UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

S.F., as Parent and Natural Guardian of S.E.F., an Infant, Plaintiff, v. ARCHER-DANIELS-MIDLAND COMPANY, CARGILL, INC., INGREDION INCORPORATED, PENFORD PRODUCTS CO., TATE & LYLE INGREDIENTS AMERICAS, LLC, and ROQUETTE AMERICA, INC., Defendants.	Civil Action No. 13-CV-00634S Chief Judge William M. Skretny

MEMORANDUM OF LAW BY ARCHER-DANIELS-MIDLAND COMPANY, CARGILL, INC., INGREDION INCORPORATED, AND TATE & LYLE INGREDIENTS AMERICAS LLC IN SUPPORT OF THEIR MOTION TO DISMISS

Dated: Buffalo, New York
August 30, 2013

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INTRODUCTION

Plaintiff seeks to blame a single ingredient in the nation's food supply — high fructose corn syrup, or HFCS — for her development of diabetes. But her Complaint alleges nothing to substantiate that implausible accusation. All the Complaint says is that Plaintiff believes she ate HFCS in foods she cannot identify, the fructose in HFCS somehow causes diabetes, and because Defendants make HFCS they owe her over $5 million.

The Supreme Court requires a complaint to allege sufficient facts to establish a plausible claim for relief. It is not enough to show that a claim is "conceivable" or to show "a sheer possibility that a defendant has acted unlawfully." Plausibility is the standard.

The Complaint in this case does not even come close to pleading facts establishing a plausible claim. Plaintiff's most fundamental failure of pleading is of causation: she does not, and cannot, plead that HFCS caused her diabetes, which several Supreme Court decisions require her to do because there are many different known causes of diabetes. The Complaint simply speculates that HFCS caused Plaintiff's diabetes, without alleging a single fact to lead to that conclusion, such as any facts about her consumption of HFCS or her consumption of other sugars or other foods, or any facts at all about any of the factors that may play a role in the development of an individual's diabetes, such as weight, levels of physical activity, genetics, family background, and so on. The Complaint fails to establish that HFCS can cause diabetes (general causation) or that it caused Plaintiff's diabetes (specific causation). In the end, the Complaint simply does not plausibly allege causation.

In a very similar case, plaintiffs blamed their obesity and diabetes on eating at a particular restaurant. The court in that case concluded that only "wild speculation" could lead to a finding of proximate cause. The same is true here. And the problem cannot be fixed with repleading,

for Plaintiff has already admitted that she does not know which of the foods she ate contained HFCS. The Complaint should be dismissed.

The Complaint also fails to establish any connection between Plaintiff and any particular Defendant. The Complaint uniformly treats Defendants as a single unit, making allegations about them collectively rather than individually, even though they are separate, unrelated companies. Without knowing which of the foods she ate actually contained HFCS, Plaintiff cannot establish that any individual Defendant made any HFCS that she may have eaten.

In addition, the Complaint violates the fundamental tort principle that over-consuming a type of food, such as sugars, cannot lead to liability for its maker. All foods consumed in excess can, over time, have ill effects on the body, a fact that is well-known to American consumers. The Complaint tries to sidestep this principle by characterizing HFCS as a uniquely dangerous sweetener — a "toxin" — but the Complaint cannot avoid the simple fact that the HFCS used in foods and beverages is, like table sugar and honey, a roughly 50/50 blend of the simple sugars fructose and glucose. All of them are treated as "Sugars" and disclosed cumulatively on the familiar FDA-mandated food nutrition label. If Plaintiff's diabetes resulted in some part from eating too many calories or too much sugars, Defendants are not to blame.

Finally, Plaintiff's failure to warn claim, in which she blames Defendants for not warning her that HFCS supposedly causes diabetes, fails for the additional reason that Defendants do not sell HFCS to consumers. They sell HFCS to food companies, which use HFCS as one ingredient among many in foods and beverages. Defendants have no ability to put warning labels on the packages of food that other companies sell to consumers, such as soda cans and cookie boxes, and therefore do not owe Plaintiff any duty to warn.

Putting aside those irremediable pleading defects, the Complaint should also be dismissed because federal law conflicts with, and therefore preempts, Plaintiff's claims. All of them depend on HFCS being defectively designed (for the Complaint alleges no problem with its manufacture), but federal law establishes the design and composition of the HFCS used in foods and beverages, including its required fructose levels. Defendants cannot be held liable under state law for making HFCS to federally required specifications.

In addition, Plaintiff's causes of action all rely on the Complaint's allegation that HFCS is an unreasonably dangerous "toxin," but federal law establishes that HFCS is safe in any food. The Food and Drug Administration has specifically found that HFCS is safe and that there is no evidence of a difference in safety between HFCS and other sugars, such as table sugar and honey, that have similar amounts of fructose. Plaintiff's claims should therefore be dismissed.

Dismissal on all of the above grounds should be without leave to replead. Plaintiff has admitted facts demonstrating that she cannot fix her pleading problems, and obviously she cannot change federal law. This suit should be dismissed with prejudice.

BACKGROUND

The Complaint is long on words but short on facts. After the legal conclusions and repetitive boilerplate are stripped away, as the Supreme Court instructs must be done when reviewing the sufficiency of a complaint's allegations, this is what remains.

Plaintiff, identified as "S.E.F.," is fourteen years old and lives with her mother "S.F." in New York. (Compl. ¶ 4.) She "unknowingly consumed foods in many forms, all of which contained HFCS." (*Id.* ¶ 70.) Sometimes those unidentified foods were properly labeled with HFCS as an ingredient, but sometimes they were not. (*Id.*) Plaintiff does not know "which food products [that she ate] contained" HFCS. (*Id.* ¶ 65.) She now has type 2 diabetes, which she blames on eating those unidentified foods. (*Id.* ¶¶ 68, 73, 76, 81.) She seeks over $5 million

from the Defendants, because they make HFCS.[1] (*Id.* ¶ 57 and page 17.) That is the sum total of everything the Complaint discloses about Plaintiff.

Almost the entire body of the Complaint is comprised of allegations (many of them false or misleading) about HFCS itself, rather than about Plaintiff or her experience with it. (*Id.* ¶¶ 17-56.) HFCS is a combination of the simple sugars glucose and fructose. (*Id.* ¶¶ 18-19.) The Complaint blames the fructose in HFCS for somehow causing type 2 diabetes. (*Id.* ¶¶ 20-39, esp. ¶¶ 23-24, 28, 31, 38.) Based on the unsupported conclusion that "HFCS is a toxin," the Complaint asserts that Defendants are liable to Plaintiff for the defective design of HFCS, and failing to warn about it, in negligence and strict liability. (*Id.* ¶¶ 40, 57-81.)

STANDARD OF REVIEW

To avoid dismissal under Rule 8, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This means the complaint's "factual content" must allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). It is not enough to plead facts showing that a claim is "conceivable," *Twombly*, 550 U.S. at 570, so a complaint must do more than present "a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. Facts that are "'merely consistent with' a defendant's liability" are insufficient because they "'stop[] short of the line between possibility and plausibility of entitlement to relief.'" *Id.*, quoting *Twombly*, 550 U.S. at 557.

When considering whether a complaint states a plausible claim, one must put aside "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements..." *Id.* Conclusions "are not entitled to the assumption of truth," and Rule 8 "does not

[1] Actually, not all of them make HFCS. Defendant Penford Products Co. does not, and on that basis Penford was voluntarily dismissed from this case. (DE 15.)

unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 678-79. Only "well-pleaded factual allegations" may "plausibly give rise to an entitlement to relief." *Id.* at 679.

ARGUMENT

I. The Complaint fails to state a plausible claim.

The Complaint seeks over $5 million in damages based on the bare allegations that Defendants made HFCS, Plaintiff believes she consumed some HFCS in foods she cannot identify, the fructose in HFCS somehow leads to diabetes, and Plaintiff is diabetic. Those allegations fail in at least four different ways to state a plausible claim.

A. Causation

A complaint must be dismissed if it lacks factual allegations plausibly showing that the defendant's unlawful conduct, rather than some other cause, is responsible for the plaintiff's injury. *Twombly* itself illustrates this principle.

In *Twombly*, the plaintiff alleged that telecommunications companies engaged in anticompetitive "parallel conduct" that allowed them to inflate telephone and internet charges. *Twombly*, 550 U.S. at 550. The "crucial question" was whether this parallel conduct was the result of an independent decision at each company, which would be unobjectionable, or the result of a conspiracy among the companies, which would be illegal. *Id.* at 553. Given those two possible alternative causes, the Supreme Court refused to assume that illegal conduct was the cause: "parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Id.* at 557. The parallel conduct "could just as well be independent action." *Id.* The Supreme Court dismissed

the complaint for failure to make non-conclusory, factual allegations sufficient to show that the inflated charges were caused by illegal conduct.[2]

By requiring factual allegations to show which alternative cause was responsible for the plaintiff's injury, the Supreme Court in *Twombly* was following and reinforcing its conclusion to that effect two years earlier in *Dura Pharmaceuticals v. Broudo*, 544 U.S. 336 (2005). There, the plaintiff alleged that he bought Dura's stock at a price that was inflated because of false statements the company made about its products. *Id.* at 338-39. The Supreme Court recognized that when the stock's price later fell, there were many potential causes other than an earlier misrepresentation: "that lower price may reflect, not the earlier misrepresentation, but changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price." *Id.* at 343. Given those other potential causes, which the complaint did not address, the Supreme Court held that the complaint must be dismissed for failing the "simple test" of "pleading ... proximate causation." *Id.* at 346.

The Complaint in this case suffers from exactly the same failure that required the dismissal of the complaints in *Twombly* and *Dura*. Plaintiff alleges she has type 2 diabetes, a condition well-known to be associated with a wide variety of risk factors. These include age, obesity, low level of physical activity, genetics (including family history of diabetes), family

[2] For examples of similar decisions in recent product liability cases, *see, e.g.*, *White v. Volkswagen Group*, 2013 WL 685298, at *6 (W.D. Ark.) (dismissing product liability claim because the complaint failed to address a "number of plausible causes" for the injury); *Thunander v. Uponor, Inc.*, 887 F. Supp. 2d 850, 870 (D. Minn. 2012) (dismissing product liability claim for failure to allege "sufficient facts" to show that the product contained "a toxin capable of causing injury to humans, let alone that Plaintiffs themselves have experienced any symptoms attributable to the alleged toxin"); *cf. McCarthy v. Olin Corp.*, 119 F.3d 148, 152 (2d Cir. 1997) (affirming dismissal of a products liability complaint for failure to establish proximate cause).

background in certain groups (African American, Asian American, Hispanic / Latino, and others), and many other factors.[3] The Complaint in this case makes no attempt to address these risk factors as causes of Plaintiff's condition.

What's more, the risk factors for diabetes are themselves often multifactorial. For example, obesity is the result of some combination of the type and amount of food eaten, level of physical activity, genetics, metabolism, and other factors. *Pelman v. McDonald's*, 237 F. Supp. 2d 512, 539 (S.D.N.Y. 2003). HFCS is only one tiny part of only one of those factors—food. And HFCS is not the sole source of sugars or fructose for any person. Other sources include table sugar, honey, sugars found naturally in fruit, and so on. And sugars are only one source of calories in food, in addition to other carbohydrates, protein, and fat. It simply is not plausible to pretend that a single sweetener — which is just one type of sweetener among many sweeteners, which is just one type of food among many foods, which is just one among many potential causes of obesity, which is just one among many risk factors for diabetes — is responsible for diabetes. This is made all the more obvious by Plaintiff's allegation that HFCS was first made in the late 1960s (Compl. ¶ 17), while diabetes has been known since antiquity.

The Complaint has nothing to say about any of this beyond Plaintiff's age. It does not allege what foods she ate containing HFCS, how much of those foods she ate, how much HFCS she ate, or when she ate it. It is clear that Plaintiff does not even know any of that information. (*Id.* ¶¶ 65, 70.) Nor does the Complaint allege anything about the other sugars she ate, the other foods she ate, her genetics, her family background, her physical activity, or anything else. All it alleges is that she believes she ate some unidentified amount of HFCS in some unidentified

[3] National Diabetes Information Clearinghouse, U.S. Department of Health and Human Services, *Causes of Diabetes, available at* http://diabetes.niddk.nih.gov/dm/pubs/causes/; National Diabetes Education Program, U.S. Department of Health and Human Services, *Diabetes Risk Factors, available at* http://ndep.nih.gov/am-i-at-risk/DiabetesRiskFactors.aspx.

foods at some unidentified times and wound up diabetic. Under *Twombly* and *Iqbal*, that "threadbare" conclusion, without any factual support, does not validly assert a plausible claim. There are millions of people in this country who eat food containing HFCS without becoming diabetic. As discussed below, the FDA has affirmed that HFCS is Generally Recognized as Safe and is just as safe as other sugars. In the face of all of this, Plaintiff has offered no reason at all for this Court to conclude that HFCS is responsible for her diabetes.

Plaintiff has thus failed to plead both general causation (whether the type of injury can be caused by the product) and specific causation (whether plaintiff's own injury was actually caused by the product). Both are required in a product liability case, and their absence is fatal to Plaintiff's claims. *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 250 n.1 (2d Cir. 2005); *In re Rezulin Prod. Liab. Litig.*, 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006).

The Complaint in this case bears a striking resemblance to the complaint in *Pelman v. McDonald's*, in which several New York teenagers blamed their obesity, and one blamed his diabetes, on foods they ate at McDonald's restaurants. (One distinction, however, is that at least in *Pelman* the plaintiffs sued the company that sold them the food, rather than an ingredient supplier.) The plaintiffs in *Pelman* failed to allege how often they ate at McDonald's, and they did not address the other variables for obesity besides food, such as "social behavioral, physiological, metabolic, cellular, ... molecular" and "cultural and genetic factors." *Pelman*, 237 F. Supp. 2d at 539. Regarding other diseases related to obesity, such as diabetes, the complaint in *Pelman* failed to allege that "such diseases were not merely hereditary or caused by environmental or other factors." *Id.* The court therefore concluded that "No reasonable person could find [proximate] cause based on the facts in the Complaint without resorting to wild

speculation," *id.* at 538 (internal quotation omitted), and dismissed the complaint.[4] This Court should likewise dismiss the Complaint.

B. Connection to Defendants

The Complaint in this case relies on the discredited practice of "group pleading": making undifferentiated allegations against the defendants collectively without giving each individual defendant fair notice of what it is supposed to have done wrong. *Zalewski v. T.P. Builders*, 2011 WL 3328549, at *5 (N.D.N.Y.); *Automated Transaction v. New York Cmty. Bank*, 2013 WL 992423, at *4 (E.D.N.Y.). Under *Twombly* and *Iqbal*, it is impossible to state a plausible claim "without any details about who did what ... Each defendant is entitled to know what he or she did that is asserted to be wrongful. A complaint based on a theory of collective responsibility must be dismissed." *Bank of America v. Knight*, — F.3d —, 2013 WL 4016522, at *3 (7th Cir. 2013); *see also Atuahene v. City of Hartford*, 10 F. App'x 33, 34 (2d Cir. 2001); *Ochre LLC v. Rockwell Architecture Planning and Design*, 2012 WL 6082387, at *6-7 (S.D.N.Y.); *Ogbon v. Beneficial Credit Services*, 2011 WL 347222, at *2 (S.D.N.Y.).

After identifying the Defendants by name (Compl. ¶¶ 5-16), the Complaint never again refers to any of them individually. They are always a group: "Defendants, ARCHER-DANIELS-MIDLAND COMPANY, CARGILL, INC., INGREDION INC., PENFORD

[4] A later amended complaint in *Pelman*, asserting different causes of action than are at issue in the present case, did allege how often the plaintiffs ate at McDonalds, which is far more information than Plaintiff alleged in the present case. But that later complaint failed to "isolate the particular effect of McDonald's foods on their obesity and other injuries." *Pelman v. McDonald's*, 2003 WL 22052778, at *11 (S.D.N.Y.). It did not "address the role that a number of factors other than diet may come to play in obesity and the health problems of which the plaintiffs complain." *Id.* And it did not answer "[o]ther pertinent [] questions" such as "What else did the plaintiffs eat? How much did they exercise? Is there a family history of the diseases ...?" The district court therefore dismissed the amended complaint with prejudice. The Second Circuit reversed, *Pelman v. McDonald's*, 396 F.3d 508 (2d Cir. 2005), in a decision that came before, and is entirely inconsistent with, the Supreme Court's decisions in *Dura*, *Twombly*, and *Iqbal*.

PRODUCTS CO., TATE & LYLE INGREDIENTS AMERICAS, LLC and ROQUETTE AMERICA, INC." (*Id.* ¶¶ 46-52, 54-57, 59-66, 71-72, 75, 78-80.) Even items that are plainly different for each Defendant, such as its own knowledge about certain topics, or the "malice" with which it supposedly acted, are pleaded collectively. (*E.g., id.* ¶¶ 61,72, 78, 80.)

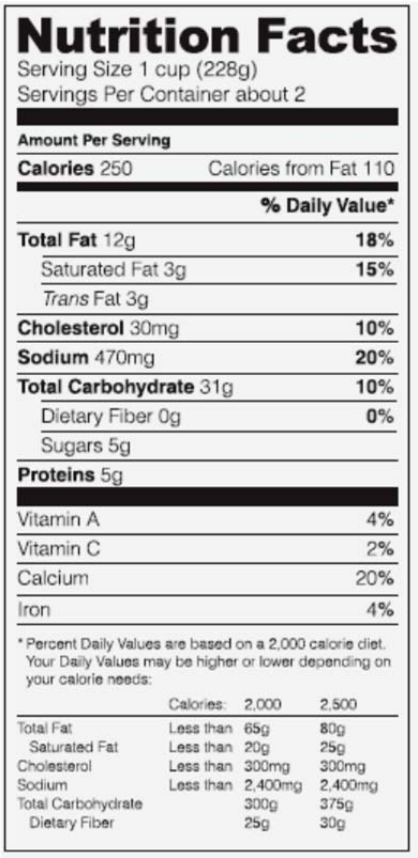
"Under New York law, the plaintiff bears the burden of showing that the defendant was the manufacturer of the product at issue." *Tuosto v. Philip Morris*, 672 F. Supp. 2d 350, 366 (S.D.N.Y. 2009). It is insufficient to "implicate[] a class of products, but no one product in particular." *Id.* That is all Plaintiff has done here: point her finger at a group of unidentified products that may (or may not) have contained HFCS. Completely missing from the Complaint is any allegation that the Plaintiff ate any particular food or that any individual Defendant actually made the HFCS that was in the food. (As noted above, Plaintiff even sued a Defendant that does not make HFCS.) She does not know what food she ate (Compl. ¶¶65, 70), and as a result no Defendant can be linked to any harm that Plaintiff claims to have suffered. For that reason as well, the Complaint should be dismissed with prejudice.

C. Overconsumption of Sugars

Fundamental principles of tort law prevent a plaintiff from asserting claims based on her own choice to eat too much food. "Many products cannot possibly be made entirely safe for all consumption, and any food ... necessarily involves some risk of harm, if only from overconsumption. Ordinary sugar is a deadly poison to diabetics... That is not what is meant by 'unreasonably dangerous.' ... 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." RESTATEMENT (SECOND) OF TORTS § 402A cmt. i; *see also Gorran v. Atkins Nutritionals*, 464 F. Supp. 2d 315, 324 (S.D.N.Y. 2006) (increasing the risk of disease does not make food defective). There is no

allegation in the Complaint that Plaintiff ate *contaminated* HFCS. Instead, the allegation is that eating sugar in the form of HFCS over time led to diabetes—the very claim that is out of bounds.

Food package nutrition labels reinforce the fact that consumers are responsible for their own intake of sugars. The following is a sample label from the FDA's website:



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container about 2

Amount Per Serving

Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	**18%**
Saturated Fat 3g	**15%**
Trans Fat 3g	
Cholesterol 30mg	**10%**
Sodium 470mg	**20%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Proteins 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Those familiar labels require the seller to report the total grams of sugars (in the image above, "Sugars 5g"), which is "defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose)." 21 C.F.R. § 101.9(c)(6)(ii). The FDA does not treat HFCS any differently than table sugar or honey on food package nutrition labels; on the contrary, the FDA requires HFCS to be included among the "Sugars." All HFCS, table sugar, honey, sugars occurring naturally in fruit, and other calorie-bearing sweeteners are counted together to show

the product's total sugars content.[5] Thus, the Complaint's claims should in any event be dismissed on the ground that the amount of sugars in the food was obvious to anyone who ate it (or gave it to a child to eat). *Mills v. Giant of Maryland*, 441 F. Supp. 2d 104, 111 (D.D.C. 2006) (holding under Restatement § 402A that liability cannot be based on "an obvious ingredient" in food).

Plaintiff tries to avoid this result by arguing HFCS is somehow uniquely dangerous as a sweetener. But for two reasons, the Complaint does not and cannot factually plead that point. First, the Complaint ignores the fact that the Food and Drug Administration has affirmed that HFCS is Generally Recognized as Safe, and may safely be used in any food. 21 C.F.R. § 184.1866(c). The "GRAS" affirmation for HFCS is discussed in detail below.

Second, Plaintiff cannot claim that HFCS is uniquely dangerous, because the Complaint cannot distinguish HFCS from other sweeteners. HFCS is a blend of the simple sugars fructose and glucose. The two types of HFCS commonly used in food and beverages in the United States are "HFCS 42" and "HFCS 55." *HFCS: Q&A*.[6] HFCS 42 is 42 percent fructose, and HFCS 55 is 55 percent fructose, with the remainder glucose and water. 21 C.F.R. § 184.1866(a); *HFCS: Q&A*. The words "High Fructose" in HFCS distinguishes it from the ordinary variety of corn syrup, which is pure glucose. *HFCS: Q&A*.

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[5] When adopting this regulation in 1993, the FDA specifically rejected proposals for food labels to distinguish between naturally occurring sugars and sugars added to food: "The Agency is not persuaded that there is a need for mandatory disclosure of added sugars in place of, or in addition to, total sugars. There is no scientific evidence that the body makes any physiological distinction between added sugar molecules and those naturally occurring in food." Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2,079-01, 2,098 (Jan. 6, 1993).

[6] Food and Drug Administration, *High Fructose Corn Syrup: Questions & Answers* [*HFCS: Q&A*], *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditives Ingredients/ucm324856.htm. For the Court's convenience, a copy is attached hereto as Appendix B.

There is nothing unusual about a sweetener that is a blend of roughly equal parts fructose and glucose. Sucrose — better known as table sugar — is a mix of fructose and glucose in "an exact one-to-one ratio." *HFCS: Q&A; see also* 21 C.F.R. § 184.1857. For that reason, of course, the "proportion of fructose to glucose in both HFCS 42 and HFCS 55 is similar to that of sucrose." *HFCS: Q&A*; *see also* Direct Food Substances Affirmed as Generally Recognized as Safe; High Fructose Corn Syrup, 61 Fed. Reg. 43,447-01, 43,447-43,449 (Aug. 23, 1996) (the "glucose to fructose ratio[] of HFCS is approximately the same as that of honey, invert sugar, and ... sucrose"). HFCS is also similar in composition to honey, which like sucrose has "an approximately one-to-one ratio of fructose to glucose." *HFCS: Q&A.* The Complaint does not and cannot allege that the fructose in HFCS is different than the fructose in any other sweetener.

The Complaint makes only one feeble attempt to distinguish HFCS from other sugars. It alleges that "the fructose content of HFCS-55 is slightly higher than in sucrose." (Compl. ¶ 33.) That is true but irrelevant. The Complaint does not (and cannot) allege how just an extra 5 percentage points of fructose in HFCS (from 50 percent fructose in table sugar or honey to 55 percent in HFCS 55) could possibly render HFCS "a toxin" while table sugar and honey are wholesome staples in the American diet. Worse, the Complaint does not acknowledge the obvious truth that HFCS 42 has ***less*** fructose than table sugar or honey, and in the Complaint's telling should therefore be a more desirable alternative than those sweeteners. If fructose is the problem, as the Complaint asserts it is, then nothing meaningful distinguishes HFCS from table sugar or honey or any other sweetener containing fructose, nor from the fructose that is found naturally in fruit.[7]

[7] The word *fructose* combines the Latin word for fruit, *fructus*, with the standard chemistry suffix for sugar or carbohydrate, *-ose*. Fructose is commonly known as "fruit sugar" because it occurs naturally in fruits and berries. *HFCS: Q&A.*

A plaintiff's decision to eat too many calories or too much of a common ingredient such as sugars cannot create liability for the ingredient's maker. It is self-evident and a matter of common knowledge that all sugars should be consumed in moderation, and no one needs to be warned against over-consumption in order for a product's makers to avoid tort liability. *Pelman*, 237 F. Supp. 2d at 532; RESTATEMENT (THIRD) TORTS: PROD. LIAB. § 2 cmt. j; *Cook v. MillerCoors*, 872 F. Supp. 2d 1346, 1350-51 (M.D. Fla. 2012); *Pinello v. Andreas Stihl AG*, 2011 WL 1302223, at *11 (N.D.N.Y.). For all of these reasons, the Complaint should be dismissed.

D. Food Package Labels

Plaintiff's failure to warn claim fails for an additional reason beyond those explained above. That count of the Complaint states that the foods Plaintiff ate were sometimes misleadingly labeled as containing sugars other than HFCS. (Compl. ¶ 70.) The Complaint contains absolutely no facts to back up this conclusion, for example identifying a single mislabeled package for a food that Plaintiff ate, and the claim fails for that reason alone. But suppose the Complaint were correct. If a food package were mislabeled, it would be the responsibility of the company that made and sold the food, not the HFCS manufacturer. HFCS is simply an ingredient that may be included in foods, like flour or baking powder, and ingredient suppliers such as Defendants have no ability to change the label on another company's food package.

For the same reason, Plaintiffs' assertion that Defendants had a "duty to warn Plaintiff and others similarly situated and users of its product of the latent dangers including development of type 2 diabetes" (Compl. ¶ 71) is implausible. Defendants do not sell HFCS to Plaintiff or other consumers, and Defendants do not have the ability to put a warning label on packages for

food made and sold by other companies: soda cans, cookie boxes, and the like.[8] Defendants therefore cannot be liable for their labels and packages.

II. Federal law preempts Plaintiff's causes of action.

Under the Supremacy Clause, federal laws preempt conflicting state laws. *English v. GE*, 496 U.S. 72, 79 (1990). The conflict may come either because it is not possible to comply with both federal and state requirements, or because the state requirements are an obstacle to federal law achieving its full purposes. *Id.*

There are two different conflicts here. First, the Complaint asserts that HFCS is defectively designed as a matter of New York law, but the design of HFCS in foods and beverages is mandated by federal law. Second, the Complaint asserts that HFCS is "a toxin" that is unreasonably dangerous for people to eat as a matter of New York law, but federal law states that HFCS is Generally Recognized As Safe and may be used in food without limitation. For both of these independent reasons, the entire Complaint should be dismissed with prejudice.

A. Federal law mandates the design of HFCS.

In a product liability case such as this one, three types of claims are possible: manufacturing defect (the product was not made to specifications), design defect (the specifications were bad), and failure to warn. 1 N.Y. PROD. LIAB. (SECOND): DEFECT AS A CENTRAL CONCEPT § 1:2 (2013); *Colon v. BIC USA*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001). The labels "strict liability" and "negligence" do not matter: under either regime, the claims are

[8] To obtain the relief she seeks, Plaintiff would have to sue the vast array of companies that made and sold all of the actual foods containing HFCS that she may have eaten: cereals, soda, yogurt, cookies, ketchup, and so on. But, as noted above, Plaintiff has admitted she does not know what foods these are or how much of them she ate. Thus, even direct litigation against food companies would require piling speculation on speculation.

"functionally synonymous." *Pinello*, 2011 WL 1302223, at *16; *see also American Guar. & Liab. Ins. Co. v. Cirrus Design Corp.*, 2010 WL 5480775, at *3 (S.D.N.Y.).

None of the Complaint's four state-law product liability counts allege any manufacturing defect, such as an impurity or contamination in HFCS. Instead, they all depend on the assertion that HFCS is, by virtue of its design and components, sufficiently dangerous that Defendants should warn consumers about it and pay consumers who are injured by it. Plaintiff's claim is that HFCS is dangerous *per se*, by design.

Plaintiff's state-law claims all fail because federal law requires a specific design for HFCS that directly conflicts with those claims. Federal law requires HFCS 42 or 55 to be a "saccharide mixture containing either approximately 42 or 55 percent fructose, ... prepared as a clear aqueous solution from high dextrose-equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation..." 21 C.F.R. § 184.1866(a). Federal law also requires HFCS 42 or 55 to "conform to the identity and specifications listed in the monograph entitled 'High-Fructose Corn Syrup' in the Food Chemicals Codex, 4th ed. (1996), pp. 191-192..." *Id.* § 184.1866(b); *see also id.* § 170.30(h)(1). (For the Court's convenience, a copy of those pages of the Codex is attached as Appendix A. The Codex gives the same description of HFCS as the federal regulation, and it requires "42% HFCS" to have "Not less than 97.0% total saccharides, expressed as percent of solids, of which not less than 42.0% consists of fructose..." Codex at 191. The Codex gives similar requirements for "55% HFCS," including that "not less than 55.0% consists of fructose..." *Id.)*

In short, federal law dictates the design of HFCS 42 and HFCS 55, and as part of that design requires a specified amount of fructose. Defendants cannot be held liable under state law for following those federal design requirements.

The Supreme Court confronted this situation just a few months ago. The plaintiff in *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), asserted a state-law design defect claim against a company that made a generic drug. But the company "was unable to change [the drug's] composition as a matter of ... federal law," because once a drug is approved for sale, the manufacturer may not change it. *Id.* at 2470, 2471, 2475. For this and other reasons, the company was unable to comply with both state and federal law, so the Supreme Court held that the design defect claim was preempted. *Id.*

It is the same in this case. Federal law specifies the design, including the fructose content, of HFCS 42 and HFCS 55 in specific and mandatory terms. As makers of HFCS, Defendants must comply with federal law. That is fatal to Plaintiff's contrary state law claims seeking to impose liability because of HFCS's design and composition. Thus, the entire Complaint should be dismissed with prejudice.[9]

B. Federal law affirms that HFCS is safe.

[9] Another approach to the same point is that, in light of federal law, Plaintiff's state-law claims would in any event fail. Plaintiff could never prove a design defect claim, because "[u]ltimately, the inquiry in a design defect case requires a fact finder to make a judgment about the manufacturer's judgment in choosing to design a product in a certain way." *Colon*, 199 F. Supp. 2d at 83 (citations omitted). Defendants here never made a judgment about the design; it was established by federal law. In addition, a design defect claim requires proof "that a safer, feasible design alternative existed at the time of manufacture." *Id.; see also Goldin v. Smith & Nephew*, 2013 WL 1759575, at *4 (S.D.N.Y.) (dismissing for failure to plead a safer alternative design); *Reed v. Pfizer*, 839 F. Supp. 2d 571, 578 (E.D.N.Y. 2010) (same). Here, federal law bars any alternative design.

The Complaint labels HFCS a "toxin" that is "unreasonably dangerous ... even when used in its intended manner"—as an ingredient in food to be eaten. (Compl. ¶¶ 40, 58.) HFCS allegedly leads to "development of type 2 diabetes." (*Id.* ¶ 71.) All of the counts in the Complaint seek to impose liability on Defendants on the basis of these assertions.

Under federal law, however, HFCS was "reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS)." 21 C.F.R. § 184.1(a). The GRAS affirmation states that HFCS 42 and 55 may be used as an "ingredient ... in food with no limitation other than current good manufacturing practice." 21 C.F.R. § 184.1866(c).

When used in connection with food, the term "[s]afe ... means 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); *see also id.* § 170.30(a) ("General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly ... added to food"). Safety is determined by examining the "probable consumption of the substance," the "cumulative effect of the substance in the diet," and "[s]afety factors." *Id.* § 170.3(i)(1), (2), (3). Determining whether food is safe is uniquely within the FDA's expertise: "The FDA ... knows how to weigh conflicting studies and determine the most accurate and up-to-date information regarding product safety. Although courts can resolve whether a product has been approved as safe, the question of whether a product should be approved as safe requires the FDA's expertise." *Aaronson v. Vital Pharm.*, 2010 WL 625337, at *2-3 (S.D. Cal.) (internal citation omitted) (deferring to "the FDA's unique ability to discern scientific data and ensure uniform regulation in the field").

The FDA's Final Rule on HFCS explains that the agency "fully evaluated" HFCS and determined that it is safe in food. 61 Fed. Reg. 43,447-01 at 43,447. The process began in 1988,

when the FDA proposed to affirm that HFCS is GRAS. *Id.* In its proposal was (1) the agency's evaluation of data in petitions previously submitted about HFCS, (2) discussion of reports by a GRAS committee, and (3) discussion of a report by the FDA's Sugars Task Force. *Id.* The FDA's assessment included both HFCS-55, the higher-fructose version of HFCS, and HFCS-42, the lower-fructose version. *Id.* at 43,447-48, 43,449.

One of the comments that the FDA received on its proposed rule was from the Diabetes Research Center. *Id.* at 43448. The Center "stated its opinion that the safety of HFCS as it relates to diabetics has not been totally established. It suggested that th[is] fact ... should be stated somewhere on the product label." *Id.* The Center's suggestion bears a startling resemblance to Plaintiff's failure to warn claim.

The FDA emphatically rejected the Center's suggestion: "FDA's Sugars Task Force stated in its report ... that it ***could not find any basis in the scientific literature to conclude that there was the potential for an adverse effect in diabetics from increased fructose consumption***." *Id.* (emphasis added). The FDA also noted that the American Diabetes Association's Nutrition Principles for the Management of Diabetes and Related Complications "do not include a recommendation to avoid any specific sweetener because of safety concerns." *Id.* The FDA concluded "that ***there is no evidence to suggest that HFCS is any less safe for diabetics than any other commonly used sweetener***." *Id.* (emphasis added). Finally, when assessing the impact of the rule it was considering, the FDA found "***there will be no increase in the health risks faced by consumers resulting from this final rule***" affirming that HFCS is safe. *Id.* at 43,450 (emphasis added).

Nothing has changed in the years since the FDA affirmed that HFCS is safe. Here is the FDA's current statement on the subject, posted by the FDA just this year:

> **Is HFCS less safe than other sweeteners?**
>
> FDA receives many inquiries asking about the safety of HFCS, often referring to studies about how humans metabolize fructose or fructose-containing sweeteners. These studies are based on the observation that there are some differences between how we metabolize fructose and other simple sugars.
>
> ***We are not aware of any evidence, including the studies mentioned above, that there is a difference in safety between foods containing HFCS 42 or HFCS 55 and foods containing similar amounts of other nutritive sweeteners with approximately equal glucose and fructose content, such as sucrose, honey, or other traditional sweeteners.*** The 2010 Dietary Guidelines for Americans recommend that everyone limit consumption of all added sugars, including HFCS and sucrose. FDA participated in the development of the Dietary Guidelines and fully supports this recommendation.

HFCS: Q&A (emphasis added).

In sum, federal law declares that qualified scientists have found HFCS to be safe, that it is no different in safety than table sugar or honey, and that it poses no special risk even to people who are already diabetic. Those principles cannot be squared with the Complaint's assertion that state-law causes of action should be used to find that HFCS is an unreasonably dangerous "toxin" that causes diabetes. "In effect, the plaintiff is asking this Court to revoke the GRAS status" of HFCS, and to require warning "labels that are inconsistent with a finding that [HFCS] is generally recognized as safe to eat. ... This court is not the FDA...." *Cardinale v. Quorn Foods*, 2011 WL 2418628, at *6 (Conn. Super. Ct.) (dismissing complaint as preempted). FDA regulations affirm the right for HFCS to be used as "an ingredient ... in food with no limitation other than current good manufacturing practice." Allowing Plaintiff to attack the safety of HFCS, in the face of the FDA's affirmation that HFCS is safe, would frustrate the federal purpose of establishing uniform food additive regulations (on which *see* S. REP. NO. 85-2422, at

2 (1958)) and would hinder advances in food technology. All of Plaintiff's claims are therefore preempted by federal law.

III. The Complaint should be dismissed with prejudice.

In light of the deficiencies identified above, this Court should dismiss the Complaint without leave to replead. Plaintiff has already admitted that she cannot provide the necessary factual allegations to support claims against Defendants, so to allow an amended complaint would be futile. *E.g., Sorrentino v. Barr Labs., Inc.*, 2010 WL 2026135, at *5 (N.D.N.Y. 2010) (dismissing with prejudice because the pleading defects were "substantive rather than merely formal"). And given that federal law preempts her claims that HFCS is a defectively designed toxin, repleading the facts of her claims cannot in any event help her. *E.g., Jurgensen v. Felix Storch, Inc.*, 2012 WL 2354247, at *5 (S.D.N.Y.) (dismissing with prejudice due to preemption); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 203 (W.D.N.Y. 2011) (Skretny, J.) (same). This Court should therefore dismiss the entire complaint with prejudice.

CONCLUSION

For the foregoing reasons, Defendants respectfully urge this Court to dismiss the Complaint with prejudice.

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Respectfully submitted,

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