UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BRIAN HULT, an individual, and FIONA HULT, Plaintiffs	)	
vs.	)	C.A. No. 1:18-cv-10453-MPK
DANIELE INTERNATIONAL, a Rhode Island Corporation Defendant	)	

PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

Now come Plaintiffs and submit the within opposition to defendant's motion to dismiss.

SUMMARY OF CASE

The complaint involves an issue of first impression in the courts of this district and in the country. This case presents the novel question of whether federal and/or state laws require the clear labeling of **allergens added to meat products**. This case addresses the lack of judicial and regulatory clarity when the Food Allergen Labeling Consumer Protection Act ("FALCPA") and the Federal Meat Inspection Act ("FMIA") intersect in a hybrid product. Both laws require the use of common names of ingredients and mandate allergen labeling. Moreover, because there is a compelling state interest in protecting its citizens from harm by requiring manufacturers to warn consumers about allergens, common law claims involving misbranding are appropriate.

This case involves a man who has a life-threatening allergy to milk and milk protein. His wife purchased a product known as Italian Gourmet Pack, manufactured by the Defendant Daniele International, Inc. A copy of the label is Exhibit A to the complaint. It is a processed meat product that has additives in it, such as sodium caseinate. Sodium caseinate was not

labeled with its usual or common name on defendant's label nor did it indicate that it contained milk protein. Not realizing that sodium caseinate was a form of milk protein, the Plaintiff Brian Hult thought the defendant's product was safe for him to eat. While at work on January 3, 2017, he took a bite of a sandwich that he has prepared with the defendant's product. He immediately began having a life-threatening allergic reaction. He was rushed to the local hospital's emergency room where he spent several days attached to an intravenous drip of epinephrine. Had the defendant's label used the words "contains milk", the product would have been properly branded and plaintiff would have avoided eating the product and not have been harmed. See, e.g., *Colter v. Barber Greene Co.,* 403 Mass. 50, 59 (Mass., 1988); *Jones v. Walter Kidde Portable Equipment, Inc.,* 16 F.Supp.2d 123, 125 (D. Mass., 1998).

The plaintiff does not have to show a violation of a federal regulation in order to prevail on its claims. The complaint is based on common law claims whose validity does not depend upon adherence to federal regulations.

Nevertheless, Plaintiffs contend that the adding of an allergen to a meat product takes the product out of the exclusive egis of the United States Department of Agriculture ("USDA") and puts it within the realm of products FALCPA was intended to cover. The Defendant's product was not merely meat but instead contained an allergenic additive that is regulated by the Food and Drug Administration ("FDA"), making it a hybrid product. For this reason, Plaintiffs contend that the sodium caseinate was not labeled in accordance with the requirements of FALCPA and thus was misbranded.

In the alternative, Plaintiffs argue that the FMIA does itself require clear allergen and source labeling for additives to meat products that were not followed in the case at bar, making Defendant's product misbranded according to the FMIA.

Lastly, Plaintiffs argue that their state common law causes of action are not preempted by either FALCPA or the FMIA. Plaintiffs are contending that the product in the case at bar is misbranded, which is within the realm of state law claims. Because Massachusetts food labeling regulations mirror those of the federal government, federal preemption does not apply.

I. STANDARD OF REVIEW

On a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court "must assume the truth of all well-plead[ed] facts and give the plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp*., 496 F.3d 1, 5 (1st Cir. 2007). A complaint must be plausible on its face. *Bell Atl. Corp. v. Twombly, 550 U.S. 544*, 570 (2007)."The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556).

A court's task "in ruling on a Rule 12(b)(6) motion 'is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." *Cooper v. Parsky*, 140 F.3d 433, 440 (2nd Cir., 1998)(quoting *Ryder Energy Distribution Corp. v. Merrill Lynch Commodities, Inc.*, 748 F.2d 774, 779 (2d Cir. 1984)). Thus, the fundamental issue at the dismissal stage "is not whether a plaintiff is likely to prevail ultimately, but whether the claimant is entitled to offer evidence to support the claims. Indeed it may appear on the face of the pleading that a recovery is very remote and unlikely but that is not the test." *Chance v. Armstrong*, 143 F.3d 698, 701 (2d Cir. 1998), quoted in *Phelps v. Kapnolas*, 308 F.3d 180, 184-85 (2d Cir. 2002).

The notice pleading principles embodied in Rules 8 and 12 of the Federal Rules of Civil Procedure are intended to remove technical obstacles impeding access to the federal courts.

Anderson v. Coughlin, 700 F.2d 37, 43 (2d Cir. 1983); *Boston v. Stanton*, 450 F. Supp. 1049, 1053 (W.D. Mo. 1978). Thus, the federal rules allow simple pleadings and "rel[y] on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims." *Id.* at 512. The Seventh Circuit has said, "[i]nstead of asking whether the complaint points to the appropriate statute, a court should ask whether relief is possible under any set of facts that could be established consistent with the allegations." *McDonald v. Household Int'l, Inc*., 425 F.3d 424, 428 (7th Cir. 2005) (quoting *Bartholet v. Reishauer A.G. (Zurich)*, 953 F.2d 1073, 1079 (7th Cir. 1992)). Plaintiffs' complaint encompasses state common law claims of failure to warn and breach of warranty Whether these claims ultimately rest on common law duties or a failure to follow federal standards is not relevant to determine their viability.

II. ARGUMENT

A. Massachusetts courts have held that failure to warn about an allergen is actionable even when such labeling was not mandated by either FDA or Mass law

Massachusetts courts have held that an omission on a label is actionable under Massachusetts law for failure to warn. *Grocery Mfrs. of America, Inc. v. Department of Public Health*, 379 Mass. 70 (Mass., 1979). The common law duty to warn requires a warning "comprehensible to the average user and ... convey[ing] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person." *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind.App. 33, 49 (1979), quoting *Spruill v. Boyle-Midway, Inc*., 308 F.2d 79, 85 (4th Cir.1962). The adequacy of the warning has been a question that is within the purview of the factfinder; indeed courts have found that there is nothing "more appropriately left to a common

sense lay judgment than that of whether a written warning gets its message across to an average person." *Ferebee v. Chevron Chem. Co*., 552 F.Supp. 1293, 1304 (D.D.C.1982). See *Hayes v. Ariens Co*., 391 Mass. 407, 409-410 (1984).

In Massachusetts, the failure to warn the consumer about a known allergen in a product has been held to be a breach of warranty that rises to the level of a consumer protection (i.e. M.G.L. c 93A) violation. In one case, a defendant was held to have violated 93A by failing to disclose nuts in its sesame seed product. See *Newly Weds Foods, Inc. v. Superior Nut Company*, 82 Mass.App.Ct. 1110 (2012). The defendant in that case tried to argue that it was immune from liability because at the time, neither the FDA nor Massachusetts law required allergen labeling. The court was not persuaded by this argument. The court found the defendant had nevertheless committed an unfair practice and thus violated 93A by selling a product with a known but undisclosed allergen. *Id.*

Imparting a strict duty to manufacturers, the Supreme Judicial Court has held:

> "The public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons who afford it are those who market them." *Haglund v. Philip Morris, Inc.*, 446 Mass. 741, 746 (2006).

Therefore, Massachusetts courts have found defendants liable for common law failure to warn claims without any reference or deference to federal regulations.

B. <u>Meat with known allergens added falls under the egis of FALCPA</u>

Food Allergen Labeling Consumer Protection Act governs the labeling of processed food products sold in the United States. The legislation, which is a 2004 amendment to the federal Food, Drug, and Cosmetic Act (the FFDCA), amends section 403 of the FFDCA to require that the eight major food allergens (milk, egg, peanuts, tree nuts, fish, shellfish, soy and wheat) be labeled on foods that are not ***raw*** agricultural products. Under the FALCPA, "[a] food shall be deemed to be misbranded . . . [i]f it is ***not a raw agricultural commodity*** and it is, or it contains an ingredient that bears or contains, a major food allergen, unless it is labeled as containing the major food allergen." (emphasis added) 21 U.S.C. § 343(w). The term "raw agricultural commodity" means any food in its raw or natural state. 21 USC § 321(r).

What happens, however, when a product not normally governed by the rules of FALCPA has an allergen added to it? The drafters of FALCPA addressed this situation:

> "raw agricultural products into which major food allergens have been introduced by any means would be considered to be misbranded by FDA if not appropriately labeled under sections 201(n) and 403(a)(1) of the FFDCA, and even so may be considered to be adulterated by FDA under section 402(a)(1)." https://www.congress.gov/congressional-report/107th-congress/senate-report/322/1

Therefore, meat, which in its raw state is not usually regulated by the FDA, was meant to and would become subject to the FALCPA rules when an allergen is added to it.

Furthermore, sodium caseinate is classified as a food additive by the FDA, and the FDA has exclusive authority to regulate food additives.[1] The FDA regulations specifically address

[1] A food additive is defined in Section 201(s) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use). 21 U.S.C. 9, §201(s).

sodium caseinate as a product within its purview.[2] The FDA regulations specify how sodium caseinate should be labeled so that it is clear that it contains dairy:

> "When foods characterized on the label as "nondairy" contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term "nondairy" on a creamer that contains sodium caseinate, it shall include a parenthetical term such as "a milk derivative" after the listing of sodium caseinate in the ingredient list." 21 CFR 101.4 (d).

Because the ingredient sodium caseinate is subject to FDA jurisdiction, any product containing sodium caseinate would therefore be subject to FALCPA labeling requirements.

C. <u>It is not unusual for a food product to fall under both FDA and USDA regulation; i.e. meat is not always just meat</u>

There are many examples of hybrid food products that fall under the jurisdiction of both the FDA and the USDA. Sausage *meat* is inspected by the USDA but sausage *casings* are inspected by the FDA. [3] Another dually regulated product is a meat-containing sandwich. Open-faced meat sandwiches, where the ratio of meat to bread and other ingredients is more than half, are regulated by the USDA. But closed sandwiches, which have two slices of bread, are regulated by the FDA because the ratio of meat to other ingredients is less than 50 percent. A sandwich is defined by the USDA as follows:

> "SANDWICH - CLOSED: Product must contain at least 35 percent cooked meat and no more than 50 percent bread. Sandwiches are not amenable to inspection. If inspection is requested for this product, it may be granted under reimbursable Food Inspection Service. Typical —closed-faced" sandwiches consisting of two slices of bread or the top and bottom sections of a sliced bun that enclose meat or poultry, are not amenable to the Federal meat and poultry inspection laws."[4]

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[2] 21 CFR 182.1748

[3] http://www.foodsafetynews.com/2010/12/who-inspects-what-a-food-safety-scramble/#.WrO9-ech2M8

[4] Food Standards and Labeling Policy Book, Revised for Web Publication August 2005, USDA, Food Safety And Inspection Service Office of Policy, Program and Employee Development August 2005

Certain meat products, therefore, can be regulated by both the USDA and the FDA. Thus, it is disingenuous for the defendant to claim essentially that "meat is meat" and that all meat is always exclusively regulated by the USDA. As shown above, hybrid meat products often fall within the jurisdiction of both agencies. The meat in this case is just such a product.

D. <u>Even if FALCPA does not apply, USDA regulations and the FMIA do require labeling of meat additives using their common name</u>

A directive was published by the Department of Agriculture Food Safety and Inspection Service ("FSIS") on March 10, 2015, which was meant to serve as guidance for FSIS inspectors who were ordered to conduct "ongoing, monthly verification task[s] beginning April 12, 2015, to determine whether establishments accurately control and label the "Big 8" food allergens."[5] FSIS clearly stated in this directive that products containing "casein" and "caseinates" are from milk and should be labeled as such.[6] Furthermore, FSIS expressed that additives containing allergens must be correctly labeled and are not to be considered "incidental."[7]

It is well established that "[a]ll ingredients used in the formulation of meat, poultry or egg products must be declared by their common or usual name on the ingredients statement".[8] This is especially true for meat products containing food additives. FSIS has acknowledged that:

> "Substances such as dried meat, poultry stock, meat extracts, or hydrolyzed protein must be listed on the label by their **common or usual name** because their primary purpose is not flavor. They may be used as flavor enhancers, binders, or emulsifiers. ***They must be labeled using the species of origin of***

[5] UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE, WASHINGTON, DC, FSIS DIRECTIVE 7230.1, 3/10/15, ONGOING VERIFICATION OF PRODUCT FORMULATION AND LABELING TARGETING THE EIGHT MOST COMMON ("BIG 8") FOOD ALLERGENS at page 1.
[6] Id. at pages 9-10
[7] Id. at page 5
[8] *Food Safety and Protection*, edited by V Ravishankar Rai, Jamuna A Bai, CRC Press, Copyright 2018 by Taylor and Francis Group, LLC.

> ***the additive***, for example, dried beef, chicken stock, pork extract, or hydrolyzed wheat protein.(emphasis added)"[9]

Sodium caseinate is food additive in meat to help bind the product whose primary purpose is not flavor. As such, it must be labeled using its common or usual name.

Additionally, FSIS makes clear that " 9 CFR 317.2(b) and 9 CFR 381.116(a) require that the ingredients statement on the label be prominently placed with such conspicuousness and in such terms as to render it likely ***to be read and understood by the ordinary individual*** under customary conditions of purchase and use. The ingredients statement must also identify the common or usual names of the ingredients arranged in descending order of predominance." (emphasis added).[10] FSIS warns manufacturers that their "procedures should include the accurate identification of all potential allergens. If the product is incorrectly or ***insufficiently identified***, it can lead to both adulteration and misbranding."(emphasis added)[11] Therefore, the FMIA does require labels to use common names of allergens that can be understood by the ordinary individual. Any label not in conformity with these requirements is misbranded.

FSIS's guidance documents also emphasize that allergens in meat products must be declared clearly. FSIS addresses allergens added to meat in the following excerpt from its website:

> **"Can people have an allergic reaction to meat and poultry products?**
> Some processed meat and poultry products (e.g., hot dogs, chicken nuggets, and canned soup) may be formulated with known allergenic ingredients, such as nonfat dry milk or hydrolyzed wheat protein, that **must be listed** in the ingredient statement. Therefore,

[9] https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/additives-in-meat-and-poultry-products/additives-in-meat-and-poultry-products

[10] FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling November 2015

[11] Id.

consumers should carefully evaluate the ingredients statement on all meat and poultry products.(emphasis added)"[12]

Therefore, FSIS requires that sodium caseinate be listed as an allergen and as such, must be listed by its common name (milk protein) and not its biochemical name. According to FSIS requirements, an item labeled only as sodium caseinate without indicating its source or its common name of milk is misbranded by FSIS's own regulations.

In addition, the food labeling portion of the U.S. Food Code addresses how a product ingredient made from two or more ingredients (such as sodium caseinate) should be labeled regardless of which agency regulates the product. Specifically,

> "(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:
>
> (i) By declaring the established ***common or usual name*** of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.
>
> (ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, ***the common or usual name*** of every component of the ingredient without listing the ingredient itself." (emphasis added) 21 CFR 101.(b)(2).

[12] https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/allergies-and-food-safety/allergies-and-food-safety

Sodium caseinate is made by adding an acid (sodium hydroxide) to skim milk to cause the protein to coagulate, where it can be filtered to separate the curds from the whey.[13] Sodium caseinate, as an ingredient which itself contains two or more ingredients, must therefore be listed by its common or usual name, regardless of whether it is a product regulated by the USDA or the FDA.

Under the Federal Meat Inspection Act, meat products that contain an allergen not declared on the product label are adulterated because, to individuals who are allergic to the allergen, the products bear or contain a poisonous or deleterious substance. 21 U.S.C. 453(g)(1), 601(m)(1), and 1033(a)(1). Therefore, a meat product that contains a known allergen (i.e. milk) must be labeled using the common or usual name of the food or else it is considered misbranded.

E. <u>FSIS has established the best practices standard for allergen labeling</u>.

In Massachusetts, cases involving "negligent failure to warn and failure to warn under breach of warranty are to be judged by the same standard: the reasonableness of the defendant's actions in the circumstances." *Hoffman v. Houghton Chem. Corp*., 434 Mass. 624, 637 (2001). The question then becomes whether defendant's actions of not declaring milk on the label were reasonable. To make this determination, one can look to FSIS's guidance documents which set the standard of best practices for allergen labeling of meat. FSIS guidance documents state the following:

> "In addition to complete ingredient labeling, FSIS supports practices that promote accurate informative product labeling including voluntary statements on labels that alert people who have sensitivities or intolerances to the presence of specific ingredients. For example, a phrase such as "Contains: milk, wheat gluten, soy" has been accepted by the Agency on labeling immediately following the

[13] http://sci-toys.com/ingredients/casein.html

> ingredients statement. Additionally, further clarification of the source of a specific ingredient in a parenthetical statement in the ingredients statement on labeling, e.g., "whey (from milk)," is encouraged as a means of informing consumers who may be alerted to a more recognizable term." [14]

In these guidelines, FSIS supports the use of recognizable terms on labels for products with allergens, like "milk," as the best practice. Defendant chose not to follow this guidance. Plaintiffs are entitled to investigate whether this failure was reasonable in the circumstances.

F. <u>Defendant's assertion that because meat labels are approved by FSIS, there can never be a misbranded meat product is incorrect.</u>

Defendant contends that all meat labels must be approved by FSIS in advance of usage and because of that fact, there never can be a false or misleading label on meat. However, FSIS issues recalls frequently on meat products whose labels have not listed allergens. In this perfect system, there should never be a need for any recalls. This is not the case. Adulterated meat products that contain mislabeled allergens are subject to recall. This is explained in the except below from the FSIS website:

> "Could a product be the subject of a recall for the non-declaration of an ingredient that is a known allergen?
>
> Yes. If a known allergen is not declared on labeling, in most cases the voluntary recall would be classified as Class 1, particularly if the allergen was one of the "big-8." [15]

[14] FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling November 2015

[15] https://askfsis.custhelp.com/app/answers/detail/a_id/1537/related/1/session/L2F2LzEvdGltZS8xNTIxNDE4MzUzL3NpZC9mVUthdF9Eekx4eXh6aWhYV2l1c3B3bF9tdTc5SFNJN3JEUFlVNkltUlByVDRKSiU3RWcwXzZDaWpIdldrV2p4aXZCV3VScjUydzZ3VF9yaG9PUDdaamF5OTNVZ3VjcVNNbUFHbXN6WW5ZTUswOE5na3RwZnNEZURNUSUyMSUyMQ%3D%3D

In 2017, FSIS recognized that mislabeled meat containing allergens was a growing public concern. FSIS held a public meeting "to discuss the prevention of undeclared allergens in FSIS-regulated product. Specifically, the meeting will address the **continued occurrence of product recalls due to undeclared allergens** and best practices for preventing the presence of undeclared allergens **in FSIS-regulated products."** (emphasis added).[16]In fact, FSIS estimates that approximately forty percent of all recalls were due to the presence of undeclared allergens in a product. [17]

Therefore, it does not logically follow, then, that no meat label in the US is ever misbranded. The fact that there are frequent recalls of meats without proper allergen labeling shows that an FSIS approved label can later prove to be a misbranded product. Similarly, the Defendant's product was not properly labeled and should have been subject to a recall. The fact that FSIS had previously approved the label does not mean that Defendant's product was not nevertheless misbranded.

Deference is often given to regulatory authorities, but not always. The presumption that a label is "not false and misleading" is not an absolute and can be rebutted. *Kuenzig v. Kraft Foods, Inc*., No. 8:11-CV-838-T-24 TGW, 2011 WL 4031141, at *7 (M.D. Fla. Sept. 12, 2011). The Southern District Court of California found that a Certificate of Label Approval (COLA) from the Alcohol Tobacco Tax and Trade Bureau for beer labeling did not have the "force of law" because it was not issued as "the result of a formal deliberative process akin to notice and comment rulemaking or adjudication." *Hoffman v. Fifth Generation, Inc*., 2015 WL 5440330, at

[16] [Docket No. FSIS–2017–0005] Preventing Undeclared Allergens: A Strategic Approach To Reducing Recalls Federal Register 10562 Vol. 82, No. 29 Tuesday, February 14, 2017.
[17] See United States Department of Agriculture, Food Safety and Inspection Service, Undeclared Allergen Prevention Webinar, available at http://www.fsis.usda.gov/wps/wcm/connect/2a1fccb5-88e0-481f-9df8-

*7 (S.D. Cal. 2015)(citing *Von Koenig v. Snapple Beverage Corp*., 713 F. Supp. 2d 1066, 1076 (E.D. Cal. 2010)). The court in *Hoffman* held that deference and thus preemption were not warranted and did not bar plaintiff's misbranding claims. Plaintiffs here argue that because the item in the case at bar contains ingredients regulated by both the FDA and the USDA, a more thorough analysis is required than what was provided. Courts are well-suited to resolve these types of statutory conflicts. See, e.g., *Olde Towne Liquor Store, Inc. v. Alcoholic Beverages Control Commission*, 372 Mass. 152 (1977).

G. <u>Preemption does not apply to the case at bar</u>

When analyzing the issue of federal preemption, the "starting presumption [is] that Congress d[id] not intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 654 (1995). This "presumption against preemption" exists "where federal law is said to bar state action in fields of traditional state regulation." *Id.* at 655. Even "[i]f a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains." *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008) (interpreting the preemptive effect of the Federal Cigarette Labeling and Advertising Act on a Maine statute regulating unfair trade practices).

The regulation of health and safety matters "is historically within the province of the state" and claims involving health and safety matters are typically not preempted. *Medtronic v. Lohr,* 518 U.S. 470, 475 (1996); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 79 (1st Cir. 2013) (citing *Napier v. Atl. Coast Line R.R. Co.*, 272 U.S. 605, 610 (1926)); *see also Ophir v. City of Boston*, 647 F. Supp. 2d 86, 92 n. 14 (D. Mass. 2009). Indeed, this court has recognized that "state governments have primary authority to regulate health and safety." *Zogenix, Inc. v. Patrick* (D. Mass., 2014).

The leading preemption case involving labeling is *Wyeth v. Levine*, 555 U.S. 555 (2009). The Supreme Court in *Wyeth* did not find preemption of the plaintiff's failure to warn claims, noting that a manufacturer bears the "ultimate responsibility for its label." *Id*. at 571. Wyeth also held that common law tort actions, such as failure to warn claims, would not impede the FDA's statutory mission in regulating labels and should not be preempted. *Id*. at 577.

Likewise, Massachusetts courts have declined to find preemption in several cases involving federal labeling regulations and common law torts. See *Dow v. Baxter Healthcare Corp*., 899 F.Supp. 822 (D. Mass., 1995)(common law claims involving negligent design are sustainable despite FDA regulations of medical devices); *Ferrari v. Vitamin Shoppe, Inc*. (D. Mass., 2018)(claims involving dietary supplement not preempted by FDA); *MacDonald v. Ortho Pharmaceutical Corp*., 394 Mass. 131, 475 N.E.2d 65 (Mass., 1985)(warnings that complied with FDA labeling requirements did not preempt or "define the bounds" of the common law duty to warn). Therefore, allowing Plaintiffs' common law claims to proceed would be in keeping with previous caselaw which has recognized the right of the state to act when the health or safety of its citizens is at issue.

i. <u>FALCPA does not preempt all common law causes of action</u>

Having determined that additives contained in a meat product are subject to regulation by the FDA, the question becomes whether FALCPA labeling requirements preempt all state law causes of action. There have only been a handful of cases that deal with FALCPA and preemption – specifically the cases of *Cline v. Publix Supermarkets, Inc*., 2017 WL 67945 (M.D. Tenn. Jan. 6, 2017) and *Jones v. WFM-WO, INC., d/b/a Whole Foods Market*, (M.D. Tenn., 2017). The products at issue in those cases were, respectively, a cookie made in a grocery bakery that contained no labeling but was claimed to have been nut-free and a pizza made in a grocery store that was labeled as a "Vegan Garden Pizza" which contained undisclosed nuts.

In the *Publix* case, the cookie was not subject to FALCPA regulations because it was made in a bakery. *Cline v. Publix Supermarkets, Inc*., 2017 WL 67945 (M.D. Tenn. Jan. 6, 2017) Therefore, the court did not have to decide whether FALCPA preempted the plaintiff's state common law claims. However, the district court did note that plaintiff's common law claim of failure to warn would be actionable under state common law had the plaintiff argued facts that fit the state's definition of failure to warn. *Id*. at *3

The court in the *Jones* case stated that while FALCPA might preempt a state law claim for labeling, it would not preempt a claim for misbranding. *Jones v. WFM-WO, INC., d/b/a Whole Foods Market*, at *4 (M.D. Tenn., 2017). Therefore, because Plaintiffs' case involves claims of misbranding and fits the definition of failure to warn, the case is not preempted by the FALCPA statute.

ii. <u>FMIA does not preempt common law claims</u>.

The Federal Meat Inspection Act ("FMIA") addresses whether the federal government has preempted state claims involving the premises, facilities, operations and labeling of meat in the U.S. The FMIA makes an exception to the preemption doctrine for products that are adulterated or misbranded. Specifically, the FMIA states that:

> "any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are ***adulterated or misbranded*** and are outside of such an establishment." (emphasis added) 21 USC 678.

Therefore, a state may have concurrent jurisdiction to regulate a misbranded meat product. Because the issue at bar involves the misbranding of a meat product, claims based on Massachusetts law are therefore not preempted by the FIMA.

iii. Massachusetts labeling laws are identical to federal labeling laws so that preemption is not warranted

The National Uniform Nutrition Labeling Law ("NUNLL") states that "no State or political subdivision of a state may directly or indirectly establish . . . or continue in effect as to any food in interstate commerce - (2) any requirement for the labeling of food of the type required by [specified sections] of this title that is not identical to the requirement of such section." 21 U.S.C. § 343-1(a)(2). However, the labeling regulations found in the Massachusetts' State Sanitary Code, as enumerated in 105 CMR 590 et seq. are in fact identical to those required by the NUNLL. The Massachusetts Sanitary Code expressly incorporates the federal 1999 Food Code. Specifically, Massachusetts:

> "hereby adopts and incorporates by reference the federal 1999 Food Code (not including Annex 1-7) published by the United States Department of Health and Human· Services, Public Health Service, Food and Drug Administration, Washington, D.C. 20204 provided, however, that the Department does not adopt those provisions of the federal 1999 Food Code, which are specifically stricken or modified by 105 CMR 590.000". 105 CMR 590.001.

The provisions in the Massachusetts State Sanitary Code in regard to food labeling are identical to those in the federal food code. For example, 105 CMR 590.004(B) states the following: "Packaged food shall be labeled in accordance with applicable law and as specified under FC 3-202.17 and FC 3-202.18."[1] Further, 105 CMR 590.004(J), which involves the labeling of ingredients in Massachusetts, states: "FC 3-602.11 (B)(2) shall be designated as a critical item if there is one or more undeclared allergenic ingredient(s) in the ingredient statement, which would result in a Class I or II recall."

In addition, the provisions regarding allergen labeling in Massachusetts law are identical to and reference FALCPA:

[1] "FC" is an abbreviation for the federal Food Code.

> "Major Food Allergen means: (1) Milk, eggs, fish (such as bass, flounder, or cod), crustaceans (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; and (2) A FOOD ingredient that contains protein derived from a FOOD named in subsection (1). "Major food allergen" does not include: (a) Any highly refined oil derived from a FOOD specified in subsection (1) or any ingredient derived from such highly refined oil; or (b) Any ingredient that is exempt under the petition or notification process specified in the federal Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282)."105 CMR 590.002(B).

The FDA has also expressed a policy favoring state law: "The agency does not use its authority to preempt State requirements unless there is a genuine need to stop the proliferation of inconsistent requirements between the FDA and the States." 51 F.R. 25,012, at 25,016 (July 9, 1986). Moreover, the FDA has stated in response to requests for clarification as to the scope of preemption under § 343-1, "[t]he only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements." 60 F.R. 57076-01, 57120 (Nov. 13, 1995).

Massachusetts is not, as Defendant contends, "impos[ing] different or additional affirmative requirements on meat and meat food products." It requires exactly what the federal government does – clear labeling of allergens using common names. Therefore, because Massachusetts laws are identical to and not affirmatively different from federal labeling laws, Plaintiffs' claims would not be preempted by federal law.

H. <u>Cases cited in Defendant's memorandum are distinguishable from the case at bar.</u>

This is not a case, as defendant claims, of plaintiff asking for something extra to be added

to the defendants' label. Plaintiffs are merely asking that the label be in compliance with what state and federal law in fact requires. The cases cited by the defendant involve the adding of words and phrases to meat labels that are not covered or even required by regulation, such as "subtherapeutic use of antibiotics" or "percent fat free." Defendant also relies on cases involving pure meat products without allergens added to them. Here, Plaintiffs are asking merely that the label use the common name of the ingredient sodium caseinate so that consumers are adequately warned about the allergens present in Defendant's product – something that manufacturers are already required to do. Plaintiffs are not imposing a different or additional labeling requirement.

CONCLUSION

For all the reasons stated above, the Plaintiffs urge this court to hold that the Plaintiffs have stated claims against the Defendant and to DENY Defendant's Motion to Dismiss.

Date: April 5, 2018

Respectfully submitted,

/s/ Laurel J. Francoeur

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CERTIFICATE OF SERVICE

I hereby certify that I filed this Plaintiffs' Opposition to Motion to Dismiss through the ECF system and via direct email to Geoffrey W. Millsom, Esq. on the 5th day of April, 2018, and that notice will be sent electronically to all counsel who are registered participants identified on the Mailing Information for C.A. No. 1:18-cv-10453-MPK.

/s/ Laurel J. Francoeur