

No. 08-3060

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UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT

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STACY HOLK,

Plaintiff-Appellant,

v.

SNAPPLE BEVERAGE CORP.,

Defendant-Appellee.

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On Appeal from the United States District Court  
for the District of New Jersey

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BRIEF OF AMICI CURIAE PUBLIC CITIZEN AND  
CENTER FOR SCIENCE IN THE PUBLIC INTEREST  
IN SUPPORT OF APPELLANT AND  
SUPPORTING REVERSAL

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December 24, 2008

## **CORPORATE DISCLOSURE STATEMENT**

Pursuant to Federal Rule of Appellate Procedure 26.1, and Third Circuit Rule 26.1.1, amici curiae Public Citizen and Center for Science in the Public Interest state that they are each non-profit corporations with no parent corporations and that no publicly held corporation has any ownership interest in either of them.

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## **INTRODUCTION**

This case was brought under New Jersey law, seeking damages and injunctive relief against Snapple Beverage Corporation for labeling and promoting certain Snapple beverages as “all natural,” when in fact they contain high fructose corn syrup (“HFCS”). The district court held that Ms. Holk’s state-law claims are impliedly preempted by federal law because federal regulations “occupy the field” and because her claims “would create obstacles to the accomplishment of Congress’s objectives.” The decision below is incorrect.

Congress has directed that the federal food labeling laws “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted” by the statute. Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (1990). Thus, in this case, implied preemption is foreclosed by Congress’s express command. In addition, as in the Court’s recent decision in *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237 (3d Cir. 2008), the federal agency has promulgated no pertinent legal standard, and its informal views are insufficient to preempt Ms. Holk’s claims.

## **INTEREST OF AMICI CURIAE**

Amici Public Citizen, Inc. and Center for Science in the Public Interest (“CSPI”) are non-profit organizations with longstanding interests in the issues presented by this case. Public Citizen is a membership organization devoted to research, advocacy,

and education on a wide range of public health and consumer safety issues. Public Citizen has a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety regulation, and its lawyers have represented parties in significant federal preemption cases involving the Food, Drug, and Cosmetic Act. *E.g.*, *Warner-Lambert v. Kent*, 128 S. Ct. 1168 (2008) (Mem.); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Fellner*, 539 F.3d 237. Public Citizen has also worked to defend consumers' access to accurate information affecting their health. *See, e.g.*, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976); *N.Y. State Restaurant Ass'n v. N.Y. City Board of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007) (amicus); *Public Citizen v. Shalala*, 932 F. Supp. 13 (D.D.C. 1996).

CSPI is a national, non-profit advocacy organization for nutrition and health, food safety, and sound science. CSPI's advocacy was instrumental in getting Congress to consider nutrition labeling legislation in 1989 and in securing passage of the Nutrition Labeling and Education Act in 1990. In the eighteen years since then, CSPI has tirelessly advocated for effective FDA enforcement of that statute.

All parties have consented to the filing of this amicus brief.

## STATEMENT

### I. **The Food, Drug, and Cosmetic Act and the Nutrition Labeling and Education Act**

Under the Food, Drug, and Cosmetics Act (“FDCA”), the Food and Drug Administration (“FDA”) has authority to regulate certain aspects of food safety and labeling. *See* 21 U.S.C. § 371. The FDA can set food definitions and standards of quality, *id.* § 341, establish tolerance levels for poisonous or deleterious substances in food, *id.* § 346, and initiate enforcement proceedings against manufacturers of adulterated or misbranded food. *Id.* §§ 332-334; *see id.* § 342 (defining “adulterated”), § 343 (defining “misbranded”). A food may be deemed misbranded if its labeling is “false or misleading in any particular,” *id.* § 343(a)(1), or if its label does not contain required nutrition information (such as serving size, number of servings per container, or total number of calories). *Id.* § 343(q).

The Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, 2364 (1990) (“NLEA”), is codified as part of the FDCA and provides the basis for FDA regulation of nutrition labels. Among other things, the NLEA requires that nutrition labeling be placed on most packaged food, prohibits the use of terms that characterize the level of nutrients in a food unless they conform to definitions

established by the FDA, and ensures that claims about the relationship between nutrients and health conditions are supported by significant scientific agreement.

In enacting the NLEA, Congress devoted careful attention to the subject of preemption. See Sims, *The Politics of Fat: Food and Nutrition Policy in America* 199 (1998) (“The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws.”).<sup>1</sup> In the final moments of floor discussion before the House passed the final version of the bill, Representative Henry Waxman explained that a narrow preemption provision had been added to the bill by the Senate to induce the food industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) (“[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them some types of preemption of some burdensome State laws that interfered with their ability to do business in all 50 States.”). As explained by the leading Senate proponent of stronger federal preemption, “the carefully crafted uniformity section of this legislation is limited in

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<sup>1</sup>See generally Bradley, *The States’ Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990*, 49 Food & Drug L.J. 649, 659 (1994); Jordan, *Preemption and Uniform Enforcement of Food Marketing Regulations*, 49 Food & Drug L.J. 401 (1994).

scope.” 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990) (Sen. Hatch). Under that section, now codified at 21 U.S.C. § 343-1(a), state “requirements” that are “not identical” to federal requirements addressing specified topics are preempted. For example, states may not impose a standard of identity on a food subject to an FDA standard of identity, unless the state standard is identical to the federal standard. *Id.* § 343-1(a)(1). And states may not impose requirements related to nutrition labeling (the statement of serving size, calories, etc., required on food packages) or requirements regarding labeling that characterizes the level of nutrients or makes health claims related to nutrients, unless those state requirements are identical to federal requirements. *Id.* § 343-1(a)(4)-(5).

In an effort to satisfy industry concerns while remaining “sensitive to the regulatory roles played by the States,” the preemption provision was “refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory authority where it is appropriate.” 136 Cong. Rec. at S16609 (Sen. Mitchell); *see also* 136 Cong. Rec. at S16611 (Sen. Hatch) (“[T]he compromise makes clear that the national uniformity in food labeling that is set forth in the legislation has absolutely no effect on preemption of State or local requirements that relate to such things as warnings about foods or components of food.”). To make clear that, aside from § 343-1(a), the new labeling laws would “otherwise preserv[e]

State regulatory authority,” Congress added a statutory provision limiting the preemptive effect of the NLEA to state laws that fall within the NLEA’s express preemption provision:

The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1 note).

## **II. “All Natural” and High Fructose Corn Syrup**

Two related aspects of FDA regulation, or non-regulation, are relevant here: the agency’s view regarding use of terms such as “all natural” in food and beverage labeling and the agency’s views regarding whether HFCS is “natural.”

**A.** The FDA does not define or regulate use of the terms “natural” or “all natural.” However, the FDA recognizes that “natural” is used to convey that a food is somehow “more wholesome” and that “‘natural’ claims are confusing and misleading to consumers and frequently breach the public’s legitimate expectations about their meaning.” 56 Fed. Reg. 60421, 60466 (1991); *see* 58 Fed. Reg. 2302, 2407 (1993). “[B]ecause of resource limitations and other agency priorities,” the FDA has not yet defined “natural” or “all natural,” although the agency recognizes

that doing so could “abate” “the ambiguity” that “results in misleading claims.” 58 Fed. Reg. at 2407.

Although the FDA has no definition, it follows a policy of not taking enforcement action charging that a product labeled as “natural” is misbranded as long as the product has no added color, synthetic substances, or flavors. 58 Fed. Reg. at 2407. (Natural and artificial flavors are defined in 21 C.F.R. § 101.22.) Under the agency’s policy, “natural” means that “nothing artificial or synthetic has been included in, or added to, a food that would not normally be expected to be in the food.” 58 Fed. Reg. at 2407; *see also* USDA, Food Standards and Labeling Policy Book 116 (Aug. 2005), *available at* [www.fsis.usda.gov/OPPDE/larc/Policies/Labeling\\_Policy\\_Book\\_082005.pdf](http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf) (“natural” denotes that “product and its ingredients are not more than minimally processed”). This policy is binding on the agency in that the agency will not “recommend legal action against a person or product with respect to an action taken in conformity” with it. 21 C.F.R. § 10.85(d). However, the policy does not establish any requirements binding on industry or the public. *Id.* § 10.85(j) (advisory opinion “may be used in . . . court proceedings to illustrate acceptable or unacceptable procedures or standards, but not as a legal requirement”). The FDA’s answer to the “frequently asked question” “What guidance does the FDA have for Natural-Organic?” makes clear that the FDA has no law on the subject: “The

term ‘natural’ has not been defined in FDA’s law (the Federal Food, Drug, and Cosmetic Act) or in FDA’s regulations.” FDA, Food, Nutrition, and Cosmetics Questions & Answers, *available at* <http://www.cfsan.fda.gov/~dms/qa-ind7f.html> (viewed Dec. 15, 2008).

**B.** HFCS is a highly processed substance that does not occur in nature. JA 4 (district court opinion). HFCS is created by treating cornstarch with enzymes to yield glucose, and then adding additional enzymes to transform the product into fructose. *Id.* The FDA has no official position on whether HFCS is “natural.”

### **SUMMARY OF ARGUMENT**

The ability to hold companies accountable for false or misleading “natural” labeling is important because consumers are increasingly interested in buying natural foods and beverages and are willing to pay more for “natural” foods than other foods. As a report from the Food Marketing Institute explained, “[s]urging demand for natural and organic products has transformed a small market niche into a double-digit growth sector. U.S. sales of such foods and beverages reached \$28.2 billion in 2006.” FMI Backgrounder, *Natural and Organic Foods* (June 2007), *available at* [www.fmi.org/docs/media/bg/natural\\_organic\\_foods.pdf#search=%22natural%20foods%22](http://www.fmi.org/docs/media/bg/natural_organic_foods.pdf#search=%22natural%20foods%22).

In this case, the district court held that Snapple could not be held accountable for misrepresenting its beverages as “all natural” because FDA regulation occupies the

field of beverage labeling, and thus state-law unfair and deceptive trade practices claims are preempted. The court was wrong. Field preemption is primarily a question of congressional intent, *Colacicco v. Apotex*, 521 F.3d 253, 265 n.11 (3d Cir. 2008), and Congress’s intent *not* to oust all state law in the area of food labeling is expressly stated in the legislative record and reflected in § 6(c) of the NLEA.

In addition, the decision below suggests that allowing Ms. Holk’s claims to go forward would pose a obstacle to the accomplishment of federal objectives. However, the FDA does not regulate use of terms like “all natural” and “100% natural,”and it has no official position on whether HFCS is or is not “natural.” *Fellner*, 539 F.3d at 243 (no preemption where no federal law addresses relevant topic). The FDA has expressed concern, however, that companies use the terms in ways that are misleading to consumers. Thus, holding companies liable for misleading consumers about whether their products are “all natural” does not frustrate any federal objective and is fully consistent with the FDA’s concerns.

## **ARGUMENT**

The decision below holds that Ms. Holk’s claims are impliedly preempted and seems to rely on both implied field preemption and implied conflict preemption. The decision is wrong on both points.

## **I. Fundamental Preemption Principles Guide The Resolution Of This Case.**

The federal preemption doctrine has its origin in the Supremacy Clause, article VI, clause 2 of the Constitution of the United States, which provides the constitutional authority for the proposition that conflicts between federal and state law are resolved in favor of federal law. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819); *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992). Preemption can be express or implied. It is express if a federal statute explicitly addresses the domain of state law that is or is not preempted, and it is implied if the structure and purpose of federal law, but not its actual words, preempt state law. *See Cipollone*, 505 U.S. at 516. The implied preemption doctrine is itself divided into two types: field preemption and conflict preemption. Field preemption applies where a state law seeks to “regulate[s] conduct in a field that Congress intended the Federal Government to occupy exclusively.” *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990). Conflict preemption is further subdivided into two types, one occurring when it is impossible to comply simultaneously with both federal and state law and the other when state law frustrates the purposes of federal law. *See, e.g., Geier v. Am. Honda Motor Corp.*, 529 U.S. 861, 886 (2000).

When considering the preemptive scope of federal law, courts recognize a strong presumption *against* preemption that may be overcome only by “clear and manifest”

congressional intent to the contrary. *Altria v. Good*, 555 U.S. \_\_\_, 2008 WL 5204477, \*4 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994). A party seeking preemption of state law thus bears a heavy burden, for “[p]reemption of state law by federal . . . regulation is not favored ‘in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained.’” *Chicago & N. W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)). And where, as here, the federal regulatory scheme does not itself provide a damages remedy, the Supreme Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English*, 496 U.S. at 87-90; *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (“perfectly rational for Congress not to preempt common-law claims” when preempting state regulatory law because common-law claims “perform an important remedial role in compensating accident victims”).

Accordingly, even if the answer to the preemption question here were ambiguous, that ambiguity would be resolved in Ms. Holk’s favor. *See Altria*, 2008 WL 5204477, \*4. In fact, as shown below, the answer is not ambiguous: Ms. Holk’s claims are not impliedly preempted.

## II. The NLEA Forecloses Implied Preemption.

“The NLEA explicitly forecloses the possibility that state law would be impliedly preempted.” *N.Y. State Restaurant Ass’n v. N.Y. City Board of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007). Specifically, § 6(c) the NLEA states that it “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under” 21 U.S.C. § 343-1(a). 21 U.S.C. § 343-1 note. As the FDA has explained, this statutory language “clearly manifests Congress’s intention that the 1990 amendments” are not to preempt state law beyond the NLEA’s express terms: “If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption.” 56 Fed. Reg. 60528, 60530 (1991).

Thus, Congress has directed and the FDA has recognized that “the *only* State requirements that are subject to preemption are those that are affirmatively different on matters that are covered by section [343-1] of the act.” 58 Fed. Reg. 2462 (1993) (emphasis added); *see* 60 Fed. Reg. 57076, 57120 (1995) (“If there is no Federal requirement to be given preemptive effect, preemption does not occur.”). In this respect, the NLEA’s preemption provisions are “somewhat unusual,” in that “[t]he NLEA can be analyzed only in terms of express preemption, because its express

provisions prohibit any implied preemption under the statute.” Burk, *The Milk-Free Zone: Federal and Local Interests*, 22 Colum. J. Env’tl L. 227, 259 (1997); accord *In re Farm Raised Salmon*, 175 P.2d 1170, 1179 (Cal. 2008), petition for cert. filed (U.S. Apr. 18, 2008) (No. 07-1327); *Vermont Pure Holdings, Ltd. v. Nestle Waters N. Am.*, 2006 WL 839486 (D. Mass. Mar. 28, 2006); cf. *AT&T Commc ’ns of Ill. v. Ill. Bell Telephone Co.*, 349 F.3d 402, 410 (7th Cir. 2003) (similar anti-preemption clause “precludes a reading that ousts the state legislature by implication”).

The district court found that the state-law claims alleged here are impliedly preempted because the FDCA and FDA regulations “so thoroughly occupy the field of beverage labeling” and because the claims “would create obstacles to the accomplishment of Congress’s objectives.” The court’s decision is contradicted by Congress’s express command and, therefore, must be reversed.

**A. As The Statute States, The FDA Does Not Occupy The Field Of Food Labeling.**

Section 6(c) of the NLEA (21 U.S.C. 343-1 note) is dispositive of the implied preemption issue, and the Court need look no further to reject Snapple’s implied preemption arguments. Below, the court apparently was unaware of § 6(c). Holding that the case should be dismissed based on field preemption, the court relied on the FDA beverage labeling regulations and three cases. None overcomes the plain

language of the statute, which makes clear that the NLEA does not occupy the field of food labeling.<sup>2</sup>

Federal law can preempt state law under a field preemption theory when a “scheme of federal regulation” is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.” *English*, 496 U.S. at 79 (citation omitted). No such federal scheme exists here. Rather, in several ways, the NLEA makes plain that Congress did not intend to occupy the field of food labeling in general or beverage labeling in particular. To begin with, the express preemption provision, section 343-1 identifies specifically which statutory provisions preempt state law. “Congress’ enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted” under field preemption principles. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 290 (1995) (quoting *Cipollone*, 505 U.S. at 517). Indeed, an express preemption provision would be “pure surplusage if Congress had intended to occupy the entire field.” *Wis. Public Intervenor v. Mortier*, 501 U.S. 597, 613 (1991). In addition, the express *non-*

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<sup>2</sup>Although the district court stated that field preemption applied, it also stated that it did not “believe[] that in enacting the [FDCA] Congress intended to displace all state regulation of foods and beverages.” JA 21 n.4. The court stated that its decision was based instead on the finding that “the statutory scheme created by the [FDCA] and its implementing regulations” impliedly preempted claims regarding the labeling of Snapple’s “all natural” beverages. *Id.* Thus, it is not clear that the court intended to find field preemption, as opposed to conflict preemption.

preemption of requirements otherwise preempted under section 343-1(a)—the requirements that are identical to federal requirements on the specified topics—contradicts the field preemption theory. Likewise, § 6(c), which states unequivocally that state law outside the scope of section 343-1 is not preempted, is incompatible with field preemption. In short, the NLEA’s limited express preemption provision and its anti-preemption provision demonstrate that Congress did not intend to displace all state law with regard to food labeling.

Moreover, even without sections 343-1 and 6(c), field preemption simply does not apply here. The contention that FDA has comprehensively regulated use of terms such as “natural” is belied by FDA’s repeated statements that it sees the value of adopting a definition and that it has not yet adopted one. Even comprehensive regulations do not necessarily preempt state law. *English*, 496 U.S. at 87. To find field preemption in a situation where Congress has emphasized the continuing role of the states and where the agency has plainly stated that it has not addressed the pertinent matter would be unprecedented. *Cf. Sprietsma*, 537 U.S. at 68 (Federal Boat Safety Act does not occupy the field of recreational boats safety regulation so as to foreclose state-law remedies). The rarity with which the U.S. Supreme Court holds that state-law remedies are precluded by field preemption further evidences the extent to which the law must be stretched to find field preemption here.

Nonetheless, after reviewing FDA regulations and the decision to defer regulation, the court below concluded that the FDCA and FDA regulations “thoroughly occupy the field.” JA 19. First, listing the FDA’s labeling regulations shows what the agency has done in the area of food and beverage labeling, but ignores what the agency has not done—notably, its decision not to regulate use of “natural.” In any event, whether or not the regulations listed are “comprehensive,” “[t]o infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulation will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.” *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985). “[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field.” *Id.*

Second, the notion that the decision not to define “natural” can support field preemption runs counter to both Supreme Court and Third Circuit precedent. As the Supreme Court explained in *Sprietsma*, an agency’s decision not to regulate a matter within its purview, or—as in *Sprietsma* and here—a decision not *yet* to regulate that matter, does not suggest that the agency determined that a regime free of regulation

was an aspect of its overall regulatory plan, absent an “‘authoritative’ message of a federal policy against [regulation].” *Sprietsma*, 537 U.S. at 67, *quoted in Fellner*, 539 F.3d at 246. Here, the FDA’s own statements unambiguously demonstrate that it has no policy against regulating use of the term “natural;” it just does not have enough resources to promulgate a regulation. *See* 58 Fed. Reg. at 2407. Under these circumstances, even if §§ 341-1(a) and 6(c) and the legislative history reviewed above (at 4-5) did not unequivocally manifest Congress’s rejection of field preemption, Snapple’s theory would be meritless.

The cases relied on by the district court do not support field preemption here. First, the court relied on *C.E.R. 1988, Inc. v. Aetna Casualty & Surety Co.*, 386 F.3d 263 (3d Cir. 2004), to support its holding that Congress had “so thoroughly occupied the field” of beverage labeling “that it would be unreasonable to infer that Congress intended the states to supplement this area.” JA 19. Yet although the defendant in *C.E.R. 1988* raised field preemption, the Court declined to decide the issue. *Id.* at 269.<sup>3</sup>

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<sup>3</sup>*C.E.R. 1988* involved state-law tort claims brought against an insurer for improper handling of a National Flood Insurance Program insurance policy. Under federal regulations implementing the program, private insurers were authorized to issue policies for flood damage. However, the private insurers were essentially administrators of the federal program, and the federal government, not those companies, paid any claims made on the policies. 386 F.3d at 267. The Court found  
(continued...)

Next, the decision below cites *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990). *Sandoz* involved claims under federal law, not state law, and so preemption was not an issue and was not discussed.<sup>4</sup>

The district court also relied on *Cohen v. McDonald's Corp.*, 808 N.E.2d 1 (Ill. App. 2004). In *Cohen*, a consumer brought a deceptive business practices act claim, arguing that the nutritional information provided by McDonald's misrepresented the nutritional value of foods such as hamburgers for children under age four, although such foods were intended for those children. The state appellate court held that the

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<sup>3</sup>(...continued)

that “a central purpose of the Program is to reduce fiscal pressure on federal flood relief efforts,” *id.* at 270, and that state-law tort claims against the private insurers would impede this objective, given that the federal government “ordinarily would be responsible for the costs of defending the lawsuit.” *Id.* at 271. In addition, the federal scheme provided a monetary remedy. *Id.* at 271 n.10. Accordingly, the Court held that the claims were preempted under conflict preemption principles.

<sup>4</sup>*Sandoz* was a Lanham Act case in which the plaintiff alleged that the labeling of Vicks's cough medicine was false because it listed an “active” ingredient, known as a demulcent, as an “inactive” ingredient. *Id.* at 230. An FDA regulation defines “active” ingredients, but the agency had not classified demulcents as either active or inactive. The Court held that whether an ingredient is “active” under the federal regulatory standard is a decision for the FDA, not for a district court in a Lanham Act case. *Id.* at 232. The Court distinguished cases involving claims that labeling and advertising were misleading to consumers, rather than claims that a label failed to meet federal regulatory standards. *Id.* at 231 n.11. And the Court suggested that it would have reached a different conclusion in the case had the claim been that the label was misleading to consumers. *Id.* Here, of course, there is no federal regulatory standard for “all natural” beverage labeling, and Ms. Holk's claims are based on labeling and promotion that is misleading consumers.

claims were preempted, without noting the existence of the anti-preemption provision, § 6(c). In addition, the court’s holding turned on its understanding that the lawsuit “would have this court place labeling requirements on restaurants that provide foods intended for children under the age” of four, and that it did “not have the authority” “to interpret a federal statute”—concerns inapplicable here, both because the NLEA’s restaurant labeling requirements are not at issue and because the Court plainly has authority to interpret statutes. 808 N.E.2d at 9-10.

At the same time, the court in *Cohen* agreed that a state deceptive practices action that adopted the federal statute or regulations as the standard of conduct would *not* be preempted. *Id.* at 9; *see also Lohr*, 518 U.S. at 495-96; *Bates v. Dow AgroSciences*, 544 U.S. 431, 447 (2005); *English*, 496 U.S. at 89 (“[o]rdinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law.”). Thus, the court recognized that federal law did not preempt the field of food labeling, and that state law did not always pose an obstacle to the accomplishment of federal objectives regarding food labeling.

**B. Ms. Holk’s Claims Do Not Pose An Obstacle To The Accomplishment Of A Federal Objective.**

Notwithstanding Congress’s express statement that § 343-1 defines the complete scope of preemption under the NLEA, Snapple argued below, and the district court

seemed to agree, *see supra* note 3, that the claims alleged here are impliedly preempted because they pose an obstacle to accomplishing federal objectives. JA 21. Even without § 6(c), that contention would be wrong and incompatible with the Court’s recent decision in *Fellner*.

Under implied conflict preemption principles, federal law preempts state law when the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Sprietsma*, 537 U.S. at 64 (citation omitted). “State law is not preempted whenever an agency has merely ‘studied’ or ‘considered’ an issue; state law is preempted when federal *law* conflicts with state law.” *Fellner*, 539 F3d at 254 (emphasis in original). Here, because the FDA does not define or regulate use of the terms “natural” or “all natural” (much less have a formal position on whether HFCS is “natural”), preemption of Ms. Holk’s “all natural” claims is not warranted under this theory either. And although Snapple argued below in general terms for obstacle preemption, Snapple never explained how promoting its products as “all natural” advances any federal objective.

Concluding that the claims alleged here would pose an obstacle to Congress’s objective in enacting the NLEA, the decision below relies primarily on *Geier*, 529 U.S. 861. There, the Supreme Court considered the preemptive effect of federal regulations, issued after notice-and-comment rulemaking, that addressed in detail the

types of passive restraints required and permitted in automobiles. The Court found that the agency “deliberately provided the manufacturer with a range of choices among different passive restraint devices” in order to “bring about a mix of different devices introduced gradually over time,” in an attempt to “lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance—all of which would promote [the regulations’] safety objectives.” *Id.* at 875. Based on these findings, the Court held that the plaintiff’s claim seeking to hold Honda liable for failing to install one particular passive restraint would frustrate the federal purpose.

This case could not be further from *Geier*. No federal statute or regulation defines or requires the FDA to define “all natural.” Although the FDA has a “policy” that guides its own exercise of enforcement discretion, *see supra* p. 4, that policy does not impose any labeling requirement on any food company. 21 C.F.R. § 10.85(d), (j); *see Fellner*, 539 F.3d at 252 (FDA guideline stating policy for taking enforcement action does not preempt state law). In fact, the FDA’s policy of taking enforcement action when “natural” is used in some circumstances does not state that use of “natural” in other circumstances is lawful (under state or federal law), only that, as a matter of policy, the FDA will not take action with regard to those statements. In contrast to the extensive notice-and-comment rulemaking and lengthy Federal

Register notice explaining the agency’s goals in formulating the particular safety regulation at issue in *Geier*, here the FDA has deferred taking regulatory action. It has acknowledged that the term “natural” is sometimes used in misleading ways, and that a regulatory definition of the term might be useful, 58 Fed. Reg. at 2407 (1993), but, so far, has declined to define the term. *Id.* (“Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for ‘natural’ at this time.”). Ms. Holk’s claims thus would not impede any federal objective with regard to “natural labeling” because the FDA has not expressed a view on this topic in any legally meaningful way. And “the cases leave no doubt that a mere decision not to regulate . . . alone will not preempt state law.” *Fellner*, 539 F.3d at 254. At the same time, Ms. Holk’s “natural” claims are fully consistent with the FDA’s observation that use of such terms on food labels “may be misleading.” 58 Fed. Reg. 2897, 2903 (1993) (“no specific prohibition against use” of the term “natural,” but FDA “has discouraged use” of the term because it is “ambiguous and may be misleading”).<sup>5</sup>

Accordingly, the facts of this case are analogous, not to *Geier*, but to *Altria*, *Sprietsma* and *Fellner*. In *Altria*, the plaintiff alleged that tobacco company Philip

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<sup>5</sup>*Cf. Penn. Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239, 251-52 (3d Cir. 2007) (claim alleging deceptive advertising of prescription drug preempted where claims challenge “the veracity of statements approved by the FDA”).

Morris violated Maine’s unfair and deceptive trade practices act by marketing cigarettes as “light” and “lowered tar and nicotine” to falsely convey to consumers that those cigarettes deliver less tar and nicotine and, therefore, are less harmful than regular cigarettes. 2008 WL 5204477, \*2. Philip Morris moved for summary judgment, arguing that the plaintiff’s claims were both expressly preempted by the Federal Cigarette Labeling and Advertising Act and impliedly preempted by Federal Trade Commission (“FTC”) policy allowing use of descriptors such as “light.” *Id.* at \*3-\*4. The Supreme Court rejected both arguments. With respect to implied preemption, the defendant’s argument was based on FTC compliance documents addressing tar and nicotine disclosure, FTC consent orders, and FTC’s inaction in allowing “light” descriptors. The Supreme Court stated that the agency’s failure to require defendants to correct their allegedly misleading use of “light” descriptors was *not* evidence of a policy authorizing such representations because “agency nonenforcement of a federal statute is not the same as approval.” *Id.* at \*10. Much like the FDA had done in 1991 with respect to “natural,” the FTC had in 1997 stated in a Federal Register notice that “[t]here are no official definitions for’ the terms ‘light’ and ‘low tar,’” and had sought comment on whether the agency should provide “official guidance with respect to the terms.” *Id.* at \*11 (citing 62 Fed. Reg. 48163 (1997)). Again, much like the FDA here, the FTC did not then take action on the

matter. Nonetheless, the Court held the FTC's actions and inactions did not "even arguably justif[y] the pre-emption of state deceptive practices rules." *Id.* at \*11.

In *Sprietsma*, the Supreme Court considered whether the Coast Guard's decision not to require propeller guards on motor boats impliedly preempted a state-law damages action alleging that the manufacturer's motor boat was unreasonably dangerous because the motor was not protected by a propeller guard. Rejecting the manufacturer's preemption argument, the Court explained that it was "quite wrong" to view the decision not to issue a federal regulation as the "functional equivalent" of a prohibition against state regulation of the subject matter. 537 U.S. at 65. Rather, that decision was "fully consistent with an intent to preserve state regulatory authority." *Id.*; see also *Freightliner Corp.*, 514 U.S. at 289 (where agency had no standard either requiring or prohibiting antilock brakes, state common-law claim regarding antilock brakes not preempted); *Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum*, 485 U.S. 495, 501-04 (1988) (absent explicit statement of intent, federal inaction has no preemptive effect). As in *Sprietsma*, the agency's decision not to undertake rulemaking to define "natural" or "all natural" has no preemptive effect.

In *Fellner*, this Court considered whether failure-to-warn claims brought by a woman who suffered mercury poisoning after eating tuna were preempted by FDA activities. There, the agency had taken several steps addressing health risks posed by

mercury in tuna: It had issued a consumer advisory, a “backgrounder,” and a compliance policy guiding the FDA’s exercise of enforcement action, and the FDA Commissioner had sent a letter to an attorney handling a different lawsuit stating the view that its consideration of the matter preempted state-law claims. Yet the FDA had taken no formal step to address mercury warnings or disclosures on tuna labels. Holding that the plaintiff’s claims were not preempted, the Court “decline[d] to afford preemptive effect to less formal measures lacking the ‘fairness and deliberation’ which would suggest that Congress intended the agency’s action to be a binding and exclusive application of federal law.” 539 F.3d at 245 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)). Reviewing Supreme Court case law, including *Sprietsma*, the Court explained that “mere deliberate agency inaction—an agency decision not to regulate an issue—will not alone preempt state law.” *Id.* at 247.

The district court’s decision in this case cannot be reconciled with *Fellner*, which was issued after the decision below. Just as the lack of FDA regulatory action with regard to mercury in tuna doomed the preemption argument in that case, the FDA’s inaction with regard to use of the term “natural” dooms Snapple’s argument here. As explained above (at 6-7) and in the district court’s opinion, the FDA has stated its decision to defer regulation, and it has set forth an informal policy to guide its own conduct until such time as it chooses to regulate. Under *Fellner*, “nothing

short of federal law can have [preemptive] effect.” 539 F.3d at 243. Because there is no federal law regulating use of the term “natural,” there is no preemption here.

Finally, the district court opinion cites *Lindsey v. Caterpillar, Inc.*, 480 F.3d 202 (3d Cir. 2007), which held that a product liability claim alleging that a tractor was defective because it did not have a rollover protective structure was not preempted by Occupational Health and Safety Administration (“OSHA”) regulation concerning such structures. Because the legislative intent of the relevant statute was “the assurance of worker safety,” the regulation of rollover protective structures did not apply to tractors and did not forbid the protective device, and the agency “recommend[s] that workers be afforded that protective device,” the Court found no conflict between the plaintiff’s claims and the federal regulation. *Id.* at 212. Likewise here, Ms. Holk’s claims are consistent with the legislative purpose of providing consumers with accurate information about the food they purchase; no FDA regulation defines terms such as “all natural,” much less requires Snapple to use the term; and the agency has expressed its concern that such terms may mislead consumers. Like § 6(c) of the NLEA, and the decisions in *Sprietsma* and *Fellner*, *Lindsey* supports reversal of the decision below.

## CONCLUSION

For the foregoing reasons, the decision of the district court should be reversed.

December 24, 2008

Respectfully submitted,

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## COMBINED CERTIFICATION OF COUNSEL

I hereby certify that

1) I am a member of the bar of this Court.

2) The foregoing brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief was prepared in proportionately spaced, 14-point type. As calculated by my word processing software, WordPerfect X3, the brief (not including those parts not required to be counted) contains 6,207 words.

3) The text of the electronic brief is identical to the text in the paper copies.

4) A virus detection program has been run on the file containing the electronic brief, and no virus was detected. The virus protection program run was Symantec Endpoint Protection.

5) On December 24, 2008, I caused 10 copies of the foregoing Brief of Amici Curiae to be sent to the Clerk's Office for filing, and two copies to be served by first-class mail, postage prepaid, on counsel for all parties, as follows:

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