Food, Drug, Cosmetic Cos. Should Expect More Additive Suits

By **Connor Sears** (August 26, 2022)

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The U.S. Food and Drug Administration is given the "responsibility to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled."[1] Under that power, the FDA has approved many additives and excipients as being safe to use in the manufacture of drugs, cosmetics and food.

Yet recently, there appears to be a trend of cases filed against food, pharmaceutical and cosmetic manufacturers and distributors that assert a variety of claims that center around the allegation that an FDA-approved additive or excipient causes negative health effects.[2]

Moreover, many of these lawsuits note that the FDA-approved additive or excipient has been banned or limited in other countries because of health concerns.

For example, in Thames v. Mars Inc., filed in the U.S. District Court for the Northern District of California on July 14, the plaintiffs assert that a coloring additive used for food — titanium dioxide — causes a variety of adverse health consequences. The complaint alleges that the European Food Safety Authority determined that titanium dioxide causes genotoxicity and, consequently, is not safe for consumption.

The plaintiffs seek class certification for: (1) violation of California's Unfair Competition Law; (2) violation of the Consumers Legal Remedies Act; (3) breach of implied warranty; (4) violation of California's False Advertising Law; (5) fraud; (6) fraudulent inducement; (7) fraudulent omissions or concealment; and (8) breach of quasi-contract and unjust enrichment. Additionally, the plaintiffs seek punitive damages.

Likewise, in Environmental Health Advocates Inc. v. Sephora USA Inc., filed on May 5 in the Superior Court of the State of California in and for the County of San Francisco, the plaintiffs allege that a variety of cosmetics contain titanium dioxide, which violates California's Proposition 65 because it exposes customers to a known carcinogen without an adequate warning.

As another example, in Stuve v. Kraft Heinz Co., filed in the U.S. District Court for the Northern District of Illinois on April 6, 2021, the plaintiffs assert that as a result of the manufacturing process, phthalates end up in the defendants' macaroni and cheese product, and that phthalates cause a variety of health issues.

In making that claim, the complaint notes that the European Parliament endorsed a bar on certain types of phthalates in toys and child care products.

In Stuve, the plaintiffs seek class certification for: (1) violations of deceptive and unfair

trade practices acts; (2) false advertising; (3) unjust enrichment; (4) breach of express warranty; (5) breach of implied warranty; and (6) violations of fraud and deceptive trade practices acts.

In addition to noting the FDA's disparate treatment of various additives and excipients compared to other countries' administrative bodies, these lawsuits appear to be driven by recent studies and literature that suggest links between various additives and excipients and health issues.[3]

Because this trend of additive- and excipient-related lawsuits appears to be targeted to additives that are banned or limited in other countries and have studies or literature that suggest adverse health effects, one question is what other types of additive- and excipient-related lawsuits might be filed in the future.

There are numerous articles listing a wide variety of additives that are FDA-approved, yet limited or banned in other countries.[4] Some of the common additives mentioned include: astaxanthin, rBST, rBGH, brominated vegetable oil, Yellow 5, Yellow 6, Red 40, azodicarbonamide, BHT and potassium bromate.

These additives are used in a wide variety of food products, including fish, cereal, meat, dairy, candy, drinks, pastries, crackers and bread; cosmetics; and pharmaceuticals. Additionally, other excipients that have been mentioned in recent literature include those that are used in a wide variety of pharmaceuticals, such as propyl gallate, butylparaben and thimerosal.

Considering the wide scope of products that may face future lawsuits, manufacturers and distributors may be curious about how courts have treated similar lawsuits.

Thames, Environmental Health Advocates and Stuve are all in the incipient stage of the lawsuit, and the courts have not addressed any motions to dismiss or other dispositive motions. Consequently, those cases do not provide guidance for how courts may address these types of cases.

Cases involving partially hydrogenated oil, or PHO, however, may provide guidance. In the mid-to-late 2010s, there were a handful of cases filed involving food products that contained PHO, which contains trans fat.

The cases asserted that in 2015, the FDA determined that PHO is unsafe for food. Yet Congress passed a bill stating that PHOs were permissible in food products until 2018.

One example of these types of cases is Hawkins v. Kellogg Co., filed on Jan. 21, 2016, in the U.S. District Court for the Southern District of California. In Hawkins, the plaintiff alleged that a variety of cookies manufactured by Kellogg contained PHOs, which are banned in many parts of the world as a carcinogen.

The plaintiff cited literature discussing the harmful effects of trans fat, and alleged that in 2015, the FDA determined that PHO is unsafe for use in food, and causes a variety of adverse health effects. In the complaint, the plaintiff sought class certification for unfair practices, unlawful practices, nuisance and breach of implied warranty of merchantability.

Kellogg filed a motion to dismiss the complaint. In the motion to dismiss, Kellogg argued that:

- The plaintiff lacked Article III standing to challenge the inclusion of PHOs in food, because the plaintiff had not suffered any physical or emotional injury;

- The plaintiff's claims were preempted under the supremacy clause, because Congress passed a bill stating that PHOs were permissible in food products until 2018;

- The plaintiff could not plausibly allege any unlawful or unfair act, because PHO use was lawful;

- The plaintiff's claims were barred by the primary use doctrine;[5]

- The plaintiff failed to state a claim for nuisance, because plaintiff had not suffered special injury;

- The plaintiff failed to state a claim for breach of implied warranty of merchantability, because the products were fit for their intended use; and

- The plaintiff lacked standing to pursue injunctive relief.

The court granted Kellogg's motion, and dismissed the complaint with prejudice.

In making its ruling, the court found that the plaintiff sufficiently alleged a physical injury, but failed to allege economic injury, because there was not false or misleading information advertised on the product, the plaintiff ate the cookies and the plaintiff received the benefit of the bargain.

The court found there was Article III standing. Even so, the court dismissed the complaint based on preemption. The court noted that PHOs were specifically allowed until 2018. Because of that, until 2018, products containing PHOs did not violate federal law, and the plaintiff's claims were preempted.

Hawkins may be predictive of how courts may treat these claims. But even if a court did not find that such claims are preempted, plaintiffs may have difficulty establishing that a class action is warranted.

More specifically, common issues of law and fact may not predominate, and typicality of claims and defenses may not be met. For example, the purported injuries of the putative

class members would likely differ.

The plaintiffs would likely have disparate claims about whether they currently have a health problem, or instead are worried about a future health problem — and the claimed health problems themselves would likely differ widely. Moreover, to the extent plaintiffs are asserting health problems, there would be individualized issues about causation of the specific health problem.

For example: Did the specific plaintiff have other risk factors for the health condition? Or did that plaintiff even consume enough of the additive/excipient to be at a heightened risk of the alleged health problem? In addition, some plaintiffs may not be asserting a health problem at all, but instead may be asserting a purely economic injury.

Further, class treatment would likely be problematic when considering other issues specific to each plaintiff, such as whether a specific plaintiff had knowledge of the additive and the purported health effects — and whether, even if the plaintiff did not have knowledge, that knowledge would be material to the plaintiff in their decision to use the product.

Finally, some of these lawsuits have sought to require manufacturers or distributors to provide additional warnings about additives or excipients in products. Those sorts of claims likely raise First Amendment concerns for forced speech.

Ultimately, this trend of additive- and excipient-related lawsuits is likely to continue — and manufacturers and distributors of food, pharmaceuticals and cosmetics are likely to see some novel claims and allegations.

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[1] 21 U.S.C. § 393(b)(2)(A).

[2] Excipients are inactive substances in a drug, such as coloring agents, preservatives and fillers.

[3] See, e.g., Joshua Pottel et al., The Activities of Drug Inactive Ingredients on Biological Targets, Science, 369 (6502): 403-413 (2020).

[4] See, e.g., Common US Foods that Are Banned in Other Countries, Chicago Tribune, Nov. 3, 2021, https://www.chicagotribune.com/dining/table-talkers/sns-stacker-us-foods-banned-other-countries-20211103-gxobzgtxvnf6pnt26ugjstmxka-photogallery.html.

[5] The primary jurisdiction doctrine is a "prudential doctrine under which courts ... may determine that the initial decision making responsibility should be performed by the relevant agency rather than the courts." Syntek Semiconductor Co. v. Microchip Tech. Inc., 307 F.3d 775, 781 (9th Cir. 2002).