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Litigation Update

Recent Investigations by the Texas Attorney General Piggyback on Federal 'Make America Healthy Again' Initiatives

By Allyson Baker, Peter V. Lindsay, Avi Weitzman and Sripriya Narasimhan

Texas Attorney General Ken Paxton recently announced that his office is investigating some of the country's most ubiquitous home brands — including Colgate-Palmolive, Proctor & Gamble, and General Mills — for allegedly deceptively marketing products such as toothpaste and cereal to Texas consumers, particularly children. These investigations follow the federal government's recent growing interest in these and other products as part of the Make America Healthy Again (MAHA) initiatives launched by U.S. Secretary of Health and Human Services Robert F. Kennedy Jr.

On May 1, 2025, Attorney General Paxton announced that his office had sent civil investigative demands (CIDs) to Colgate-Palmolive and Proctor & Gamble for "marketing toothpaste products to parents and children in ways that are misleading, deceptive, and dangerous."[1] The attorney general claims that Colgate-Palmolive and Proctor & Gamble flavored their products and marketed them to "encourage kids to ingest fluoride toothpaste" and "mislead their parents" to use more toothpaste than recommended for small children by the Centers for Disease Control and the American Dental Association.[2] This, in his view, has harmed Texas children given the alleged "statistically significant association between fluoride exposure and lower IQ scores in children."[3]

Nearly two weeks later, on May 13, 2025, Attorney General Paxton sent a separate CID to General Mills based on a similar harm-to-children theory.[4] In this investigation, Attorney General Paxton claims that the food company misrepresented its food products — and, in particular, cereals like Trix and Lucky Charms — as a "good source" of vitamins and minerals and as "healthy," despite the inclusion of petroleum-based food colorings in its ingredients.[5] In addition, the attorney general faults General Mills for failing to include any warnings about the potential negative health effects of these dyes.[6]

Federal Activity

Both of these investigations follow widespread reporting that, as part of his MAHA agenda, Secretary Kennedy has taken a new interest in curbing the use of these substances in household products. In early April, Secretary Kennedy announced that he planned to "tell the Centers for Disease Control and Prevention to stop recommending fluoridation in communities nationwide" and that he will assemble a task force of health experts to study the issue and make new recommendations.[7] This announcement came on the heels of U.S. Environmental Protection Agency Administrator Lee Zeldin's press conference at which he announced that the EPA was reviewing "new scientific information" on potential health risks of

fluoride in drinking water.[8] Just a couple of weeks later, Secretary Kennedy unveiled a plan that directs the U.S. Food and Drug Administration (FDA) to revoke authorization for two synthetic food colorings and to "work with the food industry to eliminate six remaining synthetic dyes used in cereal, ice cream, snacks, yogurts, and more" by the end of next year.[9] And in his own press release about his investigation of General Mills, Attorney General Paxton stated that he is "proud to stand with the Trump Administration and Secretary Kennedy in taking on petroleum-based synthetic dyes."[10]

Hurdles Raised by Preemption

Attorney General Paxton's theory underlying both of these investigations also raises interesting questions about the scope of the FDA's authority in regulating the safety of these household products — and the ability for states to regulate alongside the FDA.

The FDA has had a long history of regulating the safety of fluoride and food dyes in household products. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act.[11] The FDCA authorized the FDA to regulate food safety and labeling — including by setting tolerance levels for poisonous substances in food and enforcing the act's ban on "misbranded" food.[12] In 1960, Congress went further and enacted the Color Additive Amendments, which subjected all food coloring to premarket approval and rigorous safety standards.[13] Then, in 1990, Congress passed the Nutrition Labeling and Education Act, which introduced a number of reforms, including requiring the FDA to regulate health claims on packages and the ingredient labels on food packages.[14]

Over-the-counter drugs, like fluoride toothpaste, are regulated by the FDA as well.[15] And the FDA's most recent monograph for these products permits the sale of toothpaste and other related products with fluoride as an active ingredient when they include claims regarding decay prevention but requires, among other things, a warning against use of excessive amounts by small children.[16]

It is unclear the extent to which Attorney General Paxton's theories of harm run headlong into the FDA's prerogative to set the outer limits for the labeling and safety requirements of these products. While it is true that courts assume that a "federal statute has not supplanted state law" in areas of traditional state regulation, such as health and safety issues,[17] "unless Congress has made such an intention clear and manifest,"[18] "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."[19] Preemption can be established in three different ways: (1) when Congress expressly displaces state law and regulation; (2) when it is impossible for a private party to comply with both state and federal requirements; and (3) when state law stands as an obstacle to the accomplishment of a particular important federal objective.

This is not the first time preemption has arisen in the intersection between state consumer-protection statutes and FDA regulations. For example, district courts have held that the NLEA preempts state consumer-protection laws that impose labeling requirements for artificial food dyes or flavoring that do not match the FDA's requirements.[20] And, similarly, courts have held that claims arising under state law as to the safety and efficacy of fluoride in toothpaste are preempted.[21] Targets of investigations and litigation arising out of state regulations that operate in the same space as the FDA's labeling or safety requirements should consider whether Congress and the FDA have acted to displace the state in this traditional space — and whether any preemption defenses are available to them.

For Attorney General Paxton's part, this approach is of a piece with his — and many other states' — theory of preemption of state regulations. Recently, Texas along with 22 other states filed an amicus brief in *GenBioPro*, *Inc*. *v*. *Raynes* in the U.S. Court of Appeals for the Fourth Circuit.[22] The states argued that the FDA's approval of mifepristone, one of two drugs used for medication abortions, does not preempt West Virginia's near total ban on the use of medication for abortions. In their view, FDA regulations set a floor for restrictions on access to drugs upon which states are free to build additional restrictions that are purportedly aimed at safety. The upshot of this view is that it is virtually impossible for state regulations

that ostensibly go to safety to come into conflict with federal law sufficient to trigger preemption principles. This case is still pending. But if that view prevails — and is applied to the food and over-the-counter drug contexts — clients should carefully consider how that rule may affect their businesses, particularly those that operate nationally.

What's Next

Texas is not the only state to turn its focus to the food dyes and fluoride that have been the focus of Secretary Kennedy's efforts to Make America Healthy Again. This year alone, lawmakers in more than 20 states — both red and blue — are pushing to legislatively restrict access to some food dyes. And both Utah and Florida have recently implemented statewide bans on the inclusion of fluoride in water systems. With this surge of interest in limiting the inclusion of these chemical compounds in our daily lives, it is possible that the same kinds of theories that have been pushed by Attorney General Paxton will be embraced by other state attorneys general.

As clients navigate this intersection of federally regulated ingredients and ubiquitous household goods, they should think critically about the additives used in their products, analyze the specific theories behind any potential investigations, and work proactively with experienced counsel to monitor and respond to state (and federal) investigations arising under these initiatives.

Moreover, companies are at increased risk of consumer class action lawsuits advanced by the plaintiff's bar based on the same theories of harm to children. Already, several such lawsuits have been filed.[23] These initiatives thus will result in multipronged exposure for companies, for which a unified strategy and approach must be considered.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

New York

Avi Weitzman
+1-212-318-6920
aviweitzman@paulhastings.com

Washington, D.C.

Allyson Baker
+1-202-551-1830
allysonbaker@paulhastings.com

Sripriya Narasimhan
+1-202-551-1869
sripriyanarasimhan@paulhastings.com

Peter V. Lindsay
+1-202-551-1922
peterlindsay@paulhastings.com

1 *Attorney General Ken Paxton Launches Investigations into Companies for Illegally Marketing Toothpaste Products Containing Fluoride to Kids*, Office of the Texas Attorney General, Press Release (May 1, 2005), *available at* https://www.texasattorneygeneral.gov/news/releases/attorney-general-ken-paxton-launches-investigations-companies-illegally-marketing-toothpaste.

2 *Id*.

3 *Id*.

[4] *Attorney General Ken Paxton Takes Action Against General Mills as Part of Investigation into the Company for Violations of Texas Law*, Office of the Texas Attorney General, Press Release (May 13, 2025), *available at* https://www.texasattorneygeneral.gov/news/releases/attorney-general-ken-paxton-takes-action-against-general-mills-part-investigation-company-violations.

[5] *Id*.

[6] *Id*.

[7] *RFK Jr. says he plans to tell CDC to stop recommending fluoride in drinking water*, The Associated Press (Apr. 7, 2025), *available at* https://apnews.com/article/fluoride-cdc-epa-6f4dbc64b5dc511f712a82cd2d252d76.

[8] *Id*.

[9] *RFK Jr. unveils plan to phase out 8 artificial food dyes in the US*, ABC News (Apr. 22, 2025), *available at* https://abcnews.go.com/US/rfk-jr-plans-phase-artificial-food-dyes-us/story?id=121034287.

[10] *Attorney General Ken Paxton Takes Action Against General Mills as Part of Investigation into the Company for Violations of Texas Law*, Office of the Texas Attorney General, Press Release (May 13, 2025), *available at* https://www.texasattorneygeneral.gov/news/releases/attorney-general-ken-paxton-takes-action-against-general-mills-part-investigation-company-violations.

[11] Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[12] 21 U.S.C. § 341, 342-43.

[13] Pub. L. No. 86-618, 74 Stat. 397 (1960).

[14] 21 U.S.C. § 343 *et seq*.

[15] These products may be the subject of a New Drug Application or, more frequently, meet the requirements of a monograph. 21 U.S.C. §§ 355, 355h.

[16] *Anticaries Drug Products for Over-the-Counter Human Use; Over-the-Counter Monograph M021* (May 2, 2023), *available at* https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2023-05/OTC%20Monograph%20M021-Anticaries%20Drug%20Products%20for%20OTC%20Human%20Use%2005.02.2023.pdf.

[17] Health and safety issues, including the regulation of food and beverage labeling and branding, have long been areas traditionally belonging to the province of state regulation. *Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894).

[18] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (internal citations and quotations marks omitted).

[19] *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (internal citations and quotation marks omitted).

[20] *See*, *e.g.*, *Morris v. Walmart*, *Inc*., No. 2:19-cv-650, 2020 WL 470287 at *2 (N.D. Ala. Jan. 29, 2020) (holding that the NLEA was intended to establish "uniform national standards for ... nutrient information displayed on food labels," including food dyes); *cf. Lam v. Gen. Mills*, *Inc*., 859 F. Supp. 2d 1097, 1102-03 (N.D. Cal. 2012) (claims based on mislabeling are preempted where the claims are based on provision covering artificial flavorings and colors).

[21] *See*, *e.g.*, *Patellos v. Hello Products*, *LLC*, 523 F. Supp. 3d 523, 530 (S.D.N.Y. 2021) ("[T]he Court dismisses as preempted ... any claims in the SAC that might be construed as relating to the safety or efficacy of fluoride in Hello's products, including based on the interaction of fluoride with other ingredients.").

[22] No. 23-2194, Doc. 73 (4th Cir. Apr. 15, 2024).

[23] *See*, *e.g.*, *Gibson v. Perrigo Co*., No. 25-00348 (N.D. Ill.); *Gurrola v. Proctor & Gamble Co*., No. 25-00358 (N.D. Ill.); *Harden v. Colgate-Palmolive Co*., No. 25-00362 (N.D. Ill.); *Gurrola v. Chattem Inc*., No. 25-00366 (N.D. Ill.).