A Weak Link In Consumers' FDA Test Claims

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For certain consumer products, U.S. Food and Drug Administration regulations mandate specific testing procedures or methodologies that must be followed in order to make particular claims about the product's features or use. These types of regulations cover, for example, over-the-counter monograph products, such as anti-cavity dental products or sun protection factor sunscreens. These types of regulations also cover nutrient content claims for foods and dietary supplements — everything from sugar content for cereals, to protein content in protein shakes, to vitamin content in supplements.

Federal statutes, in turn, contain express preemption provisions that preclude liability against manufacturers based on testing that does not meet the FDA's precise regulatory requirements. As one example, the Nutrition Labeling and Education Act of the Food, Drug, and Cosmetic Act provides that with limited express exceptions "no State or political subdivision of a State may directly or indirectly establish ... any requirement respecting any claim ... made in the label or labeling of food that is not identical to the requirement of Section 403(r) of this title," which governs nutrient content claims and health claims.[1]

FDA regulations provide that nutrition content claims "will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in [Title 21 of the Code of Federal Regulations] § 101.9."[2] As another example, the FDA has mandated highly specific testing procedures for SPF levels on sunscreens.[3]

For products governed by such regulations, state law claims are therefore preempted if they are premised on different, and non-FDA compliant, testing standards. As one court explained, "Plaintiffs' testing is not in compliance with the [FDA's] Final Rule, and if Plaintiffs seek to use that testing in support of their Complaint, ... they would in essence be asking this Court to find Defendants liable based on a change or deviation from the testing requirements as set out in the Final Rule."[4]

That is impermissible under the express preemption clauses. As the U.S. Court of Appeals for the Seventh Circuit noted in Turek v. General Mills Inc. in the related context of a dietary fiber claim, "[it] is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy."[5] Moreover, testing for OTC monograph drugs like sunscreen likewise requires uniform national standards, otherwise SPF 15 might mean something different in one state than it would in another.

As class action plaintiffs set their sights on more and more categories of consumer products, and challenge a broader array of label claims, they are increasingly wading into these FDA-required testing procedures. That presents an opportunity to scrutinize plaintiffs' claims at the threshold.

Typically, plaintiffs asserting this variety of false advertising and/or consumer protection claims allege in the complaint that they have conducted their own testing and have obtained results contrary to whatever the particular defendant's product says. For such claims, a split has emerged among district courts over what level of factual pleading is sufficient to state a nonpreempted claim and survive dismissal.

On one side, some courts have let plaintiffs survive a motion to dismiss based on the mere allegation of compliance with FDA testing protocols. In their view, such pleading was sufficient under Twombly and Iqbal because "[whether] independent testing along the lines of §101.9(g)(2) confirms Plaintiff's claim of overstated [nutrient] content is an issue of proof, and Plaintiff does not need to prove his case at the pleading stage of the case."[6]

On the other side, however, a growing number of cases in federal districts across the country have properly recognized that simply alleging that the testing which forms the basis of a plaintiff's compliant complied with FDA regulations is a bare legal conclusion that is "'not entitled to be assumed true,'" because "the notice-pleading rule 'does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.'"[7] Stating a viable claim requires a plaintiff to "do more than insert a conclusory allegation that the testing was identical"[8] and "include some facts about [plaintiff's] testing procedure in order to make it plausible that defendant's label was not in compliance" with the relevant FDA protocols.[9]

Beyond recognizing that "compliance with FDA-mandated testing is a threshold issue," these cases also enforce the commonsense proposition that, if plaintiffs "are relying on testing that does not comply with FDA methodology in support of their claims, Plaintiffs cannot show that Defendants' statements on the product labels violated the FDCA labeling requirements."[10] Such claims are therefore preempted, because the "labeling is not identical to the requirements set out in federal law."[11]

In one case, for example, delineating the plaintiffs' own testing results actually showed that they "appear[ed] to have pleaded facts demonstrating preemption."[12] In another case, the plaintiffs attempted to rely on testing conducted by a magazine that did not purport to comply with FDA protocols.[13]

The court held that the plaintiffs could not state a nonpreempted claim based on the magazine's testing that admittedly did not comply with the regulations.[14] In other words, requiring factual substantiation about the plaintiffs' testing may well reveal dispositive cracks in the plaintiff's case at the outset.[15]

These authorities and trends offer valuable strategic considerations for manufacturers facing false advertising and consumer protection claims based on FDA-regulated protocols. Insisting that plaintiffs plead facts to support the conclusion that their own testing complied with federal law not only maintains adherence to Twombly and Iqbal, but it can pay immediate dividends if the plaintiff does not or cannot plead a nonpreempted claim.

Even if a court will ultimately grant leave to amend, there are strategic benefits to challenging the sufficiency of plaintiffs' testing allegations. It properly puts the plaintiffs' testing under scrutiny early in the case, and it helps to ensure that ultimately preempted claims are not being waived through to discovery based on facially noncompliant testing that has just been hidden from view.

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DISCLOSURE: Fougere and Fradette represented Bayer Healthcare Inc. in Curran v. Bayer Healthcare, mentioned in footnote 7.

[1] 21 U.S.C. §§343-1(a)(5).

[2] 21 C.F.R. 101.13(o).

[3] 21 U.S.C. § 379r & 21 C.F.R. § 201.327 (similar for sunscreen testing and labeling requirements).

[4] Anglin v. Edgewell Pers. Care Co., No. 4:18-CV-00639-NCC, 2018 WL 6434424, at *8 (E.D. Mo. Dec. 7, 2018).

[5] Turek v. General Mills, Inc., 662 F.3d 423, 426-27 (7th Cir. 2011) ("The disclaimers that the plaintiff wants added to the labeling of the defendants' inulin-containing chewy bars are not identical to the labeling requirements imposed on such products by federal law, and so they are barred.").

[6] Gubala v. CVS Pharmacy, Inc., No. 14 C 9039, 2016 WL 1019794, at *8 (N.D. Ill. Mar. 15, 2016) (holding, in whey protein power case, that attaching one test result rather than full 12-sample tests required by FDA regulations was sufficient at pleading stage); see, e.g., Muir v. NBTY, Inc., No. 15 C 9835, 2016 WL 5234596 (N.D. Ill. Sept. 22, 2016) (holding, in case challenging content of St. John's Wart dietary supplement, that the failure to allege compliance with FDA's 12-sample testing protocol was not dispositive, but noting split of authority).

[7] Curran v. Bayer Healthcare LLC, No. 17-cv-7930, 2018 WL 2431981, at *4 (N.D. Ill. May 30, 2018) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678-79, 681 (2009)).

[8] Curran, 2018 WL 2431981, at *4.

[9] Id.; see also, e.g., Burke v. Weight Watchers Int'l, Inc., 983 F. Supp. 2d 478, 483 (D.N.J. 2013) (allegations insufficient when they "generally" cite "to laboratory tests performed 'in accordance to, and in compliance of, FDA guidelines, including 21 C.F.R. 101.9'"); Salazar v. Honest Tea, Inc., 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014) (complaint failed to allege it tested antioxidant claims on bottled tea according to FDA regulations); Baker v. NNW, LLC, No. 15-00222, 2015 WL 12843827, at *3-4 (W.D. Mo. July 8, 2015) ("[B]ecause Plaintiff does not allege that he subjected the Healthy 100% Whey to the Section 101.9(g) testing, his claims are preempted."); Dougherty v. Source Nats., Inc., 148 F. Supp. 3d 831, 835 (E.D. Mo. 2015) ("[n]othing in the pleadings avers that Plaintiff complied with § 101.9(g)(2) in testing the Multivitamin"); Anglin, 2018 WL

6434424, at *10 ("Plaintiffs offer nothing more than a conclusory statement that the testing complied with the FDA Final Rule, an ultimate question this Court may be called upon to decide in the future."); Parker v. Wal-Mart Stores, Inc., 367 F. Supp. 3d 979, 983 (E.D. Mo. 2019) ("[A]ny NLEA claim that relies on scientific testing of a food's nutritional components must include an allegation that the food does not meet the labeling requirements when subjected to the twelve-sample FDCA protocol."); Forouzesh v. CVS Pharmacy, Inc., No. 2:18-CV-04090, 2019 WL 652887, at *4 (C.D. Cal. Feb. 15, 2019) (plaintiff "fail[ed] to plausibly allege that his independent testing [for SPF claims] is FDA-compliant").

[10] Anglin, 2018 WL 6434424, at *10.

[11] Curran, 2018 WL 2431981, at *3.

[12] Rubio v. Orgain, Inc., No. 18-2237, 2019 WL 1578379, at *4 (C.D. Cal. Mar. 5, 2019); see also Mee v. I A Nutrition Inc., 2015 WL 2251303, at *3 (N.D. Cal. May 13, 2015) (dismissing complaint where testing protocol attached to complaint facially did not comply with FDA requirement).

[13] Curran, 2018 WL 2431981, at *3 ("To the extent plaintiff is claiming that the sunscreen's label needed to reflect the testing conducted by Consumer Reports, those claims are preempted, because such labeling is not identical to the requirements set out in federal law.");

[14] Id.; see also In re: Whole Foods Mkt. Inc., 163 F. Supp. 3d 385, 392-93 (W.D. Tex. 2016) (same).

[15] See, e.g., Welk v. Nutraceutical Corp., No. 3:17-CV-02266, 2018 WL 3818033, at *5 (S.D. Cal. Aug. 10, 2018) (dismissing claims against dietary supplement manufacturer after "Plaintiff's opposition effectively concedes that the 'scientific testing' upon which her claims rely does not comply with the requirements for testing under 21 C.F.R. § 101.9(g)(2)"); Vital v. One World Co., No. 12-cv-00314, 2012 WL 13029487, at *2 (C.D. Cal. Nov. 30, 2012) (same, after converting motion to dismiss into summary judgment motion).

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