

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

Sneed v. The Procter & Gamble Company

Sneed · No. 23-cv-05443-JST · Decided April 4, 2025

SUMMARY

The United States District Court for the Northern District of California denied Procter & Gamble’s motion to dismiss the second amended complaint in a putative class action concerning ZzzQuil products labeled “Non-Habit Forming.” The court declined to find the plaintiffs’ California consumer-protection, warranty, and unjust-enrichment claims preempted under 21 U.S.C. § 379r and held that the allegations and cited scientific sources sufficiently supported the claims at the pleading stage. The court also declined to dismiss the express-warranty, implied-warranty, and other claims addressed in the order.

CASE DETAILS

COURT	United States District Court for the Northern District of California
WRITING FOR THE COURT	Jon S. Tigar
JURISDICTION	United States District Court for the Northern District of California
DECIDED	April 4, 2025
DOCKET	23-cv-05443-JST
DISPOSITION	other
PROCEDURAL POSTURE	Defendant moved under Federal Rule of Civil Procedure 12(b)(6) to dismiss plaintiffs' second amended complaint in a putative consumer class action.
STANDARD OF REVIEW	On a Rule 12(b)(6) motion, the Court accepts factual allegations as true and construes the pleadings in the plaintiffs' favor, asking whether the complaint states a facially plausible claim. Dismissal is appropriate only when the complaint lacks a cognizable legal theory or sufficient facts to support one.
PRECEDENTIAL VALUE	district court order; precedential status unknown

TOPICS

- motions to dismiss
- consumer protection
- deceptive trade practices
- federalism
- judicial notice

PRACTICE AREAS

consumer protection

civil procedure

federal preemption

evidence

QUESTIONS PRESENTED

1. Whether plaintiffs' California consumer-protection, warranty, and unjust-enrichment claims were expressly preempted by 21 U.S.C. § 379r(a).
2. Whether the second amended complaint plausibly alleged that P&G's non-habit-forming representations were false or likely to deceive reasonable consumers under California's UCL, FAL, and CLRA.
3. Whether plaintiffs adequately pleaded an express-warranty claim based on product labeling and advertising.
4. Whether plaintiffs adequately pleaded an implied-warranty-of-merchantability claim despite citing the express-warranty provision of the California Commercial Code and allegedly lacking contractual privity.
5. Whether plaintiffs could maintain an unjust-enrichment claim alongside their warranty claim.

HOLDINGS

1. The plaintiffs' state-law claims were not preempted by 21 U.S.C. § 379r(a) because P&G identified no federally approved ZzzQuil label containing the challenged representation, and the cough-medicine labels and FDA informational materials did not establish that the ZzzQuil claims would require information different from or additional to federal labeling.
2. Plaintiffs sufficiently stated claims under California's Unfair Competition Law, False Advertising Law, and Consumers Legal Remedies Act by alleging facts and citing scientific sources that plausibly supported the claim that diphenhydramine can lead to habit formation with prolonged use.
3. Plaintiffs adequately stated an express-warranty claim because they alleged economic losses including a price premium paid for products allegedly sold with misleading habit-forming representations; they did not necessarily seek recovery of the entire purchase price.
4. Plaintiffs adequately stated an implied-warranty claim based on the alleged failure of ZzzQuil products to conform to promises or affirmations on their packaging and labeling, and the California privity exception for reliance on a manufacturer's written labels or advertisements applied.
5. Plaintiffs' unjust-enrichment claim was not barred by their express-warranty claim because the alleged warranty arose from product labeling and advertising rather than an express agreement governing the parties' rights.
6. The Court took judicial notice of the existence and FDA approval of the submitted FDA documents and incorporated the scientific sources referenced in the complaint, but did not accept the truth of disputed conclusions in those materials or use them to resolve factual disputes on the motion to dismiss.

KEY QUOTATIONS

“The Court will deny the motion.”

“Dismissal is appropriate only in “the rare situation” where the facts make “it impossible for the plaintiff to prove that a reasonable consumer was likely to be deceived.””

“Discovery may expose that those studies contain vital flaws, but it is enough for now that the studies do not plainly refute the allegations in the complaint.”

FACTUAL BACKGROUND

Procter & Gamble sells ZzzQuil nighttime sleep-aid products containing diphenhydramine hydrochloride. Plaintiffs alleged that P&G represented the products as non-habit-forming even though diphenhydramine may lead to dependency, tolerance, misuse, or habit formation when used over time. The second amended complaint added scientific studies and a declaration addressing the alleged habit-forming potential of diphenhydramine, including when used as directed.

PROCEDURAL HISTORY

Plaintiffs filed a putative class action alleging that Procter & Gamble falsely and misleadingly advertised, labeled, and packaged ZzzQuil nighttime sleep-aid products as non-habit-forming. After the Court previously dismissed or otherwise addressed claims in an earlier amended complaint, plaintiffs filed a second amended complaint supported by additional scientific sources. The Court denied P&G's motion to dismiss the second amended complaint.

DISPOSITION

other

CASES CITED

- *Mendiondo v. Centinela Hospital Medical Center*, 521 F.3d 1097, 1104 (9th Cir. 2008)
- *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)
- *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556-557, 570 (2007)
- *Kniesel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005)
- *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998-1002 (9th Cir. 2018)
- *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003)
- *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001)
- *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010)
- *Townsend v. Wells Fargo Bank, N.A.*, 2019 WL 4145464, at *2 (N.D. Cal. Aug. 30, 2019), *aff'd*, 831 F. App'x 338 (9th Cir. 2020)
- *Snellink v. Gulf Resources, Inc.*, 870 F. Supp. 2d 930, 937 (C.D. Cal. 2012)
- *Wilson v. Amneal Pharmaceuticals, L.L.C.*, 2013 WL 6909930, at *6-*7 (D. Idaho Dec. 31, 2013)
- *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1126 n.1 (N.D. Cal. 2013)
- *Wilson v. Frito-Lay North America, Inc.*, 260 F. Supp. 3d 1202, 1207 (N.D. Cal. 2017)
- *Kettner v. Cadista Holdings, Inc.*, 2019 WL 11583314, at *2 (W.D. Tenn. Aug. 12, 2019)

- *Gerritsen v. Warner Bros. Entertainment Inc.*, 112 F. Supp. 3d 1011, 1029 (C.D. Cal. 2015)
- *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010)
- *Cohen v. Apple Inc.*, 46 F.4th 1012, 1027 (9th Cir. 2022)
- *Beaver v. Tasadia Hotels*, 816 F.3d 1170, 1178 (9th Cir. 2016)
- *Carter v. Novartis Consumer Health*, 582 F. Supp. 2d 1271, 1279, 1283, 1286 (C.D. Cal. 2008)
- *Morgan v. Albertsons Companies, Inc.*, 2023 WL 3607275, at *5-*6 (N.D. Cal. Mar. 13, 2023)
- *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1290 (9th Cir. 2021)
- *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995)
- *McGinity v. Procter & Gamble Co.*, 69 F.4th 1093, 1097 (9th Cir. 2023)
- *Williams v. Gerber Products Co.*, 552 F.3d 934, 939 (9th Cir. 2008)
- *Moore v. Trader Joe's Co.*, 4 F.4th 874, 882 (9th Cir. 2021)
- *Locklin v. StriVectin Operating Co., Inc.*, 2022 WL 867248, at *4 (N.D. Cal. Mar. 23, 2022)
- *Graham v. Central Garden & Pet Co.*, 2023 WL 2744391, at *2 (N.D. Cal. Mar. 30, 2023)
- *Sonner v. Schwabe North America, Inc.*, 911 F.3d 989, 992-993 (9th Cir. 2018) (per curiam)
- *In re MyFord Touch Consumer Litigation*, 291 F. Supp. 3d 936, 966 (N.D. Cal. 2018)
- *DiGiacinto v. RB Health (US) LLC*, 668 F. Supp. 3d 950, 966-967 (N.D. Cal. 2023)
- *Hadley v. Kellogg Sales Co.*, 273 F. Supp. 3d 1052, 1096 (N.D. Cal. 2017)
- *Clemens v. DaimlerChrysler Corp.*, 530 F.3d 852, 858 (9th Cir. 2008)
- *California Medical Association, Inc. v. Aetna U.S. Healthcare of California, Inc.*, 94 Cal. App. 4th 151, 172 (2001)
- *Deras v. Volkswagen Group of America, Inc.*, 2018 WL 2267448, at *3 (N.D. Cal. May 17, 2018)
- *Shin v. Sanyo Foods Corp. of America*, 2024 WL 4467603, at *4 (C.D. Cal. Aug. 13, 2024)
- *Strumlauf v. Starbucks Corp.*, 192 F. Supp. 3d 1025, 1033 (N.D. Cal. 2016)

OPINION

1 2 3 4 UNITED STATES DISTRICT COURT 5 NORTHERN DISTRICT OF CALIFORNIA 6 7
STEPHEN SNEED, et al., Case No. 23-cv-05443-JST 8 Plaintiffs, ORDER DENYING MOTION
TO 9 v. DISMISS SECOND AMENDED COMPLAINT 10 THE PROCTER & GAMBLE
COMPANY, Re: ECF No. 52 Defendant. 11 12 13 Before the Court is Defendant Procter &
Gamble Company's ("P&G") motion to dismiss 14 the second amended complaint.

ECF No. 52. The Court will deny the motion. 15 I. BACKGROUND 16 Because the facts are
well-known to the parties and the Court has summarized the 17 background of this action in detail
in its prior order, ECF No. 45, the Court will not elaborate them 18 in their entirety here.

In sum, P&G sells several "Nighttime Sleep Aid" products (hereinafter, 19 "Product(s)")
containing diphenhydramine hydrochloride ("diphenhydramine") under the ZzzQuil 20 brand.
ECF No. 47 ¶ 2, 4, 12 ("SAC"). Plaintiffs Stephen Sneed and Nickolas Cannon bring this 21
putative class action against P&G for allegedly "falsely and misleadingly advertis[ing], label[ing],

22 and packag[ing] certain” of its ZzzQuil Nighttime Sleep Aid products as “Non-Habit Forming” 23 (hereinafter, “Habit Representation” and/or “Challenged Representation”).

Id. ¶ 2. Plaintiffs 24 allege that the Products contain diphenhydramine, which “is an ingredient that can lead consumers 25 to frequently use the Product over a prolonged period, contrary to the Challenged Representation 26 disclaiming the Products’ potential to be ‘habit forming.’” Id. ¶ 3. Plaintiffs further contend that 27 such representations coax “reasonable consumers, including Plaintiffs, to incorrectly believe that 1 Plaintiffs bring claims for (1) violation of California’s Unfair Competition Law (“UCL”), 2 Cal. Bus. & Prof.

Code §§ 17200 et seq; (2) violation of California’s False Advertising Law 3 (“FAL”), Cal. Bus. & Prof Code §§ 17500 et seq.; (3) violation of California’s Consumers Legal 4 Remedies Act (“CLRA”), Cal. Civ. Code §§ 1750 et seq.; (4) breach of warranty in violation of 5 Cal. Comm. Code §§ 2313 et seq.; and (5) unjust enrichment under California law. Id. at 32-49.

6 II. JURISDICTION 7 The Court has jurisdiction under 28 U.S.C. § 1332(d). 8 III. LEGAL STANDARD 9 To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a 10 complaint must contain “a short and plain statement of the claim showing that the pleader is 11 entitled to relief.” Fed. R. Civ. P. 8(a)(2). Dismissal “is appropriate only where the complaint 12 lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory.” 13 *Mendiondo v. Centinela Hosp.*

Med. Ctr., 521 F.3d 1097, 1104 (9th Cir. 2008). “[A] complaint 14 must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible 15 on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 16 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual 17 content that allows the court to draw the reasonable inference that the defendant is liable for the 18 misconduct alleged.” *Ashcroft*, 556 U.S. at 678.

While this standard is not “akin to a ‘probability 19 requirement’... it asks for more than a sheer possibility that a defendant has acted unlawfully.” 20 Id. (quoting *Twombly*, 550 U.S. at 556). “Where a complaint pleads facts that are ‘merely 21 consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and 22 plausibility of entitlement to relief.’” Id. (quoting *Twombly*, 550 U.S. at 557).

In determining 23 whether a plaintiff has met the plausibility requirement, a court must “accept all factual allegations 24 in the complaint as true and construe the pleadings in the light most favorable” to the plaintiff. 25 *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). 26 IV. JUDICIAL NOTICE AND INCORPORATION BY REFERENCE 27 “As a general rule, [courts] ‘may not consider any material beyond the pleadings in ruling 1 2011) (quoting *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir.

2001)). “When ‘matters 2 outside the pleading are presented to and not excluded by the court,’ the 12(b)(6) motion converts 3 into a motion for summary judgment under Rule 56,” unless those matters satisfy the 4 “incorporation-by-reference doctrine” or the standard for “judicial notice under Federal Rule of 5 Evidence 201.” *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir.

2018) (quoting 6 Fed. R. Civ. P. 12(d)). The Ninth Circuit has expressed concern with the practice of “exploiting 7 these procedures improperly to defeat what would otherwise constitute adequately stated claims at 8 the pleading stage.” *Id.* The Ninth Circuit also cautioned that “[i]f defendants are permitted to 9 present their own version of the facts at the pleading stage—and district courts accept those facts 10 as uncontroverted and true—it becomes near impossible for even the most aggrieved plaintiff to 11 demonstrate a sufficiently ‘plausible’ claim for relief.” *Id.* at 999.

12 “Judicial notice under Rule 201 permits a court to notice an adjudicative fact if it is ‘not 13 subject to reasonable dispute,’” i.e., the fact “is ‘generally known,’ or ‘can be accurately and 14 readily determined from sources whose accuracy cannot reasonably be questioned.’” *Id.* (quoting 15 Fed. R. Evid. 201(b)). “Unlike rule-established judicial notice, incorporation-by-reference is a 16 judicially created doctrine that treats certain documents as though they are part of the complaint 17 itself.” *Id.* at 1002.

Documents “may be incorporated by reference into a complaint if the plaintiff 18 refers extensively to the document or the document forms the basis of the plaintiff’s claim,” 19 *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003), and “the documents’ authenticity... is 20 not contested,” *Lee*, 250 F.3d at 688 (alteration in original) (quotation marks and citation omitted).

21 “[T]he mere mention of the existence of a document is insufficient to incorporate the contents of a 22 document.” *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010). 23 Defendants request that the Court consider twenty documents under the incorporation-by- 24 reference doctrine or take judicial notice of those documents: (1) a letter sent by the Food and 25 Drug Administration (“FDA”) to the Halsey Drug Company, Inc., dated June 5, 1986, approving 26 the abbreviated new drug application (“ANDA”) for Beldin Cough Syrup, ECF No. 53-2 (Exhibit 27 1); (2) a letter sent by the FDA to Richardson-Vicks, Inc., dated February 19, 1987, approving the 1 report titled Side Effects of Sleep Drugs, published by the FDA on its website, ECF No. 53-5 2 (Exhibit 3); and (4) seventeen sources cited by Plaintiffs in the SAC, comprised mostly of 3 scientific articles, ECF Nos. 53-6–53-22 (Exhibits 4–20).

4 A. FDA Documents (Exhibits 1–3) 5 P&G argues that the Court may take judicial notice of the three FDA documents because 6 they are “government documents,” including public information on a government agency website. 7 ECF No. 53 at 2. Plaintiffs argue that the Court should deny P&G’s request because (1) the three 8 FDA documents constitute improper extrinsic evidence outside the scope of Plaintiffs’ SAC; (2) 9 the three FDA documents are reasonably subject to

dispute and not capable of immediate and 10 accurate determination; (3) the two FDA letters are not publicly available documents; (4) P&G 11 improperly seeks to use the FDA documents to ask the Court to resolve factual issues in a motion 12 to dismiss; and (5) the three FDA documents constitute inadmissible hearsay.

ECF No. 59 at 3–7. 13 While Plaintiffs argue that the FDA documents are “‘subject to reasonable dispute’ and 14 cannot be deemed ‘accurately and readily determined from sources whose accuracy cannot 15 reasonably be questioned,’” they merely quote the language from Rule 201 without explaining 16 how those documents are “subject to reasonable dispute” or raising any actual attack on the 17 documents’ authenticity.

ECF No. 59 at 4. Plaintiffs also argue that the Court should not take 18 judicial notice of Exhibits 1 and 2 because they are not publicly accessible—Exhibit 1 was 19 retrieved from P&G’s files (P&G had acquired Richardson-Vicks, Inc. in 1985) and Exhibit 2 was 20 obtained from the website of FOI Services, Inc., which represented that it obtained the document 21 from the FDA through the Freedom of Information Act.

ECF No. 59 at 5. But the two cases cited 22 by Plaintiffs, see *id.*, both involved challenges to the authenticity of the documents. See 23 *Townsend v. Wells Fargo Bank, N.A.*, No. 18-CV-07382-NC, 2019 WL 4145464, at *2 (N.D. Cal. 24 Aug. 30, 2019), *aff’d*, 831 F. App’x 338 (9th Cir. 2020) (“The Court declines to take judicial 25 notice of the loan modification agreement.

Townsend disputes the authenticity of that document 26 and contends that it is not publicly available.”); *Snellink v. Gulf Res., Inc.*, 870 F. Supp. 2d 930, 27 937 (C.D. Cal. 2012) (“Plaintiffs dispute the authenticity of SCHC and SYCI’s SAIC documents 1 authorization of a Gulf company representative was required for access.”). 2 Here, Plaintiffs do not dispute that the FDA in fact approved for market the two products 3 and their corresponding labels described in Exhibits 1 and 2.

And the approval of these two 4 products is readily verifiable on the FDA’s website such that they are fit for judicial notice. See 5 *Wilson v. Amneal Pharms., L.L.C.*, No. 1:13-CV-00333-CWD, 2013 WL 6909930, at *6 (D. Idaho 6 Dec. 31, 2013). 7 Because Courts routinely take judicial notice of similar FDA guidance documents, the 8 Court grants P&G’s requests for judicial notice of the FDA documents.

See, e.g., *Gustavson v. 9 Wrigley Sales Co.*, 961 F.Supp.2d 1100, 1126, n.1 (N.D. Cal. 2013) (taking judicial notice of an 10 FDA guidance document about food labeling and an FDA response letter); see also *Wilson v. 11 Frito-Lay N. Am., Inc.*, 260 F. Supp. 3d 1202, 1207 (N.D. Cal. 2017) (taking judicial notice of a 12 letter from a public interest group to the FDA, FDA food labeling guidance, and warning letters 13 sent from the FDA to other companies); *Kettner v. Cadista Holdings, Inc.*, No. 14 219CV02123TLPCGC, 2019 WL 11583314, at *2 (W.D.

Tenn. Aug. 12, 2019) (taking judicial notice of FDA documents approving an ANDA). However, the Court agrees with Plaintiffs that judicial notice extends only to recognizing the existence of Exhibits 1–3, and not truth of the conclusions contained within them. See ECF 18 No. 59 at 4 (citing *Gerritsen v. Warner Bros. Entm’t Inc.*, 112 F. Supp. 3d 1011, 1029 (C.D.

Cal. 19 2015)). Accordingly, the Court takes judicial notice of Exhibits 1 and 2 to indicate that the FDA granted approval of the products therein and their corresponding product labels, “not whether the contents of [the letter or the labels] were in fact true,” i.e., whether the use of diphenhydramine at the respective doses of those products is in fact non-habit forming.

Von Saher v. Norton Simon Museum of Art at Pasadena, 592 F.3d 954, 960 (9th Cir. 2010) (internal quotation marks omitted); *Wilson*, 2013 WL 6909930, at *7 (taking judicial notice of “when certain approvals occurred, and what was being approved—whether it was the transfer of the ANDA for Generic Bactrim, or the labels for Brand Name Bactrim and what those labels stated”—and not “the entirety of the [approval] letters’ contents”).

The Court similarly takes judicial notice of Exhibit 3 to indicate 1 webpage are in fact true. 2 B. Scientific Sources Incorporated by Reference (Exhibits 4–20) 3 P&G argues that the scientific sources contained in Exhibits 4–20 have been incorporated 4 by reference into the complaint because Plaintiffs have cited them to support their claim that the 5 Products can be habit forming.

See ECF No. 53 at 3. 6 Plaintiffs argue that while the seventeen scientific studies and articles cited by them in their 7 SAC may be incorporated by reference, the Court should only take notice of those articles’ 8 existence and not consider P&G’s own interpretation of the articles’ “merits, methods, findings, or 9 scope.” ECF No. 59 at 7. 10 The Court finds that Exhibits 4–20 have been incorporated by reference.

First, Plaintiffs 11 do not dispute the authenticity of any of these documents, and the SAC references them 12 repeatedly. See generally ECF No. 47. Second, Plaintiffs allege that these sources demonstrate 13 that diphenhydramine is capable of being habit forming. See, e.g., *id.* ¶¶ 14–15, 28–29.

Because 14 each document forms the basis for a necessary element of Plaintiffs’ claims—i.e., that the Habit 15 Representations are false—each is properly incorporated by reference. See *Khoja*, 899 F.3d at 16 1002. The Court thus grants the requests for judicial notice as to Exhibits 4–20 as to their 17 existence but, as discussed further below, declines to consider the documents on the merits beyond 18 their general conclusions.

19 V. DISCUSSION 20 A. Preemption 21 P&G argues that Plaintiffs’ state-law claims are preempted by 21 U.S.C. § 379r because 22 the FDA has “already considered whether diphenhydramine could be habit forming and repeatedly 23 concluded that the medicine has no such effect.” ECF No. 52 at 20–22. 24 The Court’s previous order considered the preemptive

effect of the FDA's tentative final 25 monograph and final monograph regarding OTC nighttime sleep-aids and declined to find 26 Plaintiffs' state-law claims preempted.

See ECF No. 45 at 8. P&G now urges the Court to 27 reexamine the FDA's regulatory history regarding diphenhydramine and has also provided two 1 well as a July 31, 2007 report titled Side Effects of Sleep Drugs, published by the FDA on its 2 website. See ECF No. 52 at 21; ECF Nos. 53-2, 53-4, 53-5. 3 "Preemption of state law, by operation of the Supremacy Clause, can occur in one of 4 several ways: express, field, or conflict preemption." *Cohen v. Apple Inc.*, 46 F.4th 1012, 1027 5 (9th Cir.

2022) (quoting *Beaver v. Tasadia Hotels*, 816 F.3d 1170, 1178 (9th Cir. 2016)). Enacted 6 as Section 751 of the Food and Drug Administration Modernization Act of 1997, Pub L. No. 105- 7 115, 111 Stat. 2374-76 (1997), Section 379r(a) includes an express preemption clause that 8 provides that "no State... may establish or continue in effect any requirement... that is different 9 from or in addition to, or that is otherwise not identical with" federal law.

21 U.S.C. § 379r(a); 10 see *Carter v. Novartis Consumer Health*, 582 F. Supp. 2d 1271, 1279 (C.D. Cal. 2008). 11 Effectively, "Section 379r(a) preempts state law claims to the extent that those claims 'would [] 12 require a manufacturer to include additional or different information on a federally approved 13 label.'" *Morgan v. Albertsons Companies, Inc.*, No. 22-CV-02948-JST, 2023 WL 3607275, at *5 14 (N.D.

Cal. Mar. 13, 2023). "[C]laims are not preempted to the extent that they are at variance with 15 the FDA-approved label." *Id.* And in a similar vein, "state law claims 'that go beyond the FDA- 16 approved labeling and advertising,' are not preempted because such claims would not be 'at 17 variance with FDA regulations.'" *Id.* (quoting *Carter*, 582 F. Supp. 2d at 1283, 1286).

18 Because the Court has already explained in its previous order why the FDA's drafting 19 history of its tentative final monograph and final monograph regarding OTC-sleep aids do not 20 support preemption, ECF No. 45 at 7–8, it addresses only the new FDA documents submitted by 21 P&G—which the Court also finds do not require preemption. 22 First, P&G points to two approval letters where the FDA approved for marketing two 23 cough syrups containing diphenhydramine and their corresponding labels describing the products 24 as "non-habit forming." ECF No. 52 at 24.

Those products involved cough medicines where the 25 approved dosages were two teaspoons (25 mg diphenhydramine total) every 4 hours, for up to 75 26 mg over 12 hours. ECF No. 52 at 24 (citing ECF Nos. 53-2, 53-4). P&G argues that because the 27 FDA approved the "non-habit forming" label "on a product that contains a higher dosage of 1 language might be misleading, [] the FDA had by that time reversed its tentative view as it 2 evaluated additional studies." ECF No. 52 at 24 (emphasis in original).

3 The Court is not persuaded. While the maximum daily dosage of diphenhydramine 4 suggested for the cough medicines is greater than that of ZzzQuil (50 mg), the amount of 5 diphenhydramine present per dose in the cough medicines (25 mg) is less than that of ZzzQuil (50 6 mg).

Moreover, Plaintiffs argue that cough medicines are “entirely different products” from sleep 7 aids, particularly because cough medicines “are intended for infrequent use only when someone 8 has a cough,” whereas sleep aids “relate to a daily occurrence [and] are intended for more regular 9 use than a sporadic need for a cough remedy.” ECF No. 58 at 22. Critically, “state law claims 10 related to advertising that are ‘premised ultimately upon the inadequacy of the product label’ are 11 treated the same as a state law claim about the label itself,” so the preemptive effect of a federally 12 approved product label extends to advertising materials that are “materially identical” to the 13 representation on the approved product label.

Cohen v. ConAgra Brands, Inc., 16 F.4th 1283, 14 1290 (9th Cir. 2021) (quoting Taylor AG Indus. v. Pure-Gro, 54 F.3d 555, 561 (9th Cir. 1995)). 15 Because the above differences between the cough medicines and ZzzQuil render them not 16 “materially identical,” the FDA’s approval of the product labels submitted by P&G do not preempt 17 Plaintiffs’ claims here regarding ZzzQuil.

18 The Court is similarly unpersuaded by P&G’s argument that because the FDA approved 19 the “non-habit forming” cough-medicine labels after it published its tentative final monograph, the 20 FDA must have “reversed its tentative view [on diphenhydramine being potentially habit forming] 21 as it evaluated additional studies.” ECF No. 52 at 24.

The key inquiry under Section 379r(a) is 22 whether the state law claims “would [] require a manufacturer to include additional or different 23 information on a federally approved label.” Morgan, Inc., 2023 WL 3607275, at *5 (internal 24 quotation marks omitted).

Here, there is no federally approved label for ZzzQuil as to the Habit 25 Representations. And the circumstantial evidence surrounding the approval of a different drug 26 with a different dosage—even if containing the same main ingredient—does not pose the risk of 27 conflicting factual determinations about whether ZzzQuil specifically is habit forming. 1 2007 consumer information booklet published on its website that “OTC sleep aids are non-habit 2 forming.” ECF No. 52 at 24.

Because the 2007 FDA booklet is merely informational and does 3 not carry the force of law for purposes of the preemption inquiry, it has no bearing on the Court’s 4 preemption analysis. See Morgan v. Albertsons Companies, Inc., No. 22-CV-02948-JST, 2023 5 WL 3607275, at *6 (N.D. Cal. Mar. 13, 2023) 6 Accordingly, the Court declines to find Plaintiffs’ state-law claims preempted.

7 B. Failure to State a Claim 8 1. UCL, FLA, CLRA 9 To succeed on their state law claims, Plaintiffs must prove that P&G made false or 10 deceptive statements. See McGinity v. Procter & Gamble Co., 69 F.4th 1093, 1097 (9th Cir. 11 2023) (holding that claims under the UCL, FAL, and

CLRA “require[] that [plaintiffs] ‘show that 12 members of the public are likely to be deceived’” (citation omitted)).

The Ninth Circuit has made 13 clear that granting a motion to dismiss is appropriate only in “the rare situation” where the facts 14 make “it impossible for the plaintiff to prove that a reasonable consumer was likely to be 15 deceived.” *Williams v. Gerber Prod. Co.*, 552 F.3d 934, 939 (9th Cir. 2008).

Under the reasonable 16 consumer standard, “information available to a consumer is not limited to the physical label and 17 may involve contextual inferences regarding the product itself and its packaging.” *Moore v. 18 Trader Joe’s Co.*, 4 F.4th 874, 882 (9th Cir. 2021). 19 The Court previously found that Plaintiffs in their first amended complaint failed to cite 20 materials sufficient to “demonstrate that ZzzQuil or diphenhydramine can actually lead to habit 21 formation when used over prolonged periods.” ECF No. 45 at 13.

More specifically, the Court 22 found that while Plaintiffs cited numerous articles generally discussing the rise of sleep-aids and 23 how habits are formed, Plaintiffs included only one source addressing whether ZzzQuil products 24 and diphenhydramine could cause habit formation—and this single article did not include citations 25 to any clinical studies. *Id.* at 12–13.

Plaintiffs have since amended their complaint to include 26 citations to a variety of scientific studies and articles. See, e.g., ECF No. 47 ¶¶ 14–15, 28–29. 27 Some of the most directly relevant materials include: (1) a declaration submitted by Dr. 1 document that patients who initially take diphenhydramine as directed often escalate their dosages 2 to excessive levels,” discusses how the progressive use of diphenhydramine “can result in 3 dependency on the drug and withdrawal symptoms when its use is discontinued,” and concludes 4 that “diphenhydramine is habit-forming with regular use,” ECF No. 47-5 ¶¶ 8, 12; (2) a 2008 5 study where the researchers detected “a cocaine-like pattern of stimulation of [dopamine] 6 transmission” in rats after the rats were provided with intravenous doses of diphenhydramine;¹ (3) 7 a 2002 study finding that individuals rapidly developed tolerance to the sedative effects of 8 diphenhydramine when administered a 50 mg dose twice a day; 2 and (4) a 2021 study reporting a 9 63% increase in intentional diphenhydramine exposures from 2005 to 2016, including a 230% rise 10 in misuse among adults aged 55 and older.³ 11 P&G argues that Plaintiffs’ SAC continues to lack evidence capable of establishing that 12 ZzzQuil or diphenhydramine can be habit forming when used as directed.

ECF No. 52 at 12. The 13 heart of P&G’s argument is that the numerous scientific sources now cited by the SAC do not 14 support Plaintiffs’ claims because the sources either (1) do not focus on diphenhydramine 15 specifically, (2) are based on anecdotes, (3) involve the significant abuse of diphenhydramine 16 rather than the use of the drug as directed, or (4) involve studies that expose test subjects to 17 diphenhydramine at levels exceeding 50 mg per day.

See *id.* at 13–19. P&G further challenges 18 the Nemanich Declaration for relying on a review of these same flawed sources. *Id.* at 19–20. 19 Unlike with the Plaintiffs’ first amended complaint, the Court now finds that Plaintiffs 20 have sufficiently bolstered their SAC with sources that demonstrate that diphenhydramine can lead 21 to habit formation when used over time.

While P&G raises several challenges to the 22 methodology, limitations, and comparability of the scientific sources (which P&G has moved to 23 incorporate by reference), the Court finds that the sources discussed above sufficiently support 24 Plaintiffs’ claims regarding habit formation for diphenhydramine consumption. Plaintiffs have 25 1 Gianluigi Tanda, et al., Cocaine-Like Neurochemical Effects of Antihistaminic Medications, 106 26 J. Neurochem.

147, 147 (2008), ECF No. 53-19 (Ex. 17). 2 Gary S. Richardson, et al., Tolerance to Daytime Sedative Effects of H1 Antihistamines, 22 J. of 27 Clin. Psychopharmacology 511 (2022), ECF No. 53-21 (Ex. 19). 1 included citation to scientific studies that support their claim that even the directed usage of 2 diphenhydramine can lead to dependency, tolerance, and abuse.

See ECF No. 47 ¶¶ 14–15, 28–29. 3 And heeding the Ninth Circuit’s warning in *Khoja* regarding the overuse of incorporation- 4 by-reference, the Court declines to use these “extrinsic documents to resolve competing theories 5 against the complaint [and] risk[] premature dismissals of plausible claims that may turn out to be 6 valid after discovery.” *Khoja*, 899 F.3d at 998.

As one other court in this district explained, “[t]he 7 cited studies reference at least [the diphenhydramine] identified in the complaint and purport to 8 document their [tendency for misuse and potential habit formation]. Discovery may expose that 9 those studies contain vital flaws, but it is enough for now that the studies do not plainly refute the 10 allegations in the complaint.” *Locklin v. StriVectin Operating Co., Inc.*, No. 21-CV-07967-VC, 11 2022 WL 867248, at *4 (N.D.

Cal. Mar. 23, 2022); see also *Graham v. Cent. Garden & Pet Co.*, 12 No. 22-CV-06507-JSC, 2023 WL 2744391, at *2 (N.D. Cal. Mar. 30, 2023) (“Defendant’s 13 interpretation of the studies requires the Court to draw inferences in its favor, whereas the Court 14 must draw all reasonable inferences in Plaintiff’s favor at the motion to dismiss stage.”) (internal 15 citations omitted); *Sonner v. Schwabe N. Am., Inc.*, 911 F.3d 989, 992–93 (9th Cir.

2018) (per 16 curiam) (finding that the persuasiveness of an admissible report by an expert is for the factfinder to 17 decide). 18 Accordingly, the Court finds that Plaintiffs have sufficiently stated a claim under the UCL, 19 FLA, and CLRA. 20 2. Express Warranty 21 P&G argues that Plaintiffs have failed to state an express warranty claim because their 22 claim “seeks to recover the entire purchase price of the medicine” rather than ““the diminution in 23 value between the [product] as warranted and the [product] as sold,”” and Plaintiffs have not 24 alleged that the Products would lose all their value without the Habit Representation.

ECF No. 52 25 at 26 (quoting *In re MyFord Touch Consumer Litig.*, 291 F. Supp. 3d 936, 966 (N.D. Cal. 2018)). 26 While P&G recites the correct standard for measuring the damages under a breach of 27 express warranty claim, P&G have not cited to—and the Court is not aware of—any cases that 1 Plaintiffs counter, Plaintiffs allege that they have suffered “economic losses... including... the 2 amounts paid for the Products”—not that the amount they seek to recover is the total amount paid.

3 See ECF No. 58 at 25 (quoting ECF No. 47 ¶ 127). Indeed, Plaintiffs allege elsewhere in their 4 SAC that they overpaid a “premium” for the Products, see ECF No. 47 ¶¶ 3, 4, 6, 45, 81, 89, 97, 5 including that they seek “a monetary recovery of the price premium Plaintiffs and consumers 6 overpaid for [Defendant’s] Products.” *Id.* ¶ 6. 7 The Court thus declines to dismiss Plaintiffs’ express warranty claim.

8 3. Implied Warranty of Merchantability 9 P&G next argues that the Court should dismiss Plaintiffs’ claim for breach of implied 10 warranty of merchantability because (1) Plaintiffs cite only to the code section for express 11 warranties in their SAC, see ECF No. 47 ¶¶ 122–30 (citing Cal. Comm. Code § 2313); (2) the 12 implied warranty claim falls with the express warranty claim; (3) Plaintiffs have not alleged that 13 ZzzQuil is not fit for the ordinary purpose of such goods; and (4) Plaintiffs do not allege privity of 14 contract with P&G or identify any exceptions to the privity requirement.

15 Because the Court finds that Plaintiffs have adequately stated a claim for breach of express 16 warranty, Plaintiffs have also adequately stated a claim for breach of the implied warranty of 17 merchantability premised on the same mislabeling. See *DiGiacinto v. RB Health (US) LLC*, 668 18 F. Supp. 3d 950, 966–67 (N.D. Cal. 2023) (holding that “since the breach of express warranties 19 claim is sufficiently pleaded, the court denies the motion to dismiss the breach of implied 20 warranties claim”) (citing *Hadley v. Kellogg Sales Co.*, 273 F. Supp. 3d 1052, 1096 (N.D.

Cal. 21 2017)). 22 Nevertheless, the Court will briefly address the remainder of P&G’s arguments. First, 23 while Plaintiffs do cite to the code section governing express warranties (Cal. Comm. Code 24 § 2313), they set out their allegations regarding the breach of the implied warranty of 25 merchantability clearly and separately in its own section so as to give P&G notice of this cause of 26 action.

See ECF No. 47 ¶ 125. 27 Second, as this Court explained in its previous order, the implied warranty can be violated 1 not “[c]onform to the promises or affirmations of fact made on the container or label if any.” Cal. 2 Com. Code § 2314.

Although P&G argues that Plaintiffs have not alleged that ZzzQuil is not “fit 3 for the ordinary purposes for which such [consumer] goods are used,” Plaintiffs’ implied warranty 4 claim is not based on that prong of the statute. Rather, Plaintiffs argue that P&G’s products do not 5 “conform

to the promises or affirmations of fact made on the Products' packaging and labeling." 6 ECF No. 47 ¶ 125.

7 Finally, contrary to P&G's argument, Plaintiffs have identified an exception to the privity 8 requirement. Plaintiffs correctly identify in their opposition that "[w]hile vertical contractual 9 privity between parties is usually required to establish the existence of an express warranty in 10 California,... the California Supreme Court has recognized an exception to the privity 11 requirement where "the plaintiff relies on written labels or advertisements of a manufacturer." 12 ECF No. 58 at 27 (quoting *Clemens v. DaimlerChrysler Corp.*, 530 F.3d 852, 858 (9th Cir.

2008)). 13 Because Plaintiffs' implied warranty claim is based on the written labels and advertisements 14 surrounding the sale of P&G's products, the above exception to the privity requirement applies. 15 4. Unjust enrichment 16 P&G last argues that Plaintiffs' unjust enrichment claim is barred because Plaintiffs' 17 express warranty claim impliedly alleges that there is an express contract governing the sale of 18 ZzzQuil.

19 Under California law, "a quasi-contract action for unjust enrichment does not lie where [] 20 express binding agreements exist and define the parties' rights." E.g., *California Med. Ass'n, 21 Inc. v. Aetna U.S. Healthcare of California, Inc.*, 94 Cal. App. 4th 151, 172 (2001). This Court 22 has previously found that a plaintiff cannot plead both an unjust enrichment claim and an express 23 warranty claim if the latter is based upon a valid express contract covering the same subject matter 24 as the former.

See *Deras v. Volkswagen Grp. of Am., Inc.*, No. 17-CV-05452-JST, 2018 WL 25 2267448, at *3 (N.D. Cal. May 17, 2018) (finding that the new vehicle warranty was a valid 26 express contract that barred the plaintiff's unjust enrichment claim). 27 Here, however, Plaintiffs do not bring their express warranty claim based on any express 1 their lack of privity," ECF No. 58 at 27-28, and they bring their express warranty claim based on 2 || the "labeling and advertising" surrounding the sale of ZzzQuil, ECF No. 47 4 124.

The Court thus 3 || finds that there is no express agreement that bars Plaintiffs' unjust enrichment claim and declines 4 || to dismiss Plaintiffs' unjust enrichment claim. See *Shin v. Sanyo Foods Corp. of Am.*, No. 2:23- 5 || CV-10485-SVW-MRW, 2024 WL 4467603, at *4 (C.D. Cal. Aug. 13, 2024) ("[B]ecause Plaintiff 6 || did not purchase the goods in question directly from Sanyo Foods, there is no express agreement 7 || between Plaintiff and Defendants.

Therefore, Plaintiffs quasi-contract claim is not barred by her 8 express warranty claim."); but see *Strumlauf v. Starbucks Corp.*, 192 F. Supp. 3d 1025, 1033 9 (N.D. Cal. 2016) ("Even though there was no written contract at issue in this case, Plaintiffs still 10 allege an express contract by alleging Count 1.

Thus, no quasi-contract claim may stand.”). 11 CONCLUSION 12 For the foregoing reasons,
P&G’s motion to dismiss denied. 13 IT IS SO ORDERED. 14 [] Dated: April 4, 2025. 15 JON S.
TIGAR a 16 nited States District Judge 19 20 21 22 23 24 25 26 27 28