who "believe a product is unsafe").

53 *Id.*

Respectfully submitted,

ANNE E. COHEN
(*Counsel of Record*)
aecohen@debevoise.com
BETHANY A. DAVIS NOLL
BERGLIND HALLDORSDOTTIR BIRKLAND
DEBEVOISE & PLIMPTON LLP
919 Third Avenue
New York, NY 10022
(212) 909-6000

Attorneys for Amicus Curiae

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNSEL, INC.
1850 Centennial Park Drive
Suite 510
Reston, VA 20191
(703) 264-5300

August 27, 2010

APPENDIX A

Corporate Members of the
Product Liability Advisory Council
as of 8/24/2010

3M
A.O. Smith Corporation
ACCO Brands Corporation
Altec Industries
Altria Client Services Inc.
Anheuser-Busch Companies
Arai Helmet, Ltd.
Astec Industries
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Brown-Forman Corporation
Caterpillar Inc.
Chrysler LLC
Continental Tire the Americas LLC
Crown Equipment Corporation
Daimler Trucks North America LLC
The Dow Chemical Company
E.I. duPont de Nemours and Company
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies

Exxon Mobil Corporation
Ford Motor Company
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
Hawker Beechcraft Corporation
The Heil Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jaguar Land Rover North America, LLC
Jarden Corporation
Johnson & Johnson
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Leviton Manufacturing Co., Inc.
Lincoln Electric Company
Magna International Inc.
Marucci Sports, L.L.C.
Mazak Corporation
Mazda (North America), Inc.
Medtronic, Inc.
Merck & Co., Inc.
Microsoft Corporation
Mitsubishi Motors North America, Inc.
Mueller Water Products

Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc.
Panasonic
Pella Corporation
Pfizer Inc.
Porsche Cars North America, Inc.
Purdue Pharma L.P.
Remington Arms Company, Inc.
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Segway Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Stanley Black & Decker, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Techtronic Industries North America, Inc.
Terex Corporation
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.

Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.