UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	**SACV 15-01026 JVS (RAOx)** consolidated with SACV 15-02018 JVS(RAOx)	Date	November 1, 2016
Title	In re Fontem US, Inc. Consumer Class Action Litig.		

Present: The Honorable	James V. Selna	
Karla J. Tunis		Not Present
Deputy Clerk		Court Reporter
Attorneys Present for Plaintiffs:		Attorneys Present for Defendants:
Not Present		Not Present

Proceedings: **(IN CHAMBERS) Order Granting in Part and Denying in Part the Defendant's Motion to Dismiss the Second Amended Complaint**

In the Second Consolidated Amended Complaint ("SCAC"), Plaintiffs Larry Diek, Frank Perez, Michael Whitney, Paul Pisciotto, and Tanya Mullins (collectively, "Plaintiffs") purport to bring causes of action under the laws of California, Illinois, and New York on behalf of themselves and similarly situated consumers against Defendants LOEC, Inc., Lorillard, Inc., Reynolds American, Inc.; ITG Brands, LLC; Fontem US, Inc.; and Fontem Holdings 4 B.V. (collectively, "Defendants"). (See generally SCAC, Docket ("Dkt.") No. 71.)

On July 1, 2016, pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants filed a motion to dismiss the SCAC on the grounds that Plaintiffs' claims are expressly preempted by a recent final rule promulgated by the Food and Drug Administration ("FDA"). (Mot., Dkt. No. 74.) Plaintiffs oppose. (Opp'n, Dkt. No. 80.) Defendants replied. (Reply, Dkt. No. 81.)

For the following reasons, the Court grants in part, and denies in part, Defendants' motion to dismiss.

I. Background

The factual background of this dispute is discussed at length in this Court's previous order granting in part, and denying in part, Defendants' earlier motion to

dismiss. (Order, Dkt. No. 60 pp. 2–10.) In the Order, the Court denied, without prejudice, Defendants' motion to dismiss on primary jurisdiction grounds. The Court contemplated that there was a possibility that, sometime after the hearing on Defendants' motion, the FDA would issue regulations precluding Plaintiffs' claims in this case. (See id. pp. 24–25.)

Since the Order was issued, the FDA has issued a final rule titled "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (the "Final Rule"). 81 Fed. Reg. 28974 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143). The Final Rule concludes that e-cigarettes are deemed "tobacco products" and fall under the FDA's authority to regulate tobacco products. See Final Rule, 81 Fed. Reg. 28974, 28976. As of the effective date of the Final Rule (August 8, 2016) the newly deemed products, including e-cigarettes, are subject to certain Food, Drug, and Cosmetic Act requirements related to cigarettes and other tobacco products, as well as "additional provisions." Id. These "additional provisions" include a minimum age for purchase requirement, a prohibition (subject to certain conditions) on vending machine sales, and, most importantly for this order, a requirement for health warnings for product packages and advertisements.[1] Id.

The Final Rule requires a particular warning label. According to the Final Rule, "[p]ackaging and advertising for all newly deemed products other than cigars must display an addictiveness warning that states: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."[2] Final Rule, 81 Fed. Reg. 28974, 28988; see also 21 C.F.R. § 1143.3(a)(1). The FDA mandates that the warnings must appear on at least 30 percent of the two principal display panels of the package, and 20 percent of the area of advertisements. Final Rule, 81 Fed. Reg. 28974, 28988; see also 21 C.F.R. § 1143.3(a)(2), (b). The heading of this part of the regulation is "Minimum Required

[1] The effective date that the health warning requirements takes effect is May 10, 2018. Final Rule, 81 Fed. Reg. 28974, 28976; 21 C.F.R. § 1143.13.

[2] There is an alternative warning for nicotine-less products. Manufacturers of those products may use a warning that states: "This product is made from tobacco."

Warning Statements." 21 C.F.R. pt. 1143. The FDA has stated that the heading was implemented "in order to clarify that part 1143 is not intended to prevent tobacco product manufacturers from including truthful, non-misleading warnings on their products' packaging or advertisements voluntarily or as a result of FDA guidance." Final Rule, 81 Fed. Reg. 28974, 28990.

The Final Rule also addresses preemption. During the comment period, competing comments wanted an explicit statement by the FDA that the Final Rule's warning requirements did, or did not, preempt state and local warning requirements. See Final Rule, 81 Fed. Reg. 28974, 28989. The FDA declined to make such a comment, referring the commenters to 21 U.S.C. § 387p. Id. However, the FDA did state the following: "No State or local laws in effect at the close of the public comment period were identified that FDA determined would be preempted by this final rule." Id.

II. Discussion

Defendants argue that by deeming e-cigarettes a "tobacco product," the FDA made e-cigarettes subject to the Family Smoking Prevention and Tobacco Control Act's ("TCA")[3] provision regarding the preemption of state requirements pertaining to tobacco products. They argue that the preemption provision "draws a bright line around activity that can be performed by the FDA alone" and they cite to 21 U.S.C. § 387p(a)(2)(A). (Mot. p. 3.)

In full, the applicable preemption provision is as follows:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

[3] The TCA is codified as a subchapter of the Federal Food, Drug and Cosmetic Act.

21 U.S.C. § 387p(a)(2)(A). Defendants contend that the specific prohibition of State requirements "different from, or in addition to" requirements relating to "tobacco product standards" and "labeling" mean that all claims in the SCAC are preempted by federal law.

Plaintiffs respond that "controlling authorities' analysis of similar preemption provisions, the preservation and savings clause in the TCA, and FDA's analysis of its own regulation" mandate a conclusion that the TCA and the Final Rule do not preempt state warning requirements and that Defendants' motion should be denied. (Opp'n p. 1.)

A. Legal Authorities on Express Preemption

When faced with a task of interpreting a statute that expressly preempts state law, courts begin by identifying "the domain expressly pre-empted" by the language of the preemption provision. Medtronic, Inc. v. Lohr, 518 U.S. 470, 484 (1996) (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517 (1992)). Courts analyze those preemption statutes starting with the "assumption that the historic police powers of the State were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Id. at 485 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

Turning attention to the statute relevant to the present case, the Court observes that the clear and unambiguous language of the preemption provision of the TCA preempts states from requiring any particular "labeling" of tobacco products. 21 U.S.C. § 387p(a)(2)(A). The definition of "labeling" is found elsewhere in the Federal Food, Drug, and Cosmetic Act. According to the definitions used throughout the Federal Food, Drug, and Cosmetic Act, "[t]he term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). Moreover, the term "label" means "a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or

wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper." 21 U.S.C. § 321(k).

Consequently, by the express terms of 21 U.S.C. § 387p(a)(2)(A), no State can impose "any requirement which is different from, or in addition to" the FDA's requirements regarding the written, printed, or graphic matter that appears on tobacco products or accompanies those products.

The FDA has promulgated a "labeling" requirement for e-cigarettes. The FDA's required warning statement regarding addictiveness of nicotine specifically says that the required warning statement must be on the package label. 21 C.F.R. § 1143.3(a)(1). The regulation also prescribes visibility, font, and size requirements for the warning. 21 C.F.R. § 1143.3(a)(2). The types of requirements contained in the regulation are very similar to the warning requirements for cigarettes and smokeless tobacco. Compare 21 C.F.R. § 1143.3(a) with 15 U.S.C. § 1333(a); 15 U.S.C. § 4402(a).

The Court finds that the preemption analysis is straightforward: the FDA, under the authority it possesses under the TCA, see 21 U.S.C. § 387f(d)(2), has promulgated a labeling requirement that applies to e-cigarettes. Therefore, state labeling requirements that apply to e-cigarettes that are "different from, or in addition to" the FDA's requirement are preempted. Nevertheless, the Court addresses the Plaintiffs arguments as to why, in their view, the Final Rule does not have a preemptive effect.

1. Medtronic v. Lohr

Plaintiffs contend that this labeling requirement falls short of having a preemptive effect. Plaintiffs argue that the federal warning requirement applicable to the Defendants' products is "generic and limited" and consequently does not preempt more specific state law claims. (See Opp'n pp. 4–9.) Plaintiffs cite Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) ("Lohr"), for this proposition.

Lohr is clearly distinguishable. In Lohr, the regulation at issue involved a labeling requirement that generically required manufacturers of medical devices to "include with the device a label containing 'information for use, . . . and any relevant hazards,

contraindications, side effects, and precautions.'" 518 U.S. at 497 (quoting 21 C.F.R. §§ 801.109(b) and (c) (1995).) The Court held that "the generality of those requirements [made] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." Id. at 501.

In contrast, in the present case, the FDA has specified a scripted statement mandating that the package label specify that the tobacco product contains nicotine and that nicotine is addictive. The FDA has mandated particular language, size, font, and visibility requirements for the warning label. These facts make the warning requirement a far more specific mandate compared to those requirements found to be not preemptive in Lohr. Consequently, the Court rejects Plaintiffs' argument that "the scope of the federal warning requirement applicable to Defendants' Products is generic and limited." (Opp'n p. 7.) See also Papike v. Tambrands Inc., 107 F.3d 737, 739–42 (9th Cir. 1997) (finding express preemption under the Medical Devices Amendments to the Federal Food, Drug, and Cosmetic Act where the FDA promulgated specific tampon labeling regulations and the plaintiffs attempted to bring claims under state tort law for failure to warn).

At the hearing, Plaintiffs argued that Lohr is similar to the present case because in both Lohr and the case at bar, the regulations were directed to general product categories. Further discussion of Lohr is warranted. In Lohr, the Court was considering the preemption provision of a different subchapter of the Federal Food, Drug, and Cosmetic Act. That provision stated:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect *with respect to a device* intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement *applicable* under this chapter *to the device*, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the

device under this chapter.

21 U.S.C. § 360k (emphasis added). The Court noted that the preemption clause "expressly states that a federal requirement must be 'applicable to the device' in question before it has any preemptive effect." Lohr, 518 U.S. at 498. The Court further observed that according to the FDA regulations, "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device'" Id. citing (21 C.F.R. § 808.1(d) (1995)).

Here, Plaintiffs fail to point to language in the TCA's preemption provision that would similarly lead the Court to conclude that preemption is a product specific inquiry. Nor do plaintiffs point to regulations stating that state requirements are preempted only if there are counterpart, product-specific requirements for tobacco products. Instead, in the preemption provision of the TCA, Congress specified the types of state requirements that *are* preempted. Those state requirements include "labeling" requirements. Finally, because the FDA has promulgated a specific, federal "labeling" requirement (i.e., the Final Rule), such requirement can, and does, have a preemptive effect.

2. FDA's requirement is only a "minimum" warning

Plaintiffs' stronger argument is that the Final Rule mandates only a "minimum" nicotine addictiveness warning and does not impose any requirement related to health safety warnings. Plaintiffs argue that the Plaintiffs' claims "requiring Defendants to disclose that their Products cause exposures to toxic chemicals other than nicotine will in no way contradict the federal requirement that Defendants disclose that the nicotine in their Products is addictive." (Opp'n p. 7.)

This would be a persuasive argument if the issue was whether the state requirement conflicted with the federal requirement. However, the express language of the preemption provision of the TCA is broader: "No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, **or in addition to**, any requirement . . . relating to tobacco product . . . labeling . . . ." 21 U.S.C. § 387p(a)(2)(A) (emphasis added). The Court cannot ignore this express language or the fact that the claims of the SCAC would have the Court impose,

by virtue of state law, *additional* labeling of the Defendants' e-cigarette products. The Court will not merely assume that Congress meant "conflicting" when Congress used the term "different from, or in addition to." The use of this language means that the TCA's preemption clause "sweeps widely." Nat'l Meat Ass'n v. Harris, 132 S. Ct. 965, 970 (2012) (analyzing a similar preemption clause in the Federal Meat Inspection Act that "prevents a State from imposing **any** additional or different**—even if non-conflicting—**requirements that fall within the scope of the [Federal Meat Inspection Act]." (emphases added)).[4]

3. Distinction between "requirements under the provisions of this subchapter" and "rules promulgated under this subchapter"

At the hearing, Plaintiffs raised (for the first time) a clever textual argument regarding why the Final Rule should not have a preemptive effect. In essence, their argument leads to the conclusion that no regulation promulgated by the FDA concerning tobacco products could have a preemptive effect.

Plaintiffs arrive at this conclusion by arguing that the preemption provision is quite narrow, and only the statute itself can have preemptive effect. Plaintiffs contend that textual differences between § 387p(a)(1) and § 387p(a)(2)(A) mandate this conclusion. In the preemption provision, § 387p(a)(2)(A), Congress used the phrase "the provisions of this subchapter" to refer to the type of requirements that can have preemptive effect. In contrast, in § 387p(a)(1), referring to the federal requirements to do not have a preemptive effect, Congress used the term "nothing in this subchapter, **or rules promulgated under this subchapter** . . . ." In essence, Plaintiffs argue that Congress intended to only make sections of the TCA preemptive, and never permit rules promulgated by the FDA to be preemptive under this section. See also Greene v. Five Pawns, Inc., No. SACV 15-1859 DOC (DFMx) (Aug. 30, 2016) at pp. 13–14 (concluding

[4] Plaintiffs' efforts to minimize the holding of National Meat Association fail. Although the facts in that case indicated that the state regulation in some ways supplanted the federal requirements, the express holdings and language of the unanimous opinion indicated that the preemption clause broadly preempted "much state law involving slaughterhouses," including state law requirements that did not conflict with, or undermine, the federal requirements. Nat'l Meat Ass'n, 132 S. Ct. at 970, 974 n.10.

that text and structure of provision shows "Congress' intent to give express preemptive force only to specific sections and subsections of the TCA, and demonstrates that Congress' use of the word 'labeling' in 21 U.S.C. § 387p(a)(2)(A) does not mean the ordinary sense of the word or the FDCA's definition, but rather the TCA subsection entitled 'Origin Labeling.'").

The Court appreciates Plaintiffs' argument, but ultimately concludes that it is not a correct reading of the statute. If Congress intended to give preemptive effect to only certain requirements specifically mandated by the TCA itself (i.e., the requirements of § 387g, § 387j(a)(2), § 387b, § 387c, § 387t(a), § 387e, § 387f(e); and § 387k), then Congress could have specifically referenced those sections. Instead, Congress listed categories of requirements that were to have preemptive effect. One of those categories is labeling, and the FDA has promulgated a regulation that constitutes a requirement, under the TCA, regarding labeling. The Court would have to consider the FDA's regulations to not be a "requirement[] under the provisions of the [TCA]" in order to accept Plaintiffs' arguments, and the Court is not prepared to do that.

B. TCA's Preservation Clause

1. Use or Exposure / Labeling and Point of Sale Warnings

Plaintiffs next argue that, assuming 21 U.S.C. § 387p(a)(2)(A) applies to Plaintiffs' claims, the claims are exempted from preemption under the TCA's preservation and savings clauses because their claims are based on use or exposure. (Opp'n p. 9.)

In full, the savings clause of the TCA reads:

> Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of Title 5 shall be treated as

a trade secret and confidential information by the State.

21 U.S.C. § 387p(a)(2)(B). To summarize, any requirement relating to "labeling" is preempted by the TCA, but requirements relating to "exposure to" or "use of" tobacco products are exempted from preemption.

This is not, however, a case solely about exposure to, or use of, tobacco products. The SCAC asserts the following seven counts: (I) Violations of the Consumer Legal Remedies Act ("CLRA"), (II) Violations of Unfair Competition Law ("UCL"), (III) Violation of False Advertising Law for Deceptive, False, and Misleading Advertising ("FAL"), (IV) Violations of UCL based on violations of Proposition 65, (V) Violation of New York General Business Law ("GBL"), (VI) Fraudulent Concealment under Illinois Law, and (VII) Violations of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"). Each count is about disclosure of information, rather than exposure to tobacco products.

The counts for violation of the CLRA, UCL (unfair and fraudulent prong), and FAL are all premised on an alleged omission of material facts that the Defendants allegedly had a duty to disclose. (See SCAC ¶¶ 121–23, 137, 139, 149–50.) So are the counts for violation of the GBL, fraudulent concealment under Illinois law, and violation of the ICFA. (See id. ¶¶ 182–84, 195–96, 198, 205–206.) Plaintiffs efforts to claim that these consumer protection statutes regarding representations and omissions are actually claims regarding use of or exposure to tobacco products wholly ignore the very nature of these claims. Instead, all of the CLRA, UCL (unfair and fraudulent prong), FAL, GBL, ICFA, and fraudulent concealment under Illinois law claims rely on the purportedly "deceptive and misleading" acts by Defendants of warning of certain risks relating to nicotine, and listing of ingredients (but not "hidden ingredients") ***on Defendants' products' packaging*** and impliedly representing that those are the only health-related risks related to the Defendants' e-cigarettes. (See id. ¶¶ 2, 7, 9, 17–26, 41–42, 92–95.) Consequently, these claims are premised on what is, and what is not, included on the product's label. For the reasons discussed in Part I.A, supra, these claims are preempted by the prohibition on additional or different labeling requirements.

The count for violation of the UCL premised on violations of Proposition 65

warrants further consideration because a Ninth Circuit case, Chemical Specialities Manufacturers Association v. Allenby, 958 F.2d 941 (9th Cir. 1992) ("Allenby"), has specifically held that the warning requirements of Proposition 65 do not necessarily constitute additional labeling. Id. at 945.

California has promulgated a non-exhaustive list of methods to provide a proper warning under Proposition 65. Cal. Code Regs. tit. 27, § 25603.1 (2016).[5] The warning *can* be a label. Cal. Code Regs. tit. 27, § 25603.1(a). The warning could also be a point of sale warning. Cal. Code Regs. tit. 27, § 25603.1(b). Or, alternatively, the warning could be a system of public advertising or "any other system that provides clear and reasonable warnings." Cal. Code Regs. tit. 27, § 25603.1(d).

"To find that Proposition 65 is preempted . . . [a] court must determine that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of the federal statutes." Allenby, 958 F.2d at 943. The question of whether the UCL claims premised on violations of Proposition 65 are preempted therefore turns on whether all consumer product warnings conflict with provisions of the TCA and the FDA's Final Rule.

Defendants argue that "[i]n the instant action, the labeling and disclosures Plaintiffs claim were requirements, and which they seek to impose under Proposition 65 or otherwise, are expressly preempted." (Mot. p. 13.) The Court agrees only to the extent Plaintiffs claims are premised on a failure to label. The Court finds there will be no liability for, and no affirmative relief granted, pertaining to the failure to include on product packaging any Proposition 65 warning.

But labeling is not the only method of providing a warning under Proposition 65. In Allenby, the Ninth Circuit considered whether point-of-sale warnings constituted "labeling." The Ninth Circuit found that they did not, because "point-of-sale signs are not attached to the immediate container of a product and will not accompany the product

[5] § 25603.1 is operative only until August 30, 2018. On and after August 30, 2018 a warning must meet different requirements. See http://oehha.ca.gov/proposition-65/crnr/notice-adoption-article-6-clear-and-reasonable-warnings

during the period of use." 958 F.2d at 946.

Defendants cite American Meat Institute v. Leeman, 180 Cal. App. 4th 728 (2009) ("Leeman"), as distinguishing Allenby and questioning its validity in light of Kordel v. United States, 335 U.S. 345 (1948). Ultimately, although this Court concludes that the Leeman decision makes some interesting points about the relationship between Kordel and Allenby,[6] and whether the Allenby court properly applied Kordel, this Court is obliged to follow Ninth Circuit precedent, including precedent that purports to discern when a Supreme Court precedent applies, or not.

Consequently, the Court finds that Proposition 65's point-of-sale provisions are not preempted because they do not constitute "labeling" as that term is used in the Federal Food, Drug, and Cosmetic Act and the TCA.[7]

2. Advertising

Plaintiffs further argue that there are other methods of Proposition 65 compliance available to Defendants that fall outside of the TCA's preemption provision. The Court agrees. Defendants may comply with Proposition 65 by "a system of signs, public advertising identifying the system and toll-free information services that provides clear and reasonable warnings" regarding exposure to carcinogens. Cal Code Regs. tit. 27, § 25603.1(d).[8]

Defendants assert that such a "warning system in the form of signs, public

[6] See Leeman, 180 Cal. App. 4th at 754–755 (claiming that the Allenby court considered Kordel but failed to consider "the most applicable" portions of the decision).

[7] The differences in the definitions of "label" and "labeling" in the Federal Insecticide, Fungicide, and Rodenticide Act, as interpreted in Allenby, and in the present case do not warrant a different result from that of Allenby. Compare Allenby, 958 F.2d at 945–46 with 21 U.S.C. § 321(k)–(l).

[8] The new California regulations pertaining to Proposition 65 that go into effect on August 30, 2018 do not contemplate the use of a "system of signs" as described in the current regulation. See http://oehha.ca.gov/media/downloads/crnr/art6regtextclean090116.pdf (pp. 5–6, § 25602)

advertising, and toll-free information services to comply with Proposition 65 requirements, as Plaintiffs suggest, would clearly involve a method of labeling, not advertising." (Reply p. 7.) The Defendants utterly fail to explain how this is so. Particularly where Ninth Circuit authority already holds that point-of-sale warnings do not constitute labeling, it is highly doubtful that a warning system involving signs and public advertising would constitute labeling.

For the foregoing reasons, the Court concludes that the Plaintiffs' UCL claim premised on Proposition 65 is not preempted, because there are methods of compliance with Proposition 65 that do not constitute "labeling" as the term is used in 21 U.S.C. § 387p.

C. FDA's Determinations Regarding Preemption

Finally, Plaintiffs argue that the FDA has expressly determined that the TCA and the Final Rule do not preempt warning requirements such as the claims of the SCAC. (Opp'n pp. 15–17.) The Court disagrees. The FDA, in answering comments requesting a statement regarding preemption merely referred back to 21 U.S.C. § 387p, stated that a State or local statute is facially preempted only if no set of circumstances exists under which the statute would be valid, and that no state or local laws were identified that FDA determined would be preempted by the final rule. Final Rule, 81 Fed. Reg. 28974, 28989. The Court agrees with Defendants' that this amounts to a statement that the FDA did not find preemption or non-preemption. This is consistent with the Court's finding that the Proposition 65 claim is *not* preempted, because there exists a set of circumstances where Proposition 65 is valid.

The Court also agrees with Defendants that nothing in the Final Rule implies that changing the heading of the applicable section, 21 C.F.R. part 1143, from "Required Warning Statements" to "Minimum Required Warning Statements" was to indicate that the Rule does not preempt state law requirements. Instead, the title change was made "in order to clarify that part 1143 is not intended to prevent tobacco product manufacturers from including truthful, non-misleading warnings on their products' packaging or advertisements voluntarily or as a result of FDA guidance." Final Rule, 81 Fed. Reg. 28974, 28990.

D. Timing

The statutory language demonstrates that preemption regarding e-cigarettes began on August 8, 2016. The regulation recites that "[n]o State or political subdivision of a State may establish or *continue in effect* with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product . . . labeling." 21 U.S.C.S. § 387p(a)(2)(A) (italics supplied). In addition, the rule regarding e-cigarettes "[was] effective August 8, 2016." 81 Fed. Reg. 28,974; see also 21 C.F.R. § 1143.1. Based on this language, preemption also began once the rule became effective on August 8, 2016.

However, the FDA has created several different compliance dates for certain provisions. Id.; see also 21 C.F.R. § 1143.13. For instance, the "FDA has considered the comments and the time and resources it will take for manufacturers to comply with the health warnings requirements and the need to provide these messages to consumers and has determined that the proposed effective date of 24 months after publication of this rule for the warning requirements in part 1143 is appropriate." 81 Fed. Reg. 29,006. Therefore, manufacturers do not need to comply with the provision until May 10, 2018. See 21 C.F.R. § 1143.13. Nevertheless, the FDA did not include language that suggest the effective date for preemption also begins on May 10, 2018, so even though manufacturers have more time to comply with the regulation, the regulation still began to preempt state statutes on the date that the regulation became effective. In conclusion, preemption began on August 8, 2016.[9]

III. Conclusion

For the foregoing reasons, the Court concludes that Plaintiffs' claims, with the exception of the claim for violation of the UCL by virtue of violation of Proposition 65, are preempted by the Final Rule and the TCA. The Court dismisses counts 1–3 and 5–7 with prejudice. The Court does not dismiss count 4.

[9] Plaintiffs argue that the analysis in Landgraf v. USI Film Products, 511 U.S. 244, 265 (1994), controls. (Suppl. Opp'n, Docket No. 91 at 9.) However, the United States Supreme Court did not discuss preemption in Landgraf. 511 U.S. at 265.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. **SACV 15-01026 JVS (RAOx)** consolidated with SACV 15-02018 JVS(RAOx) Date November 1, 2016

Title In re Fontem US, Inc. Consumer Class Action Litig.

The Court does not reach the arguments pertaining to the Illinois state law claims because the Court finds these claims are preempted.

IT IS SO ORDERED.

: 00

Initials of Preparer kjt