UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

DR. JOSEPH CICCIO et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 3:19-cv-00845**
	)	**Judge Aleta A. Trauger**
	)	
SMILEDIRECTCLUB, LLC et al.,	)	
	)	
Defendants.	)	

MEMORANDUM

The defendants have filed a Motion to Dismiss Certain of Plaintiffs' Claims on the Pleadings (Doc. No. 256), to which the plaintiffs have filed a Response (Doc. No. 267), and the defendants have filed a Reply (Doc. No. 278). The plaintiffs have filed a Motion for Leave to Amend the Complaint (Doc. No. 311), to which the defendants have filed a Response (Doc. No. 314), and the plaintiffs have filed a Reply (Doc. No. 315). For the reasons set out herein, both motions will be denied.

I. BACKGROUND[1]

The court has written several opinions in this case already and will not belabor the details here. In short, SmileDirectClub, LLC ("SmileDirect") is a company that sells plastic aligners for orthodontic use. SmileDirect and a number of affiliated companies and individuals were sued by a group of consumers and orthodontists, who alleged that SmileDirect had engaged in various types of wrongdoing in order to deceive consumers into viewing SmileDirect's products and

[1] Unless otherwise indicated, the facts herein are taken from the Second Amended Complaint (Doc. No. 241) and are accepted as true for the purposes of the motion for judgment on the pleadings and motion for leave to amend.

services as a suitable alternative to traditional orthodontic treatment, which they were not. The consumer plaintiffs are no longer active plaintiffs in the case, leaving only the orthodontists and their practices.

On December 13, 2019, the defendants filed a Motion to Dismiss the Plaintiff Orthodontists' Claims. (Doc. No. 68.) On June 2, 2020, the court denied that motion. (Doc. No. 95.) Despite having had that initial opportunity to challenge the sufficiency of the orthodontist plaintiffs' pleading, the defendants now seek to dispute the adequacy of that pleading again, albeit in a relatively limited way. Specifically, the defendants seek judgment on the pleadings with regard to any claims based, in whole or in part, on allegations that SmileDirect improperly marketed itself as in compliance with federal regulations governing dental devices. In the defendants' briefing, they acknowledge that the reason for this oddly-timed request is that the defendants seek to narrow the scope of discovery, which, as the record makes readily apparent, has been fought bitterly and relentlessly by both the plaintiffs and defendants in this case.[2] (*See* Doc. No. 257 at 1–2.)

The defendants' motion is directed at the plaintiffs' claims based on allegations set forth in Section H of the Second Amended Complaint (hereinafter, "SAC"). (Doc. No. 246 ¶¶ 128–41.) That relatively short section—which does not itself set forth claims, but rather pleads facts in support of the claims stated more expressly elsewhere in the SAC—describes SmileDirect's past dealings with the Food and Drug Administration ("FDA") and its alleged violations of state dental licensing laws. The plaintiffs allege that "[a]t no time has SmileDirect informed consumers that it is in violation of the [Food, Drugs, and Cosmetics Act ('FDCA')] and illegally practicing dentistry" and that "[b]oth of these nondisclosures are highly material and highly fraudulent

[2] Indeed, this is not even the first substantive motion that is actually an attempt to re-open and win a discovery dispute that the movant lost. The plaintiffs tried the same general tactic, unsuccessfully, with a motion seeking to add hundreds of John Does as named defendants, apparently so that the plaintiffs would have a clearer ground for obtaining those John Does' identities. (*See* Doc. Nos. 179, 204 at 9–10, 238.)

because consumers would be reluctant to use SmileDirect's aligners in any capacity if they knew that they were being sold in violation of both federal and state law." (*Id.* ¶¶ 130–31.) With regard to the FDA, the plaintiffs specifically allege that, "[a]s a manufacturer of its aligners, SmileDirect was legally obligated to seek FDA clearance for such product,"[3] but that it has instead opted to "flout these legal requirements and is selling its product, which should be labeled and sold only by prescription, in an essentially over-the-counter fashion." (*Id.* ¶ 136.) The plaintiffs explain, however, that they are not merely alleging that SmileDirect is in technical noncompliance with federal laws governing medical devices; rather, they allege that SmileDirect's practice of "deliberately hiding" the regulatory status of its products from consumers has affected consumer decisions in SmileDirect's favor. (*Id.* ¶ 140.) That "attempt to profit at the expense of customers and at the expense of traditional orthodontics," the plaintiffs allege, "is negligent, fraudulent, deceptive, and a violation of the Lanham Act," as well as the Tennessee Consumer Protection Act ("TCPA"). (*Id.* ¶¶ 141, 212.) The defendants argue that the court should dismiss any such claims because "only the Food and Drug Administration can enforce the FDCA." (Doc. No. 256 at 1.) The defendants also argue that the allegations related to dental licensing are legally insufficient, although those allegations pose no particular issue involving the FDA. (*Id.*)

Also pending before the court is a request by the plaintiffs for leave to amend their SAC to add a claim for class damages under the TCPA, a statute under which they had already pleaded

[3] "The Medical Device Amendments of 1976 ('MDA'), 21 U.S.C. §§ 360c–360k, 379–379a, establish[] the framework for federal regulation of medical devices. As amended, the MDA requires the FDA to place a device into one of three classes reflecting different levels of regulation." *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1003 (7th Cir. 2020). Pursuant to that system, "[m]ost medical devices fall into Class II," which covers devices that are not so dangerous and/or questionably useful to require the FDA's most stringent process of premarket approval, but which must comply with certain "special controls . . . tailored to the device such as performance standards and postmarket surveillance," in addition to the "general controls" that cover all devices. *Id.* The plaintiffs' allegation assumes that SmileDirect's aligners are most likely Class II devices that therefore would need FDA "clearance" through what is referred to as "§ 510(k) review." *See id.* at 1004.

claims, but only for injunctive relief on behalf of the class and damages on behalf of individual plaintiffs. (Doc. No. 246 ¶¶ 214–15.) The plaintiffs characterize this proposed amendment as warranted based on intervening "recent case law" favorable to the inclusion of such claims. (Doc. No. 311 at 1.)

II. LEGAL STANDARD

A. Motion for Judgment on the Pleadings

Rule 12(c) of the Federal Rules of Civil Procedure provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). Rule 12(c) motions for judgment on the pleadings and Rule 12(b)(6) motions to dismiss are evaluated under the same standard of review. *Fritz v. Charter Twp. of Comstock*, 592 F.3d 718, 722 (6th Cir. 2010). For either, the court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff." *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007); *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 619 (6th Cir. 2002).The Federal Rules of Civil Procedure require only that the plaintiff provide "a short and plain statement of the claim that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). The court must determine only whether "the claimant is entitled to offer evidence to support the claims," not whether the plaintiff can ultimately prove the facts alleged. *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 511 (2002) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

The complaint's allegations, however, "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The plaintiff cannot rely on "legal conclusions" or "[t]hreadbare recitals of the elements of a cause of action," but, instead,

the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679; *Twombly*, 550 U.S. at 556.

B. Motion to Amend

Rule 15(a)(2) of the Federal Rules of Civil Procedure states that leave to amend should be freely given "when justice so requires." In deciding whether to grant a motion to amend, courts consider factors including undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment. *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005).

In addition, however, the Sixth Circuit has recognized that a motion for leave to amend filed after the deadline for such motions has expired "implicates" Rule 16 of the Federal Rules of Civil Procedure, in addition to Rule 15. *Carrizo (Utica) LLC v. City of Girard*, 661 F. App'x 364, 367 (6th Cir. 2016) (quoting *Leary v. Daeschner*, 349 F.3d 888, 904 (6th Cir. 2003)). Under Rule 16, a scheduling order "must limit the time to . . . amend the pleadings," and the schedule may only be modified "for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(3)(A), (b)(4). Thus, "notwithstanding Rule 15's directive freely to give leave to amend, a party seeking leave to amend after the scheduling order's deadline must meet Rule 16's good-cause standard in order for the district court to amend the scheduling order." *Carrizo*, 661 F. Appx. at 367 (citing *Leary*, 349 F.3d at 909). "The primary measure of Rule 16's 'good cause' standard is the moving party's diligence in attempting to meet the case management order's requirements. Another relevant

consideration is possible prejudice to the party opposing the modification." *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625 (6th Cir. 2002) (internal citations omitted).

III. ANALYSIS

A. Claims Premised on FDCA Violations

1. Law of the Case

As a preliminary matter, the plaintiffs argue that the court should not even consider the defendants' argument for judgment on the pleadings, because doing so would violate the "law of the case" doctrine. As the plaintiffs acknowledge, "[d]istrict courts have authority both under common law and Rule 54(b) to reconsider interlocutory orders and to reopen any part of a case before entry of final judgment." *Rodriguez v. Tenn. Laborers Health & Welfare Fund*, 89 F. App'x 949, 959 (6th Cir. 2004) (citing *Mallory v. Eyrich*, 922 F.2d 1273, 1282 (6th Cir. 1991)); *see also In re Life Investors Ins. Co. of Am.*, 589 F.3d 319, 326 n.6 (6th Cir. 2009) ("[A] district court may always reconsider and revise its interlocutory orders while it retains jurisdiction over the case.") (citing *Rodriguez*, 89 F. App'x at 959; *Mallory*, 922 F.2d at 1282). The only way for litigation to move forward expeditiously, however, is for the court to use that authority sparingly. Typically, then, "[t]he law-of-the-case doctrine precludes reconsideration of a previously-decided issue at a subsequent stage in the litigation 'unless one of three exceptional circumstances exists: [1] the evidence in a subsequent trial was substantially different; [2] controlling authority has since made a contrary decision of law applicable to such issues; or [3] the decision was clearly erroneous, and would work a substantial injustice.'"[4] *J.L. Spoons, Inc. v. Ohio Dep't of Pub. Safety*, 509 F. App'x

[4] There is some room for debate with regard to what it means to be at a *subsequent* stage in litigation, as opposed to merely later in the *same* stage, particularly when the claims at issue have not been subject to something like an intervening appeal. But, as the court has already noted once in this case, that distinction is not particularly important, because the court must consider similar factors whether one characterizes a party's request as involving either (1) departing from the law of the case or (2) merely reconsidering an earlier ruling. (*See* Doc. No. 117 at 7 n.1.)

464, 469 (6th Cir. 2012) (quoting *Poundstone v. Patriot Coal Co.*, 485 F.3d 891, 895 (6th Cir. 2007)).

The defendants' motion does not present an instance where the evidence or the controlling law has changed, meaning that the first two grounds for departing from the law of the case cannot be satisfied here. Moreover, given the amount of dilatory and unnecessary behavior that has already brought this litigation to a snail's pace, the court is hesitant to reward any party for raising an argument that it could—and should—have raised earlier. The Rules of Civil Procedure provide ample opportunities for the parties to press their cases, without every key ruling being followed by a flurry of motions for reconsideration and/or clarification, as the parties in this case have often deemed necessary. It is therefore tempting to exercise the court's discretion to deny the defendants' motion on the ground that they have, at most, merely raised a colorable argument for dismissal that could have been raised before as part of their broader challenge to an earlier version of the complaint, not a ground for concluding that the court's prior ruling was clearly erroneous.

Ultimately, however, the court is convinced that declining to address the issue raised by the defendants' motion would do substantially more harm than good. For one thing, while the court has rejected some legal arguments for dismissing these aspects of the active plaintiffs' claims, it has not, in fact, considered this precise argument, at least not in the form it has been presented here. The degree to which the law of the case is even at issue is therefore debatable. The defendants have identified a substantial legal issue that, while it should have been raised earlier, is nevertheless of genuine importance to resolving this case. If the court declined the opportunity to get that issue out of the way now, despite the fact that it has been fully briefed and appears to be interfering with discovery, the court would simply be adding to the list of events that have bogged this case down

so severely from the start. The court, accordingly, will consider the defendants' argument on the merits, pursuant to the ordinary standard governing Rule 12(b)(6) and Rule 12(d) motions.

2. Preclusion/Preemption

Federal law provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337. Accordingly, no private litigant—whether an injured consumer, an aggrieved competitor, or anyone else—can sue the manufacturer of a drug, food item, or cosmetic product under that Act. The FDCA, however, is only one of many statutes and state common law doctrines applicable to sales of such items. Many of those other statutes or rules touch on topics that the FDCA addresses, but, unlike the FDCA, some of those laws *do* allow private causes of action. For example, state products liability law addresses issues of product safety that are also considered by regulators under the FDCA. *See Garcia v. Wyeth-Ayerst Lab'ys*, 385 F.3d 961, 967 (6th Cir. 2004) (discussing the interplay between the FDCA and Michigan products liability law).

In light of these overlaps, courts and legislators have taken various steps to try to harmonize the FDCA's top-down, regulator-driven regime with the existence of private causes of action involving the same general subject matter. Sometimes, legislators and courts have envisioned the FDCA and other sources of law working hand-in-glove with each other toward the same shared purposes. *See, e.g.*, Tenn. Code Ann. § 29-39-104(d)(1)(a) (basing types of damages available on whether a product was "manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the Federal Food, Drug, and Cosmetic Act"). Other times, the FDCA and other sources of law have been held to function in parallel—both regulating the same general subject matter with neither getting too much in the way of the other. *See, e.g.*, *POM Wonderful LLC v. Coca-Cola Co.*, 573

U.S. 102, 106 (2014) (holding that the same labeling defect could be subject to both FDA regulation and the Lanham Act). And, finally, courts have sometimes concluded that certain general laws simply intrude too much on the FDCA's domain for both to apply. In these cases, the FDCA, as a statute that is (1) federal and (2) specific in its subject matter, typically prevails, and the other law is held to be preempted or precluded.[5] *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (holding that certain state law claims were preempted by the FDCA).

The Lanham Act, 15 U.S.C. § 1051 *et seq.*, is a federal statute that governs various types of unlawful marketing practices, most famously by forbidding the use of trademarks and trade dress likely to confuse the public about the origins of a product or service. The Act also prohibits unfair competition through the use of misrepresentations of fact about one's own or another's goods, services, or business activities. *See* 15 U.S.C. § 1125(a). Section 1125(a)(1)(B) of the Act provides:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . .
>
> > (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). The Sixth Circuit has described the elements of a Lanham Act false advertising claim as:

> 1) the defendant has made false or misleading statements of fact concerning his own product or another's; 2) the statement actually deceives or tends to deceive a

[5] "Preemption" refers to when a federal statute displaces state law; "preclusion" refers to when one federal statute displaces another federal statute. *See POM Wonderful*, 573 U.S. at 111 (explaining distinction).

> substantial portion of the intended audience; 3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions; 4) the advertisements were introduced into interstate commerce; 5) there is some causal link between the challenged statements and harm to the plaintiff.

Grubbs v. Sheakley Grp., Inc., 807 F.3d 785, 798 (6th Cir. 2015) (quoting *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 185 F.3d 606, 613 (6th Cir. 1999)).

Although the ultimate subject of a false advertising claim is the effect on consumers, the Lanham Act specifically contemplates enforcement by commercial competitors, not the consumers themselves. "A plaintiff must allege an injury to a commercial interest in reputation or sales. A consumer who is hoodwinked into purchasing a disappointing product may well have an injury-in-fact cognizable under Article III [of the Constitution], but he cannot invoke the protection of the Lanham Act . . . ." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 132 (2014). In this regard, a false advertising claim mirrors a traditional trademark infringement claim based on likelihood of consumer confusion: while it is consumers who may have been deceived, the lawsuit itself is typically between sellers. *See* 15 U.S.C. § 1125(a)(1)(A) (setting out trademark cause of action based on likelihood of confusion).

The Supreme Court specifically considered the relationship between the Lanham Act and the FDCA in *POM Wonderful LLC v. Coca-Cola Co.*, ultimately concluding that "[c]ompetitors, in their own interest, may bring Lanham Act claims . . . that challenge food and beverage labels that are regulated by the FDCA." 573 U.S. at 106. In *POM Wonderful*, the plaintiff, a juice distributor, sued a competitor over what it alleged were misleading claims, on FCA-regulated labels, regarding the amount of pomegranate and blueberry juice in a particular commercial juice blend. *Id.* The FDA had promulgated specific regulations addressing precisely that subject matter—that is, how a seller could represent the amounts of various components of "diluted

multiple-juice beverage[s]" on its labels. 21 C.F.R. § 102.33. The subject matter, in other words, was not simply one that technically fell within the scope of the FDCA; it was a topic in which the FDA had demonstrated specific regulatory interest and about which the FDA therefore could (and did) exercise regulatory discretion. The plaintiff, however, unsatisfied to wait and hope that the FDA would intercede, sued for false advertising under the Lanham Act. The Ninth Circuit Court of Appeals eventually rejected that challenge, holding that, because the plaintiff's cause of action so closely resembled a false labeling action under the FDCA, the FDCA's reservation of enforcement authority to the federal government could not be reconciled with the recognition of the Lanham Act claim.

The Supreme Court, however, disagreed, concluding that "the FDCA and the Lanham Act complement each other in the federal regulation of misleading food and beverage labels." *POM Wonderful*, 573 U.S. at 106. "[T]he Lanham Act and the FDCA," the Court observed, "have coexisted since the passage of the Lanham Act in 1946," without Congress ever seeing the need to suggest that one must yield to the other. *Id.* at 113. The Supreme Court rejected the argument that the plaintiff, by pursuing a Lanham Act claim that theoretically could be an FDCA enforcement claim, was impinging on the federal government's authority as sole regulator. The plaintiff, the Court straightforwardly concluded, "s[ought] to enforce the Lanham Act, not the FDCA or its regulations," and "[t]he centralization of FDCA enforcement authority in the Federal Government does not indicate that Congress intended to foreclose private enforcement of other federal statutes." *Id.* at 117.

The Supreme Court considered—and rejected—a compromise position, urged by the federal government itself, "that a Lanham Act claim is precluded 'to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of [the] label.'" *Id.* at 118–19

(quoting Brief for United States as Amicus Curiae at 11). In declining to adopt the government's position, the Supreme Court cited both the "practical concerns" that such line-drawing would raise and the fact that, while the government's proposed standard was, in a sense, a middle ground, it did not actually resolve any of the formal infirmities that had led the court to reject the defendant's position in the first place; just as nothing in the FDCA or the Lanham Act called for complete preclusion, nothing in either Act called for partial preclusion. *Id.* at 119–20.

It is, therefore, definitively settled that a plaintiff can bring a Lanham Act claim based on the features of an FDA-regulated label or marketing material—even a feature that the FDA has specifically regulated in a manner bearing directly on the subject matter of the underlying lawsuit—without necessarily running afoul of preclusion. The defendants, however, point out an aspect of this case that was not present in *POM Wonderful*: the fact that the plaintiffs have alleged that SmileDirect's marketing was misleading *with regard to* the FDA status of the aligners. The plaintiff in *POM Wonderful* did not allege that the defendant falsely suggested that its beverages had been determined by the FDA to contain a certain amount of pomegranate juice; the FDA was implicated because the Lanham Act claim touched on a product in the FDA's jurisdiction, but the plaintiff's Lanham Act claim was not actually about the FDA process itself. The defendants argue that these plaintiffs' claims, therefore, more seriously intrude on the FDA's prerogatives under the FDCA.

Based on that distinction, the defendants liken this case, not to *POM Wonderful*, but *Buckman Company v. Plaintiffs' Legal Committee*, in which the Supreme Court held that a state tort claim could not be based on the allegation that the defendant had defrauded the FDA to receive clearance of its product, because, among other things, "the relationship between a federal agency and the entity it regulates is inherently federal in character." 531 U.S. at 347. Some courts have

held that, despite the general rule of *POM Wonderful*, a similar analysis would preclude federal claims based on non-FDCA statutes that, rather than simply overlapping with the FDA's concerns, actually "attempt to enforce requirements of the FDCA." *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959, 969 (Fed. Cir. 2019); *see also Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1199 (11th Cir. 2018) (holding that the FDCA precludes a plaintiff's "private action[] under the Lanham Act premised on enforcement determinations that the FDA and other regulatory agencies did not themselves make") (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010)); *but see Innovative Health Sols., Inc. v. DyAnsys, Inc.*, No. 14-CV-05207-SI, 2015 WL 2398931, at *7 (N.D. Cal. May 19, 2015) ("The Court finds that to the extent plaintiff alleges that defendants have falsely represented that they obtained FDA approval for their products, those claims are not precluded or preempted.").

These plaintiffs, however, are not attempting to police or otherwise interfere with SmileDirect's dealings with the FDA, nor are they trying to enforce any provision of the FDCA in the FDA's stead. The plaintiffs argue, rather, that SmileDirect's marketing misled the public about the reality of SmileDirect's status under the FDA's review process and that those misleading actions actually affected consumer behavior to the plaintiffs' detriment. *See JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1000 (C.D. Cal. 2014) ("[I]f a product has been approved [by the FDA], consumers may take some assurance that it . . . meets the agency's . . . standards. This makes an FDA-approved product a more attractive product . . . ." (emphasis omitted)). The plaintiffs' allegations, moreover, are not that SmileDirect's disclosures (and nondisclosures) violated the FDCA or that there is any general duty to disclose whether a product available to consumers was FDA-cleared or -approved. Rather, the plaintiffs argue that SmileDirect's particular marketing strategy and materials, in the unique context of the orthodontic industry and

the particular consumer expectations predominant in that industry, were misleading in a way that could have been, but was not, rectified by such a disclosure. Such a claim under the Lanham Act is permissible for the same reasons that the claim in *POM Wonderful* was—that the Lanham Act applies to this industry just like any other, and "[n]othing in the text, history, or structure of the FDCA" suggests a carve-out for this particular type of unfair competitive practice. 573 U.S. at 106.

Indeed, even the defendants, in their Reply, ultimately concede that "a false affirmative claim that a product is FDA-approved can support Lanham Act liability." (Doc. No. 278 at 2–3.) They argue, however, that, even if some sort of claim along the lines proposed by the plaintiffs would be permissible in light of such an affirmative statement, the plaintiffs have failed to plead any actually misleading statements by SmileDirect regarding the FDA status of its product. This argument, unlike the preclusion argument, does effectively recapitulate issues that the court already addressed when resolving the motion to dismiss, and the court finds the defendants' argument no more persuasive now. The court previously wrote:

> The defendants argue, first, that the plaintiffs have failed to identify a relevant "commercial advertising or promotion," as required by 15 U.S.C. § 1125(a)(1)(B). "[T]he elusive phrase 'commercial advertising or promotion' . . . is defined neither in statute nor in legislative history." *Grubbs*, 807 F.3d at 800. The Sixth Circuit, however, has adopted the following definition: "(1) commercial speech; (2) for the purpose of influencing customers to buy the defendant's goods or services; (3) that is disseminated either widely enough to the relevant purchasing public to constitute advertising or promotion within that industry or to a substantial portion of the plaintiff's or defendant's existing customer or client base." *Id.* at 801. The relevant commercial speech "need not necessarily resemble traditional television, radio, print, or Internet advertisements." *Id.* at 799 (citing *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 112 (6th Cir. 1995)).
>
> The plaintiffs allege that SmileDirect has engaged in an "omni-channel approach to marketing, using billboards (including in Times Square and the NYC Subway), Google, Facebook, Instagram, and other social media platforms," as well as having "purchased advertising time during televised national sporting events, such as college football games." (Docket No. 36 ¶ 75.) The plaintiffs have also compiled a

number of "literal falsities" and misleading statements that they attribute to those advertising campaigns, some of which the plaintiffs quote verbatim. (*Id.* ¶¶ 77, 96, 115.) The plaintiffs have also identified, as a further example, a specific blog post from SmileDirect's "Grin Life" blog, containing what the plaintiffs identify as a false or misleading statement equating the care received in the SmileDirect Program with conventional, face-to-face orthodontic care. (*Id.* ¶ 80.) While the plaintiffs have not given specific dates and times for the false or misleading statements in the "omni-channel" marketing effort, that requirement can be, as the court has explained, relaxed in the case of false advertising claims based on sustained, repeated communications. Moreover, courts have acknowledged, in other cases applying Rule 9(b) to complex schemes involving numerous false statements, that a plaintiff can satisfy the Rule by describing the scheme and providing "representative" examples, rather than listing every wrongful act. *See* [*U.S. ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 444–45 (6th Cir. 2008)]. By identifying specific claims and specific advertising venues through which the claims were conveyed, the plaintiffs have satisfied these requirements sufficiently to serve the purposes of Rule 9(b). The defendants therefore are not entitled to dismissal based on the plaintiffs' alleged failure to plead commercial communications within the meaning of the Lanham Act.

The defendants argue, next, that none of the relevant statements was false or misleading as those terms are used in the Lanham Act. Some of the marketing assertions that the plaintiffs have highlighted, such as the boast that SmileDirect's customers were highly satisfied, may ultimately turn out to be the type of vague puffery that cannot support statutory liability. *But see La.-Pac. Corp. v. James Hardie Bldg. Prod., Inc.*, 928 F.3d 514, 519 (6th Cir. 2019) ("[T]he context of a message can transform unactionable puffery into an empirically verifiable, factual claim."). Other aspects of SmileDirect's characterization of its products and services, however, involve more concrete and specific assertions amenable to being true or false and being material to customers' decisions. For example, the Grin Life blog post highlighted by the plaintiffs included the claim that "[a]n individual who is requesting treatment by using SmileDirectClub's aligners is receiving the same level of care from a treating dentist-orthodontist as an individual visiting a traditional orthodontist or dentist for treatment." (Docket No. 36 ¶ 80.) The plaintiffs have identified specific ways in which SmileDirect's internet-based teledentistry system falls far below the level of care involved in a traditional dental setting, particularly with regard to the limited diagnostic tools available in the SmileDirect setting and the comparatively lesser role played by dentists rather than non-dentist support personnel. (*Id.* ¶¶ 81–87.) While the phrase "level of care" may contain some vagueness, whether it has a sufficiently fixed meaning that it can serve as the crux of a false advertising claim is a question of fact inappropriate for a Rule 12(b)(6) motion.

The plaintiffs have also alleged that SmileDirect claimed, in its advertising, that SmileDirect's plastic aligners work "three times faster than braces." (*Id.* ¶ 96.) As the plaintiffs point out, such a statement suggests that the aligners perform a

> comparable service to traditional braces, which the plaintiffs have alleged is false. . . .
>
> The plaintiffs have also adequately alleged that the relevant statements were material to, and likely influenced, consumers' purchasing decisions. From the plaintiffs' description of SmileDirect's product and marketing, it is clear that consumers with orthodontic needs would consider SmileDirect and more traditional, in-person orthodontic treatment as competitive services. When choosing between competitive services, the degree to which one service actually offers an adequate substitute for the other is an obviously important consideration. . . . The plaintiffs have therefore adequately pleaded the second and third elements of a false advertising claim. Moreover, their description of SmileDirect's massive advertising expenditures pleads entry into interstate commerce, satisfying the fourth.

(Doc. No. 95 at 21–24.) The court reiterates and re-adopts that general analysis of the plaintiffs' allegations and concludes that the plaintiffs sufficiently pleaded that the defendants misleadingly characterized their products and services as equivalent to traditional orthodontic treatment. All that is left, then, is to determine whether the FDA-related issues addressed by the pending motion involve facts relevant to demonstrating the false or misleading nature of such a claim.

Admittedly, none of the marketing materials that the court previously discussed included the specific claim that SmileDirect's aligners were FDA-cleared or -approved. The plaintiffs' theory of the case, however, is that, in the context of orthodontic care, a reasonable consumer would read SmileDirect's assertions of equivalence to traditional orthodontic treatment to suggest that such approval or clearance occurred. Whether that is actually true is a factual question, and the plaintiffs will have to actually establish that fact in order to prevail. At the pleading stage, however, it is sufficient that the theory is plausible and was pleaded with particularity.

The defendants' position that the FDCA *does* preclude false advertising claims based on implicit statements of FDA clearance or approval but *does not* preclude false advertising claims based on explicit statements of FDA approval, moreover, makes little sense. The possibility that a consumer can be misled by omission and/or implication is both factually undeniable and well-

recognized by the law. *See, e.g.*, *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 65 (2d Cir. 2016) ("To prevail on a Lanham Act false advertising claim, a plaintiff must establish that the challenged message is . . . either literally *or impliedly* false . . . .") (citing *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255–56 (2d Cir. 2014)); *Pegasystems, Inc. v. Appian Corp.*, 424 F. Supp. 3d 214, 223 (D. Mass. 2019) ("An omission is actionable under the Lanham Act if it 'renders an affirmative statement false or misleading.'") (quoting *Lokai Holdings LLC v. Twin Tiger USA LLC*, 306 F. Supp. 3d 629, 639-40 (S.D.N.Y. 2018)). Why, then, would that type of well-recognized claim be precluded, if a substantively equivalent claim based on an affirmative statement would not?[6] If anything, the argument for the position that the defendants ultimately concede in the Reply—that *all* Lanham Act claims based on assertions of FDA approval or clearance should be considered precluded, not just ones based on omission or implications—makes much more sense than drawing an artificial line based on the unrelated issue of implicit versus explicit falsehood. Either version of the argument, however, is unpersuasive in light of *POM Wonderful*.

The same analysis applies with regard to the issue of dental licensure. The plaintiffs have pleaded the existence of a particular model of dental consumer, whereby a reasonable consumer would have been misled by SmileDirect's marketing into assuming that SmileDirect was not violating any state licensure laws, which, according to the SAC, it was. Whether that depiction of a reasonable consumer's mindset is actually true is undoubtedly fair ground for debate. At this

[6] The court notes that there would also likely be substantial practical challenges to applying such a rule. "[E]very misrepresentation involves an omission of the true information," and a plaintiff may, "[t]hrough word games, . . . style his or her complaint as a material misrepresentations [case] or [an] omissions case" without any change in the substance. *Simpson v. Specialty Retail Concepts*, 823 F. Supp. 353, 356 n.7 (M.D.N.C. 1993). Treating one type of claim as wholly precluded and the other as permissible would cause the viability of a plaintiff's claim to hinge on distinctions too malleable to be safely relied upon, at least in borderline cases.

stage, however, all that matters is that it is plausible—which it is—and that it was pleaded with particularity[7]—which it was.

Finally, the court reaches the same conclusion with regard to the state law claims that, the defendants argue, also run afoul of the FDCA. The fact that the FDCA and the TCPA overlap in their subject matter is acknowledged in the TCPA itself. *See, e.g.*, Tenn. Code Ann. § 29-39-104(d)(1)(a). While it is true that the FDCA may well preempt discrete parts of the TCPA—and, indeed, this court has held as much before, *see Heath v. C.R. Bard Inc.*, No. 3:19-CV-803, 2021 WL 3172315, at *14 (M.D. Tenn. July 27, 2021) (Trauger, J.)—the defendants identify no binding caselaw suggesting that the court should treat the FDCA as having wholly preempted a TCPA claim based on the theory that, by characterizing a service as equivalent to conventional orthodontics, a company falsely suggested, among other things, that its products were FDA-cleared. It may be that, once the facts of SmileDirect's dealings with the FDA are established and in the record, the plaintiffs will be unable to state any theory of the case under the TCPA that would avoid *Buckman*-type preemption because any such claim would improperly call on this court to intrude on the FDA's decisionmaking. There is, however, no basis for jumping to that conclusion now. The court, accordingly, will deny the defendants' motion for judgment on the pleadings in full.

B. Motion to Amend

On June 9, 2021, the plaintiffs moved for leave to file a Second Amended Complaint that would have substantially expanded this case, including by adding over 200 new defendants. The court considered the request pursuant to the ordinary standard imposed by Rule 15(a)(2),

[7] As the court previously noted, it is not entirely clear whether Rule 9(b)'s requirement of pleading with particularity applies to these claims, which are somewhat, though not entirely, fraud-like in character. (*See* Doc. No. 95 at 18–21.) The court, however, will continue to apply that Rule, as it did with regard to the motion to dismiss, on the assumption that it more likely than not applies.

ultimately allowing a few minor amendments but rejecting most aspects of the plaintiffs' requests in light of, among other things, their dilatory nature and the severe prejudice to which the amendments would have subjected the defendants. (Doc. No. 238.) Now, the plaintiffs request to make an admittedly smaller change. (Doc. No. 311.) Specifically, they seek to add a request for damages to the TCPA claims they have already pleaded on behalf of a putative class, in light of a recent Eastern District of Michigan ruling that the TCPA's bar against class actions should be construed as a procedural rule inconsistent with, and therefore preempted by, the Federal Rules. *See Reynolds v. FCA US LLC*, 546 F. Supp. 3d 635, 657 (E.D. Mich. 2021) ("After considering [the preexisting] split in authority, the Court finds more persuasive the decisions holding that class action prohibitions in certain state consumer protection statutes are procedural.") (citing *In re FCA US LLC Monostable Elec. Gearshift Litig.*, 355 F. Supp. 3d 582, 600 (E.D. Mich. 2018)).

The parties disagree about whether the plaintiffs' motion is timely. As the defendants point out, the deadline for Motions to Amend included in the Initial Case Management Order was October 29, 2021. (Doc. No. 116 at 5.) On June 18, 2021, the active plaintiffs filed a motion "request[ing] that the Court extend the July 14, 2021 discovery deadline for Provider Plaintiffs under the Initial Case Management Order for one year and modify the dates set forth in the Initial Case Management Order accordingly." (Doc. No. 194 at 1.) On July 6, 2021, the court referred that motion to the Special Master, on the ground that he was "in the best position to determine the appropriate length for an extension of the discovery deadline." (Doc. No. 222 at 1.) October 13, 2021, the Special Master entered an Amended Scheduling Order in which he stayed merits discovery and set forth a number of new deadlines related to class certification discovery. (Doc. No. 265 at 2–3.) The Amended Scheduling Order makes no mention of any change to the deadline for filing motions to amend. The plaintiffs, however, argue that the Order "implicitly suspended"

that deadline, because it "necessarily must be reset to follow merits discovery." (Doc. No. 312 at 8–9.) This disagreement matters because, if the motion is untimely, it is subject to the "good cause" standard for modifying a scheduling order set forth by Rule 16(a)(4), not the comparatively more lenient "when justice so requires" standard set forth in Rule15(a)(2).

The plaintiffs are probably correct that the Amended Scheduling Order, though focused on discovery, should have provided for extensions of some of the substantive deadlines as well. Indeed, the defendants themselves agree that "merits-related deadlines necessarily must change once the class-certification phase is complete," although they do not agree that the deadline for motions to amend should be among those to be altered. (Doc. No. 314 at 3–4.) Even if such an amendment is called for, however, the plaintiffs are not correct that such an amendment has actually occurred. An initial case management order "controls the course of the action unless the court modifies it." Fed. R. Civ. P. 16(d). The Amended Scheduling Order contained no mention whatsoever of the deadline for seeking leave to amend pleadings. When one order of the court suggests that another order of the court needs amending, the appropriate course of action is to *request that necessary amendment*, not simply to assume that the amendment already occurred *sub silentio*. Litigation is complicated enough—especially between these parties—without requiring the court and litigants to deduce an unwritten calendar of deadlines from the interstices of what the court has actually said.

In any event, the court would deny this motion under either Rule 15 or Rule 16. The only reason that the plaintiffs have given for seeking this amendment now is the Eastern District of Michigan's opinion in *Reynolds*, but the relevant portion of *Reynolds* is just a few short paragraphs consisting primarily of citations to cases that had already considered this very issue and "reached different conclusions as to whether class action bars in consumer protection statutes are substantive

or procedural." 546 F.Supp.3d at 657. In other words, the contested status of this issue was already clear long before the plaintiffs' motion was filed. Indeed, there was appellate-level caselaw noting this issue—and supporting the plaintiffs' position—at least as early as 2008. *See Thorogood v. Sears, Roebuck & Co.*, 547 F.3d 742, 746 (7th Cir. 2008) ("Sears argues that the Tennessee rule precludes the maintenance of the present case as a class action. That is wrong. The procedure in diversity suits is governed by federal law.").

Reynolds itself, in fact, was issued while the plaintiffs' prior request for leave to amend was still pending and could have been supplemented. Regardless, even if one does treat *Reynolds* as arising too late to have been part of that motion, all that *Reynolds* does is conclude, without much elaboration, that, "[a]fter considering th[e] split in authority, the Court finds more persuasive the decisions holding that class action prohibitions in certain state consumer protection statutes are procedural." *Id.* The court sees nothing wrong with the Eastern District of Michigan's succinct approach; there are only so many times various courts can rehash the same either-or question in painstaking detail before it becomes a waste of resources. Nevertheless, that court's reliance on earlier decisions' reasoning means that *Reynolds* is, at most, a fresh vote on one side of the ledger with regard to this issue; it is not an intervening change in the law or even a meaningful substantive alteration of the persuasive authority. The delay in requesting an amendment is therefore unjustified.

Weighing against the proposed amendment, moreover, is the potential prejudice to the defendants. While this amendment would not change the substantive proof required to establish liability, it would expand the scope of issues relevant to the class certification decision, after a great deal of class discovery has already been completed. (*See* Doc. No. 312 at 4 (plaintiffs' stating that the proposed amendment would "provide another basis for certifying a damages class under

Rule 23(b)(3)"). The plaintiffs protest that no such hardship would arise because this damages request is largely redundant with other class damages requests already pleaded. But, as the defendants point out, the plaintiffs are trying to have it both ways. If this amendment is mostly redundant, then there is little reason to think that justice requires it; but if it is significant enough for justice to require it, then it must entail some hardship.

The issue of good faith also counsels against allowing the plaintiffs' amendment. The plaintiffs have already been admonished by the court for their abuse of the amendment process. This motion is an improvement over the last one in terms of the scope of the request, but the evidence of good faith largely ends there. Particularly troubling to the court is the plaintiffs' assertion that *Reynolds* provides a sufficient basis for changing the SAC's approach to damages, when the *Reynolds* opinion *acknowledges in its own text* that this issue had already been addressed repeatedly by the courts. The defendants have identified a litany of cases that identified this as a contested issue before *Reynolds*. The proposition that *Reynolds* somehow changed the landscape in such a way as to justify amending the SAC *now* is not only unconvincing but so implausible as to be evidence of abuse of the Rule 15 process.[8]

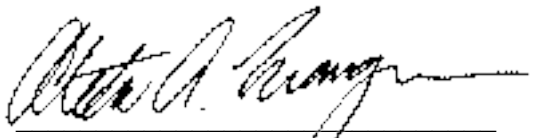
The court therefore concludes that the plaintiffs have not met the requirements for obtaining leave to amend their Second Amended Complaint, under either the "good cause" standard or the "as justice so requires" standard, and this motion will be denied. If there are any deadlines that have not been expressly amended but need to be, the court requests that the parties confer about the matter, try to reach an agreement about revisions, and file a joint request to that effect as soon as reasonably practicable.

[8] Because these factors weigh so heavily against allowing the amendment, the court will not undertake an unnecessary futility analysis based on the question of whether Rule 23 or the TCPA's class action bar should prevail. Suffice it to say that, as the court noted in *Reynolds*, that issue is contestable and unsettled, with colorable arguments on both sides.

IV. CONCLUSION

For the foregoing reasons, the defendants' Motion to Dismiss Certain of Plaintiffs' Claims on the Pleadings (Doc. No. 256) and the plaintiffs' Motion for Leave to Amend the Complaint (Doc. No. 311) will be denied.

An appropriate order will enter.



ALETA A. TRAUGER
United States District Judge