SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

IN RE RANTIDINE CASES	No. JCCP 5150 No. 23CV057906 (*Toftee v. GSK*) **ORDER DENYING WITHOUT PREJUDICE BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY ADJUDICATION ON PLAINTIFF'S CAUSE OF ACTION FOR MANUFACTURING DEFECT**

I. INTRODUCTION

In this JCCP 5150, *Toftee v. GalaxoSmithKline*, No. 23CV057906, was scheduled to go forward as a bellweather trial. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") filed a motion for summary judgment and, in the alternative, summary adjudication addressing the plaintiffs' product liability claim based on an alleged manufacturing defect as set forth in the Third Amended Master Complaint. The matter was first heard in June 2025. At the hearing, the plaintiffs argued a new theory—that BI's entire manufacturing process was defective. The Court ordered further briefing. Thereafter, the plaintiffs filed supplemental and reply briefs, and BI filed a supplemental opposition. The matter was heard again on August 20, 2025. Although the *Toftee* trial was taken off calendar for effective case management purposes in this coordinated action, the Court will rule on this issue because of its wider application to the JCCP.

The Court notes that the issue before the Court is difficult and somewhat novel, and the Court's prior orders by different judges have struggled with it. (*See In re Ranitidine Cases* (Cal. Super. 2024) 2024 WL 2115449; *Bautista v. GlaxoSmithKline, LLC* (Cal. Super. 2024) 2024 WL 5316949; *In re Ranitidine Cases* (Cal. Super. 2024) 2024 WL 5316955.) The Court finds it appropriate to independently clarify its ruling on this cause of action for the JCCP based on the record and arguments on this motion.

II. FACTUAL BACKGROUND AND ISSUE[1]

In the Third Amended Master Complaint, the plaintiffs assert a claim for manufacturing defect against BI for manufacturing the drug Zantac in a manner that causes cancer. The plaintiffs' theory is that the molecule ranitidine, the active ingredient in Zantac, degrades to form a molecule known as N-nitrosodimethylamine ("NDMA"). Evidence shows that the ranitidine molecule contains both a nitrite and a dimethylamine group, which can combine to form NDMA and that, over time, ranitidine degrades to form NDMA. (*See, e.g.*, Emery Pharma report (Ex. 25); Valisure Citizen Petition (Ex. 17); GlaxoSmithKline ("GSK") study by Searle (2020) (Ex. 7).) NDMA is a listed carcinogen. Sufficient evidence exists to find that heat and humidity accelerate ranitidine's degradation and NDMA formation. GSK's 2020 study concluded that "The amount of NDMA present in ranitidine drug substance has been shown to increase in solid samples, when subjected to elevated temperature and humidity." (Searle (2020) (Ex. 7 at 21).) The plaintiffs claim that the NDMA that they unwittingly ingested through the Zantac pills caused their respective cancers.

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[1] For further background, *see* Order Granting Motion For Summary Adjudication On Punitive Damages (*Toftee*) also dated September 15, 2025.

BI argues that the plaintiffs' theory presents a claim for design defect because NDMA formation inheres in Zantac's design using ranitidine as the active ingredient. The Court has previously held that a design defect claim based on the chemical composition of ranitidine as approve by the FDA is preempted. (*In re Ranitidine Cases (Browne)* (Cal. Super. 2022) 2022 WL 3336509 at *1; *In re Ranitidine Cases* (Cal. Super. 2024) 2024 WL 2115449, at *5; *see also Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110.) The problem lurks in the nature of the ranitidine molecule. BI points to the plaintiffs' expert's statements that NDMA is not an external contamination, that the ranitidine molecule itself generates the impurity, and that ranitidine's degradation into NDMA is inherent in the molecule's chemistry. (Supp. Opp. at 5.) The evidence on this motion does not show that BI's manufacturing of any pills deviated from its intended processes.

Neither party, however, claims that BI intended to create NDMA in the pills.

The plaintiffs run with that point. They argue that BI's particular method of manufacturing was defective because it applied unnecessary heat and moisture to the ranitidine tablets that actually generated NDMA as part of the manufacturing process. This excessive and unnecessary heat and moisture resulted in excessive and unnecessary NDMA in BI manufactured pills that BI did not intend to include. No evidence shows a meaningful distinction between the pills the plaintiffs ingested or the batch they came from and all the other BI manufactured pills. Nor does the evidence show that any pills deviated from the norm. The plaintiffs' contend, however, that BI's manufacturing process was flawed, that this flaw plagued the entire product line, and this process differed from processes followed by other manufacturers and from what BI could have done to make safer pills. The NDMA that BI generated through its manufacturing process is in addition to what is generated by the post-production degradation process. In short,

although BI intended to create a pill that contained ranitidine without contamination, it ended up manufacturing a different pill that included NDMA, an unintended carcinogenic presence.

Plaintiff's theory presents legal and factual issues.

First, does California law recognize a claim for product liability based on manufacturing defect on the theory that BI manufactured Zantac under a uniform process that it intended to use that resulted in excessive amounts of NDMA in the pills that BI did not intend? Even though the Court requested supplemental briefing to address this issue, neither party submitted any strong authority from any jurisdiction.

Second, if California law recognizes this theory, do the plaintiffs have evidence that BI's manufacturing process created excess and unnecessary NDMA in addition to any NDMA formed by the degradation of ranitidine that results from other viable manufacturing processes or ordinary degradation? And, if so, did the excess and unnecessary NDMA created by BI's manufacturing process, which would be the defect caused by the allegedly flawed manufacturing process, cause the plaintiffs' cancer?

III. LEGAL DISCUSSION

A. Development of Product Liability

California's product liability law flowed out of a Coke bottle that exploded in a waitresses hand. (*Escola v. Coca Cola Bottling Co. of Fresno* (1944) 24 Cal.2d 453.) The *Escola* majority affirmed a plaintiff's judgment on *res ipsa loquitor* grounds. But Justice Traynor argued in concurrence, "In my opinion it should now be recognized that a manufacturer incurs an absolute liability when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings. . . . Even if there is no negligence, however, public policy demands that responsibility be fixed wherever it

will most effectively reduce the hazards to life and health inherent in defective products that reach the market." (*Id.* at 462.)

About 20 years later, Justice Traynor for the Supreme Court made this California law in *Greenman v. Yuba Power Products, Inc.* There, the "Shopsmith," a combination power tool that included a lathe, spat out a piece of wood that struck the plaintiff in the forehead. The court held, "A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." ((1963) 59 Cal.2d 57, 62.) The court set forth the basic policy behind strict product liability that controls today: "[T]o insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." (*Id.* at 63.)

The early decisions did not articulate clear distinctions between manufacturing and design defects. *Cronin v. J.B.E. Olson Corp.* addressed the distinction. ((1972) 8 Cal.3d 121.) *Cronin* involved an "aluminum safety hasp" designed to hold bread trays in place in a vehicle that broke during an auto accident sending loose a bread tray that struck the plaintiff. The court held that product liability does not require a showing that the product is "unreasonably dangerous to the user or consumer." (*Id.* at 123.) In addressing reasons to drop the "unreasonably dangerous" requirement, *Cronin* explained:

> We recognize that the words "unreasonably dangerous" may also serve the beneficial purpose of preventing the seller from being treated as the insurer of its products. However, we think that such protective end is attained by the necessity of proving that *there was a defect in the manufacture or design of the product* and that such defect was a proximate cause of the injuries. Although the seller should not be responsible for all injuries involving the use of its products, it should be liable for all injuries proximately caused by any of its products which are adjudged "defective."
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> We can see no difficulty in applying the *Greenman* formulation to the full range of products liability situations, including those involving "design defects." A *defect may*

emerge from the mind of the designer as well as from the hand of the workman.

(*Id.* at 134. [emphasis added].) *Cronin* held that a plaintiff satisfies the burden of proof under *Greenman* in both "manufacturing defect" and "design defect" contexts by proving the existence of a "defect" and that the "defect" proximately caused the injuries. (*Id.* at 133-134.)

The Supreme Court then addressed the meaning of "defect" and defined the distinction in the seminal case of *Barker v. Lull Engineering Co.* ((1978) 20 Cal.3d 413, 419-20.) There, the plaintiff was injured at a UC Santa Cruz construction site when a high-lift loader he was operating tipped, causing him to jump from the loader and to be struck by falling timber. The court noted that the "term defect as utilized in the strict liability context is neither self-defining nor susceptible to a single definition applicable in all contexts." (*Id.* at 413.) The court explained that, under precedent, the "defect or defectiveness concept has embraced a great variety of injury-producing deficiencies" from products that "deviate from the manufacturer's intended result," *e.g.*, an exploding coke bottle, "to products which, though 'perfectly' manufactured, are unsafe because of the absence of a safety device," and products that lack adequate warnings or instructions. (*Id.* at 428.) To give the law guidance on the meaning of "defect," the court held:

> In general, a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line . . . . A design defect, by contrast, cannot be identified simply by comparing the injury-producing product with the manufacturer's plans or with other units of the same product line, since by definition the plans and all such units will reflect the same design. Rather than applying any sort of deviation-from-the-norm test in determining whether a product is defective in design for strict liability purposes, our cases have employed two alternative criteria.

(*Id.* at 429 [emphasis added].) *Barker* then set forth the consumer-expectation and the risk-benefit tests[2] that form the principal tests applied today. (*Id.* at 431.)

In addition to manufacturing and design defects, a product may be defective even though it is *flawlessly manufactured and designed* if it fails to provide a warning where warranted. (*See, e.g.*, *Finn v. G. D. Searle & Co.* (1984) 35 Cal.3d 691.)

B. Product Liability in Drug Cases

California's product liability law has developed with regard to drugs, where particular policy concerns apply. In *Finn*, the plaintiff sued for optic nerve damage caused by a drug, Diodoquin, which was approved by the FDA. It was brought on a theory of "failure to warn" of severe side effects which the defendant knew or should have known. (35 Cal.3d at 698.) The Court explained:

> "Failure-to-warn" cases involving claims that the manufacturer knew or should have known of the asserted danger and accordingly should have supplied a warning have been subject in California to a distinct form of analysis in the strict liability arena. The unique nature of the "defect" within this context was recently well described as follows: "[T]he jury cannot compare the product with other units off the same assembly line, nor can they at least weigh the reasonableness of the design against alternative designs presented by the plaintiff [citation]. Instead, they must decide whether a product flawlessly designed and produced may nevertheless possess such risks to the user without a suitable warning that it becomes 'defective' simply by the absence of a warning."

(*Id.* at 699 [quoting *Cavers v. Cushman Motor Sales, Inc.* (1979) 95 Cal.App.3d 338, 347].) The court, however, did not address how *Barker* would apply because the plaintiff did not pursue a design or manufacturing defect theory. (*Id.* at 699.)

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[2] (*See* 20 Cal.3d at 431 ["a product may be found defective in design if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner"] and ["evaluating the adequacy of a product's design pursuant to this latter standard, a jury may consider, among other relevant factors, the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design."].)

Later, *Brown v. Superior Court* addressed strict product liability for prescription drugs. ((1988) 44 Cal.3d 1049.) The court reiterated the policy behind strict liability: "[T]the manufacturer, unlike the public, can anticipate or guard against the recurrence of hazards, that the cost of injury may be an overwhelming misfortune to the person injured whereas the manufacturer can insure against the risk and distribute the cost among the consuming public, and that it is in the public interest to discourage the marketing of defective products." (*Id.* at 1056.) The court provided background on the problem of applying strict liability to prescription drugs. The court then held, "a drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability." (*Id.* at 1061.) And "because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k" to section 402A of the ALI. (*Id.*) *Brown*, however, did not directly address application of a manufacturing defect theory.

In holding that design defect strict liability does not apply to prescription drugs, the Court explained that neither the consumer expectation test nor the risk-benefit test applies. Among other things, the physician, not the patient, is the consumer of prescription drugs, and the patient's expectations are derivative of what the physician relays. (*Id.* at 1061-61.) "The manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient or if the patient relies on inaccurate information from others regarding side effects of the drug." (*Id.* at 1602.)

The court then cataloged reasons why the policies behind the risk-benefit test did not apply for prescription drugs. The court noted an important distinction between prescription drugs and other products such as construction machinery. (*Id.* at 1063.) The Court explained:

> In the latter cases, the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life.

> Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use.
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> Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases such a delay in marketing new drugs—added to the delay required to obtain approval for release of the product from the Food and Drug Administration—would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.
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> If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability—assuming insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.

(*Id.* at 1063.) The court articulated Dean Prosser's point that drugs regularly have dangerous side effects, but deterring drug companies from producing and selling them given their overall benefit to society has considerable disadvantages, considering, for example, the enormous benefits of penicillin. (*Id.* at 1064.) The court also considered the point that the "cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals." (*Id.*) Because of these policy issues, the court held, "We decline to hold, therefore, that a drug manufacturer's liability for injuries caused by the defective design of a prescription drug should be measured by the standard set forth in *Barker*." (*Id.* at 1065.)

On failure to warn theory, the court held, "For these same reasons of policy, we reject plaintiff's assertion that a drug manufacturer should be held strictly liable for failure to warn of risks inherent in a drug even though it neither knew nor could have known by the application of

scientific knowledge available at the time of distribution that the drug could produce the undesirable side effects suffered by the plaintiff." (*Id.* at 1065.)

The Supreme Court in *Carlin v. Superior Court* later clarified that a plaintiff alleging injury from ingesting a prescription drug can state a claim against the manufacturer for strict liability for failure to warn about the known or reasonably scientifically knowable dangerous propensities of its product. ((1996) 13 Cal.4th 1104 [extending *Anderson v. Owens-Corning Fiberglas Corp.* (1993) 53 Cal.3d 987, to prescription drug industry].) The Court confirmed that in *Anderson* it held that "knowledge, actual or constructive, is a component of strict liability on the failure-to-warn theory." *Carlin* explained that failure-to-warn strict liability is a hybrid of traditional strict liability and negligence doctrine. (*Id.* at 1108.) In strict liability, however, the "reasonableness of the defendants' failure to warn is immaterial." It requires that the plaintiff prove only that "the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing bet scientific and medical knowledge available at the time of manufacture and distribution." (*Id.* at 1112.) The court rejected the argument that its holding was inconsistent with federal regulatory policy and held that Congress did not preempt state tort liability for injuries from prescription drugs. (*Id.* at 1113.)

After *Brown*, *Rodriguez v. Superior Court* permitted a strict liability claim against a manufacturer of non-prescription baby aspirin to go forward based on pleadings that alleged failure to warn in conformity with *Finn* and *Brown*. ((1990) 221 Cal.App.3d 1371.) There the plaintiffs pleading stated (1) the use of the aspirin was reasonably foreseeable by defendant, (2) the use involved a substantial, foreseeable danger, and (3) adequate warnings were not given, which the court found sufficient on a failure to warn theory.

Trejo v. Johnson & Johnson addressed a product liability verdict regarding over-the-counter ibuprofen under the Motrin brand. ((2017) 13 Cal.App.5th 110.) There, the plaintiff suffered a rare skin disease (Stevens-Johnson Syndrome) after taking Motrin. The court held that the negligence and strict liability design defect verdicts on the theory that the drug should have contained "dexibuprofen" was preempted under *Mutual Pharmaceutical Co., Inc. v. Bartlett*. ((2013) 570 U.S. 472.) The Court reasoned, "Under plaintiff's theory, the design of Motrin was inherently defective because defendants used ibuprofen instead of dexibuprofen. However, federal law prohibited defendants from changing the design of Motrin by selling dexibuprofen without prior FDA approval. Defendants accordingly could not have avoided design defect liability without violating federal law." (*Id.* at 153.) The court also held that the consumer expectation test did not apply because an ordinary consumer cannot form minimum safety expectations for an over-the-counter drug under *Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 562, and related cases. *Trejo* further declined to extend *Brown* to over-the-counter drugs. Like the other decisions, *Trejo* did not involve a claim for manufacturing defect.

California courts have made clear that congress and the FDA have neither enacted express preemption nor field preemption with regard to state tort claims regarding pharmaceuticals. (*McKenney v. Purepac Pharmaceutical Co.* (2008) 167 Cal.App.4th 72, 83.) State tort claims, however, might be but are not necessarily preempted by federal law and FDA regulations under conflict preemption principles. (*Id.* at 884.)

C. Supplemental Cases

In their supplemental brief, the plaintiffs cite decisions for the proposition that a manufacturing defect claim can be based on a defect that affects the entire product line. (*Barakezyan v. BMW of North America, LLC* (9th Cir 2018) 715 Fed. Appx. 726 [stating, "[t]he

fact that the SAC alleges that all BMW CCBs exhibit the defect [bad brakes] does not preclude the defect from being a manufacturing defect—under California law a manufacturing defect encompasses instances where products differ, even uniformly, from a manufacturer's intended result or design" and citing *Barker*]; *Johnson v. Nissan North America, Inc.*, (N.D. Cal. 2017) 272 F.Supp.3d 1168 [theory of exploding sunroofs plaguing entire product line permitted to go forward on the pleadings]). These decisions are marginal and have their respective problems, but they support the basic proposition that courts have allowed claims to proceed on the theory that an entire manufacturing system was defective. These federal decisions are not inconsistent with *Barker* and the line of authorities listed above.[3]

D. Analysis of Plaintiff's Theory

The parties dispute whether the plaintiffs' theory of manufacturing defect falls under *Barker*'s definition of manufacturing defect or design defect. Any theory that Zantac was defective because it should have contained a different molecule—say famotidine—instead of ranitidine under a risk-benefit test or any test would likely be preempted under *Bartlett* as was the case in *Trejo*. Again, the Court has already ruled on this issue. And, the plaintiffs do not make that claim here. Further, the consumer expectation test for design defect would fail here under *Trejo* and *Soule* for the same reasons articulated in *Trejo*. Given the technical nature of drugs—both prescription and over-the-counter—an ordinary lay consumer is unable to form minimum safety expectations of side effects. So, any design defect claim fails.

Upon consideration, the Court finds that the plaintiffs' theory need not be exclusively in either the design defect or manufacturing defect category. The plaintiffs' theory is a hybrid theory that fits into both: It is in part design defect and in part manufacturing defect.

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[3] The Court will ignore the unpublish Court of Appeal decision the plaintiffs cited. (See CRC 8.1115(a).)

Plaintiffs theory, again, is that the NDMA in Zantac caused cancer. The plaintiffs' expert agrees that NDMA is an internal contaminant. The question is how the NDMA formed in the pills. As noted, the evidence suggests that NDMA is formed by the breakdown of ranitidine through a degradation process. This breakdown is inherent in the nature of the molecule. The evidence shows that heat and humidity accelerate the degradation process. Accordingly, even if the pills were flawlessly manufactured, as a result of time, heat, and humidity, ranitidine will likely degrade to form NDMA according to the plaintiffs' evidence. This component of the plaintiffs' theory constitutes a design defect claim under *Barker*'s definition—the breakdown of ranitidine after the manufacturing process ends because of the inherent unstable nature of the molecule.

The plaintiffs also contend that BI's particular manufacturing process applied unnecessary heat and humidity to ranitidine. This excessive and unnecessary application accelerated the degradation process and generated NDMA. The result is—under the plaintiffs' theory—that BI's pills included excessive and unnecessary NDMA in them, more than what would have resulted from another viable and safer manufacturing processes that did not apply the same heat and moisture. This additional amount of NDMA in BI's pills resulting from BI's particular manufacturing process in excess of NDMA in pills manufactured under other processes can be referred to as the "delta." The excessive application of heat and humidity was the defective process and the "delta," the resulting doses of NDMA in BI manufactured pills, made the product "defective"—according to this theory. The presence of this unnecessary "delta" of NDMA was not intended by BI in its manufacturing plan, so the final pill was not made as intended. In short, plaintiffs' theory is that BI's particular manufacturing caused much more poison to be in the pill than needed to be—poison that was unintended.

The question here is why this component of plaintiffs' theory would not be recognized by California law as a manufacturing defect claim. This question has two components.

The first issue is whether California law recognizes a manufacturing defect claim on the theory that the entire manufacturing process was defective. The plaintiffs argue that *Barker*'s definition of manufacturing defect is a disjunctive: "a manufacturing or production defect is readily identifiable because a defective product is one that differs *from the manufacturer's intended result* or *from other ostensibly identical units of the same product line."* The "or" is meaningful. So the purportedly defective product need not "differ" from others in the same product line because the product can be "defective" under *Barker* if it "differs" from the "intended result." The plaintiffs argue that the Zantac at issue differed from BI's "intended result" because it had NDMA in the pills, something that BI did not intend. In short, BI manufactured a pill that it did not intend to make.

The plaintiffs cite two federal decisions that permit a theory to go forward on the grounds that the entire product line is defective. In contrast, BI has not cited any controlling authority that would preclude a theory of liability that an entire manufacturing process was flawed and resulted in a defective product that differed from what the manufacture intended. BI's argument on this point would eliminate the disjunctive in *Barker*. That conclusion was also the Ninth Circuit's principal point in *Barakezyan*. This plaintiffs' argument is consistent with *Cronin*—the defect resulted from "the hands" of the manufacturer because of the particular method of manufacturing BI implemented. It is also consistent with the basic policy behind strict product liability. The Court finds plaintiffs' argument persuasive.

Upon supplemental briefing and argument, the Court accepts the plaintiffs' efforts to distinguish *In re Coordinated Latex Glove Litigation*. ((2002) 99 Cal.App.4th 1333.) That court

accepted that *Barker* asserted "two formulations" of manufacturing defect (*Id.* at 611) and found that the manufacturer there intended through its specifications to manufacture latex gloves to include the protein levels that the plaintiffs claimed constituted the defect. (*Id.* at 612-13.) In contrast here, BI did not intend its Zantac pills to have NDMA. *In re Coordinated Latex Glove Litigation* does not preclude the plaintiffs' theory.[4]

The second issue is whether California law recognizes this type of manufacturing defect claim with regard to over-the-counter drugs. Neither party cites any controlling California authority involving drugs. Given the dearth of controlling authorities, the Court finds that this answer best turns on how the policies in *Brown* that militated against a design defect claim for prescription drugs affects a manufacturing defect claim for over-the-counter drugs. The Court does not see a meaningful distinction between prescription and over-the-counter drugs for the purposes here. While risk-benefit and consumer expectation issues make relevant whether a doctor mediates a drug's distribution, a manufacturing defect does not. Under the plaintiffs' theory, a doctor would be just as ignorant as a patient of the problem that BI's excessive heat and humidity generated NDMA in the pills. *Trejo* did not address manufacturing defect issues.

To the extent BI's manufacturing process created excessive and unnecessary NDMA that caused cancer, allowing the plaintiffs to pursue this theory is consistent with the policy to hold the manufacturer, who can anticipate or guard against the recurrence of hazards, responsible. This outcome discourages defective products. And, it imposes the costs on the party that is able to pay—the manufacturer, which is the core policy underlying product liability.

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[4] *Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283 [design of a hair trigger on a Glock] and *McCabe v. American Honda Motor Co.* (2002) 100 Cal.App.4th 1111, 1120 [design of air bags; stating "A manufacturing defect exists when an item is produced in a substandard condition"] cited by BI do not foreclose the plaintiffs' theory. Both analyzed a design defect theory and referenced manufacturing defect in passing.

The plaintiffs' theory here should not inhibit drug companies from producing and selling drugs and improving public health—which was a significant concern in *Brown*. The plaintiffs' theory assumes (and requires showing) that there is both a safer way and a more dangerous way to manufacture ranitidine. BI, according to the plaintiffs, chose a more dangerous method. When a choice for a safer manufacturing process exists for a drug already designed and approved, holding a manufacturer responsible for choosing a more dangerous manufacturing process should not discourage drug companies from making and selling drugs. It would encourage drug companies to use the safer option, which would be beneficial. For the same reasons, the concerns regarding cost of insurance and defending lawsuits, when balanced against other policies, should not preclude this theory. Of course, if no safer option exists, the plaintiffs' theory would fail on its own terms and, likely, under FDA preemption.

Further, as *Brown* noted, all drugs can cause harm. But this is not a situation where the risks of NDMA formation were balanced against the benefits of ranitidine by the FDA and thereby approved in order to make an affordable product to improve health. Once the FDA learned of NDMA formation in ranitidine, it recalled the drug.

BI could reasonably argue that it did not know and could not have known that there was a safer option or that it chose the more dangerous option because the science during the relevant time showed neither that ranitidine degraded to form NDMA nor that applying excessive heat and humidity accelerated that degradation. Thus, it lacked a rational basis to choose a safer manufacturing option. *Brown's* policy discussion regarding the failure to warn theory discussed above supports this argument. Although this is a legitimate concern, the Court finds that this argument sounds more in negligence and does not outweigh the policies discussed above behind strict product liability.

Another reason not to recognize a manufacturing defect claim here is the difficulty and risk of jury confusion in distinguishing between the design defect component of the plaintiffs' theory, which has been dismissed and is not viable under *Brown* and *Trejo*, and the manufacturing defect component. But this is a matter of evidence. The parameters discussed below should be sufficient to cure this problem and permit the parties to litigate a meaningful distinction. A related point is that there is an insufficient showing that the NDMA generated by the heat and moisture applied during the manufacturing process, *i.e.*, the "delta," is materially different than the degradation that occurs during or after a "flawlessly manufactured" pill. But again, this is a matter of evidence. The plaintiffs will need to prove that the "delta" is material.

The Court concludes that the plaintiffs' theory is consistent with the overall body of product liability law and the policies behind them, including *Brown*. The Court has little doubt that if cyanide made its way into a pill during a manufacturing process, a manufacturing defect claim would most likely lie. While NDMA is not cyanide, it is a carcinogenic impurity, albeit an internal one, in the pills as an unintended presence. The difference is one of degree—not of kind.

To pursue this theory, however, the plaintiffs must show at least the following:

1. BI applied unnecessary heat and humidity to ranitidine in the manufacturing process when it could have manufactured Zantac under a safer viable process approved by the FDA. If the heat and humidity that BI applied was necessary to form the pills and they could not have been manufactured otherwise, no manufacturing flaw exists. In this regard, BI's manufacturing process must be compared to a viable and acceptable manufacturing process approved by the FDA that did not apply the excess heat and humidity at issue here.

2. BI's particular manufacturing process generated the "delta"—excess and unnecessary NDMA generated by its manufacturing process not present in Zantac pills manufactured under a safer process. Unless the evidence shows that BI's particular manufacturing process generated unnecessary NDMA, the plaintiffs cannot show that the NDMA was not created by the natural degradation process that follows from a flawlessly manufactured pill—*i.e.*, a breakdown inherent in the design. Further, the "delta" is what makes the pills "defective" under the plaintiffs' theory; and
3. The "delta" was a substantial factor that caused the relevant cancers. (*See Cronin* [the defect must proximately cause the injury].) In other words, the plaintiffs must prove that the amount of excess and unnecessary NDMA generated by the unnecessary heat and humidity that BI applied proximately caused the cancers. If the "delta" did not cause the cancer, then the claimed manufacturing defect cannot be distinguished from the defect in the design.

III. EVIDENCE ON THIS MOTION

BI contests whether the plaintiffs have sufficient evidence to pursue their theory, even if legally viable.

1. Whether BI applied excessive heat and moisture during manufacturing: The plaintiffs cite to the deposition of Tara Burns who testified about the manufacturing process under BI's direction and control. (Ex. 70.) She acknowledged that the label for the consumer stated that the pills should be stored in between 20 and 25 degrees Celsius. Her testimony shows that during the manufacturing process, to get from a tablet core to a film coated tablet, "water and Opadry pink" was sprayed on the pills for about three and a half hours. (Id. at 155-158, 160-61.) During this period, the tablet bed was exposed to exhaust air temperature of about 76

degrees Celsius. (Id. at 159-61.) The manufacturing process, however, could have accommodated a request to fix the heat applied during the coating process. (Id. at 252.) Further, during the packaging process when the tablets were sealed inside plastic with a foil cover, the tablets were exposed to temperatures of about 150 to 190 degrees Celsius due to the sealer. (Id. at 192-93.)

The Court finds that this evidence is sufficient to create issues of fact for trial that BI exposed ranitidine to excessive heat and moisture, although the plaintiffs must show that this was unnecessary and that a safer FDA-approved method was available. The latter is not clear from the record on this motion.

2. *Whether BI's manufacturing process generated excess and unnecessary NDMA in the pills compared to other manufacturing processes:* Plaintiffs point to the report of Emery Pharma, which tested various ranitidine tablets. (Ex. 25 at 76-77.) The report states that Emery found a range of NDMA levels from 49.3 ng per 150mg to 28,052.8 ng per 150mg in different ranitidine tablets. (The Court notes that "Appendix AI" is not attached to the submitted report.) On its face, however, the report as submitted does not clearly show BI's pills compared to others on this point. Elsewhere, the report has information tending to show that BI's pills had less NDMA than GSK's pills, which tends to contradict the plaintiffs' theory. (Id. at 81 [Chart showing average NDMA per 150mg—3169.1 for GSK and 2326 for BI].) The Emery Pharma report—*as submitted*—on its face is insufficient to find a "delta" supporting the plaintiff's theory, at least without testimony explaining it. Similarly, other reports that the plaintiffs submitted, *e.g.*, GSK's Investigation into the Root Cause for the presence of NDMA, are also insufficient without some explanation. The identified evidence does not meet the evidentiary requirements at this point.

3. *Whether the "delta" was a substantial factor in causing the cancer.* The plaintiffs have not cited to any evidence showing that the alleged "delta" was a substantial factor in causing cancer.

IV. PREEMPTION

Both parties address federal preemption. The Court does not find it appropriate to dispose of any claims on this motion based on preemption. Although BI raised federal preemption on the plaintiffs' claim based on "Columnar Crystal Morphology," (MPA at 14:12-18:1), the plaintiffs have abandoned that claim. BI did not raise preemption in their moving papers with regard to the plaintiffs' manufacturing defect claim. In their initial opposition, the plaintiffs' preemptively addressed preemption, and BI in its supplemental opposition asserts that any manufacturing defect claim is preempted because the plaintiffs do not identify any unilateral action BI could have taken to eliminate the alleged defect.

Preemption is an affirmative defense as to which defendants have the burden of proof. (*See, e.g.*, *Water Audit California v. Merced Irrigation Dist.* (2025) 111 Cal.App.5th 1147, 1193; *City and County of San Francisco v. Post* (2018) 22 Cal.App.5th 121, 129 ["The burden of proving preemption rests on appellants as the parties asserting it"].) The issue is not waivable and raises questions of subject matter jurisdiction. (*See Hartenstine v. Superior Court* (1987) 196 Cal.App.3d 206, 214). Conflict preemption with federal law, including FDA regulations, remains an issue on which BI bears the burden.

The preemption analysis here is premature. At this point, the Court lacks a clear evidentiary record on which to rule. Among other things, the plaintiffs have not presented sufficient evidence to pursue its manufacturing defect theory against BI at this point based on the clarifications in this Order. By the same token, BI has not shown at this point that it was

required by the FDA to apply the allegedly excessive heat and humidity or that it was prohibited from employing any other form of manufacturing. This is not an exclusive list as BI might have other evidence showing conflict preemption. BI may present evidence and legal argument to show conflict preemption should the plaintiffs' theory be permitted to go forward. This matter is reserved for subsequent motions or trial.

V. ORDER

This Order is intended to apply to the JCCP and not just the instant *Toftee* action. The Court understands that its ruling clarifies the law, perhaps in a novel way, on the plaintiffs' manufacturing defect claim applicable to this JCCP and that the parties did not marshal the evidence on this motion with the Court's ruling in mind. Both sides should be given that opportunity. Further, *Toftee* currently lacks a trial date; a second bellweather trial is scheduled for October 2025; and a third bellweather trial is scheduled for the first half of 2026.

Under these circumstances, the Court DENIES BI's motion for summary adjudication on the claim for manufacturing defect WITHOUT PREJUDICE to BI's right to reraise the issue in a subsequent summary adjudication motion in *Toftee* and in other cases. This process will allow the plaintiffs subsequently to marshal the evidence required under this Order and the defendants to test whether there is sufficient evidence for the manufacturing defect claim to go forward under the principles articulated here.

For the October 2025 bellweather trial, the Court will hold, if necessary, a short (no more than a half-day) Evidence Code § 402 hearing before opening statements for the plaintiffs to present sufficient evidence to permit this claim to go forward based on the parameters set forth above. As noted, any preemption issues are preserved.

IT IS SO ORDERED.

S. Raj Chatterjee

Dated: September 15, 2025

Hon. S. Raj Chatterjee

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

Case Number: JCCP005150
Case Name: **RANITIDINE PRODUCTS CASES**

Order Re: DENYING WITHOUT PREJUDICE BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY ADJUDICATION ON PLAINTIFF'S CAUSE OF ACTION FOR MANUFACTURING DEFECT

DECLARATION OF ELECTRONIC SERVICE

I certify that I am not a party to these cases, and that a true and correct copy of the foregoing document was served electronically pursuant to Pre-Trial Order No.8, entered in these coordinated proceedings on September 23, 2021, via the CASE ANYWHERE system. Execution of this certificate occurred at 1221 Oak Street, Oakland, California.

Executed on September 15, 2025

Executive Officer/Clerk of the Superior Court

By: Simka Albert
Deputy Clerk