

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

CASE NO.: 08-21894-CIV-SEITZ/O'SULLIVAN

ERIC COVINGTON, individually and on
behalf of all others similarly situated,

Plaintiff;

v.

ARIZONA BEVERAGE CO., LLC,
HORNELL BREWING COMPANY, INC.
and FEROLITO, VULTAGGIO & SONS
INC.,

Defendants.

**PLAINTIFF'S SUPPLEMENTAL MEMORANDUM
IN RESPONSE TO COURT'S DECEMBER 15, 2008 ORDER**

Jon M. Herskowitz (Florida Bar No. 814032)
e-mail: Jon@bhfloridalaw.com
BARON & HERSKOWITZ
One Datran Center
Penthouse One, Suite 1704
9100 South Dadeland Boulevard
Miami, Florida 33156
Telephone No.: (305) 670-0101
Fax No.: (305) 670-2393

December 31, 2008

(Additional counsel listed after signature page)

The Court has requested briefing to address two related issues: “whether the FDA’s policy on the use of the term ‘natural’ and the July 3, 2008 letter to the Corn Refiners Association . . . constitutes ‘federal law’ for purposes of the supremacy clause and whether the FDA’s decision not to engage in rule making regarding the use of the term ‘natural’ constitutes an authoritative federal determination that the area should be unregulated.” Because the express preemption provision of the Nutrition Labeling and Education Act of 1990 (“NLEA”) does not address “natural” labeling, these issues concern only whether Ms. Covington’s claims are impliedly preempted. For the reasons stated below and in the opposition to the motion to dismiss, Ms. Covington’s claims are not impliedly preempted. The motion to dismiss should be denied.

I. The FDA Policy And The Employee’s Letter Do Not Constitute Federal Law.

A. As the Court’s Order implicitly recognizes, no federal statute or regulation defines “all natural.” In 1991, in a notice issued “in response to” the NLEA, the FDA proposed regulations for nutrient content claims, such as “low,” “reduced,” and “light,” among other things. The FDA notice also sought comment from the public on whether and how to define the term “natural” on food labeling. 56 Fed. Reg. 60421, 60466 (1991). The FDA explained that “uses of ‘natural claims are confusing and misleading to consumers and frequently breach the public’s legitimate expectations about their meaning.” *Id.* After reviewing the comments received, the FDA concluded that “if the term ‘natural’ is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated.” 58 Fed. Reg. 2302, 2407 (1993). However, “[b]ecause of resource limitations and other agency priorities,” the agency stated that it was “not undertaking rulemaking to establish a definition for ‘natural’ at this time.” *Id.* Instead, the FDA chose to maintain “its informal policy,” 56 Fed. Reg. at 60466. Further evincing its informal nature, the policy was apparently first stated in a letter. *Id.* (citing as basis for its policy “Ref. 53,” described

as “Raymond E. Newberry, letter to Clinton K. Davies, PhD, September 29, 1988”).

Under the FDA’s policy, the agency does not “attempt[] to restrict use of the term ‘natural’ except for added color, synthetic substances, and flavors.” *Id.* The July 2008 letter referred to in the Court’s order reiterates six times that the FDA’s position on “natural” labeling is simply a “policy.” And the FDA’s answers 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).

FDA regulations provide that a “statement of policy” set forth in Federal Register notice constitutes an “advisory opinion.” 21 C.F.R. § 10.85(d). The agency is obligated to follow the advisory opinion. *Id.* § 10.85(e). That is, the FDA cannot penalize a company for conduct in compliance with an advisory opinion. At the same time, however, an advisory opinion does not impose any requirements on regulated companies. *Knipe v. SmithKline Beecham*, ___ F. Supp. 2d ___, 2008 WL 4090995, *17 (E.D. Pa. 2008) (advisory opinion is “binding only on the agency and changeable at any time without notice and comment”) (citing 21 C.F.R. § 10.85(d)(1), (e), (g)); *cf. Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 252 (3d Cir. 2008) (FDA guideline for allocating resources set forth in Compliance Policy Guide “will not alone preempt state law”). Indeed, an FDA regulation states that an advisory opinion “may be used in . . . court proceedings to illustrate acceptable or unacceptable procedures or standards, but *not as a legal requirement*.” 21 C.F.R. § 10.85(j). Plainly, if a policy does not constitute a “legal requirement,” it does not constitute “federal law.”¹

¹Further illustrating an advisory opinion’s informal character, when the FDA wants to amend or revoke an advisory opinion, notice “will be given in the same manner as notice of the advisory

B. Likewise, the July 2008 letter from an individual at the FDA to the Corn Refiners Association does not constitute “law.” *See* Pltf Opp Memo 6-7 (FDA employee first stated to a reporter that HFCS is not “natural” and later stated in a letter that whether HFCS is “natural” depends on production process). Rather, the letter constitutes “an informal communication that represents the best judgment of that employee at that time.” 21 C.F.R. § 10.85(k). The letter “does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.” *Id.* Put simply, an employee cannot create law by writing a letter.²

In *Fellner*, the Third Circuit recently considered whether failure-to-warn claims brought by a woman who suffered mercury poisoning after eating tuna were preempted by FDA activities, including an FDA letter. There, the letter on which the defendant relied was signed, not by a member of the FDA staff, but by the FDA Commissioner himself. 539 F.3d at 242. Even so, the Third Circuit rejected the notion that the letter carried any preemptive effect. That court observed, “[w]e have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption.” *Id.* at 245. The same is true here. “[F]ederal law capable of

opinion was originally given or in the Federal Register.” 21 C.F.R. § 10.85(g). In contrast, when an agency wants to amend or revoke a regulation—which *does* have the force of law—it must engage in notice-and-comment rulemaking under the Administrative Procedure Act, 5 U.S.C. § 551(5) (“APA”). *Compare* 5 U.S.C. § 553 (providing that APA section on rulemaking “does not apply” to “general statements of policy”).

²Moreover, the letter states that whether high fructose corn syrup (“HFCS”) is “natural” under the FDA’s policy is a fact-specific inquiry that depends on the manufacturing process. At this stage of the case, there is no evidence before the Court concerning AriZona’s manufacturing process, and thus no basis for determining whether or not Ms. Covington’s claims mirror federal policy. *See In re Farm Raised Salmon*, 175 P.3d 1170, 1175 (Cal. 2008) (state requirements identical to federal requirements not preempted by NLEA).

preempting is [not] created every time someone acting on behalf of an agency makes a statement or takes an action within the agency’s jurisdiction.” *Id.* at 245-46.

II. The FDA Has Not Determined That The Term “Natural” Should Be Unregulated.

A. The FDA has made clear that the lack of a federal regulation defining the term “natural” is *not* a decision that the term is best left unregulated. To the contrary, as discussed, above, the FDA has acknowledged that the term “natural” is often used in ways that mislead consumers and that a definition could abate this problem. Nonetheless, “because of resource limitations and other agency priorities,” the agency stated that it was “not undertaking rulemaking to establish a definition for ‘natural’ *at this time.*” 58 Fed. Reg. at 2407 (emphasis added).

The FDA’s decision to defer rulemaking does not preempt state law. As the FDA has stated, “If there is no Federal requirement to be given preemptive effect, preemption does not occur.” 60 Fed. Reg. 57076, 57120 (1995) (FDA statement regarding preemptive scope of preemption under NLEA). *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (“quite wrong” to view decision not to issue federal regulation as “functional equivalent” of prohibition against state regulation on subject matter; decision not to regulate “fully consistent with an intent to preserve state regulatory authority.”); *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).

For example, in *Fellner*, the FDA 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. 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, 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. Rather, "some extant law or regulation" must evince an "authoritative message" that an issue should be free of regulation. *Id.* No such law or regulation conveys that message here, and, accordingly, Arizona's preemption argument cannot be reconciled with *Fellner*.

"[N]othing short of federal law can have [preemptive] effect." *Id.* at 243. Because there is no federal law regulating use of the term "natural," there is no preemption here.

B. On December 15, 2008, the Supreme Court decided *Altria v. Good*, 555 U.S. ___, 2008 WL 5204477 (2008). In that case, the plaintiff alleged that tobacco company Philip 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. 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." After reiterating the "assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *id.* at *4, the Supreme Court rejected both arguments. With respect

to the implied preemption argument—which was based on FTC compliance documents addressing tar and nicotine disclosure, FTC consent orders, and FTC’s inaction in allowing “light” descriptors—the 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. *Id.* at *10 (“agency nonenforcement of a federal statute is not the same as approval”). And 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.

Under *Altria*, *Fellner*, and *Sprietsma*, the FDA’s decision not to define “natural” can have no preemptive effect. Thus, even if Congress had not enacted a provision (§ 6(c)) explicitly foreclosing conflict preemption under the NLEA, and even if Congress had not enacted a provision (21 U.S.C. § 343-1(a)) defining the scope of preemption under the statute, the FDA’s inaction would not preempt Ms. Covington’s the state-law claims.

Dated: December 31, 2008

Respectfully submitted,

By: /s/ Jon M. Herskowitz
Jon M. Herskowitz (Florida Bar No. 814032)
e-mail: Jon@bhfloridalaw.com
BARON & HERSKOWITZ
One Datran Center
Penthouse One, Suite 1704
9100 South Dadeland Boulevard
Miami, Florida 33156
Telephone No.: (305) 670-0101
Fax No.: (305) 670-2393

ADDITIONAL PLAINTIFF'S COUNSEL

Joseph L. "Josh" Tucker
e-mail: josh@jacksonandtucker.com
JACKSON, TUCKER & ANGWIN, P.C.
2229 1st Ave North
Birmingham, Alabama 35203
Telephone No.: 205-252-3535
Fax No.: 205-252-3536

G. Richard Baker
BAKER LAW, PC
700 29th Street South
Birmingham, Alabama 35233
Telephone No.: 205-714-7166

Anna Dean Farmer
LAW OFFICES OF ANNA DEAN
FARMER, P.C.
440 Louisiana, Suite 900
Houston, Texas 77002
Telephone No.: 713-965-0095

Christopher K. Gilbert
THE GILBERT LAW FIRM
2223 Cheshire Lane
Houston, Texas 77018
Telephone No.: 832-541-3747

Allison M. Zieve
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
Telephone No.: 202-588-1000

CERTIFICATE OF SERVICE

I hereby certify that on December 31, 2008, I caused a true and correct copy of the foregoing Plaintiff's Supplemental Memorandum In Response to Court's December 15, 2008 Order to be filed electronically with the Clerk of the Court using CM/ECF. I further certify that the foregoing document is being served this day on all parties required to be served, through counsel listed below, via transmission of a notice of electronic filing generated by the Court's CM/ECF system.

Robert P. Donovan
McElroy, Deutsch, Mulvaney & Carpenter,
LLP
Three Gateway Center
100 Mulberry Street
Newark, NJ 07102

Stephen Bernard Gillman
Shutts & Bowen
201 South Biscayne Boulevard
Suite 1500 Miami Center
Miami, FL 33131

By: /s/ Joseph L. "Josh" Tucker
 JOSEPH L. "JOSH" TUCKER