UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MILTON MILLS, M.D., et al., **Plaintiffs,** **v.** **GIANT OF MARYLAND, LLC, et al.,** **Defendants.**	**Civil Action 05-02211 (HHK)**

MEMORANDUM OPINION AND ORDER

Plaintiffs—Milton Mills, Rashid Gholson, Hua-Wei Cherng, Norma Humphries, Lynette Garner, Darrell Bransome, Paul Miller, Glenda Costner, Sybil Harold, and Elizabeth Russell—bring this putative class action on behalf of "all those lactose intolerant persons who, unaware of their condition, have purchased milk in Washington, D.C., and suffered the consequences of their condition." Compl. ¶ 29. Plaintiffs seek injunctive relief and an award of damages as a result of what they allege was the defendants'—Giant of Maryland, LLC; Safeway, Inc.; Horizon Organic; Dean Foods Co.; Nestle Holdings, Inc.; Farmland Dairies, LLC; Shenandoah's Pride, LLC; Stonyfield Farm, Inc.; and Cloverland Farms Dairy, Inc.—"negligent failure to warn causing personal injury." *Id.* at 15. Plaintiffs additionally assert a products liability claim premised on defendants' sale of milk without proper warning labels. Before the court are defendants' motions

to dismiss.[1] Upon consideration of the motions, the oppositions thereto, the record of this case, and the argument of counsel at a hearing, the court concludes that plaintiffs' claims must be dismissed.

I. BACKGROUND

Plaintiffs seek to focus attention on what is purported to be a widespread, but largely unrecognized, health problem—lactose intolerance. This condition results from the absence of lactase enzymes that facilitate the digestion of lactose, the sugar found in milk. Following the consumption of milk and milk-products, those who suffer from lactose intolerance exhibit symptoms including "flatulence, bloating, cramps, and diarrhea." Compl. ¶ 2.

According to plaintiffs, while nearly all infants and young children are able to digest lactose, lactose intolerance is pervasive among adults. Plaintiffs assert that "75% of the world's population, including 90% of Asian Americans, 90% of Native Americans, 60% to 80% of African Americans, 50% to 80% of Latinos, and 6% to 22% of Caucasians are lactose intolerant." *Id.* ¶ 3.

Notwithstanding the vast number of people allegedly afflicted with lactose intolerance, plaintiffs insist that the extent to which people suffer from this condition has been minimized by the milk industry and "the government's marketing efforts." *Id.* ¶ 6. Plaintiffs maintain that defendants, with the aid of the government, have propagated the myth that milk is a necessary part of a healthy diet while simultaneously stifling information about the incidence of lactose intolerance.

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[1] With the exception of Cloverland Farms Dairy, Inc. ("Cloverland"), all defendants have moved collectively to dismiss plaintiffs' complaint (Dkt. #10). In addition, Cloverland has independently filed a motion to dismiss (Dkt. #9).

Because of the limited dissemination of information about the scope of lactose intolerance, plaintiffs contend that many individuals remain unaware that they suffer from this illness. Plaintiffs, for example, are all individuals who, "unaware of their lactose intolerance, have unwittingly been subjected to gastrointestinal pain and discomfort by purchasing and consuming milk sold by defendants." *Id.* ¶ 8.

In order to address the public's ignorance of what plaintiffs allege is a common malady, plaintiffs request that defendants be enjoined from marketing their products in the District of Columbia until they adopt a warning label that alerts consumers about the possible risks of lactose intolerance.[2] In addition, the named plaintiffs seek money damages for the injuries they have suffered as a result of milk consumption.

Defendants now move to dismiss plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).[3]

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[2] Plaintiffs suggest two possible warning labels:

> WARNING—IF YOU EXPERIENCE DIARRHEA OR STOMACH CRAMPS AFTER CONSUMING MILK, YOU MAY BE LACTOSE INTOLERANT. CHECK WITH YOUR PHYSICIAN.
>
> WARNING—LACTOSE INTOLERANT INDIVIDUALS MAY EXPERIENCE BLOATING, DIARRHEA, OR OTHER GASTROINTESTINAL DISCOMFORT FROM CONSUMING MILK. CHECK WITH YOUR PHYSICIAN.

Compl. ¶ 69.

[3] A motion to dismiss is appropriately granted "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Martin v. Ezeagu*, 816 F. Supp. 20, 23 (D.D.C. 1993) (internal quotations omitted); *see Conley v. Gibson*, 355 U.S. 41, 45–46 (1957) (stating that a complaint should not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief"). In addition, the court must construe the complaint in a light most favorable to the plaintiff and must accept as true all reasonable factual inferences drawn from

II. ANALYSIS

Defendants identify a number of bases for the dismissal of plaintiffs' complaint; foremost among them that plaintiffs' claims are preempted by federal legislation. Defendants rely upon two theories in support of their argument that the common law claims pursued by plaintiffs are preempted: explicit preemption—present when Congress's intent to preempt state law is "explicitly stated in the statute's language," *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977), and implied conflicts preemption—applicable "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (quotations and citations omitted).

A. Preemption

The statutory basis for defendants' explicit preemption argument is found in Section 6 of the National Labeling & Education Act of 1990 ("NDEA"), 104 Stat. 2353, which added Section 403A to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 343-1(a). Section 403A reads in pertinent part:

> Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 341of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title . . . .

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well-pleaded factual allegations. *In re United Mine Workers of Am. Employee Ben. Plans Litig.*, 854 F. Supp. 914, 915 (D.D.C. 1994); *see also Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979) (stating that the court must give the plaintiff "the benefit of all inferences that can be derived from the facts alleged").

21 U.S.C. § 343-1(a)(1). Because, pursuant to 21 C.F.R. § 131, milk and cream are subject to a "standard of identity,"[4] defendants contend that any common law claims that would have the effect of mandating particular cautionary statements on milk labels would necessarily run afoul of Section 403A.

In response, plaintiffs submit that *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), establishes that common law claims like those raised in plaintiffs' complaint are not, in fact, preempted by the NDEA or FDCA. *Bates*, however, did not address the NDEA or FDCA. Rather, *Bates* examined whether the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C.A. § 136(v)(b), preempted the petitioners' claims for breach of express warranty, fraud, violation of the Texas Deceptive Trade Practices-Consumer Protection Act, strict liability (including defective design and defective manufacture), and negligent testing. *Id.* at n.15. In *Bates*, petitioners contended, *inter alia*, that the respondent, a herbicide manufacture, had a duty to warn consumers that the herbicide in question should not be applied to soils with a pH-level of 7.2 or greater since such application could result in harm to crops. Respondent argued that such claims were unsustainable given FIFRA's preemption clause, which in pertinent part states: "Such state shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* at 439 (*citing* 7 U.S.C. § 136(v)(b)).

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[4] Section 401 of the FDCA, 21 U.S.C. § 341, empowers the Food and Drug Administration ("FDA") to promulgate "regulations fixing and establishing for any food . . . a reasonable definition and standard of identity." These regulations, among other things, typically dictate the content of any label affixed to a food governed by the statute.

In a decision that was moored tightly to the specific preemption clause at issue, the Court held that a number of petitioners' claims—defective design, defective manufacture, negligent testing, and breach of express warranty—did not constitute requirements for "labeling or packaging" and consequently, were not preempted. *Id.* at 444. The Court rejected the proposition that adverse determinations on these claims might induce respondent to supplement its packaging with a warning and, consequently, that the claims fell within the ambit of FIFRA's preemption provision. By comparison, the Court held that petitioners' fraud and negligent-failure-to-warn claims did regulate labeling or packaging, and therefore proceeded to the second step of the analysis: determining whether the duties imposed by these common law claims expanded those established under FIFRA. *Id.* at 446.

Because there was no lower court finding that the duties imposed by the common law were "in addition to or different from" those imposed by FIFRA—specifically, FIFRA's requirement that "labeling or packing" not contain false or misleading statements, or inadequate instructions or warnings—the Court concluded that a finding of preemption was impossible. *Id.* at 447. The Court remanded the case in order to resolve this issue, noting, however, that a finding of inconsistent duties would in turn require preemption. *Id.* at 453.

Nothing in *Bates* categorically defeats defendants' argument that plaintiffs' claims are precluded by FDCA's preemption clause. Rather, *Bates* merely underscores the need to pay close attention to the scope of the FDCA's preemption clause and assists the court in framing the questions to be addressed: first, whether the duty imposed by the relief which plaintiffs seek is "a

requirement for a food which is the subject of a standard of identity," and second, whether this duty "is identical" to the labeling requirements of the FDCA.[5] *See id.* at 444. The court answers both questions in the affirmative.

With respect to the initial question, there is little doubt that the common law duties plaintiffs seek to impose constitute "requirements for a food which is the subject of a standard identity." The scope of FDCA's preemption clause is much broader than FIFRA's, prohibiting "any" requirements as opposed to merely requirements "for labeling or packing." Accordingly, the concern that plaintiffs' common law claims lie beyond the reach of FDCA's preemption clause are not as acute as they were in *Bates*. In addition, there is no dispute that milk is subject to a standard of identity, as such, these obligations are "requirements for a food which is the subject of a standard of identity."

Addressing next whether the labels are identical, a warning label of the nature requested by plaintiffs would far exceed the labeling requirements mandated by the standard of identity established by 21 C.F.R. § 131. A product subject to "a standard of identity" has a carefully delineated list of information that must appear on its label[6]—conspicuously absent from this list

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[5] The plaintiffs attempt to shift the focus of the court's inquiry from the labeling requirements imposed by milk's standard of identity, 21 U.S.C. § 341, to the requirements imposed by the FDCA's misbranding provisions, specifically 21 U.S.C. § 343(g). Plaintiffs' argument is unavailing. Section 343(g) is triggered when a label that is the subject of a standard of identity fails to include all relevant information mandated by the standard of identity. Here, the concern is not that defendants' have omitted information set forth in the standard of identity and therefore have misbranded, but rather that the mandated information in the standard of identity is insufficient. Plaintiffs seek to supplement the standard of identity's labeling, not enforce compliance with the existing requirements.

[6] The court provides the following excerpt from the standard of identity for milk in order to demonstrate the comprehensiveness of the labeling requirements:

is a warning against the dangers of lactose intolerance. The court rejects the contention that a label with either of the warnings suggested by plaintiffs is "identical" to a label without these warnings.

Moreover, the FDCA contemplates the possibility of deviation from the standard of identity, but only following a formal application to FDA. *See* 21 U.S.C. § 343-1(b). The FDCA will only grant such applications where the state regulation:

> (1) would not cause any food to be in violation of any applicable requirement under Federal law,
> (2) would not unduly burden interstate commerce, and
> (3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

21 U.S.C. § 343-1(b)(1)–(3). Plaintiffs seek to circumvent this process through the instant litigation, which is yet another reason why the duties imposed by the District's common law are not congruent with the strictures of the FDCA.

In the alternative, plaintiffs submit that, even assuming *arguendo* that the requirements imposed by their common law claims fall within the scope of the FDCA's preemption clause, the provision's "safety" exception counsels against preemption. The exception to which plaintiffs refer states, in pertinent part:

> The amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the *safety of the food or component of the food*.

> The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name: (i) If vitamins are added, the phrase "vitamin A" or "vitamin A added," . . . as is appropriate. The word "vitamin" may be abbreviated "vit.".

21 C.F.R. § 131.110(e)(1).

NDEA, 104 Stat. 2353, § 6(c)(2) (emphasis added).

Despite plaintiffs' protestations to the contrary, the court finds this provision inapplicable to the type of warning that plaintiffs' would require. Even when affording plaintiffs the benefit of every favorable inference, the symptoms detailed in plaintiffs' complaint do not implicate "safety" concerns as that term is understood by FDA.

While defendants cite numerous FDA interpretations of the term "safety" to support the proposition that the danger of suffering from such gastrointestinal maladies as flatulence, bloating, cramps, and diarrhea does not rise to the level of a safety concern, plaintiffs offer only the dictionary definition of "safety" to clarify the scope of the safety exception. In this context, FDA's interpretation of the terms within its regulations deserves a certain degree of deference. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 883 (2000); *Blum v. Bacon*, 457 U.S. 132, 141 (1982).

As noted by defendants, in the context of food additives, FDA has defined "safety" to mean "that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. 170.3(i). Similarly, when examining color additives, FDA has construed "safe" to mean that "there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive." 21 C.F.R. § 70.3(i).

Applying this standard, FDA has concluded that the risk of gastrointestinal irritations comparable to those experienced by the lactose intolerant does not implicate "safety" concerns.

In 1996, FDA approved olestra as a food additive.[7] Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 61 Fed. Reg. 3118 (Jan. 30, 1996). As part of this approval process, FDA determined that there was "a reasonable certainty of no harm" with respect to olestra consumption. *Id.* The determination was made notwithstanding the possibility that olestra consumption could cause "a broad range of GI [gastrointestinal] symptoms, including loose stools, cramping and bloating, fecal urgency, oil-in-the toilet, and anal leakage." Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 68 Fed. Reg. 46,403, 46,408 (Aug. 5, 2003). FDA "appli[ed] the statutory standard of 'safe,' [and] concluded that none of these effects is harmful to health." *Id.* Given this conclusion, the court sees no reason why the symptoms of lactose intolerance—very similar to those exhibited by olestra consumption—should raise any safety concerns. Consequently, the court finds that there is no basis upon which to invoke the safety exception to the FDCA preemption clause. The court concludes, therefore, that plaintiffs' complaint must be dismissed in light of the express preemption clause in the FDCA.[8]

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[7] Olestra is the common name for sucrose esterified with medium and long chain fatty acids as a replacement for fats and oils. Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 68 Fed. Reg. at 46,403.

[8] The defendants also ask the court to apply principles of implied preemption, specifically, conflict preemption. However, because the court has determined that express preemption precludes plaintiffs' claims, the court declines to address the issue of conflict preemption.

Where a statute contains an express preemption provision, it is reasonable to infer that Congress did not intend to preempt matters beyond the reach of that provision. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995). Although the court recognizes that the existence of a provision that addresses preemption does not necessarily prohibit a court from reaching the question of conflict preemption, *see Geier v. American Honda Motor Co.*, 166 F.3d 1236, 1241–42 (D.C. Cir. 1999), in this instance the court finds that "there is no need to infer congressional intent to preempt state laws from the substantive provisions [of the legislation.]"

B. Plaintiffs' Fail to State a Claim

Assuming *arguendo* that plaintiffs' claims were not precluded by FDCA's preemption provision, plaintiffs' complaint would nevertheless be dismissed as it fails to state a claim under District of Columbia law.

Plaintiffs assert two claims, both premised on defendants' failure to include a warning on milk. Plaintiffs' first claim relies on a negligence theory, the second on a theory of strict liability.[9] Under either theory, the manufacturer or seller's duty to warn remains the same,

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California Federal Savings & Loan Assn. v. Guerra, 479 U.S. 272, 282 (1987).

The court's decision to limit its analysis to express preemption is similarly informed by the notion that "[w]here, as here, the field which Congress is said to have preempted has been traditionally occupied by the States, 'we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Jones*, 430 U.S. at 525 *(quoting Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). This presumption exists to preserve the delicate balance between state and federal regulation from being "disturbed unintentionally by Congress or unnecessarily by the courts." *Id.* Though in the instant case Congress has indeed clearly and manifestly preempted the disputed state requirement, the above assumption counsels the court to limit its decision to the extent possible.

[9] The court notes that recovery based on a theory of strict liability is only available if a product is "unreasonably dangerous." In order to be considered unreasonably dangerous, "the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Restatement (Second) of Torts § 402A cmt. i (1965). In clarifying this rule, the Restatement notes that "any food or drug necessarily involves some risk of harm, if only from over-consumption," but recognizes that this alone will not render a product unreasonably dangerous. *Id.* ("Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.").

Milk is not dangerous beyond the extent contemplated by the average consumer. Any danger posed by milk and dairy products is not a hidden danger, but akin to the danger posed by sugar to a diabetic. *Id.* ("Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous . . . ."). Because the dangers posed by milk are not unreasonable, the doctrine of strict liability is inapplicable.

"essentially one of ordinary care." *East Penn Mfg. Co. v. Pineda*, 578 A.2d 1113, 1118 (D.C. 1990). "The seller or manufacturer of a product whose use could result in foreseeable harm has a duty to give a warning which adequately advises the user of attendant risks and which provides specific directions for safe use." *Id.* (*quoting Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1086 (D.C. 1976)) (emphasis omitted).

The court agrees with defendants that, in the case before the court, no such duty exists. The Restatement (Second) of Torts § 402A cmt. j, states that a "seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them." If no duty exists to warn consumers that they may be allergic to common food items, then *a fortiori*, no duty exists to warn those that consume dairy products of the potential dangers of lactose intolerance. Although hospitalization or fatalities are possible when an individual has a severe allergic reaction, *see, e.g., Bruse v. Holiday*, 790 N.Y.S.2d 765, 767 (N.Y. App. Div. 2005) (plaintiff hospitalized for anaphylactic shock caused by contact with shellfish); *St. Luke's Midland Reg'l Med. Ctr. v. Kennedy*, 653 N.W.2d 880, 882 (S.D. 2002) (claimant suffered anaphylactic shock following contact with latex), nowhere do plaintiffs allege that any such danger exists for the lactose intolerant. At worst, someone that suffers from lactose intolerance can expect to suffer gastrointestinal discomfort of the nature previously discussed.

Plaintiffs have not cited, nor has the court been able to otherwise find, any case in which a duty to warn has been imposed under similar circumstances. As defendants correctly identify, in every case relied upon by plaintiffs the duty to warn arose when the allergen contained in the

food was not an obvious ingredient. *See Edwards v. Hop Sin, Inc.*, 140 S.W.3d 13, 16–17 (Ky. Ct. App. 2003) (addressing oysters that were contaminated by bacteria); *Livingston v. Marie Callender's Inc.,* 85 Cal. Rptr. 2d 528, 533–34 (Cal. Ct. App. 1999) (soup that professed to be "made from the freshest ingredients" contained monosodium glutamate); *Brown v. McDonald's Corp.*, 655 N.E.2d 440, 443–44 (Ohio Ct. App. 1995) (addressing a failure to warn consumers that a hamburger contained an ingredient derived from seaweed). Here, the only alleged danger is purportedly posed by the inherent qualities of milk, hence, defendants have no duty to warn consumers about lactose intolerance.

III. CONCLUSION

For the reasons set forth above, the defendants' motions to dismiss (Dkt. #9/#10) are granted. An appropriate order accompanies this memorandum.

Henry H. Kennedy, Jr.
United States District Judge

Dated: August 2, 2006