SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, et al, Plaintiffs/Petitioners, v. PERRIGO COMPANY, et al, Defendants/Respondents.	No. RG20-054985 ORDER SUSTAINING DEMURRERS WITH LEAVE TO AMEND. Date: 5/5/21 Time: 10:00 a.m. Dept.: 21

Several demurrers came on for hearing on 5/5/21, in Department 21 of this Court, the Honorable Winifred Y. Smith presiding. Counsel appeared on behalf of Plaintiff and on behalf of Defendant. After consideration of the points and authorities and the evidence, as well as the oral argument of counsel, IT IS ORDERED:

The demurrer of Chattem and Sanofi-Aventis (Brand Name Defendant (R#2240283) is SUSTAINED WITH LEAVE TO AMEND.

The demurrer of Apotex (Generic Manufacturer Defendant) (R#2240282), the demurrer of Perrigo (Generic Manufacturer Defendant) (R#2242700), the demurrer of Granules USA, Inc. (Generic Manufacturer Defendant) (R#2242703), and the demurrer of Dr. Reddy's Laboratories,

Inc. (Generic Manufacturer Defendant) (R#2240276) are SUSTAINED WITHOUT LEAVE TO AMEND.

The demurrer of 7-Eleven (Retailer Defendant) (R#2240281) and the demurrer of Target Corporation (Retailer Defendant) (R#2242040) are SUSTAINED WITHOUT LEAVE TO AMEND.

BACKGROUND

These are demurrers, so the court assumes "the truth of the properly pleaded factual allegations, facts that reasonably can be inferred from those expressly pleaded and matters of which judicial notice has been taken." (*Redfearn v. Trader Joe's Co.* (2018) 20 Cal.App.5th 989, 996.)

The court GRANTS all the requests for judicial notice. In other circumstances the court might not permit this expansive use of judicial notice because it has the effect of turning a demurrer into a de facto motion for summary judgment. (*Richtek USA, Inc. v. uPI Semiconductor Corporation* (2015) 242 Cal.App.4th 651, 660.) There were no objections to the requests for judicial notice. Furthermore, the issue presented is legal in nature and the evidence relevant to the legal issue is undisputed. The evidence is disputed regarding substantive issues, but the demurrers are not about the substantive issues.

THE COMPLAINT

Defendants manufacture, import, distribute, or sell the Products. (2AC, para 34.) The Products are non-prescription, or "over the counter ("OTC"), drugs The known carcinogen

NDMA was in the Products when the consumers bought the products. Defendants know or should have known there was NDMA in the Products. (2AC, para 34, 43.)

In September 2019, there were recalls of the Products based on the presence of NDMA. (2AC, para 36.) Following the recalls, the FDA issued public alerts. (2AC, para 36.) Defendant continued to sell the products after the recalls and public alerts without giving appropriate warmings. (2AC, para 37, 44.)

The 2AC assets a single cause of action against the Defendants under H&S 25249.6 alleging that they have intentionally exposed individuals to NDMA without first giving clear and reasonable warnings. (2AC, para 45.)

The demurrers are based on the related issues of H&S 25249.10(a) and preemption. The Brand Name Manufacturers, the Generic Manufacturers, and the Private Label Retailers argue impossibility preemption. Defendant Apotex is a Generic Manufacturer and also argues field preemption and mootness. For purposes of these demurrers the court can assume that defendants marketed and sold the Products knowing that there was NDMA in the Products, whether as a result of FDA approved design or manufacturing or as a result of manufacturing contamination, storage in high heat, or delay in sale to consumers.

RELATED CASES

The court takes judicial notice of the existence of parallel mass tort proceedings concerning MDNA, ranitidine, and the Products. There is a Federal MDL in Florida, which concerns claims for personal injuries. There is a California JCCP that concerns claims for personal injuries. (*In re Ranitidine Cases*, JCCP 5150.)

PROPOSITION 65 – COMPLIANCE/LIABILITY AND REMEDY

H&S 25249.6 states: "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10."

A defendant can comply with the law by ensuring that its products do not "expose any individual to a chemical known to the state to cause cancer or reproductive toxicity." This means keeping the chemical exposure below the "no significant risk" level. (H&S 25249.10(c).)

A defendant can comply with the law by providing a "clear and reasonable warning." The warning must have certain content. (27 CCR 25603.) The content of the warning may be transmitted through product labeling, point-of-sale signs, or public advertising. (*Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 918.) (See also 27 CCR 25601(c), 25602.)

If the court finds that a defendant is in violation of H&S 25249.6, then the court can order remedies in the form of injunctions and penalties. H&S 25249.7(a) states "A person who violates or threatens to violate Section 25249.5 or 25249.6 may be enjoined in any court of competent jurisdiction." H&S 25249.7(b) states "A person who has violated Section 25249.5 or 25249.6 is liable for a civil penalty."

For purposes of this motion, it is useful to distinguish between the compliance/liability provision (H&S 25249.6) and the remedy provision (H&S 25249.7).

A defendant can comply with Prop 65 and avoid liability by either providing a warning or ensuring that its products have chemical exposure below the "no significant risk" level. (H&S 25249.6 and 25249.6.10(c).) A lack of warning can result in liability.

Assuming a lack of compliance, which is liability, then the court can order a remedy. The court can order injunctions and penalties. (H&S 25249.7(a) and (b). The court can order a warning as a remedy.

The analysis in this order is focused on the liability provision, H&S 25249.6, which is limited by the exemption provision, H&S 25249.10(a), which states that there is no Proposition 65 liability for "an exposure for which federal law governs warning in a manner that preempts state authority." The analysis in this order does not address or decide whether under the remedy provision of H&S 25249.7 the court could order a defendant to manufacture the products free of contaminants, to take greater care in storing the products, and to set expiration dates to require sale before the degradation of the products.

If the preemption analysis were a de facto inquiry into the scope of relief that the court can order under H&S 25249.7(a), then the court would permit the Attorney General to file an amicus brief and on that issue and to present evidence of any policies that might be relevant to statutory interpretation. (*Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 14-15.) The court does not do that because the preemption analysis is focused on compliance/liability under H&S 25249.6.

PROPOSITION 65 – SELF-EXEMPTION TO COMPLIANCE/LIABILITY WHERE THERE IS FEDERAL PREEMPTION OF WARNING.

Prop 65 states that there is an exemption to the compliance/liability provision when federal law governs warnings. H&S 25249.10(a) states: "Section 25249.6 [the compliance/liability provision] shall not apply to any of the following: (a) An exposure for which

federal law governs warning in a manner that preempts state authority." This self-exception does more than state the obvious, which is that federal law preempts state law.

The self-exception states that if federal law for an exposure governs warning in a manner that preempts state authority, then there is no violation of the compliance/liability provision. This in turn means that if federal law on warning preempts state law on warning, then there is no liability for an exposure under H&S 25249.6, whether based on either lack of warning or knowing exposure to chemicals, and thus the court cannot order any non-warning injunctive relief or award any penalties.

Plaintiff argues that this is an improper reading of H&S 25249.10(a) because it limits Proposition 65 more than the direct application of federal preemption. The court is giving effect to the plain words in the statute. Proposition 65 is focused on providing warnings and reasonably does not apply to "An exposure for which federal law governs warning in a manner that preempts state authority."

The FDCA has an express preemption provision for non-prescription ("OTC") drugs such as ranitidine. (21 USC 379r.) The express preemption provision has wide scope and includes "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." (21 USC 379r(c)(2).) The FDCA's express preemption provision would preempt Proposition 65 as applied to OTC drugs, except that the provision has an express exception for any "State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997." (21 USC 379r(d)(2).) "Proposition 65 is the only state enactment that falls within the savings clause." (*Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 918.)

The FDCA's exclusion of Proposition 65 from the FDCA's express preemption clause does not exempt Proposition 65 from implied preemption. "[E]ven where the express preemption provision in [21 U.S.C. § 379r] is not applicable, implied preemption may arise … the savings clause does not foreclose the possibility that conflict preemption may arise from federal sources other than 21 U.S.C. § 379r.']. (*Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 150-151.) Therefore, the court cannot determine whether the Proposition 65 express exemption (H&S 25249.10(a) applies unless the court goes through the analysis of implied preemption to determine whether "federal law governs warning in a manner that preempts state authority."

The court notes, by way of observation, that the Proposition 65 self-exception under H&S 25249.6 is not part of other statutes. The effect of impossibility preemption operating through the Proposition 65 self-exception is different from impossibility preemption operating in isolation. There might be state law remedies other than Proposition 65 that are not preempted and that would apply if, as alleged, a drug manufacturer is selling, or had sold, drugs that comply with FDA labelling requirements but expose California consumers to hazardous chemicals because the drugs are contaminated, or improperly stored, or not timely sold.

PREEMPTION – GENERALLY.

The United States Congress has the power to preempt state law concerning matters that lie within its authority. (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1087.) Preemption of state law may be express or implied. Implied preemption occurs "'(i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) when compliance with both

federal and state regulations is an impossibility [citation]; or (iii) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. (*Solus Industrial Innovations, LLC v. Superior Court* (2018) 4 Cal.5th 316, 332.)

"[F]ederal preemption presents a pure question of law." (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1089 fn 10; *Coleman*, 223 Cal.App.4th at 422.) The court focuses on the intent of Congress. (*Spielholz v. Superior Court* (2001) 86 Cal.App.4th 1366, 1371.)

"Ordinarily, there is a presumption against preemption. (*Solus Industrial Innovations, LLC v. Superior Court* (2018) 4 Cal.5th 316, 332.) The strength of the presumption is heightened in areas where the subject matter has been the longstanding subject of state regulation in the first instance." (*Quesada v. Herb Thyme Farms, Inc.* (2015) 62 Cal.4th 298, 313.)

IMPOSSIBILITY PREMPTION - GENERALLY

"Federal preemption applies when state and federal laws directly conflict. … When it is impossible for a private party to comply with both state and federal requirements, a direct conflict exists. (*Teva Pharmaceuticals USA, Inc. v. Superior Court* (2013) 217 Cal.App.4th 96, 105.) "A defendant cannot establish impossibility preemption "merely by demonstrating it is difficult or costly to comply. Rather, it must show using point of sale signs is a "physical impossibility." (*People v. Cotter & Co* (1997) 53 Cal.App.4th 1373, 1393-1394.)

FDA REGULATION – GENERALLY

A Brand Name Manufacturer must demonstrate to the FDA that a new drug is safe and effective. (21 U.S.C. 355(a), (b)(1); 21 C.F.R. 314.1–314.3, 314.50.) When a Brand Name Manufacturer seeks approval for an OTC version of a prescription medication, the manufacturer

shows the FDA that the medication is appropriate for self-administration. (21 C.F.R. § 310.200(b); 21 U.S.C. §§ 353(b)(3), 355(c)–(d).)

The FDA approves the language in the labelling. The Brand Name Manufacturer must use the *exact* language approved by FDA in the labeling or packaging. (21 C.F.R. 214.70(b), (c), 314.71.)

The FDCA requires that OTC manufacturers provide *only* those warnings in OTC labeling approved by FDA in precisely the approved manner. (21 U.S.C. § 355.)

IMPOSSIBILITY PREMPTION – BRAND NAME MANUFACTURERS

The demurrer of Chattem and Sanofi-Aventis (Brand Name Defendant (R#2240283) is SUSTAINED WITH LEAVE TO AMEND.

The impossibility preemption demurrer of the Brand Name Defendants presents the issues of whether compliance with Proposition 65 was impossible given: (1) the ability of the Brand Name Defendants to change labelling under the Changes Being Effected process and (2) the ability of the Brand Name Defendants to add a Proposition 65 warning to the FDA approved warnings.

THE CBE PROCESS

A Brand Name Defendant can change a label without FDA approval in certain limited circumstances. "Major changes" require FDA preapproval, while certain labeling changes separately defined as "moderate changes" do not. (21 CFR 314.70(c)(6)(iii).)

A Brand Name Defendants can unilaterally make moderate changes, but those are limited to "changes … to reflect newly acquired information … [t]o add or strengthen a contraindication,

warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter." (21 CFR 314.70(c)(6)(iii).) The CBE process only permits changes "add[ing] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction" for a "clinically significant hazard" for which there is "reasonable evidence of a causal association" with the drug. (21 CFR 201.57.)

Wyeth v., Levine (2009) 555 US 555, addresses the CBE process and preemption. Procedurally, *Wyeth* was decided after trial. In *Wyeth*, a consumer sued the brand-name drug manufacturer for failure to provide an adequate warning on the drug's labeling. (555 US at 559-560). The Supreme Court held that the consumer's labeling claims were not pre-empted because the Changes Being Effected ("CBE") process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the labeling, without waiting for FDA approval. (555 US at 568-569.) The Court stated that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both its federal-law and state-law duties "absent clear evidence that the FDA would not have approved" a labeling change. (555 US at 571) The brand-name drug manufacturer "offered no such evidence," and the fact that the FDA had previously approved the labeling did "not establish that it would have prohibited such a change." (555 US at 572-573.)

To state a claim for failure-to-warn that is not preempted by the FDCA, a plaintiff must plead "a labeling deficiency that [Defendants] could have corrected using the CBE regulation." (*Gibbons v. Bristol-Myers Squibb Co.* (2nd Cir. 2019) 919 F.3d 699, 708.)

Turning to this case, the 2AC does not allege that the Brand Name Manufacturers could use the CBE process to present a Proposition 65 warning.

The CBE process requires Brand Name Manufacturers to demonstrate that there a "clinically significant hazard" for which there is "reasonable evidence of a causal association" with the drug. (21 C.F.R. 201.57.)

Proposition 65 applies unless a Brand Name Manufacturer can demonstrate that "the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity. (H&S 25249.10(c).)

There is a gap where an exposure is above the level that arguably requires a Proposition 65 warning but below the level that permit a Brand Name Manufacturer to "unilaterally strengthen" the labelling by adding a CBE warning. If the NDMA exposure is in this gap, then federal law preempts Proposition 65. If the NDMA exposure is so high that it both requires a Proposition 65 warning and the manufacturer can use the CBE process, then there is no impossibility preemption because a defendant can comply with both state and federal law.

Plaintiff's may amend, if possible, to allege that the NDMA exposure presented a "clinically significant hazard" for which there is "reasonable evidence of a causal association" with the drug. (21 C.F.R. 201.57) and as a result the Brand Name Manufacturers could use the CBE process to unilaterally strengthen the warning on the labeling without waiting for FDA approval. Plaintiff is not required to allege evidentiary facts to support this allegation. "[A] complaint ordinarily is sufficient if it alleges ultimate rather than evidentiary facts." (*Doe v. City of Los Angeles* (2007) 42 Cal.4th 531, 550.) Furthermore, preemption is an affirmative defense and a plaintiff is not required to anticipate and "plead around" a defendant's affirmative

defenses. (*Stowe v. Fritzie Hotels, Inc.* (1955) 44 Cal.2d 416, 422.) That said, pleadings that define the issues clearly are important for framing discovery, summary judgment, and trial.

WARNINGS

The Brand Name (and Generic) Manufacturers argue that the FDCA regulates warnings for OTC drugs, that Proposition 65 warnings are a form of warning, it is impossible to comply with both federal and state law requirements for warnings, and that impossibility preemption applies. Plaintiff argues that the FDCA does not regulate warnings in the advertising of OTC drugs, that Proposition 65 warnings can be provided through advertising, it is possible to comply with both federal and state law requirements, and that impossibility preemption does not apply. Counsel for plaintiff succinctly summarized the argument at the hearing on 5/5/21 with the phase "That which is possible is not impossible." The court concludes that impossibility preemption applies to warnings.

The court starts with Proposition 65. H&S 25249.10(a) states that Proposition 65 does not apply if "federal law governs warning in a manner that preempts state authority." A warning is defined by the substantive content. (27 CCR 25603.) A warning can be transmitted through various mechanisms. (H&S 25249.11(f) [warning "may be provided by general methods such as labels, …, posting of notices, placing notices in public news media, and the like"]; 22 CCR 3202 [warnings can be delivered through signs, notices, or newspapers].) The Proposition 65 regulations repeatedly distinguish between "Warnings-Content" and "Warnings-Methods of Transmission." (27 CCR 25601 et seq.)

The court turns to the FDCA. The FDA must approve a manufacturer's warnings as they appear on a drug's labels and labelling. (21 USC 355(b)(1)(A)(6), (d).) The FDA must similarly

approve warnings in a generic manufacturer's labels and labelling. (21 USC 355(j)(2)(A)(i) and (v), (j)(4)(G) and (H).) A generic manufacturer cannot change the content or form of the "warnings" section of the labelling. (21 USC 355(j)(10)(A)(2).))

The FDCA regulations state that "warning" is part of "content." (21 CFR 201.66(c)(5).) The FDCA regulations state the format for disclosing the warnings. (21 CFR 201.66(d)(10).) The location for the warning is on "The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper." (21 CFR 201.66(c).) "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." (21 U.S.C. § 321(k).) There are regulations about what must be on a label on a container (21 CFR 201.66(c)), or, if the containers lacks space for the information, on accompanying printed material (21 CFR 201.66(c)(10).) "Labeling" is more broadly defined to include "all labels and other written, printed, or graphic matter (1) upon any article or any article or any of its containers or wrappers, or (2) accompanying such article." (21 U.S.C. § 321(m).) There are no FDA regulations about point of sale or shelf disclosures for OTC drugs.

The FDCA does not regulate the advertising of OTC drugs. The FTC regulates the advertising of OTC drugs. (CEH RJN, Exh. 5, at 2; Brand Name Manufacturers RJN, Exh. F, at 13 n.25.)

The court's focus is on the word "warning" and the substantive content of the information in the communication. A Proposition 65 warning is a warning. A Proposition 65 warning on a "label" (21 U.S.C. 321(k)) does not become less of a warning if it is on "labelling" (21 U.S.C. 321(m)) and does not cease to be a warning when it is in "advertising."

A Proposition 65 warning is a "warning" within the definition of the FDCA definition of "warning" used in the FDCA regulations on "Format and content requirements for over-the-

counter (OTC) drug product labeling." (21 CFR 201.66(c)(5).) The FDCA approves "warnings" for OTC drugs, the Brand Name Manufacturers must use the FDA approved "warnings," it is impossible for the Brand Name Manufacturers to deviate from the approved warnings, so there is impossibility preemption, so the H&S 25249.10(a) self-exception applies. Proposition 65 does not apply to exposures in the OTC drugs. This ends the analysis.

LABELS, LABELLING, AND ADVERTISING

Much of the briefing and analysis was based on the assumption or argument that the scope of FDCA regulation of the Content of "warnings" was defined by the Methods of Transmission of the warnings. (27 CCR 25601 et seq. [Distinguishing between "Warnings-Content" and "Warnings-Methods of Transmission"].) This is reasonable. The FDCA regulation of "warnings" is very specific regarding labels, is less specific regarding labelling, and is non-existent regarding advertising. In the interest of thoroughness, the court covers three issues related to the means of transmitting the warnings: (1) the definition of labelling under the FDCA and (2) the voluntary nature of advertising, and (3) plaintiff's argument that "That which is possible is not impossible."

LABELS, LABELLING, AND ADVERTISING THE FDCA

Plaintiff argues that the Brand Name Manufacturers does not prevent them from transmitting Proposition 65 warnings to consumers through advertising and that therefore it is possible to continues to transmit only FDCA approved warnings in labels and labelling while transmitting California required Proposition 65 warning in advertising. This argument fails because "labelling" under the FDCA includes all means of transmitting warnings.

The FCDA at 21 USC 321(m) states: "(m) The 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*." (Emphasis added.)

The Meat Inspection Act (MIA) also includes the phrase "accompanying such article." In *American Meat Institute v. Leeman* (2009) 180 Cal.App.4th 728, the court held that for purposes of the MIA the phrase "accompanying such article" in the definition of labelling means that the MIA preempted Proposition 65's warning requirements. *Leeman* cited to *Kordel v. United States* (1948) 335 US 345, for the proposition that 21 USC 321(m) in the FDCA defined "labeling" to include supplemental literature not attached to the product.

Talking a detour from *Leeman*, in *Leeman* the court quotes *Kordel*, 335 US at 350, which states:

> One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant. ...
>
> The false and misleading literature in the present case was designed for use in the distribution and sale of the drug, and it was so used. The fact that it went in a different mail was wholly irrelevant whether we judge the transaction by purpose or result. ...
>
> ... The [FDCA] cannot be circumvented by the easy device of a 'sale' of the advertising matter where the advertising performs the function of labeling.

> Petitioner points out that in the evolution of the Act the ban on false advertising was eliminated, the control over it being transferred to the Federal Trade Commission. ... We have searched the legislative history in vain, however, to find any indication that Congress had the purpose to eliminate from the Act advertising which performs the function of labeling. Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on the article or on the containers or wrappers. As we have said, physical attachment or contiguity is unnecessary under s 201(m)(2).

Kordel makes plain that a plaintiff cannot avoid federal preemption by characterizing labelling as advertising matter "where the advertising performs the function of labeling."

Leeman, 180 Cal.App.4th at 758, finds that *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir., 1992) 958 F.2d 941, is not persuasive regarding the interpretation of "accompanying" in FIFRA and, if persuasive, the FIFRA analysis does not apply to the phrase "accompanying such article" as used in the MIA. *Leeman* arguably requires this court to find Allenby is not persuasive. (*Auto Equity Sales, Inc. v. Superior Court of Santa Clara County* (1962) 57 Cal.2d 450, 455.) This court independently does not find *Allenby* persuasive for the reasons stated in *Leeman*.

Leeman, 180 Cal.App.4th at 761, concludes, "Thus, because (1) point of sale warnings are "labeling" within the meaning of the FMIA, and (2) there is no dispute that the warnings required by Proposition 65 are "in addition to, or different than" the labeling required by the FMIA (21 U.S.C. § 678), we conclude that the trial court properly ruled that Proposition 65's

point of sale warning requirements with respect to meat are preempted by the FMIA." The MIA and the FDCA definitions of "labeling" both use the phrase "accompanying such article."

Also relevant are the FDCA regulations at 21 CFR 202.1(l) which distinguish "advertisements" from "labeling" by the target audience. For purposes of prescription drugs, "advertisements" advertisements directed to the general public whereas "labeling" is "Brochures, booklets, mailing pieces, detailing pieces, ... for use by medical practitioners, pharmacists, or nurses." (*In re Lipitor* (D. S.C., 2016) 185 F.Supp.3d 761, 772 ["advertising to the general public, as opposed to materials for use by medical professionals, is not considered labeling and, thus, can be changed without the need to invoke the CBE regulation."].) Where prescription drugs are involved, "medical practitioners, pharmacists, or nurses" are the persons who make those decisions and "the duty to warn runs to the physician, not to the patient." (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1116.) When the target audience is defined, 21 CFR 202.1(l) supports a reading of "labelling" to include any information transmitted to the person who makes the decision whether the drug is appropriate. With OTC drugs, the target audience is the general public, so all content transmitted to the general public is arguably "labelling."

Leeman, Kordel, and 21 CFR 202.1(l) compel the conclusion that any information that is transmitted to the person who makes the drug use decision serves the purpose of labelling and is "labelling" under the FDCA. Plaintiffs cannot avoid impossibility preemption by conflating labeling and advertising and suggesting that defendants can transmit the Proposition 65 warning in advertising.

Numerous lower federal courts have consistently held that FDA regulation of "labels" and "labelling" results in preemption of claims regarding any failure to transmit warnings through any communication channel. "While [California trial courts] are not bound by decisions

of the lower federal courts, even on federal questions, they are persuasive and entitled to great weight. … where the decisions of the lower federal courts on a federal question are "both numerous and consistent," we should hesitate to reject their authority." (*Etcheverry v. Tri-Ag Service, Inc.* (2000) 22 Cal.4th 316, 320-321.) (*Fair v. BNSF Railway Co.* (2015) 238 Cal.App.4th 269, 287.)

Representative federal cases include:

1. *Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013) 737 F.3d 378, 394 ["Because such advertising and promotional materials are considered labeling, and because labeling is limited by federal law to the information contained in the brand-name drug's labeling, all of the warranty claims against the Generic Manufacturers based on these materials are preempted under *Mensing*."]
2. *Guarino v. Wyeth* (11th Cir. 2013) 719 F.3d 1245, 1249 ["Guarino's attempt to elude *Mensing* by clothing her allegations as "failure-to-communicate" claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing*'s grasp."]
3. *Montero v. Teva Pharmaceuticals USA Inc.* (S.D. N.Y. 2020) 2020 WL 1862593 at *3 ["Plaintiff alleges inadequate warnings … in Defendants' communications with healthcare providers and advertisements to the public. The preemption of failure-to-warn claims extends to these latter types of communications as well."]
4. *In re Fosamax Products Liability Litigation* (S.D.N.Y 2013) 965 F.Supp.2d 413, 419 ["This Court joins the majority of other courts to consider this issue in holding that any

claims stemming from the generic defendants' alleged failure to communicate additional warnings through some method other than their package inserts are preempted"]

5. *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices And Products Liability Litigation* (S.D. IL. 2015) 2015 WL 7272766 *5 ["Plaintiff's claims "are premised on misrepresentations or inadequacies in ... labeling, promotions, and advertisements. As such, [generic manufacturer] could only avoid liability as to these claims by unilaterally strengthening their warning labels in violation of federal law or by leaving the marketplace altogether. *Mensing* and *Bartlett* establish that such challenges to ... labeling are preempted."]

The specific definition of "labeling" in the FDCA is significant to the preemption analysis, as other federal statutes have other definitions and therefore have other scopes of preemption. The court focuses on the definition of labeling in 21 USC 321(m) and gives no weight to the analysis of preemption regarding statutes with other definitions or scopes.

One example of a different statute is the federal Hazardous Substances Act (FHSA), which has a preemption provision that applies to "cautionary labeling" (15 U.S.C. § 1261(b)(1)(A)) and defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any substance" (15 USC 1261(n)). *People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, held that the FHSA did not preempt Proposition 65 claims, noting that the preemption provision was expressly limited to information "upon the immediate container" or accompanying literature regarding instructions for use. (53 Cal.App.4th at 1387.)

Another example is the federal Alcohol Administration Act (AAA) (27 USC 201 et seq.) and Alcoholic Beverage Labeling Act. ("ABLA") (27 USC 213 et seq.), which regulate

"warnings or other information on alcoholic beverage containers," and the scope of preemption is limited to "statement[s] ... placed on any container of an alcoholic beverage, or on any box, carton, or other package." This court in *CEH v. GT Living Foods*, RG19-047748 [Order of 5/12/20], held that the AAA/ABLA did not preempt Proposition 65 regarding point of sale information because it was not on the places identified in the statute.

THE VOLUNTARY NATURE OF ADVERTISING

Plaintiff's argument that the Brand Name Manufacturers can transmit warnings through advertisement that they cannot transmit though the current FDA approved labels and labelling suggests some conceptual distinction between labelling and advertising. The court sua sponte considered this issue in the tentative decision and it was the subject of discussion at the 5/5/21 hearing. The court concludes that "advertising" is by definition voluntary in nature, which means that if Proposition 65 is compelling a manufacturer to transmit a warning then the transmittal is by definition not through "advertising," which means that it is through "labelling" as defined in and regulated under the FDCA.

Federal, state or local authorities can mandate the transmittal of information to consumers for public health and safety interests as a condition of permitting sales to consumers. The FDA requires certain information about drug on labels and in labelling (21 CFR 201.1 et seq), the FDA requires warnings on packs of cigarettes (21 CFR 1141.5), and California requires warnings when there is exposure to a chemical known to the state to cause cancer or reproductive toxicity (H&S 25249.6). In contrast, private persons voluntarily decide to advertise their products. If a person decides to advertise, the existence, content, and form of advertising is generally at the discretion of the advertiser.

This suggests a distinction between required or compelled speech and voluntary speech. This distinction is subject to two exceptions. Voluntary speech cannot be false to misleading. Voluntary speech can also be conditioned on mandated disclosures "as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." (*National Ass'n of Manufacturers v. S.E.C.* (D.C. Cir. 2015) 800 F.3d 518, 519.) Regulatory authorities can require the transmittal of "purely factual and uncontroversial information." (*National Ass'n of Manufacturers*, 800 F.3d at 523.) For example, the FDA requires the Brand Name Manufacturers to transmit certain information as a condition of the approval to sell the Products. Putting aside restrictions on false and misleading information and mandated disclosures, the "general rule" is "that the speaker has the right to tailor the speech" and that advertisers have First Amendment discretion regarding "expressions of value, opinion, or endorsement" and also "to statements of fact the speaker would rather avoid." (*National Ass'n of Manufacturers*, 800 F.3d at 523.)

At the hearing on 5/5/21, plaintiff noted that in *Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy* (1992) 4 Cal.App.4th 963, 973-974, the Court of Appeal affirmed a trial court's ability to order affirmative disclosure of information as a remedy for previous consumer deception and argued that this shows that compelled speech can be "advertising." *Alta-Dena* used the word "advertising" to describe the defendant's prior misrepresentations. Regarding the remedy of compelled speech, the Court of Appeal referred to "the court's authority to order the placement of warnings on its consumer products" and "the placement of a warning on products sold in the future." (4 Cal.App.4th at 974, 975 and fn 6.)

This broad-brush analysis of the distinction between compelled speech and voluntary speech suggests that as soon as a regulatory authority (or Proposition 65 plaintiff) asserts that a

warning is mandated then the warning is no longer voluntary "advertising." Under this analysis, when a party asserts that the Proposition 65 warning is mandatory then the obligation to provide a warning cannot be categorized as "advertising" under the FDCA and is more properly categorized as "labeling" under 21 USC 321(m). If it its "labeling," then impossibility preemption applies and the H&S 25249.10(a) self-exclusion applies.

PROPOSITION 65 WARNINGS ARE POSSIBLE, SO THEY ARE NOT IMPOSSIBLE

At the hearing on 5/5/21, plaintiff noted that the FDCA does not prevent defendant from transmitting Proposition 65 warnings in advertising, advanced the maxim of "That which is possible is not impossible," and argued that the impossibility preemption does not apply.

The "not impossible" argument finds plausible support in *Leipart v. Guardian Industries, Inc.* (9th Cir., 2000) 234 F.3d 1063, 1070-1071, where the court held it was "not impossible" for a glass door to have both the Consumer Product Safety Act ("CSPA") mandated label and also a different state common law tort based warning. *Leipart* is distinguishable because although federal law mandated a federal label on the glass door and provided a labelling "floor," the manufacturer's responsibility to provide the mandated CPSA federal warning does not prevent the manufacturer from providing additional warnings to meet the California tort duty to warn.

The "not impossible" argument also finds plausible support in *Clark v. Citizens of Humanity, LLC* (S.D. Cal., 2015) 97 F.Supp.3d 1199, 1205-1206, where the court held it was "not impossible" for defendants to comply with the federal standard for using a "Made in the U.S.A." label and the different California standard for the same label. The court reasoned that defendant could sell the clothes with no label or could or use a distinct label for clothing sold in California. *Clark* is distinguishable because the "Made in the U.S.A." label was in the nature of

voluntary advertising. In this case, in contrast, the FDCA prevents the sale of the Products unless they have the FDA approved labels and labelling.

The "not impossible" argument calls attention to the distinctions between federal laws that prohibit actions, that mandate actions, that mandate actions as a condition of otherwise voluntary actions, and that permit actions. In *Leipert*, federal law permitted additional state warnings. In *Clark*, federal law permitted federal and state labels, but did not require either as a condition of selling the product. With OTC drugs, the FDCA mandates the use of the FDA approved labels and labelling as a condition of marketing and sales. Unlike *Leipert*, the federal labelling for OTC drugs is not a labelling "floor" and instead determines the content and the means of transmission for warnings about OTC drugs.

The "not impossible" argument fails because although the FDCA might not prevent the defendants from voluntarily putting Proposition 65 warnings in advertisements for the Products, the FDCA's regulation of warnings on labels and in labelling means that "federal law governs warning in a manner that preempts state authority", which means that the H&S 25249.10(a) self-exception applies.

IMPOSSIBILITY PREMPTION – GENERIC MANUFACTURERS

The demurrer of Apotex (Generic Manufacturer Defendant) (R#2240282) is SUSTAINED WITHOUT LEAVE TO AMEND. The demurrer of Perrigo (Generic Manufacturer Defendant) (R#2242700) is SUSTAINED WITHOUT LEAVE TO AMEND. The demurrer of Granules USA, Inc. (Generic Manufacturer Defendant) (R#2242703) is SUSTAINED WITHOUT LEAVE TO AMEND. The demurrer of Dr. Reddy's Laboratories,

Inc. (Generic Manufacturer Defendant) (R#2240276) is SUSTAINED WITHOUT LEAVE TO AMEND.

The impossibility preemption demurrer of the Generic Manufacturer Defendants presents the issues of whether compliance with Proposition 65 was impossible given: (1) the obligation of the Generic Manufacturer Defendants to provide the same label and labelling information as the Brand Name Defendants (the "duty of sameness") and (2) the ability of the Brand Name Defendants to provide Proposition 65 Warnings in the form of advertising.

THE CBE PROCESS, DUTY OF SAMENESS, AND THE EXPIRATION DATE EXCEPTION

Generic drug manufacturers have an ongoing federal duty of sameness that requires "that the warning labels of a brand-name drug and its generic copy must always be the same." (*PLIVA v. Mensing* (2011) 564 US 604, 613.)

An application for a generic drug (Abbreviated New Drug Application or ANDA), the applicant must provide information about the labeling. (21 USC 355(j)(2)(A)(i) and (G).)

The proposed labelling on warnings must be the same as the labelling on warnings for the original approval. An application for a generic drug must not "include a change to the "Warnings" section of the labeling." (21 USC 355(j)(10)(A)(iii).) The FDA may withdraw approval for a generic drug if it finds that the drug product's labeling "is no longer consistent with that for the listed drug." (21 C.F.R. 314.150(b)(10).)

The result is that unlike the holders of the original FDA approvals, the holder of generic approvals cannot use the CBE process. Generic drug manufacturers can use the CBE process only after the holder of the original FDA approval has used the CBE process. The CBE process allows "changes to generic drug labels only when a generic drug manufacturer changes its label

to match an updated brand-name label or to follow the FDA's instructions." (*Mensing*, 564 U.S. at 614.)

PLIVA v. Mensing (2011) 564 US 604, and *Mutual Pharmaceutical v. Bartlett* (2013) 570 US 472, examines how the duty of sameness affects impossibility preemption.

In *Mensing*, consumers of generic drugs sued the generic drug manufacturers for failure to provide adequate warnings on the drugs' labeling. The Supreme Court held that the consumers' labeling claims were pre-empted because the generic drug manufacturers could not "independently" change the labeling while remaining in compliance with federal law. The generic drug manufacturers' "duty of 'sameness'" under federal law required them to use labeling identical to the labeling of the equivalent brand-name drug. Thus, the CBE process was unavailable to the generic drug manufacturers to change labeling absent a change to the brand-name drug's labeling. Because any change that the generic drug manufacturers made to the drugs' labeling to comply with duties arising under state tort law would have violated federal law, the state tort claims were pre-empted.

In *Bartlett*, the Supreme Court expanded on *Mensing* and held that even though a generic drug manufacturer could in theory comply with both federal and state law by removing the drug from the market, that was "no solution." The Supreme Court reasoned pre-emption case law "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." (570 US at 488.) The Supreme Court reasoned that this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in the Court's preemption case law. (570 US at 475, 488-490.) (See also *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110,150-151 [discussing stop-selling as remedy].)

There is one arguably applicable specific exception to the duty of sameness and thus one arguably applicable exception to the impossibility preemption analysis of *Mensing* and *Bartlett*. Generic manufacturers have no duty under federal regulations to use the same expiration date on their drugs as the brand name equivalent.

When a Generic manufacturer submits an ANDA request for approval to the FDA, then 21 C.F.R. 314.94(a)(8) generally requires that the generic ANDA label have the same information as the brand name NDA label. The exception is that 21 C.F.R. 314.94(a)(8)(iv) states: "Labeling ...proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required ... because the drug product and the reference listed drug are produced or distributed by different manufacturers. Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, ..."

Addressing this specific exception, *in re Zantac (Ranitidine) Products Liability Litigation* (S.D. Fl., 2020) 2020 WL 7864213 at *5, states, "With limited exceptions, the FDA may approve the ANDA only if it finds that the generic drug and its proposed labeling are the same as the listed drug and the listed drug's labeling. ... One such exception is that the generic drug's proposed labeling "may include differences in expiration date" from the listed drug."

Turning to this case, as a matter of law the Generic Manufacturers cannot use the CBE process to present a Proposition 65 warning. If the Brand Name Manufacturers did not have a Proposition 65 warning on their labels or labelling, then the Generic Manufacturers cannot have a Proposition 65 warning on their labels or labelling. Impossibility preemption applies, which means the H&S 25249.10(a) self-exception applies.

The expiration date exception to the duty of sameness exists and affects impossibility preemption regarding expiration dates, but has no effect on the H&S 25249.10(a) self-exception analysis. The H&S 25249.10(a) self-exception states that Proposition 65 does not apply to "An exposure for which federal law governs warning in a manner that preempts state authority." The FDCA governs warnings. An application for a generic drug must not "include a change to the "Warnings" section of the labeling." (21 USC 355(j)(10)(A)(iii).) Expiration dates are part of labels and labelling, but they are not warnings. As a result, the H&S 25249.10(a) self-exception applies to OTC drugs even though the duty of sameness and thus impossibility preemption does not apply to expiration dates.

LABELLING AND ADVERTISING

A Generic Manufacturer must provide information about OTC drugs to consumers through FDA approved labelling but can voluntarily provide additional information to consumers through advertising.

As discussed above in the context of the Brand Name Manufacturers, the court concludes that any mandated Proposition 65 warning fits within the FDCA's definition of "labeling," which means that it concerns "An exposure for which federal law governs warning in a manner that preempts state authority" under H&S 25249.10(a).

IMPOSSIBILITY PREMPTION - RETAILERS

The demurrer of 7-Eleven (Retailer Defendant) (R#2240281) is SUSTAINED WITHOUT LEAVE TO AMEND. The demurrer of Target Corporation (Retailer Defendant) (R#2242040) is SUSTAINED WITHOUT LEAVE TO AMEND.

The impossibility preemption demurrer of Target Corporation and 7-Eleven, Inc. ("Retailer Defendants") presents the issues of whether compliance with Proposition 65 was impossible given: (1) the Retailer Defendants have no approvals from the FDA to manufacture or market the Products and (2) the ability of the Retailer Defendants to provide Proposition 65 Warnings about the Products in the form of advertising.

THE CBE PROCESS AND DUTY OF SAMENESS

The Retailer Defendants do not hold any approvals from the FDA for the manufacture or labelling of the Products. (Retailer RJN ¶ 2, Ex. A.) The 2AC asserts that all defendant manufacture the Products, but "allegations in the pleading may be disregarded if they are contrary to facts judicially noticed." (*Scott v. JPMorgan Chase Bank, N.A.* (2013) 214 Cal.App.4th 743, 751.)

Because the Retailer Defendants do not hold any approvals from the FDA for the Products, the Retailers are not subject to any FDA oversight with respect to the Products. The Retailer Defendants are therefore analytically distinct from the Brand Drug manufacturers and the Generic Manufacturers.

The Retailer Defendants are not required by FDA approvals to provide any FDA approved label or labelling. In the absence of any obligation to provide any FDA approved labelling, it is immaterial whether the Retailer Defendants provided warnings that were the same as the labelling that the FDA approved for the Brand Name Manufacturers or could have used the CBE process to provide different warnings.

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LABELLING AND ADVERTISING

A Retailer Defendant can voluntarily provide information to consumers through advertising.

As discussed above in the context of the Brand Name Manufacturers, the court concludes that any mandated Proposition 65 warning fits within the FDCA's definition of "labeling," which means that it concerns "An exposure for which federal law governs warning in a manner that preempts state authority" under H&S 25249.10(a).

FIELD PREEMPTION – APOTEX

Defendant Apotex is a Generic Manufacturer and argues field preemption. The field preemption argument has no merit.

Field preemption is "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation." (*In re Jose C.* (2009) 45 Cal.4th 534, 551.)

Apotex makes what appears to be a novel argument. Apotex argues that the FDA has paid extensive attention to the Products in the time period after it was publicized that the Products contained NDMA and that this extensive attention in this discrete time period is field preemption.

The Apotex field preemption argument has no merit. The court starts with congressional intent. Congress intended through the FDCA to regulate drugs generally, not to regulate the Products specifically. There is no indication of Congressional intent to regulate the Products specifically, so there is no field preemption of the Products specifically. Assuming congressional intent focused on the Products, there is no indication that the regulation was

sufficiently comprehensive to suggest that Congress "left no room" for supplementary state regulation." The Apotex argument suggests that there was no field preemption until September 2019 and that the FDA's attention in that discrete time frame then created field preemption in that discrete time frame.

Using the agrarian definition of field by analogy, Apotex argues that field preemption does not need to encompass the field and that under an appropriate set of facts there can be field preemption for a small patch of grass that for purposes of a lawsuit can be defined as its own separate field. This is not the law.

MOOTNESS – APOTEX

Defendant Apotex is a Generic Manufacturer and argues mootness. The mootness argument has no merit.

"A case is considered moot when "the question addressed was at one time a live issue in the case," but has been deprived of life "because of events occurring after the judicial process was initiated."" (*Wilson & Wilson v. City Council of Redwood City* (2011) 191 Cal.App.4th 1559, 1574.)

Apotex argues that the case is moot because it has voluntarily recalled the Product. That does not make the claim moot.

Plaintiff could prove liability at trial by demonstrating that Apotex knowingly and intentionally exposed consumers to NDMA without first giving clear and reasonable warning. (H&S 25249.6.) The evidence might be that Apotex has for a long time known that contamination in its manufacturing process resulted in NDMA in the Product and that as a result

of how the Product was stored and for how long it was stored the amount of NDMA in the product increase before sale to consumers.

Assuming liability, the court can order remedies in the form of injunctions and penalties. (H&S 25249.7(a).)

The court cannot determine at the inception of the case that injunctive relief will not be permissible and appropriate at the conclusion of the case. Assuming liability, the court will at the conclusion of the case determine whether Apotex is selling or has an intent to sell the Products. (*Robinson v. U-Haul Company of California* (2016) 4 Cal.App.5th 304, 315-316 [need for injunctive relief is decided at trial].) The court will not presume that the factual landscape will remain unchanged from the filing of the complaint through the completion of trial. This is not a case like *Madrid v. Perot Systems Corp.* (2005) 130 Cal.App.4th 440, in which the court can determine at the pleading stage that there is no possible risk of continuing conduct.

The court cannot determine at the inception of the case that penalties will not be permissible and appropriate at the conclusion of the case. "An award of civil penalties under [Proposition 65] is a statutory punitive exaction … designed to deter misconduct and harm." (*DiPirro v. Bondo Corp.* (2007) 153 Cal.App.4th 150, 183.) Assuming Apotex knowingly and intentionally exposed consumers to NDMA, then penalties might be appropriate to deter similar actions in the future by Apotex and others.

ATTORNEYS' FEES – APOTEX

Defendant Apotex is a Generic Manufacturer and seeks to strike the prayer for attorneys' fees. Apotex points out that it recalled the Products before the Plaintiff filed this lawsuit and

asserts that plaintiff cannot prove a causal connection between the filing of the lawsuit and the recall.

Plaintiff could prevail at trial if plaintiff demonstrated that Apotex knowingly and intentionally exposed consumers to NDMA before September 2019 without first giving clear and reasonable warning. (H&S 25249.6.) For purposes of establishing liability, it is immaterial that Apotex no longer distributes the Product. The court could order penalties even if the court decided that injunctive relief was not appropriate.

In addition, it is immaterial whether the prayer for relief includes a request for attorneys' fees. If plaintiffs prevail at trial, then under CCP 1032 they can recover costs and under CCP 1033.5(a)(10 costs includes fees. (*Khavarian Enterprises, Inc. v. Commline, Inc.* (2013) 216 Cal.App.4th 310, 327.) (See also *Snatchko v. Westfield LLC* (2010) 187 Cal.App.4th 469, 497.)

FURTHER PROCEEDINGS

Plaintiff must file any third amended complaint on or before 6/4/21.

Dated: May 7, 2021

Winifred Y. Smith
Judge of the Superior Court

Superior Court of California, County of Alameda
Department 21, Administration Building

Case Number: RG20054985
Case Name: Center for Environmental Health vs. Perrigo Company

RE: ORDER SUSTAINING DEMURRERS WITH LEAVE TO AMEND

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown at the bottom of this document, and that the mailing of the foregoing and execution of this certificate occurred at 1221 Oak Street, Oakland, California.

Executed on May 11, 2021

Executive Officer/Clerk of the Superior Court

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