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No. 08- OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether state-law tort claims based upon failure to warn of the risks of methylmercury in tuna fish products are preempted by the Federal Food, Drug, and Cosmetics Act and regulatory actions of the Food and Drug Administration, including a written determination that state-law warning requirements concerning methylmercury in tuna products are preempted by federal law and denial of a petition to require such warnings.

2. Whether a “presumption against preemption” applies in conflict preemption cases.

**PARTIES TO THE PROCEEDING AND RULE
29.6 DISCLOSURE**

The parties to the proceeding are as follows: Petitioner Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea International, was the defendant in the district court and the appellee in the court of appeals. Respondent Deborah Fellner was the plaintiff in the district court and the appellant in the court of appeals.

Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea International, is a California limited liability company. Tri-Union Seafoods, L.L.C. is a wholly owned subsidiary of Thai Union International, Inc., a California corporation that has not issued shares or securities that are publicly traded. No publicly owned company owns ten percent or more of the stock of Thai Union International, Inc.

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JURISDICTION

The judgment of the court of appeals was entered on August 19, 2008. App., *infra*, 1a. The court of appeals denied a petition for rehearing on September 15, 2008. *Id.* at 55a-56a. On December 5, 2008, Justice Souter extended the time to file a petition for a writ of certiorari to January 13, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution provides, in relevant part:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. Art. VI.

Relevant provisions of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq.*, are reprinted in the Appendix. App., *infra*, 57a-62a.

STATEMENT

1. FDA's Regulation Of Food Safety.

Congress has entrusted the Food and Drug Administration ("FDA") with responsibility to protect the safety of food products in the United States. See Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Under the FDCA, FDA has broad authority to regulate the labels of food products. See 21 U.S.C. § 343 *et seq.* In addition, the FDCA prohibits the transmission in interstate commerce of food that is adulterated or misbranded and authorizes FDA to enforce those prohibitions. See 21 U.S.C. §§ 343(a)(1) & 321(n).

FDA's basic approach to regulating food safety is to (1) prohibit the marketing of foods that may pose health risks and (2) develop tolerance and "action" levels to limit the amount of potentially dangerous substances in foods. See, *e.g.*, 42 Fed. Reg. 52,814 (Sept. 30, 1977). If foods exceed tolerance or action levels established by FDA, the agency may find that they are "adulterated" in violation of the FDCA.

In exercising its authority to regulate food labeling, FDA has opted not to require warnings for every ingredient or product that has possible deleterious effects. Instead, FDA relies primarily on disclosure of ingredient and nutrition information on food labels and directs manufacturers to provide warnings on labels only in exceptional

circumstances.¹ FDA has adopted this regulatory approach to avoid overexposing consumers to warnings, which could confuse consumers or cause them to ignore all such statements. See, *e.g.*, 63 Fed. Reg. 37,030, 37,035 (July 8, 1998) (concluding that "too many warning labels on foods could result in loss of consumer credibility and effectiveness"); 44 Fed. Reg. 59,509, 59,513 (Oct. 16, 1979) ("A requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decisionmaking, and would not advance the public health.").

¹ For example, FDA requires that any food containing the sweetener aspartame must include the following statement on the label: "Phenylketonurics: contains phenylalanine." 21 C.F.R. § 172.804(d)(2). Juices that have not been pasteurized must include the following statement on the label: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious injury in children, the elderly, and persons with weakened immune systems." 21 C.F.R. § 101.17(g). Food products that derive more than 50 percent of their total caloric value from whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and are represented for use in weight reduction, must include the following statement on the label: "WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women." 21 C.F.R. § 101.17(d).

In 1990, Congress amended the FDCA to expressly preempt certain state requirements concerning nutrition labeling, food standards of identity, and other label requirements. Nutrition Labeling and Education Act of 1990 (“NLEA”), Pub. L. No. 101-535, 104 Stat. 2353, 2364. Section 6(c) of the NLEA, entitled “Construction,” provides that the express preemption provisions should not be construed to preempt state food warning requirements, but that nothing in the 1990 amendments should be construed to affect preemption, “express or implied,” of any state requirement under the Constitution, any provision of the FDCA not amended by the NLEA, or any other federal law. 104 Stat. at 2364.

2. FDA’s Regulation Of Methylmercury In Fish. FDA has studied the risks of methylmercury in fish for decades. In 1979, FDA determined that a methylmercury action level of 1.0 part per million is safe for seafood. 44 Fed. Reg. 3,990, 3,993 (Jan. 19, 1979). In the ensuing decades, FDA has engaged in an extensive program to evaluate the risks of mercury in fish. Based on this evaluation, FDA has taken a series of regulatory actions, including: (1) issuing consumer advisories targeted at vulnerable subpopulations concerning the risks of methylmercury in fish, (2) rejecting a petition to require product-label warnings about the risks of mercury in fish, and (3) issuing a written determination that state-law warning requirements concerning the risks of mercury in tuna are preempted by federal law.

a. *FDA’s Consumer Advisories.* FDA first issued an advisory on methylmercury in fish in 1995. The 1995 Advisory, entitled “Is Mercury in Fish a Safety Concern?,” stated: “FDA food specialists say that eating a variety of types of fish, the normal pattern of consumption, does not put anyone in danger of mercury poisoning. It is when people eat fad diets—frequently eating only one type of food or a particular species of fish—that they put themselves at risk.” C.A. App. A155. The 1995 Advisory stated that “consumption advice is unnecessary for the top 10 seafood species,” including “canned tuna.” *Id.*

The current Advisory, entitled “What You Need to Know About Mercury in Fish and Shellfish,” was issued jointly by FDA and the Environmental Protection Agency (“EPA”) in 2004. EPA-823-R-04-005, <http://www.cfsan.fda.gov/~dms/admehg3.html> (March, 2004) (“2004 Advisory”). The 2004 Advisory states that “[f]ish and shellfish are an important part of a healthy diet.” *Id.* They “contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids.” Because “[a] well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children’s proper growth and development,” FDA and EPA advise that “women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits.” *Id.*

The Advisory further states that “nearly all fish and shellfish contain traces of mercury.” FDA and EPA advise that, “[f]or most people, the risk from mercury by eating fish and shellfish is not a

