Filed 8/15/18 (unmodified opn. attached)

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION ONE

POST FOODS, LLC, et al., Petitioners, v. THE SUPERIOR COURT OF LOS ANGELES COUNTY, Respondent; RICHARD SOWINSKI, Real Party in Interest.	B284057 (Los Angeles County Super. Ct. No. BC516747) ORDER MODIFYING OPINION, GRANTING JUDICIAL NOTICE, AND DENYING REHEARING [NO CHANGE IN JUDGMENT]

THE COURT:

It is ordered that the opinion filed herein on July 16, 2018, be modified as follows:

1. In section A of the FACTUAL AND PROCEDURAL BACKGROUND, on page 6, the first sentence of the last paragraph, which reads:

Notably, the OEHHA heeded the FDA's advice letters and deferred to the FDA's approach to acrylamide.

Is modified to read as follows:

Notably, the California authorities heeded the FDA's advice letters and deferred to the FDA's approach to acrylamide.

2. In section E of the FACTUAL AND PROCEDURAL BACKGROUND, on page 13, the first two sentences of footnote 5, which read:

Neither party addressed whether a Proposition 65 warning on whole grain cereals would lead to labels on other foods, but this presents a concern. Proposition 65 warnings on foods containing acrylamide above California's nonsignificant risk levels would cause many otherwise healthy foods to appear to consumers to be unhealthful and vice versa.

Are modified to read as follows:

Neither party addressed whether a Proposition 65 warning on whole grain cereals would lead to labels on other otherwise healthful foods, but this presents a concern. Proposition 65 warnings on foods containing acrylamide above California's nonsignificant risk levels would cause many such foods to appear to consumers to be unhealthful and vice versa.

3. In section V of the DISCUSSION, on page 24, the last sentence on that page, which reads:

Dr. Sowinski characterizes them as "old letters," but California regulators complied with them, so the FDA had no reason to issue further advice letters regarding Proposition 65 warnings for acrylamide.

Is modified to read as follows:

Dr. Sowinski characterizes them as "old letters," but California regulators heeded them, so the FDA had no reason to issue further advice letters regarding Proposition 65 warnings for acrylamide.

4. In section V of the DISCUSSION, on page 24, at the end of the last sentence on that page:

Insert a new footnote number 9, which will require renumbering of all subsequent footnotes, that reads as follows:

Notably, it is not the FDA's letters that preempt the proposed Proposition 65 acrylamide warnings here, but the numerous federal statutes enacted by Congress to increase Americans' consumption of whole grains, whose policy objectives would be obstructed by such a warning. For this reason, *Reid v. Johnson & Johnson* (2015) 780 F.3d 952, in which the Ninth Circuit held that a particular FDA letter lacked any preemptive effect, is inapposite. Moreover, *Reid* merely held the FDA letter at issue lacked the force of law necessary to preempt state law, largely due to its "equivocal language" regarding the FDA's intentions. That letter was "couched in tentative and non-committal terms" and did "not promise that the FDA will not enforce its … regulation" but instead provided "that the FDA 'intends to *consider* the exercise of enforcement discretion' in certain circumstances." (*Id.* at p. 965, italics added.) By contrast, the FDA letters here were unequivocal. The 2003 FDA letter stated, "[A] requirement for warning labels on food might deter consumers from eating foods with such labels. Consumers who avoid eating some of these foods, such as breads and cereals, may encounter greater risks because they would have less fiber and other beneficial nutrients in their diets. For these reasons, premature labeling requirements would conflict with FDA's ongoing efforts to provide consumers with effective scientifically based risk communication to prevent disease and promote health." In its 2006 letter, the FDA stated, "California should not require acrylamide warning labels for foods under Proposition 65

before completion of scientific studies adequate to assess the potential risk of acrylamide to consumers and until FDA determines, based on our risk assessment, that risk management measures (beyond our current advice to eat a balanced diet) are needed."

5. In section V of the DISCUSSION, on page 25, the last sentence of the partial paragraph, which reads:

This shows that the FDA continues to execute on the strategy outlined in its advice letters and has not endorsed California's 0.2 microgram/day standard that would require many foods to be labeled.

Is modified to read as follows:

This shows that the FDA continues to execute on the strategy outlined in its advice letters and has not endorsed California's 0.2 microgram/day standard that would require whole grain cereals to be labeled.

There is no change in the judgment.

Real party in interest's request for judicial notice is granted.

Real party in interest's petition for rehearing is denied.

CERTIFIED FOR PUBLICATION

ROTHSCHILD, P. J. CHANEY, J. JOHNSON, J.

Filed 7/16/18 (unmodified version)

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION ONE

POST FOODS, LLC, et al., Petitioners, v. THE SUPERIOR COURT OF LOS ANGELES COUNTY, Respondent; RICHARD SOWINSKI, Real Party in Interest.	B284057 (Los Angeles County Super. Ct. No. BC516747)

ORIGINAL PROCEEDING; petition for writ of mandate. Kenneth R. Freeman, Judge. Petition granted.

Arnold & Porter Kaye Scholer, Trenton H. Norris; Perkins Coie, David T. Biderman and Eric D. Miller for Petitioners.

No appearance for Respondent.

Graham & Martin and Anthony G. Graham for Real Party in Interest.

Petitioners Post Foods, LLC, General Mills, Inc., General Mills Sales, Inc., and Kellogg USA, Inc. petition for a writ of mandate directing the superior court to vacate its June 26, 2017 order denying their motion for summary judgment and issue an order granting the motion. We issued a stay pending this Court's resolution of the petition and an order to show cause why a writ of mandate should not issue.

Real party in interest Dr. Richard Sowinski's complaint alleges that Petitioners' breakfast cereals were required by California's Proposition 65 to display cancer and reproductive harm warnings because they contain acrylamide. Petitioners contend such warnings on cereals are preempted by federal law because they would pose an obstacle to federal policy objectives to increase Americans' consumption of whole grains. In support, Petitioners cite to numerous federal statutes establishing that policy, and Food and Drug Administration (FDA) letters to California regulators cautioning against Proposition 65 warnings on cereals because they could mislead consumers and cause them to avoid whole grains, resulting in health detriments. Because we agree that Dr. Sowinski's Proposition 65 claim is preempted by federal law, we grant the petition and direct the superior court to vacate its order denying Petitioners' motion and enter a new and different order granting the motion.

FACTUAL AND PROCEDURAL BACKGROUND

Acrylamide has been produced artificially since the 1950's for industrial purposes, including the manufacture of various polymers, cement, and for waste water treatment. Acrylamide has been known to pose health risks for some time. It was added to Proposition 65's list of chemicals known to cause cancer in 1990, and later was determined to cause reproductive harm in animal test subjects.

In April 2002, Swedish researchers discovered that acrylamide is generated naturally when carbohydrate-rich foods are baked, roasted, fried, or deep fried. In particular, French fries, potato chips, crackers, pretzel-like snacks, cereals, and brown breads "tend to have the highest levels of [acrylamide]." A 2010 Environmental Protection Agency study noted, however, that "since [acrylamide] appears to form from standard cooking methods like baking, frying, and roasting, it has been in the human diet for many thousands of years."

Dr. Sowinski's complaint alleges that 59 breakfast cereals manufactured by Petitioners and sold in California contain acrylamide, and therefore are required to include cancer and reproductive toxicity warnings. He alleges that Petitioners' failure to include such warnings violated the Safe Drinking Water and Toxic Enforcement Act that Proposition 65 enacted. At the outset of the case, the parties agreed to stay expert discovery pending resolution of the Petitioners' motion for summary judgment on the threshold issue of whether Dr. Sowinski's claim is preempted by federal law.

Petitioners' summary judgment papers included extensive evidence that federal agencies have been studying the health risks of acrylamide in food since it was discovered there in 2002. The FDA has coordinated its studies with other federal agencies and international science communities and is waiting until scientifically sound risk assessments have been completed before it determines what, if any, warnings are needed for acrylamide.

A. The FDA's Guidance Regarding Acrylamide and Proposition 65 Warnings

Beginning in 2003, the FDA corresponded with California's health agencies to advise against a Proposition 65 acrylamide warning on food products because of its potential to confuse and mislead consumers, and because a warning was likely to cause

consumers to avoid whole grain foods like breakfast cereals, leading to health detriments. The FDA explained that its usual approach is to disseminate advice regarding ingredients carrying health risks, require that the labels of food products containing such ingredients identify the amounts, and require package warnings only in exceptional cases. The FDA cautioned California authorities that a Proposition 65 warning on foods would conflict with FDA's ongoing efforts to provide consumers with effective, scientifically-based risk information, would confuse and mislead consumers due to the lack of context, and might be preempted because such warnings would frustrate federal objectives and conflict with federal law.

Specifically, on July 14, 2003, FDA Deputy Commissioner Lester Crawford wrote to Joan E. Denton, director of California's Office of Environmental Health Hazard Assessment (OEHHA), Proposition 65 Implementation. Noting that California "currently has a no significant risk level (NSRL) for acrylamide of .2 micrograms per day," Crawford stated, "We understand that California intends to announce a revised approach to acrylamide in the near future. FDA believes it is premature to set a level of acrylamide in food, and that California's current NSRL and future actions may frustrate federal purposes or even conflict with federal law." Crawford summarized the FDA's "Action Plan" to study acrylamide, and the work being done in coordination with the World Health Organization and an international committee of experts.

The FDA noted that California's 0.2 microgram/day standard would require many foods to be labeled. "FDA is concerned that premature labeling of many foods with warnings about dangerous levels of acrylamide would confuse and could potentially mislead consumers, both because the labeling would be so broad as to be meaningless and because the risk of

consumption of acrylamide in food is not yet clear. [¶] Furthermore, consumers may be misled into thinking that acrylamide is only a hazard in store-bought food. In fact, consumer exposure may be greater through home cooking. . . . In addition, a requirement for warning labels on food might deter consumers from eating foods with such labels. Consumers who avoid eating some of these foods, such as breads and cereals, may encounter greater risks because they would have less fiber and other beneficial nutrients in their diets. For these reasons, premature labeling requirements would conflict with FDA's ongoing efforts to provide consumers with effective scientifically based risk communication to prevent disease and promote health."

After identifying some other potential unintended negative consequences of Proposition 65 labeling of foods, the letter continued, "FDA believes that California should not require warning labels for foods under Proposition 65 before completion of scientific studies adequate to assess the potential risk to consumers . . . and until FDA determines appropriate risk management based on FDA's risk assessment. This approach will avoid confusing consumers and will assure that advice to consumers is scientifically founded." The FDA also addressed federal preemption, stating, "FDA believes that California's current requirements for acrylamide under Proposition 65 and some actions that California may propose may be preempted by federal law to the extent that they frustrate federal purposes or create conflicts with federal law. For example, as discussed above, warning labels based on the presence of acrylamide in food might be misleading."

Subsequently, in March 2006, following discussions between the FDA and the OEHHA and the Attorney General's staff regarding acrylamide and Proposition 65, FDA Director

Terry Troxell of the FDA's Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, wrote to Edward Weil, Deputy Attorney General of California, to "summarize recent and ongoing FDA activities." After describing the FDA's progress and future plans in its study of acrylamide, Troxell noted, "FDA previously wrote to OEHHA that [Proposition 65] warning language might have the following adverse effects, among others: [¶] [*] Create unnecessary and unjustified public alarm about the safety of the food supply; [¶] [*] Dilute overall messages about healthy eating; and [¶] [*] Mislead consumers into thinking that acrylamide is only a hazard in store-bought food. [¶] FDA also stated that California should not require acrylamide warning labels for foods under Proposition 65 before completion of scientific studies adequate to assess the potential risk of acrylamide to consumers and until FDA determines, based on our risk assessment, that risk management measures (beyond our current advice to eat a balanced diet) are needed. [¶] In summary, FDA has been and remains very active in the acrylamide field, and continues to believe that California should not require acrylamide warning labels for foods under Proposition 65." On the same date, the FDA wrote in similar terms to Joan Denton, chief counsel of OEHHA.

Notably, the OEHHA heeded the FDA's advice letters and deferred to the FDA's approach to acrylamide. Rather than require a Proposition 65 warning, on its own webpages OEHHA summarized the current FDA guidance for acrylamide: "The U.S. Food and Drug Administration (FDA) and other health and scientific organizations continue to study the prevalence of acrylamide in food, its formation during cooking, its effect on health, and cooking methods that can reduce acrylamide levels in foods. The FDA has not advised the public to stop eating foods that contain acrylamide. This research may form the basis for

more specific dietary advice or federal regulation of specific food products in the future. [¶] In the interest of promoting overall good health, the FDA recommends eating a balanced diet that includes foods high in dietary fiber, like fruits, beans, vegetables, and whole grains."

In March 2016, the FDA issued its Guidance for Industry, Acrylamide in Foods, in which it outlined ways that growing conditions of crops and industrial food processing can be modified to reduce the production of acrylamide. In the section concerning cereal-based food, including "breakfast cereals," the report states, "Reducing whole grain content may also reduce acrylamide [citations], but FDA does not recommend this approach given the benefits of whole grains [citations]."

Similarly, the OEHHA Web site FAQ's on acrylamide and Proposition 65 provides guidance on cooking methods that reduce the production of acrylamide during cooking. The FAQ's summarize cooking recommendations offered by the U.S. National Toxicology Program and provides links to the FDA's 2010 dietary guidelines for further reading.[1]

B. Petitioners' Motion for Summary Judgment

Petitioners moved for summary judgment on two distinct grounds. First, they contended that Dr. Sowinski's claim seeking to require Proposition 65 acrylamide warning labels on their cereals is expressly preempted by the Nutritional Labeling and Education Act (NLEA), title 21 United States Code section 343-1(a), because such warnings are not identical to the FDA's regulations authorizing certain health claims on cereals. Second, Petitioners contended that Dr. Sowinski's claim is preempted because a Proposition 65 warning would pose an obstacle to

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[1] See <https://oehha.ca.gov/proposition-65/acrylamide-frequently-asked-questions> (as of June 1, 2018).

Congress' nutrition policies and programs aimed to increase Americans' consumption of whole grain cereals containing fiber and important vitamins and minerals. Petitioners' obstacle preemption argument is based on the FDA's advice letters to California regulators and several federal statutes and regulations establishing policies to promote the consumption of whole grains and the vitamins and minerals they contain to improve public health.

C. The Trial Court's Summary Judgment Ruling

The court denied Petitioners' motion for summary judgment on both grounds. First, the court ruled that Petitioners "have not satisfied their burden [of showing] that the Proposition 65 claim in this case is expressly preempted by federal law." Second, the court ruled that Petitioners failed to satisfy their burden of showing that "conflict preemption applies." Petitioners challenge only the trial court's ruling on conflict preemption.

The trial court began its analysis of conflict preemption by stating, "The question thus becomes whether Proposition 65's acrylamide warning requirement either renders it impossible for the Defendants to comply with both state and federal requirements, or otherwise stands as an obstacle to the accomplishment and execution of the full purposes and objectives o[f] Congress."

The trial court judicially noticed and extensively quoted from the FDA's guidance concerning acrylamide, and the OEHHA's incorporation of FDA guidance. The court considered obstacle preemption in light of that evidence and concluded, "California's Proposition 65 acrylamide warning requirement, as set forth in the operative complaint, would not stand as an obstacle to the accomplishment and full purposes and objectives of the federal government in encouraging the consumption of whole grains (pursuant to the statutes referenced *supra*). This is

because there has been no acrylamide warning *requirement* at the federal level. None of the items for which Defendants seek judicial notice prohibit California from requiring such a warning under Proposition 65. Importantly, the fact that the FDA itself has recognized that research is ongoing reveals that no current federal standard is in place."

Next, the trial court concluded, "Nor would it be *impossible* for Defendants to comply with both state and federal requirements. It is apparent the documents for which Defendants seek judicial notice reveal an important national policy of increasing consumers' intake of whole grains (which would include breakfast cereal). The FDA advises consumers to '[c]onsume at least half of your total grain choices as whole grains' because they 'are a source of important vitamins and minerals and are typically high in dietary fiber, too.' The FDA has assisted HHS [U.S. Departments of Health and Human Services] in articulating a national health goal of doubling the average intake of whole grains by Americans. Again, though, it would not be *impossible* for Defendants to comply with Proposition 65 and the federal policies encouraging consumption of whole grains. Proposition 65 is a warning requirement on the presence of acrylamide; it does not purport to establish any nutritional guidelines. The acknowledgment by the FDA itself that it is waiting for new research results *before considering* whether new advice on acrylamide is needed shows that there is no conflict preemption at this time. [¶] Further, the fact that the FDA has commented that breakfast cereals, among other foods, 'are larger sources of acrylamide in the diet,' and that reducing consumption of such foods is one way to reduce acrylamide intake, at the very least, shows that the research is unresolved. In any event, though, this also illustrates that it is not 'impossible' for Defendants to comply with state and federal

requirements. At best, this is an 'ambiguous case,' such that the Court is 'reluctant to infer preemption[.]' " (Fns. omitted.)

We pause to note that the court's paraphrasing of the FDA's advice is misleadingly incomplete. The cited FDA document states, "Some foods are larger sources of acrylamide in the diet, including certain potato products (especially French fries and potato chips), coffee, and foods made of grains (such as breakfast cereal, cookies, and toast). These foods are all part of a regular diet. However, if you want to lower acrylamide intake, reducing consumption of these foods is one way to do so, keeping in mind that its best to limit intake of foods that are high in saturated fats, *trans* fats, cholesterol, salt (sodium), and added sugars. *FDA does not recommend reducing intake of healthful grain products (e.g., whole grain cereals) that are a good source of whole grains and fiber*." (Second italics added.)

At oral argument, Dr. Sowinski's counsel contended the FDA's use of the adjective "healthful" was intended to distinguish between healthful and unhealthful whole grains. We disagree. The parenthetical that follows, "(e.g., whole grain cereals)" undercuts the interpretation Dr. Sowinski urges. Viewing the document as a whole, the FDA advises consumers to reduce their consumption of foods like potato chips, french fries and coffee, but not cereals rich in whole grains or fiber. Indeed, the two pages (of the three-page document) that immediately follow the quote describe how toast should be prepared to a "light brown" instead of "dark brown," and french fries should be baked rather than fried and prepared to a "golden yellow" rather than "brown." There is no discussion of whole grain cereals, let alone any distinction made between healthful and unhealthful whole grain cereals.

D. Petition for Writ of Mandate

As noted, Petitioners challenge only the trial court's ruling on obstacle preemption. They contend the court mistakenly applied only the impossibility test for conflict preemption, even when it purported to apply the obstacle preemption test. As a result, Petitioners contend, the trial court failed to consider the FDA's balancing of the federal statutory goal of promoting the consumption of whole grains with the goal of protecting consumers' health, FDA's nuanced approach to accomplishing the purposes and objectives of Congress, and the obstacle Proposition 65 warnings would pose to that scheme.

E. Real Party Dr. Sowinski's Return

In his return to our order to show cause, Dr. Sowinski asserts that Petitioners' summary judgment motion "was brought on the sole ground of federal preemption pursuant to Nutritional Labeling and Education Act of 1990." That is incorrect. Petitioners based their *express* preemption argument on the NLEA, but based their *obstacle* preemption ground for summary judgment on federal statutes and regulations the trial court found to have established an important national policy of increasing consumers' intake of whole grains. We highlight this distinction because Dr. Sowinski contends the NLEA's savings clause precludes preemption of Proposition 65 warnings by that statute.[2] Dr. Sowinski also asserts that Proposition 65 warnings

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[2] In support, Dr. Sowinski quotes the trial court's *tentative* order that framed Petitioners' obstacle preemption argument as presenting the issue of whether a Proposition 65 warning would pose "an obstacle to the accomplishment and execution of the full purposes and objectives o[f] Congress *in enacting the NLEA*." (Italics added.) In its finalized order, the trial court corrected this error by deleting the italicized reference to the NLEA. Moreover, the portions of the trial court's order Dr. Sowinski

cannot conflict with the NLEA because the Act " 'does not in any way regulate carcinogens or other, non-nutritive substances in foods,' " quoting *Sciortino v. Pepsico, Inc.* (N.D.Cal. 2015) 108 F.Supp.3d 780, 806 (*Sciortino*).[3]

Dr. Sowinski also contends the trial court correctly held that obstacle preemption was not triggered because it would not be impossible for Petitioners to comply with both state and federal labeling requirements. In addition, Dr. Sowinski contends that even if conflict preemption applies, disputed issues of material fact precluded summary judgment because not all of Petitioners' 59 cereals at issue contain whole grains or are eligible for a "health claim."

At oral argument, Dr. Sowinski's counsel suggested there could be no conflict between a Proposition 65 warning and federal law because only some whole grain cereals contain acrylamide, and consumers should be able to determine which ones do not.[4]

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relies upon are drawn from the court's ruling that NLEA did not *expressly* preempt a Proposition 65 warning for acrylamide, and are not relevant to Petitioners' conflict preemption contentions.

[3] Even if the NLEA were at issue, *Sciortino* does not support Dr. Sowinski's contention. *Sciortino* held that a Proposition 65 warning claim based on a color additive in soda was not preempted because it did not pose an obstacle to federal rules establishing unsafe levels for that color additive. (108 F.Supp.3d at p. 810.) Not surprisingly, no federal laws or policies promoting the consumption of soda were identified for the court.

[4] Dr. Sowinski's counsel did not identify any whole grain cereals that do not contain acrylamide, but the FDA's digest of several studies lists only a few common breakfast foods that contain nondetectable amounts of acrylamide, including oatmeal, white enriched bread, hominy (corn) grits, and cream of wheat.

This ignores the FDA's expertise on consumer behavior. The FDA explained, "[A] requirement for warning labels on food might deter consumers from eating foods with such labels. Consumers who avoid eating some of these foods, such as breads and cereals, may encounter greater risks because they would have less fiber and other beneficial nutrients in their diets. For these reasons, premature labeling requirements would conflict with FDA's ongoing efforts to provide consumers with effective scientifically based risk communication to prevent disease and promote health."[5]

At oral argument, Dr. Sowinski's counsel also suggested that a Proposition 65 warning would encourage cereal producers to reformulate their cereals to reduce the amounts of acrylamide they contain. In its letters to California regulators, the FDA expressly stated it wanted to avoid premature efforts at reformulation: "In addition, any warning label requirements imposed under Proposition 65 might encourage manufacturers to take premature steps to remove acrylamide from food by introducing additives or changing cooking processes. Such steps

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(See <https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm053566.htm> [as of June 1, 2018].)

[5] Neither party addressed whether a Proposition 65 warning on whole grain cereals would lead to labels on other foods, but this presents a concern. Proposition 65 warnings on foods containing acrylamide above California's nonsignificant risk levels would cause many otherwise healthy foods to appear to consumers to be unhealthful and vice versa. Peanut butter, rye bread, whole wheat bread, sunflower seeds, sweet potatoes, and prune juice would bear Proposition 65 warnings. But hot dogs, bologna, salami, pork sausage, canned refried beans, frozen chicken pot pie, and macaroni and cheese would not. (See <https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm053549.htm> [as of June 1, 2018].)

could have unforeseen adverse consequences on public health if the consequences of these changes o[r] the introduction of other health hazards are not scientifically and thoughtfully considered. Currently, not enough is known about acrylamide formation to identify safe, effective, and practical modifications to food processing techniques that will clearly prevent or reduce formation. Studies on formation and methods to reduce acrylamide are currently underway in many labs around the world including the FDA's National Center for Food Safety and Technology."

These studies are ongoing. The FDA published its Guidance for Industry, Acrylamide in Foods in March 2016 and invited comments. The guidance, which draws from dozens of studies from around the world, explains, "Acrylamide reduction is an area of ongoing research, and some approaches discussed may still be at a research stage, rather than in general use." The guidance "provides information to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods." The eight-page section devoted to cereal-based foods, including breakfast cereals, discusses possible changes to ingredients and cooking techniques, but some of these involve trade-offs. For example, the FDA noted that in breakfast cereals, sodium chloride can reduce acrylamide formation, but cautioned that "Sodium chloride also may mitigate acrylamide in breakfast cereals [citation], but avoidance of excess dietary sodium also should be considered."[6] The FDA states it "will update this

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[6] With respect to wheat, the FDA concluded (based on a British study) that soil with adequate sulfates and without excessive nitrogen fertilization produces less asparagine, from which acrylamide is formed, and "may help reduce acrylamide in cereal-based foods." Other studies show some varieties of wheat produce less asperagine. The FDA guidance discusses one of the

guidance as needed to reflect new developments in the field of acrylamide reduction." Notably, in its 2003 letter to California regulators, the FDA expressed concern that a warning "might discourage manufacturers from sharing data with FDA or with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), which is running the Acrylamide InfoNet for FAO/WHO. Such data would be helpful to FDA in its exposure and risk assessments for acrylamide."

DISCUSSION

I. Standard of Review

"Since a motion for summary judgment or summary adjudication 'involves pure matters of law,' we review a ruling on the motion de novo to determine whether the moving and opposing papers show a triable issue of material fact." (*Travelers Casualty & Surety Co. v. Superior Court* (1998) 63 Cal.App.4th 1440, 1450.) Under Code of Civil Procedure section 437c, a defendant may move for summary judgment on the grounds that there is a complete or affirmative defense to the action. (Code Civ. Proc., § 437c, subd. (o)(2).) Once a defendant meets the burden of establishing the elements of the affirmative defense, the burden shifts to the plaintiff to show that there are triable issues of one or more material facts regarding the affirmative defense. To survive summary judgment, the plaintiff must adduce admissible evidence showing the existence of such material issues of fact. (Code Civ. Proc., § 437c, subd. (c).)

"most effective practices adopted by manufacturers" of cookies, chips and pretzels that involves treating dough with asparaginase, which reduced acrylamide by 35 to 90 percent. However, the method is ineffective on whole grains because of "limited penetration of asparaginase into the product."

II. Federal Preemption

Federal preemption of state law under the supremacy clause of the United States Constitution, article VI, clause 2, " 'may be either express or implied, and "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." ' " (*Shaw v. Delta Air Lines, Inc.* (1983) 463 U.S. 85, 95.)

" 'In determining whether federal law preempts state law, a court's task is to discern congressional intent. [Citation.] Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority. [Citation.] Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) when compliance with both federal and state regulations is an impossibility [citation]; or (iii) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." ' " (*Eckler v. Neutrogena Corp.* (2015) 238 Cal.App.4th 433, 447.)

Petitioners challenge only the trial court's ruling on obstacle preemption. Whether state law poses an obstacle to accomplishing the purposes of federal law "is a matter of judgment," "informed by examining the federal statute as a whole and identifying its purpose and intended effects." (*Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 373 (*Crosby*).) If, after examining the "entire scheme" of the federal law, the court determines that its purpose and operation are frustrated by the state law, then the state law is preempted. (*Ibid.*) Even if a state statute "attempts to achieve one of the same goals as federal law," it may still be preempted because "a '[c]onflict in technique can be fully as disruptive to the system

Congress erected as conflict in overt policy.' " (*Arizona v. United States* (2012) 567 U.S. 387, 406, quoting *Motor Coach Employees v. Lockridge* (1971) 403 U.S. 274, 287.) "Where a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, *then* the pre-emptive inference can be drawn—not from federal inaction alone, but from inaction joined with action." (*Puerto Rico Dept. of Consumer Affairs v. Isla Petroleum Corp.* (1988) 485 U.S. 495, 503.)

When evaluating conflict preemption, courts have recognized that administrative agencies possess "a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " (*Wyeth v. Levine* (2009) 555 U.S. 555, 577.) For that reason, courts give weight to the determinations of the agency charged with administering the federal statutory and regulatory scheme, especially when "the subject matter is technical; and the relevant history and background are complex and extensive." (*Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, 883 (*Geier*).)[7]

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[7] In *Geier*, the Supreme Court held that state tort claims premised on Honda's failure to install airbags conflicted with a federal regulation that did not require airbags for all cars. The Department of Transportation had promulgated a rule that provided car manufacturers with a range of choices among passive restraint devices. (*Geier*, *supra*, 529 U.S. at p. 875.) Rejecting an " 'all airbag' " standard, the agency had called for a gradual phase-in of a mix of passive restraints in order to spur technological development and win consumer acceptance. (*Id.* at p. 879.) Because the plaintiff's claim was that car manufacturers had a duty to install airbags in all vehicles, it presented an obstacle to achieving "the variety and mix of devices that the federal regulation sought." (*Id.* at p. 881.)

III. Proposition 65

"Passed in 1986 by California voters to protect the health and safety of Californians, Proposition 65 requires California to create and maintain a list of chemicals 'known to the state to cause cancer or reproductive toxicity.' [Citation.] The statute provides: '[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual,' unless a specified exemption applies. [Citation.]" (*Physicians Committee For Responsible Medicine v. McDonald's Corp.* (2010) 187 Cal.App.4th 554, 566.) The Proposition 65 list identifies acrylamide as a chemical known to cause cancer and reproductive harm.

IV. Nutrition Labeling and Education Act of 1990

"The purpose of the NLEA was to create uniform national standards regarding the labeling of food and to prevent states from adopting inconsistent requirements with respect to the labeling of nutrients. [Citation.] To that end, the NLEA included an explicit preemption provision in the form of section 343–1(a) [citation], which provides that 'no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—[¶] . . . [¶] (3) any requirement for the labeling of food of the type required by section . . . 343(k) of this title that is not identical to the requirement of such section . . . .' [Citation.]" (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1086.)

Dr. Sowinski contends that Proposition 65 warning labels are exempted from preemption by the NLEA's savings clause. NLEA section 6(c)(2), states that NLEA's preemption clause "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning

concerning the safety of the food or component of the food." (Pub.L. No. 101-535 (Nov. 8, 1990) 104 Stat. 2353, § 6(c)(2).) At oral argument, Dr. Sowinksi's counsel urged us to read section 6(c)(2) broadly to cover "any form of preemption" and conclude that "Proposition 65 is exempt as it relates to food." Dr. Sowinski ignores the next paragraph of section 6(c), which states that paragraph "(2) of this subsection shall not be construed to affect preemption, express or implied, of *any such requirement* of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action. . . ." (Pub.L. No. 101–535, § 6(c)(3) (Nov. 8, 1990) 104 Stat. 2364, italics added.) "[T]he phrase 'any such requirement' in NLEA section 6(c)(3) refers to the 'requirement' discussed in NLEA section 6(c)(2)" exempting state food safety warnings from preemption. (*Farm Raised Salmon Cases*, *supra*, 42 Cal.4th at p. 1093.) Because Petitioners' obstacle preemption affirmative defense is based not on the NLEA but on a host of other federal laws and regulations promoting the consumption of whole grains, the savings clause in NLEA section 6(c)(2) does not "affect preemption, express or implied" of state laws by those other federal laws and regulations.[8]

V. Trial Court's Obstacle Preemption Ruling

The trial court judicially noticed and summarized the federal statutory directives promoting whole grains in Americans'

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[8] *Sciortino*, the federal district court case cited by Dr. Sowinski, also read NLEA's section 6(c)(2) and (c)(3) to mean that the "safety warning assertedly required under California law may be subject to implied preemption by a federal law that pre-dates (and was left unamended by) the NLEA." (*Sciortino*, *supra*, 108 F.Supp.3d at p. 808.)

diets that Petitioners rely on: "Defendants reference, among others, the following federal policies promoting consumption of whole grains: 7 U.S.C. §5341 (authorizing the establishment of 'Dietary Guidelines for Americans,' one such guideline encourages Americans to eat at least 48 grams of whole grains per day); 42 U.S.C. §300u(a)(l)-(4), (10)-(11) (part of the Healthy People Initiative, which establishes a national health goal of nearly doubling the average whole grains intake by Americans); 42 U.S.C. §300u-3 ([creating] the FDA to establish consumer education, pursuant to which the FDA encourages Americans to '[s]tart [the] day with a bowl of whole grain breakfast cereal . . . that is high in dietary fiber and low in added sugars'); and 42 U.S.C. §1786 and 7 C.F.R. §246.l0 (the Special supplemental nutrition program for women, infants, and children ('WIC')) (setting guidelines of less than 6 grams of sucrose and other sugars per dry ounce of cereal; and mandating that at least half of the cereals authorized on a State Agency's food list have at least 51% whole grain, be low in saturated fat and cholesterol, bear quantitative trans fat labeling, and contain less than 6.5 grams of total fat and 0.5 grams or 6 less of trans fat)." The trial court concluded it is "apparent the documents for which Defendants seek judicial notice reveal an important national policy of increasing consumers' intake of whole grains (which would include breakfast cereal)."

The trial court also concluded, however, that a Proposition 65 warning "would not stand as an obstacle to the accomplishment and full purposes and objectives of the federal government in encouraging the consumption of whole grains (pursuant to the statutes referenced *supra*). This is because there has been no acrylamide warning *requirement* at the federal level. None of the items for which Defendants seek judicial notice prohibit California from requiring such a warning under

Proposition 65. Importantly, the fact that the FDA itself has recognized that research is ongoing reveals that no current federal standard is in place."

The trial court correctly articulated the rule that, " 'Conflict preemption exists: (1) where it is impossible for a private party to comply with both state and federal requirements; or (2) where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " But by requiring Petitioners to identify a conflicting federal acrylamide warning or a formal prohibition on a Proposition 65 warning for acrylamide, the court applied only the impossibility strand of conflict preemption and failed to consider obstacle preemption. Having determined that Congress enacted several laws establishing an "important national policy of increasing consumers' intake of whole grains (which would include breakfast cereal)," the court's next task was to determine whether the purpose and operation of those laws would be "frustrated" by a Proposition 65 warning. (*Crosby*, *supra*, 530 U.S. at p. 373.)

We agree with the parties and the trial court that the California Supreme Court's ruling in *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910 (*Dowhal*) guides our decision here. In *Dowhal*, the FDA rejected a proposed Proposition 65 warning label on nicotine patches used to stop smoking, concerned that it might "lead pregnant women to believe that [the] products were as dangerous as smoking," and discourage them from quitting. (*Dowhal*, *supra*, at p. 929.) In a one-page advice letter the FDA approved language that encouraged pregnant women to stop smoking, indicated nicotine patches are believed to be safer than smoking, and stated their risks were not fully known. (*Id.* at p. 922.) *Dowhal* held that this determination, made in a short FDA advisory letter, had preemptive effect because a Proposition 65 warning would pose

an obstacle to the FDA's objective of encouraging smoking cessation. (*Dowhal*, *supra*, at p. 935.) The Court noted, "The mere existence of the risk . . . is not necessarily enough to justify a warning; the risk of harm may be so remote that it is outweighed by the greater risk that a warning will scare consumers into foregoing use of a product that in most cases will be to their benefit." (*Id.* at p. 934.)

Dr. Sowinski contends *Dowhal* "very specifically" held that due to the savings clause in the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. § 379r(d)(2) (Modernization Act)), conflict preemption "could only arise as to Proposition 65 if the FDA had adopted a specific warning and the Proposition 65 warning actually conflicted with it." (Bold omitted.) Dr. Sowinski misreads *Dowhal*. In its discussion of the effect of the Modernization Act's savings clause on conflict preemption, the Supreme Court concluded "that *Geier* is not a narrow holding limited to automobile safety standards; instead it established a general rule upholding conflict preemption even if the applicable federal law contains a savings clause." (*Dowhal*, *supra*, 32 Cal.4th at p. 926.) Then, based on the language and legislative history of the Modernization Act's savings clause, the Court held that it precludes conflict preemption *only* when the federal policy of uniform labeling forms the basis of the purported conflict. *Dowhal* explained, "The language of the Modernization Act's savings clause does not express an intention to preclude all conflict preemption. The legislative history suggests an intent to preclude conflict preemption in pursuit of national uniform labeling." (*Dowhal*, *supra*, at p. 926.) In support, *Dowhal* quotes Senator Barbara Boxer's statement during floor debate on the Act, that the savings clause was intended to ensure "that California's proposition 65 will not be preempted by the uniformity provisions of this bill . . . ." (*Id.* at p. 926, fn. 6.) The

Court concluded that while "a Proposition 65 warning cannot be preempted solely because it is not identical with the federal requirement," it *could* be preempted "on a basis relevant to consumer health." (*Id.* at p. 926.)

Significant for our decision here, *Dowhal* gave substantial deference to the FDA's deliberate risk-benefit balancing. The Court noted the FDA's concern that a Proposition 65 warning on nicotine patches might be misleading and cause an unintended negative effect on consumers' choices: "Whether a label is potentially misleading or incomprehensible is essentially a judgment of how the consumer will respond to the language of the label. As we have noted, a truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision. The authority of the FDA, we conclude, extends to barring warnings that are misleading in this fashion." (*Dowhal*, *supra*, 32 Cal.4th at p. 934.)

Here, the FDA's policy, described in its advisory letters to California's regulators and Attorney General, is that no Proposition 65 warning for acrylamide should be placed on foods, including breakfast cereals, unless and until the science supports such a warning. Even then, the FDA may, as it does with *trans* fats, require producers to identify foods that contain acrylamide and the amount, and educate the public about the risks and benefits of various types of breakfast cereals based on quantities consumed.

The trial court did not ignore the FDA's letters, but it also appears not to have given them much, if any, weight. In *Dowhal*, the Court rejected the plaintiff's argument that the FDA's letter responding to a citizen petition was too informal to prohibit the defendants from complying with Proposition 65. The Court concluded "that the FDA's . . . letter established a federal policy

prohibiting defendants from giving consumers any warning other than the one approved by the FDA in that letter, and that the use of a Proposition 65 warning would conflict with that policy." (*Dowhal*, *supra*, 32 Cal.4th at p. 929.) Thus, the Court found that the FDA's letter was sufficient to articulate a policy that it found to have a preemptive effect. (*Ibid*.)

The trial court was entitled to ignore the FDA's legal conclusion that Proposition 65 as applied to acrylamide is preempted by its regulatory scheme. (See *Wyeth v. Levine*, *supra*, 555 U.S. at p. 576 ["we have not deferred to an agency's *conclusion* that state law is pre-empted"].) But it should have given weight to the FDA's analysis and concerns regarding a Proposition 65 warning and the obstacles it would pose to the fulfillment of its statutorily-driven dietary goals. Courts are to focus on "an agency's explanation of how state law affects the regulatory scheme. While agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " (*Wyeth v. Levine*, *supra*, at pp. 576-577.) "The weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness." (*Id*. at p. 577.)

Here, the FDA's July 2003 and March 2006 letters were thorough, consistent, and contained persuasive reasoning why Proposition 65 acrylamide warnings on whole grain cereals would mislead consumers and lead to health detriments. Dr. Sowinski characterizes them as "old letters," but California regulators complied with them, so the FDA had no reason to issue further advice letters regarding Proposition 65 warnings for acrylamide.

Indeed, to this day, the OEHHA's Proposition 65 web page dedicated to acrylamide quotes from and refers to the FDA's advice providing a balanced approach. And the FDA's March 2016 Guidance for Industry, Acrylamide in Foods shows that acrylamide research is ongoing. The FDA quotes the conclusion of the World Health Organization/FDA Joint Expert Committee on Food Additives "that acrylamide may be 'a human health concern' " and states that the "FDA is not suggesting maximum recommended levels for acrylamide in various products at this time." This shows that the FDA continues to execute on the strategy outlined in its advice letters and has not endorsed California's 0.2 microgram/day standard that would require many foods to be labeled.

Petitioners offer as a parallel example a case concerning mercury in tuna, in which California regulators disregarded the FDA's advice and sued tuna canneries to require Proposition 65 warnings. Two excerpts from the FDA's advice letters illustrate the problem with placing Proposition 65 warnings on otherwise healthy foods that contain a chemical that poses health risks. First, the FDA explained, "The warnings that would be required on the defendants' products if the lawsuit is successful are some derivation of the following: 'WARNING: This product contains a chemical known to the State of California to cause cancer,' and 'WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.' [¶] FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly, federal law preempts these Proposition 65 warnings concerning mercury and mercury compounds in tuna."

After detailing for several pages the studies the FDA had conducted and the balancing it had undertaken before determining its approach, the letter states, "the Proposition 65 warnings purport to convey factual information, namely that methylmercury is known to cause cancer and reproductive harm. However, it is done without any scientific basis as to the possible harm caused by the particular food in question, or as to the amounts of such foods that would be required to cause this harm. Stated differently, these warnings omit facts which are necessary to place the information in its proper context. As a result, FDA believes that the Proposition 65 warnings are misleading under section 403 of the Act, causing tuna products with such warnings to be misbranded under federal law."

Following a bench trial, the superior court found that mercury was naturally occurring in tuna and thus exempt from Proposition 65. The court also ruled that "any Proposition 65 compliant warning would frustrate the purpose and objectives of the FDA's carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish . . . and thus Proposition 65 as applied to the Tuna Companies . . . was preempted by federal law." (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1559–1560 (*Tri-Union*).) The trial court relied on the FDA's advisory letter, explaining that "requiring Proposition 65 warnings would frustrate the agency's carefully nuanced approach 'to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts these Proposition 65 warnings concerning mercury and mercury compounds in tuna.' " (*Id.* at p. 1560.) "The trial court's preemption ruling also leaned heavily on [*Dowhal*'s conclusion] that the FDA's approach to warnings on nicotine replacement therapy products embodied a nuanced goal that was in conflict with California's single-

minded goal of informing consumers of the products' risks." (*Ibid.*)[9]

Here, the trial court found the federal statutes cited by Petitioners' evidence "an important national policy of increasing consumers' intake of whole grains (which would include breakfast cereal)." But then the court failed to determine whether a Proposition 65 warning for acrylamide on breakfast cereals would frustrate that policy, and failed to give weight to the FDA's advice letters describing how a Proposition 65 warning would mislead consumers and undermine federal objectives. We conclude that Petitioners' summary judgment motion papers established that a Proposition 65 warning for acrylamide on breakfast cereals would pose an obstacle to the federal scheme and therefore is preempted by federal law.

We are left to address Dr. Sowinski's contention that even if conflict preemption applies, disputed issues of material fact precluded summary judgment because not all of Petitioners' 59 cereals at issue contain whole grains or are eligible for a health claim. Dr. Sowinski is correct that 10 of Petitioners' breakfast cereals do not contain whole grains, but each of these cereals carries another ingredient that qualifies it for a health claim. Seven cereals, Frosted Flakes, Kellogg's Corn Flakes, Cocoa Pebbles, Fruity Pebbles, Rice Krispies, Crispix, and Special K qualify for health claims because they contain lipids and folic acid. The other three, All-Bran, All-Bran Buds, and Corn Pops contain dietary fiber, lipids, and folic acid.

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[9] The Court of Appeal did not address the issue of federal preemption. Instead, it affirmed the judgment solely on the ground that substantial evidence supported the trial court's finding that methylmercury in tuna is naturally occurring and thus exempt from Proposition 65 warning requirements. (*Tri-Union*, *supra*, 171 Cal.App.4th at p. 1576.)

The FDA advisory letters identified whole grain cereals as its chief concern, but also expressed concern for cereals with fiber and other nutrients: "Consumers who avoid eating some of these foods, such as breads and cereals, may encounter greater risks because they would have less fiber and *other beneficial nutrients* in their diets. For these reasons, premature labeling requirements would conflict with FDA's ongoing efforts to provide consumers with effective scientifically based risk communication to prevent disease and promote health." (Italics added.) Notably, the trial court judicially noticed several FDA nutritional guidelines that identify folic acid and dietary lipids as qualifying for health claims, and stated: "The FDA has issued certain health claims regarding food with nutrients that may reduce the risk of cancer and neural tube birth defects. As Defendants point out, the FDA allows health claims associating low fat diets with a reduced risk of cancer (see 21 C.F.R. §101.73(e)(2), addressing health claims on the relationship between dietary lipids and cancer); . . . and health claims involving folate and neural tube defects (see 21 C.F.R. §101.79)."

If Dr. Sowinski believed disputed material facts precluded summary judgment on Petitioners' affirmative defense of federal preemption, it was his burden to raise them in the trial court. Instead, in opposing summary judgment Dr. Sowinski contended in his response to Petitioners' separate statement that none of the health claims identified above was a material fact because the "presence of 'nutrients' in some cereals is not an issue in this litigation." "When a defendant moves for summary judgment on the ground there is an affirmative defense to the action, the burden shifts to the plaintiff to show there is one or more triable issues of material fact regarding the defense after the defendant meets the burden of establishing all the elements of the

affirmative defense." (*Jessen v. Mentor Corp.* (2008) 158 Cal.App.4th 1480, 1484.) Dr. Sowinski did not carry that burden.

DISPOSITION

The petition for writ of mandate is granted. Let a peremptory writ of mandate issue, directing the trial court to vacate its June 27, 2017 order denying Petitioners' motion for summary judgment and to issue a new and different order granting same. Petitioners are entitled to recover costs on appeal.

CERTIFIED FOR PUBLICATION

CHANEY, J.

We concur:

ROTHSCHILD, P. J.

JOHNSON, J.