IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

In re: BISPHENOL-A (BPA)	)	MDL No. 1967
POLYCARBONATE PLASTIC	)	Master Case No. 08-1967-MD-W-ODS
PRODUCTS LIABILITY LITIGATION	)	

ORDER AND OPINION (1) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS ON THE BASIS OF FEDERAL PREEMPTION AND (2) DENYING DEFENDANTS' MOTION TO DISMISS ON THE GROUND OF PRIMARY JURISDICTION

Pending are Defendants' motion to dismiss based on federal preemption (Doc. # 142) and motion to dismiss on the ground of primary jurisdiction (Doc. # 170). This Court already has dismissed several of Plaintiffs' claims, leaving before the Court only Plaintiffs' claims that Defendants made fraudulent omissions, that Defendants' violated various state consumer protection statutes, that Defendants breached the implied warranty of merchantability, and that Defendants were unjustly enriched. With these remaining claims pending, the Court grants in part Defendants' motion to dismiss on the basis of preemption and denies the motion to dismiss on the ground of primary jurisdiction.

I. BACKGROUND

Defendants' preemption and primary jurisdiction arguments are generally alike in that they both contend Defendants' use of Bisphenol-A (BPA) should *only* be subject to regulation by the FDA under the Food, Drug, and Cosmetic Act (FDCA). Evaluating these arguments requires an understanding of how BPA is regulated by the federal government.

Federal regulation of BPA begins with what the FDCA defines as a "food additive." Defendants' arguments do not require an in depth consideration of whether a

particular substance in fact constitutes a "food additive"[1]; rather, it is enough to know that the FDCA defines "food additive" as "any substance the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts . . . to be safe under the conditions of its intended use." 21 U.S.C. § 321(s).

The FDCA's provisions governing food additives are codified at 21 U.S.C. § 348. The FDCA presumes food additives are unsafe generally until their use is formally authorized by the FDA. *See* § 348(a). In deciding that a food additive is "safe," the FDA is not required to find with complete certainty that the additive is absolutely harmless; rather, a food additive is considered "safe" under FDA standards if "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). The FDA signals its approval of a food additive by promulgating a regulation prescribing the conditions under which such additive may be safely used. *See* § 348(c)(1)(A).

Pursuant to § 348, the FDA has issued regulations prescribing the conditions for "safe" use of resinous and polymeric coatings (21 C.F.R. § 175.300 (2009)) and polycarbonate resins (21 C.F.R. § 177.1580 (2009)). One of the prescribed conditions for resinous and polymeric coatings is that the coatings be formulated from "optional substances" that may include "[e]poxy resins" containing BPA (referred to by its chemical name, 4-4' isopropylidenediphenol). *See* § 175.300(b)(3)(viii). Similarly, one of the prescribed conditions for polycarbonate resins defines that substance as being produced by the condensation or reaction of BPA (also referred to by its chemical name) with other chemicals. *See* § 177.1580(a). Thus, BPA's presence in some resinous and polymeric coatings and in polycarbonate resins is why BPA is subject to regulation by the FDA.

Another characteristic of the FDA's regulations authorizing BPA's use is that

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[1] According to one commentator, the proper mental state for parsing the term "food additive" requires one to "[l]eave the baggage of colloquial understanding behind you, discard the mathematician's view of the concept of adding, and suspend disbelief about what is 'food.'" O'Reilly, Food and Drug Administration § 11:2 (3d ed. 2007).

they do not contain labeling requirements. The inference -- that the FDA must have thought the food additives containing BPA could be used safely without labeling requirements -- is supported by 21 U.S.C. § 348(c)(1)(A), which obligates the agency to include such requirements in the prescribed conditions if it had deemed them necessary for safety.

Defendants consistently underscore that the use of BPA has been deemed "safe" by the FDA without labeling requirements, and Defendants insist that Plaintiffs should not be allowed to overturn this determination by the FDA. Even if Defendants' point is valid, that does not end the matter. Defendants' preemption and primary jurisdiction arguments cannot succeed merely because the FDA has decided BPA may be safely used in food additives and that no labeling requirements are necessary to ensure BPA's safe use. The Court will address in turn the specific arguments raised by Defendants.

II. PRIMARY JURISDICTION

The doctrine of primary jurisdiction applies when enforcement of a claim that is originally cognizable in the courts requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body. The applicability of the doctrine in any given case depends on whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application. Among the reasons and purposes served are the promotion of consistency and uniformity within the areas of regulation and the use of agency expertise in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion. *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005). The doctrine should seldom be invoked unless a factual question requires both expert consideration and uniformity of resolution. *United States v. McDonnell Douglas Corp.*, 751 F.2d 220, 224 (8th Cir. 1984); *see also Alpharma, Inc.*, 411 F.3d at 938 (stating that the doctrine of primary jurisdiction should be invoked sparingly, since it often results in added expense and delay).

Defendants argue that Plaintiffs' claims expose them to the danger of conflicting rulings between this Court and the FDA regarding the appropriate conditions of use for BPA. Even if true, however, Defendants have not shown that factual questions at issue here require the expert consideration of the FDA. The FDA clearly has specialized expertise and experience to determine whether BPA is "safe," that is, whether "there is a reasonable certainty in the minds of competent scientists that [BPA] is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i). However, the ultimate issues in these cases are whether Defendants failed to disclose material facts to Plaintiffs and whether Defendants breached the implied warranty of merchantability through the sale of products containing BPA. The FDA cannot resolve these questions, and the FDA's decision that BPA is "safe" is not determinative of any of those issues.

Defendants dispute this conclusion with several arguments, the strongest of which is that Plaintiffs have predicated their claims on proof that BPA is in fact unsafe. According to Defendants, since Plaintiffs base their claims on such evidence, Plaintiffs' claims necessarily fall within the primary jurisdiction of the FDA. Defendants' attempt to drive Plaintiffs' claims into a conflict with the FDA is not justified by the claims Plaintiffs have actually asserted. Evidence establishing the risks of BPA exposure is not exclusively relevant to the issue whether BPA is "safe." Such evidence also is relevant to whether Defendants failed to disclose material information to Plaintiffs and whether Defendants' products were merchantable. These issues are within "the conventional competence of courts." *Nader v. Allegheny Airlines Inc.*, 426 U.S. 290, 305-06 (1976). Plaintiffs' claims are independent of the FDA's "safety" determination and the FDA does not have primary jurisdiction over them.

In addition to the desire for uniform regulation and the need for agency expertise, Defendants cite to three other factors courts have relied upon in evaluating the issue of primary jurisdiction: (1) whether agency proceedings already have begun; (2) whether the agency has shown diligence in resolving the issue; and (3) the type of relief requested. *See B.H. v. Gold Fields Mining Corp.*, 506 F. Supp. 2d 792, 803 (N.D. Okla. 2007). Although the Eighth Circuit has not expressly adopted these additional factors, this Court would find the primary jurisdiction doctrine inapplicable even if the Eighth

Circuit had done so. Taking the first two of these factors together, Defendants insist that the FDA has evaluated whether exposure to BPA is safe and continues to actively monitor the health risks of BPA. The FDA's assessment of safety is not the key to this case, however, because Plaintiffs do not challenge the FDA's safety determinations. With respect to the type of relief requested, Plaintiffs seek only monetary remedies, which the FDA cannot provide. This factor further supports denial of Defendants' claim that the FDA has primary jurisdiction over Plaintiffs' claims. *See Ryan v. Chemlawn Corp.*, 935 F.2d 129, 131 (7th Cir. 1991) ("[A]s both parties agree that the EPA cannot provide the plaintiff with any form of compensatory or punitive damages, we fail to understand what role the EPA can play in this suit nor has the district court given this court any reason to rule otherwise."). Defendants' motion to dismiss based on primary jurisdiction is denied.

III. PREEMPTION

A state law may be either expressly or impliedly preempted by federal law. A state law is expressly preempted if Congress explicitly prohibits state regulation in an area. Implied preemption can occur in more than one way, but the only way relevant to this case is where the state law "directly conflicts" with federal law. *See Fletcher v. Burlington Northern and Santa Fe Ry. Co.*, 474 F.3d 1121, 1125-26 (8th Cir. 2007); *Missouri Bd. of Examiners for Hearing Instrument Specialists v. Hearing Help Exp., Inc.*, 447 F.3d 1033, 1035 (8th Cir. 2006). A general presumption exists that federal law does not preempt state law.[2] This is particularly true in an area traditionally occupied by the historic police powers of the states, like public health and safety. *Wyeth v. Levine*, 129 S. Ct. 1187, 1194-95 (2009); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

Relying on the FDA's approval of BPA use in food additives pursuant to 21 U.S.C. § 348(a) and (c), Defendants argue that Plaintiffs' claims directly conflict with

[2] Notwithstanding Defendants' arguments to the contrary, *Wyeth* was clear that the presumption against preemption applies "'[i]n all pre-emption cases.'" 129 S. Ct. 1194-95 (citation omitted).

federal law governing BPA and are impliedly preempted. In addition, Formula Defendants -- the only defendants that actually produce food -- have filed supplemental suggestions claiming Congress expressly and impliedly prohibited state regulation in the area of food labeling, citing 21 U.S.C. §§ 343 and 343-1. The Court will address the preemption arguments applicable to all Defendants first.

A. ALL DEFENDANTS

Defendants argue that Plaintiffs' claims directly conflict with federal law (conflict preemption). To establish conflict preemption, Defendants must show that (1) compliance with both federal and state law would be impossible, or (2) state law would pose an obstacle to the accomplishment of congressional objectives. *Pet Quarters, Inc. v. Depository Trust and Clearing Corp.*, 559 F.3d 772, 780 (8th Cir. 2009).

Defendants contend[3] that Plaintiffs' claims would pose an obstacle to federal objectives regarding the use of BPA, citing the FDA's safety determination regarding BPA and the agency's decision not to require labeling requirements. In support, Defendants cite *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000). *Geier* held that a plaintiff's claim against a car manufacturer for negligently failing to install air bags was subject to conflict preemption, finding that the plaintiff's claim would interfere with the Department of Transportation's deliberate choice to provide car manufacturers options regarding which passive restraint device they would install to comply with federal safety requirements. *See* 529 U.S. at 874-81. Although Defendants contend *Geier* is controlling, *Geier* is distinguishable. Unlike *Geier*, the FDA's approval of BPA as safe without labeling requirements establishes only a regulatory *minimum*; nothing in these regulations either required or prohibited Defendants from providing the disclosures sought by Plaintiffs. *See Harris v. Great Dane Trailers, Inc.*, 234 F.3d 398, 401 (8th Cir. 2000) ("[I]f if the purpose of [the federal regulation] was merely to provide a

[3] For their first conflict preemption argument, Defendants curiously rely on *Lohr*, which involved *express* preemption, not implied preemption. 518 U.S. at 481-82. *Lohr* has no relevance in the discussion of implied preemption.

minimum federal safety standard for trailer manufacturers, it does not preempt Harris's common law claim that Great Dane is liable in tort for failing to provide greater safety protection than the minimum standard required."); *see also* O'Reilly, Food and Drug Administration § 25:4 (3d ed. 2007) ("Federal labeling laws are minimum standards; they do not necessarily shield manufacturers from state law liability.")

The Court holds that Defendants' conflict preemption argument is controlled by *Wyeth v. Levine*. *Wyeth* involved a plaintiff whose arm was amputated as a result of being directly injected with a drug manufactured by the defendant. The plaintiff sued the manufacturer, alleging, among other things, negligence with respect to the drug's labeling. 129 S. Ct. at 1191-92. In addition to arguing that conflict preemption existed because compliance with both federal and state law would be impossible (which Defendants do not assert here), the manufacturer countered that the plaintiff's claim posed an obstacle to the applicable regulatory scheme governing drug manufacturers. However, the Supreme Court distinguished *Geier* and concluded that federal law did not prevent the drug manufacturer from strengthening its drug label as necessary to comply with the standard imposed by state law. 129 S. Ct. at 1199-03; *see also In re Prempro Products Liability Litigation*, ___ F.3d ___, 2009 WL 3518245, at *11 (8th Cir. November 2, 2009) (applying *Wyeth* and rejecting drug manufacturer's argument that plaintiff's failure to warn claim was preempted). For the same reasons as in *Wyeth*, Plaintiffs' claims against Defendants are not preempted.

Defendants also contend[4] that Plaintiffs' claims pose an obstacle to Congress' procedure for FDA review and repeal of existing regulations. However, Defendants

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[4] Defendants additionally make two arguments for the first time in their reply brief, neither of which is persuasive. First, Defendants assert Plaintiffs' claims "stand as an obstacle to the stated purpose of FDA to . . . ensure the advancement of food technology" by permitting the use of food additives at safe levels. However, since Plaintiffs no longer are seeking to enjoin Defendants' use of BPA, Defendants' argument is moot. Defendants next contend that the First Amendment prohibits Plaintiffs from holding them liable for failing to disclose information unrelated to safety, citing *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72-74 (2d Cir. 1996). *Amestoy*, which is a compelled commercial speech case, stands for the proposition that consumer interest alone is insufficient to constitute a substantial governmental interest. *Id.* The Court is not persuaded that the issues addressed in *Amestoy* are present here.

support their argument with nothing more than the conclusory allegation of interference, and the Court fails to see how Plaintiffs' claims will affect the FDA's procedure for reviewing the use of BPA in food additives. This claim lacks merit. Plaintiffs' claims against Defendants are not subject to conflict preemption.

B. FORMULA DEFENDANTS

Unlike Defendants' preemption analysis, Formula Defendants' arguments do not rely on the statutes and regulations relating to the FDA's approval of BPA as a "safe" in food additives. Rather, Formula Defendants ground their claims on the FDCA's misbranding provisions and the FDA's accompanying regulations.

Generally, a food that is made up of two or more ingredients is misbranded unless it has a label bearing the name of each ingredient. To the extent that compliance with this labeling requirement is impracticable or results in deception or unfair competition, the FDA is authorized to establish exemptions. *See* 21 U.S.C. § 343(i)(2). One such exemption established by the FDA is for "[i]ncidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food." 21 C.F.R. § 101.100(a)(3). The term "incidental additive" is defined to include food additives (like resinous and polymeric coatings formulated from epoxy resins with BPA) that are used in conformity with the FDA's regulation prescribing the conditions for safe use. *See* 21 C.F.R. § 101.100(a)(3)(iii).

Formula Defendants assert that the FDA has determined epoxy resins made with BPA to be exempt from disclosure under § 101.100(a)(3)(iii). Although Formula Defendants cite no express FDA determination supporting this claim, the absence of any regulations imposing a labeling requirement on epoxy liners made with BPA supports their argument. Moreover, Plaintiffs notably do not dispute that BPA-containing epoxy liners qualify for the exemption under § 101.100(a)(3)(iii). Thus, for purposes of Formula Defendants' preemption arguments, this Court will assume that § 101.100(a)(3)(iii) exempts Formula Defendants from disclosing the presence of BPA in their products.

Like Bottle Defendants, Formula Defendants claim conflict preemption. However, Formula Defendants also assert express preemption, and this argument has merit.

As mentioned previously, express preemption exists when a federal law explicitly prohibits state regulation in a particular field. *Hearing Help Exp., Inc.*, 447 F.3d at 1035. With respect to food labeling, federal law prohibits states from establishing "any requirement for the labeling of food of the type required by section . . . 343(i)(2) . . . of this title that is not identical to the requirement of such section." 21 U.S.C. § 343-1(a)(2). Formula Defendants argue that Plaintiffs claims are expressly preempted because they would impose disclosure requirements concerning BPA, the exact opposite of the exemption § 343(i)(2) permits. The Court agrees.

Plaintiffs' counter that their claims are not expressly preempted because they allege safety concerns surrounding BPA. Plaintiffs assert this argument because Congress provided an exception to express preemption under § 343-1 for "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." National Labeling & Education Act of 1990, 104 Stat. 2353, § 6(c)(2). Ironically, if Plaintiffs had asserted this argument in opposing Defendants' primary jurisdiction argument, their claims would have been subject to dismissal because the determination whether BPA is "safe" is solely the province of the FDA and the FDA has concluded that the use of BPA in epoxy liners is "safe" so long as the manufacturer abides by the FDA's prescribed conditions. *See* 21 C.F.R. § 175.300 (2009). Given this conclusion, the Court finds that there is no basis upon which to invoke the safety exception to the FDCA preemption clause. *See Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104, 108-09 (D.D.C. 2006) (holding that lactose intolerant plaintiffs could not invoke safety exception to save claims against milk producers for failure to warn where FDA had considered plaintiffs' symptoms and concluded that plaintiffs' condition did not implicate safety concerns).

Plaintiffs dispute this conclusion, arguing that to define the safety exception to exclude what the FDA has construed to be "safe" effectively negates the exception because "a state's warning would need to be identical to a federal law before a state

could require a warning." However, with § 343-1(a)(2) Congress expressed its intent that states occupy a more restricted role in the context of food ingredient labeling, and applying the safety exception with deference to the FDA's determination of safety effectuates Congress' intent. To rule otherwise would permit a state to impose almost any requirement on food labeling that conceivably could concern food safety, a result Congress surely did not intend.

Plaintiffs also contend that, even if the safety exception does not apply, their claims for breach of express warranty are not expressly preempted because these claims impose no labeling requirements for the labeling of food, citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005). However, this Court already has determined that Plaintiffs express warranty claims must be dismissed for failure to state a cause of action. Plaintiffs no longer have a breach of express warranty claim to assert against Formula Defendants.

III. CONCLUSION

The Court grants in part and denies in part Defendants' motion to dismiss, ruling that Plaintiffs' claims against Formula Defendant are expressly preempted. Defendants' motion to dismiss on the ground of primary jurisdiction is denied.

IT IS SO ORDERED.

/s/ Ortrie D. Smith
ORTRIE D. SMITH, JUDGE
UNITED STATES DISTRICT COURT

DATE: November 9, 2009