UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

KELLY CARTER, an individual, on behalf of herself and all other persons similarly situated, Plaintiff, v. **NOVARTIS CONSUMER HEALTH, INC.** Defendants.	Case No. EDCV08-0334 MRP (JCRx) √ Case No. EDCV08-1817 MRP (JCRx) Case No. EDCV08-2574 MRP (JCRx) Case No. EDCV08-3023 MRP (JCRx) **ORDER GRANTING DEFENDANTS' MOTION TO DISMISS**

Carter v. Novartis Consumer Health, Inc.[1], CV 08-0334 MRP (JCRx), is one of four substantially identical cases before this court, along with *Ostergard v. Wyeth*, CV 08-1817 MRP (JCRx); *Ostergard v. Adams Respiratory Therapeutics, Inc., et al.*, CV 08-2574 MRP (JCRx); and *Kotler v. Johnson & Johnson*, CV 08-3023 MRP (JCRx). Defendants[2] move to dismiss the each of these four cases pursuant to Fed. R. Civ. P. 12(b)(6) on the grounds of express and

[1] Pursuant to a stipulation dated April 3, 2008, the parties dismissed the original defendants in the Carter case, Novartis Pharmaceuticals Corp., Novartis Inc., and Novartis AG; and substituted Defendant Novartis Consumer Health, Inc.

[2] Due to the consolidated briefing in this case, the Court collectively refers to the defendants in all four actions as "Defendants." Similarly, the plaintiffs in these four actions are collectively labeled "Plaintiffs."

implied preemption. In addition, Defendants move to dismiss Plaintiffs' consumer fraud claims for failure to satisfy the requirements of Fed. R. Civ. P. 9(b).

I. BACKGROUND

A. Regulation of OTC Cough & Cold Medicine

Over-the-counter ("OTC") cough and cold medicines are governed by a set of Food & Drug Administration ("FDA") regulations, called a monograph. *See* 21 C.F.R. §330.1; Mem. P. & A. Supp. Defs.' Mot. to Dismiss Pl.'s Compl. ("Defs.' Mot.")[3] at 5-7.[4] The monograph for OTC cough and cold medicines (the "OTC monograph") was promulgated by the FDA based on a process that involved the recommendation of an advisory panel of independent experts, which evaluated the safety and effectiveness of OTC drugs with numerous opportunities for public notice and comment. *See* 21 C.F.R. §330.10 (describing process for establishing monographs); *see generally* 21 C.F.R. part 341 (final monograph regulations for OTC cough and cold medicine). Among other things, the OTC monograph specifies the permissible active ingredients, indications for use, dosing instructions (which vary with age), and other mandatory labeling. *See* 21 C.F.R. §341.12 (permissible active ingredients in antihistamines); 21 C.F.R. §341.72 (labeling of antihistamines); 21 C.F.R. §341.74 (labeling of antitussives); 21 C.F.R. §341.78 (labeling of expectorants); 21 C.F.R. §341.80 (labeling of nasal decongestants). The final OTC monograph regulations for various categories of cough and cold products were issued in stages during the late 1980s and early 1990s and are the culmination of a monograph process that began in mid-1976.[5]

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[3] Because an identical Motion to Dismiss was brought in each of the four cases, all citations refer to this consolidated briefing. *See* Section I.C, *infra* (procedural history).

[4] None of the four complaints describe the OTC monograph process. However, Plaintiffs do not dispute Defendants' characterization of the basic regulatory scheme for OTC cough and cold medicine.

[5] *See* 52 Fed. Reg. 30,042 (Aug. 12, 1987) (final OTC monograph for antitussives) (describing the history of the OTC monograph process and noting that the final monograph would be published in segments); 54 Fed. Reg. 8,494 (Feb. 28, 1989) (final OTC monograph for expectorants); 57 Fed. Reg. 58,356 (Dec. 9, 1992) (final OTC monograph for antihistamines); 67 Fed. Reg. 78,158 (Dec. 23, 2002) (final OTC monograph for combination products).

In October 2007, an FDA Advisory Panel examined evidence that OTC cough and cold medicines were unsafe and ineffective for children under six years of age, and expressly recommended that those medicines not be used in children under six. *Carter* Compl. ¶14.[6] At about the same time, Defendants withdrew all of their OTC cough and cold products marketed to children under the age of two. *Id*. ¶15. Subsequently, in January 2008, the FDA adopted the Panel's recommendations for children under the age of two, concluding that "these drugs [should] not be used to treat infants and children under 2 years of age because serious and potentially life-threatening side effects can occur." FDA, PUBLIC HEALTH ADVISORY, NONPRESCRIPTION COUGH AND COLD MEDICINE USE IN CHILDREN (January 17, 2008), *available at* http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm ("OTC Public Health Advisory").

B. The Complaints

Citing the FDA's findings, various statistics, articles from the New York Times, and two recent clinical studies, Plaintiffs allege that the Defendants knew or should have known that OTC cough and cold medicines "do not work" and are dangerous to children under the age of six. *See Carter* Compl. ¶7; *Wyeth* Compl ¶8; *Adams* Respiratory Compl. ¶9; *Kotler* Compl. ¶9. In each complaint, the named Plaintiff allegedly purchased cough and cold products manufactured by one or more of the Defendants for use by a child under the age of six, and thereby suffered damages. *Carter* Compl. ¶2 (Plaintiff's four-year-old son); *Wyeth* Compl. ¶3 (Plaintiff's four-year-old son); *Adams Respiratory* Compl. ¶7 (same Plaintiff as in *Wyeth*[7]); *Kotler* Compl. ¶4 (Plaintiff's four-year-old daughter). However, they do not allege that any of the Plaintiffs' children were harmed by these medicines. The complaints are also vague as to whether the Plaintiffs' children actually took the Defendants' OTC cough and cold medicines –

[6] *See also* Final Minutes, Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee, Oct. 18-19, 2007, *available at* http://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4323m1-Final.pdf.

[7] The *Adams Respiratory* Complaint also states that Plaintiff Ostergard has a one-year-old daughter as well as the four-year-old son mentioned in the *Wyeth* Complaint. However, Plaintiffs do not dispute that Defendants no longer market their OTC cough and cold medicines to children under the age of two.

they merely state that the Plaintiffs purchased one or more of these products "for use by" their children. Indeed, despite the products' allegedly dangerous nature, Plaintiffs insist that "members of the plaintiff Class are not seeking damages for personal injuries" and such personal injury claims "are not within the scope of this case." *See, e.g., Carter* Compl. at 1. Thus, they complain of solely an economic harm: the money they paid to purchase Defendants' OTC cough and cold medicines.

The complaints assert claims under the New Jersey Consumer Fraud Act, N.J. Rev. Stat. §56:8-1 et seq., and common-law claims for unjust enrichment, false and misleading advertising, fraudulent concealment, unfair and deceptive business practices, and breach of express and implied warranties. Plaintiffs seek damages as well as injunctive relief, pursuant to various state consumer fraud statutes, to "prevent[] Defendants from falsely advertising and marketing their over-the-counter cough and cold medications as safe and effective for children under the age of six." *See, e.g., Carter* Compl. at 18. Each case also seeks to certify a class on behalf of all others similarly situated. *Id.* ¶¶20-28. The four cases differ only in the Defendants named, the relevant over-the-counter cough and cold medicines sold by those Defendants, and in some cases, the named Plaintiff who purchased one or more of those medicines.

C. Procedural History

Plaintiff Carter filed suit on March 11, 2008 in this district. A week later, Plaintiff Ostergard filed two suits – *Wyeth*, in this district, and *Adams Respiratory*, in the Superior Court of the State of California, County of Los Angeles ("Superior Court"). On April 7, 2008, Plaintiff Kotler also filed in the Superior Court. Thereafter, the *Adams Respiratory* and *Kotler* cases were removed to federal court, and, along with *Wyeth*, transferred to Judge Virginia A. Phillips.[8]

[8] These two cases were removed pursuant to 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No. 109-2, (Feb. 18, 2005) 119 Stat. 4. CAFA covers purported class actions in which "any member of a class of plaintiffs is a citizen of a State different than any defendant," where "the number of members of all proposed plaintiff classes in the aggregate is [not] less than 100," and "the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs." *See* 28 U.S.C. §§1332(d)(2) and (d)(5)(B). CAFA's nominal diversity requirement is satisfied because there is complete diversity between the named Plaintiffs in *Kotler* and *Adams Respiratory* and the respective Defendants in each of those cases. Moreover, though neither complaint specifies an amount in controversy, each is brought on behalf of a class of all purchasers of the OTC cold and cough

On May 16, 2008, Judge Phillips granted an ex parte application filed simultaneously by defendants in three of the actions, ordering consolidated briefing for the Motions to Dismiss in *Carter*, *Wyeth*, *Adams Respiratory*, and *Kotler*.[9] Identical Motions to Dismiss (save for differing captions) were filed on June 9, 2008 in all four cases. On July 23, 2008, following the conclusion of briefing on this motion, the four cases were transferred to this Court.

II. LEGAL STANDARD

Dismissal pursuant to Fed. R. Civ. P. 12(b)(6) is based either on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696 (9th Cir. 1990). In evaluating the motion to dismiss, the Court accepts all factual allegations pleaded in the complaint as true and draws all reasonable inferences "in the light most favorable to the nonmoving party." *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996).

Where a claim includes allegations of fraud, Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9.

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medicines manufactured by the named Defendants in that particular case, and each seeks economic damages that correlate directly with those Defendants' gross sales of those medicines. The Defendants in *Kotler* and *Adams Respiratory* both state that their respective gross sales exceeded $5,000,000 in 2007 alone. *See Kotler*, Notice of Removal of Action Under 28 U.S.C. §§1332(d), 1441(b) (Diversity) (stating that sales of PediaCare and Tylenol products with dosages for children under six exceeded $5 million); *Adams Respiratory*, Notice of Removal (noting sales of roughly $104.5 million in 2007 for Mucinex and Delsym products with dosages for use in children between 2 and 5). Because these sales were necessarily generated by more than 100 consumers, both the number-of-plaintiffs and amount in controversy requirements of CAFA are satisfied. Plaintiffs do not appear to have contested removal in either case.

[9] At the time Judge Phillips issued the Order Granting In Part *Ex Parte* Application for Consolidated Briefing, the *Kotler* case had been removed to federal court, but had not yet been transferred to Judge Phillips' court.

III. ANALYSIS

The Court first analyzes Defendants' argument that Plaintiffs' claims are preempted in their entirety by federal law.[10] It then considers whether Plaintiffs' consumer fraud claims are sufficient to meet the heightened pleading standard of Fed. R. Civ. P. 9(b).

A. Preemption

Under the Supremacy Clause, "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citing U.S. CONST. art. VI, cl. 2). Federal preemption of state law, however, "will not lie unless it is the clear and manifest purpose of Congress." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (citation omitted). If a federal statute contains an express preemption clause, the plain wording of the clause necessarily contains the best evidence of Congress' preemptive intent. *Id*.

Implied preemption, in contrast, may take either of two forms. First, implied "conflict" preemption requires identification of an "actual conflict" between state and federal law, *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000), or a determination that state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984).[11] Alternatively, federal law may "so thoroughly occupy a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone*, 505 U.S. at 516 (internal quotations omitted).

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[10] Plaintiffs suggest that in order to "serve the interests of judicial economy," it would be appropriate to allow briefing and oral argument on class certification issues "before ruling on any merits issues, such as preemption." *See* Pl.'s Mem. of P. & A. Opp'n Defs.' Mot. to Dismiss ("Pls.' Opp'n") at 5 n.4 (citations omitted). The Court sees no procedural advantages in pursuing class certification prior to the Motion to Dismiss.

[11] Notably, the Supreme Court has held that the implied conflict preemption inquiry is independent of the express preemption inquiry. If an express preemption clause exists in a federal statute, but is inapplicable, implied conflict preemption may still apply. *See Geier*, 529 U.S. at 869 (holding that savings clause in an express preemption provision "does *not* bar the ordinary working of conflict preemption principles," and finding conflict preemption despite applicability of savings clause) (emphasis in original). The same does not appear to be true of field preemption, however. *See Cipollone*, 505 U.S. at 547 (Scalia, J., concurring in the judgment in part and dissenting in part) (noting that "[t]he existence of an express pre-emption provision tends to contradict any inference that Congress intended to occupy a field broader than the statute's express language defines").

Here, the Defendants assert that both express preemption and implied "conflict" preemption require dismissal of Plaintiffs' state law claims.

1. Express Preemption

Defendants contend that Plaintiffs' state-law claims impose state law "requirements" that are expressly preempted under §379r of the Food, Drug, and Cosmetic Act ("FDCA"). Section 379r(a) provides that states may not establish "any requirement . . . (1) that relates to the regulation of a [nonprescription drug][12]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA] . . . ." 21 U.S.C. §379r(a).[13] Moreover, pursuant to another subsection of 379r, "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug" shall be deemed a state "requirement" that satisfies §379r(a)(1). *Id.* §379r(c)(2). Finally, section 379r also contains a savings clause, which exempts from its preemptive scope "any action . . . under the product liability law of any State." *Id.* §379r(e).

Preemption of Plaintiffs' claims turns on three successive issues. First, the Court identifies the requirements imposed by the FDA with respect to Defendants' OTC cough and cold medicine. The Court then determines which of Plaintiffs' claims constitute state-imposed "requirement[s]" that are "different from or in addition to," or "otherwise not identical with" federal requirements. Notably, the language and structure of §379r demand a comparison between the scope of FDA requirements, on one hand, and state requirements, on the other. Lastly, the Court considers whether Plaintiffs' state law claims are brought under "the product liability law of any State."

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[12] The actual language of §379r(a)(1) is, "that relates to regulation of a drug that is not subject to the requirements of section 353(b)(1) . . . of this title." 21 U.S.C. §353(b)(1) governs procedures for the distribution of prescription drugs.

[13] The express preemption clause for the regulation of nonprescription drugs was added to the FDCA as part the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), which was enacted "to improve the regulation of food, drugs, devices, and biological products." Pub. L. No. 105-115 (Nov. 21, 1997), 111 Stat. 2296.

a. FDA Requirements

Most OTC cough and cold medicines are regulated by the FDA pursuant to the OTC monograph described above. *See generally* 21 C.F.R. part 341. The only exception present in this case is Adams Respiratory's Delsym, one of the OTC products allegedly purchased by Plaintiff Ostergard, which was approved pursuant to the New Drug Application ("NDA") process.[14] *See* Defs.' Mot. at 12-13. Most relevant here, the OTC monograph sets forth the approved indications for use and age-dependent dosage instructions that must be present on the product labeling. Similarly, the labeling for drugs with NDA-approval must include directions for use, including dosage instructions. *Id*. OTC cough and cold drugs that comply with all FDA regulations are "generally recognized as safe and effective." *See* 21 C.F.R. §341.1; *see also* 21 U.S.C. §355 (drugs requiring NDA approval). Defendants emphasize that the indications for use, such as use in suppressing a cough, are approved generally and without regard to age group; only the dosage instructions vary with age. These FDA requirements form the starting point for the express preemption inquiry, and ultimately define its scope.[15]

b. State Requirements

The Court looks to two sources in defining the scope of state "requirement[s]" in §379r(a): Supreme Court precedent, and the additional statutory language in §379r(c)(2).

The language of §379r(a) speaks of requirements established by a "State or political subdivision of a State," which might suggest that only legislative and regulatory enactments by state governments are preempted.[16] However, the Supreme Court has found, in the context of

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[14] Defendants also note that two Children's Advil products manufactured by Wyeth are approved under the NDA process, rather than the OTC monograph. *See* Defs.' Mot. at 13. However, these products are not mentioned in the *Wyeth* Complaint and Defendants describe the Advil NDA "for completeness purposes only." *Id.* at 13 n.11.

[15] Pursuant to *Medtronic v. Lohr* and *Riegel v. Medtronic*, express preemption in the device law context also requires that FDA requirements, in order to trigger preemption, must be "specific counterpart[s]" to the requirements imposed under state law. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470, 499 (1996); *Riegel*, 128 S.Ct. at 1006. In so holding, the Supreme Court relied on an agency regulation that applies only to devices. *Riegel*, 128 S.Ct. at 1006 (citing 21 C.F.R. §808.1(d)). Because there is no suggestion that this regulation also applies in the context of nonprescription drugs, the Court looks to *Riegel* for guidance only in construing the scope of state requirements, not federal requirements, under §379r(a).

[16] *See also* 21 U.S.C. §379r(b) (providing process by which "a State or political subdivision thereof" may seek to exempt a requirement from preemption under §379r(a) under certain conditions).

several different statutory preemption clauses, that third party claims under state law and common law may constitute state "requirement[s]" subject to express preemption. *See Cipollone*, 505 U.S. at 521 (preemptive clause in Public Health Cigarette Smoking Act of 1969) (holding that term "requirement or prohibition" included common law duties); *Medtronic v. Lohr*, 518 U.S. 470, 503-505, 512 (1996) (preemptive clause in FDCA relating to medical devices) (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J.) (Breyer, J., concurring in part and concurring in the judgment) (forming a majority of Justices that construed the term "requirement" to include actions for negligence and strict liability); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 441 (2005) (preemptive clause in Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")).

The Court's recent decision in *Riegel v. Medtronic* adopts a particularly broad view of "requirements". *See* 128 S.Ct. 999, 1001 (2008). *Riegel* held that a plaintiff's state law claims for strict product liability, implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing and sale of a Class III medical device were preempted by §360k(a) of the FDCA. *Id.* Like the provision at issue in this case, section 360k(a) prohibits a State from establishing "any requirement . . . that is different from, or in addition to" any requirement imposed by the FDCA. *See* 21 U.S.C. §360k(a).[17] Relying primarily on an institutional competence rationale, the majority in *Riegel* concluded that "excluding common-law duties from the scope of [preemption] would make little sense." 128 S.Ct. at 1008. Because the FDA alone can balance the potentially competing concerns of safety and effectiveness, common law and state law liability that is also premised on a product's safety and effectiveness can only upset that balance. *Id*. (observing that a state court jury "sees only the cost of a more dangerous design, and is not concerned with its benefits"). In reaching this conclusion, *Riegel* did not distinguish between various common law causes of actions or the remedies sought – all qualify as potentially preempted requirements under the statute.

[17] This is the same preemption provision that was at issue in *Medtronic v. Lohr*. 518 U.S. 470 (1996).

Here, the structural similarities between §360k(a) and §379r(a), and their close relation in the overall regulatory context, compel the Court to adopt *Riegel's* expansive reading of "requirement." This definition has significant implications for the preemption inquiry. As a consequence of defining "requirement" in this way, *Riegel* held that any state law liability imposed upon a Class III device manufacturer who is otherwise in full compliance with FDA regulations may establish a "requirement" that is "different from, or in addition to" federal law. *Id*. at 1011. After *Riegel*, a state may still provide a damages remedy for claims premised on a violation of the FDA regulations themselves – so-called "parallel" claims – which, though they are also requirements imposed by a state, do not differ from FDA requirements.

In this case, the definition of state "requirements" is further expanded by language in §379r itself. Section 379r(c)(2) states that any requirement that involves public "warning[s] of any kind for a drug" will be deemed to be a requirement that "relates to the regulation of a drug" under §379r(a)(1). *See* 21 U.S.C. §379r(c)(2). A reasonable reading of §379r(c)(2) is that it expands the universe of potentially preempted state law claims to include those that require additional warnings in the advertising for nonprescription drugs, and not only on the labeling. This does not mean that advertising requirements are automatically preempted, of course; state requirements relating to public warnings must still satisfy §379r(a)(2) (the "different from or in addition to" clause), not only §379r(a)(1), in order for preemption to lie.

Taken together, *Riegel* and §379r(c)(2) suggest that virtually any state requirement that relates to the regulation of nonprescription drugs can be preempted, regardless of the common law theory under which it is brought. However, this does not mean that preemption is without any limits. Again, under the language of §379r(a), state requirements are only preempted to the extent that they differ from federal requirements.

c. Comparing State Requirements and Federal Requirements

The Court finds it helpful, in the first instance, to examine the ways in which state law claims regarding drug labeling and advertising might avoid preemption under §379r. First, as suggested in *Riegel,* "parallel" claims that independently enforce FDA regulations would still be

allowed – at least where it has been alleged that a defendant violates existing FDA regulations. Second, state law claims are not preempted if they impose requirements that lie outside the scope of FDA regulations. Again, it is the scope of federal requirements that define the extent of preemption under §379r.

Here, Plaintiffs' claims are premised on the contention that Defendants' OTC products are ineffective and dangerous for children under six. However, Plaintiffs do not allege that Defendants fail to comply with FDA regulations as they currently exist, so none of their claims are parallel enforcement claims. The inquiry that remains is whether Plaintiffs' claims seek relief that lies outside the scope of relevant federal requirements.

Plaintiffs advance three arguments as to why the remedies sought fall outside the bounds of FDA regulation. First, they assert that their claims for false and misleading advertising, fraudulent concealment, unfair & deceptive business practices, and unjust enrichment are not preempted because they are based on a "general duty not to deceive," rather than tort law. Pls.' Opp'n at 3 (citing *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 529 (1992)). Second, Plaintiffs contend that their express and implied warranty claims "arise from the manufacturer and are not requirements imposed by the state." *Id*. at 8 (citing *Ministry of Health v. Shiley Inc.*, 858 F. Supp. 1426, 1440 (C.D. Cal. 1994)). Third, they argue that their claims for economic damages merely seek to enforce "parallel" claims of the kind permitted by *Riegel*. *See* Tr. at 16:15–23, 20:18 – 21:12; Pls.' Opp'n at 10 (citing *Riegel*, 128 S.Ct. at 1013 n.1) ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.") (Stevens, J., concurring in part and concurring in the judgment). The Court examines each in turn.

1. Duty Not to Deceive

Plaintiffs allege that, pursuant to *Cipollone*, state law claims will not be preempted if they are grounded in a general duty not to deceive, rather than in tort.[18] This argument places undue reliance on the express preemption holding in that case, which has limited applicability here. The controlling preemptive clause in *Cipollone* differs in scope and structure from §379r, so the express preemption analysis necessarily differs as well. Specifically, the scope of the express preemption clause in *Cipollone*, a provision of the Public Health Cigarette Smoking Act of 1969, was limited to any "requirement or prohibition" that was "based on smoking and health." 505 U.S. at 515. Evaluated against this standard, Justice Stevens found claims alleging fraudulent misrepresentations in defendants' advertising were not preempted; they were not predicated on a duty "based on smoking or health," but on a more general "duty not to deceive." *Id*. at 528-29 (plurality opinion). However, he also found that claims based on a different theory of fraudulent misrepresentation, that the defendants' advertising "neutralized the effect of federally mandated warning labels," were preempted because they would have required additional warnings on cigarette packaging, thus constituting a "prohibition" based on smoking and health. *Id.* at 527. Even if the latter claims were also grounded in a duty not to deceive, they were nevertheless preempted under the 1969 Act. *Id.* at 528-29. Thus, even within the statutory context in which it was decided, *Cipollone* does not suggest that all claims related to deception and fraudulent concealment evade federal preemption.[19]

Moreover, unlike the clause in *Cipollone*, which was limited to "smoking and health," the preemptive clause in this case covers any "requirement under [the FDCA]." 21 U.S.C. §379r. The touchstone of preemption under §379r is the effect that a finding of liability on a particular

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[18] The savings clause of §379r exempts from preemption any claims brought under "the product liability law of any State." 21 U.S.C. §379r(e). However, Plaintiffs are not arguing here that claims grounded in the "duty not to deceive" are "product liability" claims within the savings clause.

[19] The same is true of the Court's holding in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 441 (2005). The *Bates* majority concluded that claims for defective design, defective manufacture, negligent testing, and breach of express warranty were not preempted by FIFRA, but in the context of a clause that only preempted requirements "for labeling or packaging" in addition to or different from those required by FIFRA. *Id*. at 439, 444. In contrast, *Bates* also concluded that the claims for fraud and negligent failure-to-warn were preempted, because they imposed a standard for labeling and packaging that differed from FIFRA's standard. *Id*. at 446.

claim would have on the Defendants, and not the particular common law or state law theory upon which that claim was brought. As long as that claim imposes a "requirement" that is at variance with FDA regulations, it is preempted.[20]

2. Breach of Warranty Claims

Plaintiffs argue next that *Bates* and *Cipollone* both distinguish warranty claims from other preempted requirements because they are not imposed "by the state" – but rather arise from the manufacturer. *Cipollone*, 505 U.S. at 526 n.23 (Stevens, J., for plurality) (noting that warranty claims traditionally sound in contract, not tort); *see also Ministry of Health*, 858 F. Supp. 1426, 1440 (C.D. Cal. 1994) (relying primarily on *Cipollone*). Justice Stevens later reiterated this view in *Bates*, noting that "a cause of action on an express warranty asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product." 544 U.S. at 444 (finding that express warranty claim and other common law claims "plainly do not qualify as requirements for 'labeling or packaging'" under FIFRA's preemption clause).

Again, the analysis under §379r depends not on the theory upon which the claim is brought, but its ultimate outcome: would a finding of liability impose requirements that are different from or in addition to FDA requirements? Here, Plaintiffs base their warranty claims only upon allegedly misleading statements relating to the safety and effectiveness of Defendants' products in children under six years of age. *See, e.g.*, *Carter* Compl. ¶¶17-18 (alleging that the word "toddler" in certain Triaminic product names, pictures of toddlers on the product labeling,

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[20] At oral argument, Plaintiffs articulated a variant of this duty not to deceive: that drug manufacturers have an affirmative duty, imposed by FDA regulation, to supplement their labels when presented with evidence of possible new risks. Tr. at 14:19 – 15:-21. Citing a recent district court opinion, Plaintiffs suggested that pursuant to 21 C.F.R. §201.80, manufacturers must update their labels whenever there exists "reasonable evidence of an association of a serious hazard with a drug," even where "a causal relationship [has not] been proved." Tr. at 15:5-8 (referencing *Tucker v. Smithkline Beecham Corp.*, 2008 WL 2788505, No. 1:04-cv-1748-DFH-WTL (S.D. Ind. July 18, 2008)). However, §201.80 is a regulation that only applies to certain prescription drugs, not OTC cough and cold medicines. *See* 21 C.F.R. §201.80 (limiting applicability to "human prescription drug and biological products" and "older drugs not described in §201.56(b)(1)"); *id*. §201.56(b)(1) (describing certain categories of prescription drugs). For this reason, Defendants' failure to change their labeling is not itself, as Plaintiffs suggest, a violation of FDA regulations. Similarly, §201.80 is not evidence of a more generalized duty to supplement the labels of OTC drugs.

and the fact that there are dosage instructions for children aged two to five create express and implied warranties as to medicines' safety and effectiveness in young children); *Adams Respiratory* Compl. ¶¶20-21 (identifying statements on product website that Mucinex can "clear out excess mucus" and "[d]elivers chest congestion relief in a fun-to-take form," and that "[t]he active ingredients in all MUCINEX Products for Children are recognized as safe and effective"); *Wyeth* Compl. ¶¶18-20 (raising allegations similar to the *Carter* complaint, and citing statement on product labeling and packaging that "Dimetapp Toddler's Drops Decongestant contains a formula created especially for toddlers"); *Kotler* Compl. ¶20 (highlighting statement on product website that "PediaCare Children's Long-Acting Cough effectively relieves your child's cough symptoms for up to 8 hours without drowsiness"). In this respect, Plaintiffs' warranty claims merely restate what is alleged in their other causes of action: that these statements are false and misleading in light of the fact that OTC cough and cold medicines do not work and are dangerous to young children.

However, these statements do not reflect what the Defendants, alone, say about their products. Rather, they are based entirely upon FDA-approved labeling and advertising, and explain the conditions under which the FDA has determined that OTC cough and cold medicine will be safe and effective. For example, at oral argument, Defendant McNeil-PPC, Inc. noted that the claim that PediaCare lasts "for up to 8 hours" simply restates an approved dosage instruction in the OTC monograph relating to antitussives. *See* Tr. at 51:2-21; 21 C.F.R. §341.74(d)(1)(iii) (stating that label must include under a heading titled "Directions" the statement that for "Children 2 to under 6 years of age," "oral dosage is . . . 7.5 milligrams every 6 to 8 hours"). Similarly, Plaintiffs complain that the Dimetapp decongestant cited in the *Wyeth* complaint is not "created especially for toddlers," but is simply 1/4 the adult dosage. *See* Pls.' Opp'n at 18 n.10. Far from being misleading, this labeling statement, too, is specifically approved by the FDA.[21] Claims for breach of warranty based upon these kinds of statements

[21] For oral nasal decongestants containing phenylephrine hydrochloride such as Dimetapp Toddler's Drops Decongestant, the recommended dosage for children from 2 to under 6 years old is 2.5 milligrams every 4 hours. This is exactly 1/4 the dosage recommended for adults and children over 12, which is 10 milligrams every 4 hours. *See* 21 C.F.R. §341.80(d)(1)(i) (OTC monograph for decongestants, specifying directions for use to be placed in

would impose liability upon Defendants for complying with FDA regulations, and constitute perhaps the clearest example of state law requirements that differ from federal requirements.

Of course, the Court recognizes that Plaintiffs have argued that their warranty claims are immunized under a much broader theory: that warranties should be removed from the preemption analysis entirely because they do not constitute requirements established by a state. While such a literal interpretation of 379r(a)(2) is possible (i.e., that the manufacturer itself, and not the state, establishes the requirement in a warranty claim), the Court does not find such a reading at all persuasive. Certainly, this theory is the only coherent explanation for the claim for breach of express warranty not being preempted in *Cipollone*, as that claim would otherwise have fallen within the preemption clause at issue in that case.[22] *See* 505 U.S. at 523-524. However, Justice Stevens' plurality view has not been strengthened in subsequent cases. Notably, while he reiterated in *Bates* that an express warranty should be considered a voluntary contractual obligation, the express warranty claim survived preemption in that case under a straightforward analysis of FIFRA's preemption clause that did not rely on the special status of warranty claims.[23] Moreover, implied warranty claims, at least, were not distinguished from other preempted common-law claims in *Riegel*.[24] Without more, the Court cannot permit an

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required labeling); Dimetapp Toddler's Drops FAQ, http://www.dimetapp.com/faq/faq1.asp (describing active ingredient and dosing instructions).

[22] The preemption clause in the Public Health Cigarette Smoking Act of 1969 stated, without exception, that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *See* 505 U.S. at 515 (citing Pub. L. 91-222 (April 1, 1970), 84 Stat. 87). This clause preempts even "parallel" state requirements based on smoking and health, and would certainly have preempted the plaintiff's claim that Defendants "expressly warranted that smoking . . . did not present any significant health consequences," 505 U.S. at 509-10. The plurality distinguished the express warranty claim there on the sole ground that the warranty claim was not "imposed under State law," a conclusion vigorously contested in dissent by Justice Scalia. *See* 505 U.S. at 551 (Scalia, J., concurring in the judgment in part and dissenting in part) ("For the making of a voluntary promise or representation, no less than for the commission of an intentional tort, it is the background law against which the act occurs, and not the act itself, that supplies the element of legal obligation.") Though Defendant McNeil-PPC, Inc. suggested at oral argument that the warranty claim in *Cipollone* was permissible because it went "well beyond" the required labeling, *see* Tr. at 37:17-25, the express preemption holding, at least in that case, did not rest on that ground.

[23] *See* note 19, *supra*.

[24] *Riegel* found a claim for implied warranty to be preempted along with the petitioner's other common law claims; a claim for express warranty in *Riegel* had been disposed of by the district court and was not before the Supreme Court. *Id*. at 1006 n.2.

exception that would effectively remove express warranty claims from the statutory requirements of §379r.

The Court does not hold that a claim for breach of warranty can never survive §379r preemption, but only that claims based upon FDA-approved statements in product labeling and advertising are preempted. Plaintiffs, however, fail to allege warranty claims that go beyond FDA-approved labeling and advertising here.

3. Parallel Claims for Monetary Damages

Finally, Plaintiffs argue that their claims for economic damages constitute parallel claims that survive *Riegel*.[25] Arguably, monetary damages do not force Defendants to deviate from the requirements of the OTC monograph or any applicable NDAs. Indeed, Justice Stevens has suggested that a jury verdict for damages that later prompts a manufacturer to change its labeling should not be considered a "requirement." *See Bates*, 544 U.S. at 446; *see also Riegel*, 128 S.Ct. at 1013 n.1 (Stevens, J., concurring in part and concurring in the judgment) ("[W]hile a jury's finding of liability may induce a defendant to alter its device or its label, this does not render the finding a 'requirement' within the meaning of the MDA.") Although Justice Stevens spoke for the majority in *Bates*, however, it was Justice Scalia's view that prevailed in *Riegel*. *See* 128 S.Ct. 1008 (implicitly declining to distinguish between injunctive and monetary remedies in discussing liability imposed by "a single state jury"). *Riegel*'s institutional-competence rationale simply does not admit of distinctions among the various theories of liability or the remedies sought: if the defendant is in full compliance with FDA regulations, any non-parallel state law liability, including a jury verdict for damages, imposes a "requirement" that is expressly

[25] Here, Plaintiffs seek "actual, compensatory, punitive, exemplary damages, restitution and/or disgorgements." *See, e.g.*, *Carter* Compl. at 17-18. Plaintiffs also seek "an injunction preventing Defendants from falsely advertising and marketing their [OTC] cough and cold medicines as safe and effective for children under six." *Id*. However, at oral argument, Plaintiffs conceded that granting the injunctive relief requested in their Complaints would be "difficult". *See* Tr. at 43:4-5. Because OTC cough and cold medicines are also marketed to adults and children older than six years of age, an injunction forcing Defendants to take all of their products off the shelves, but only as to children younger than six, would be unworkable. In reality, such an injunction would require a change in product labeling that would intrude upon the FDA's regulatory authority – a decidedly non-"parallel" requirement under state law.

preempted. Here, Plaintiffs do not seek to independently enforce any violations of the FDA's regulations, and their claims are not parallel.

d. Savings Clause

Having established that Plaintiffs' claims are preempted under the language of §379(a), the Court now turns to the applicability of the savings clause. Section 379r(e) provides that "[n]othing in this section shall be construed to . . . affect any action . . . under the product liability law of any State," without further defining that phrase. Defendants argue that claims for "product liability" require an element of actual injury, either harm to the plaintiff's person or to his property. *See* RESTATEMENT(THIRD) OF TORTS: PRODUCT LIABILITY §§1, 21. Thus, because Plaintiffs seek only economic damages, and not damages for any personal injuries, Defendants argue that none of Plaintiffs' claims should be considered product liability actions. Plaintiffs counter by citing Black's Law Dictionary, which defines "product liability" as including claims for breach of warranty. *See* BLACK'S LAW DICTIONARY 1245 (8th ed. 2004).

The Court finds *Kanter v. Warner Lambert Co.*, 99 Cal. App. 4th 780 (2002), to be particularly instructive on this issue. In *Kanter*, a California Court of Appeal found that state law claims relating to an OTC drug were expressly preempted under §379r, and that the savings clause in §379r(e) did not apply. *Id*. In concluding that those claims were not "product liability" actions under §379r(e), *Kanter* established that "[u]nder the product liability law of California, injury to the plaintiff from a defective product is an essential element of a cause of action," and that "if the damage consists solely of economic losses, recovery on a products liability theory is unavailable." *Id*. at 790 (canvassing the California case law). This Court is obligated to follow *Kanter*, at least to the extent it speaks to the contours of California product liability law. *See In re Bartoni-Corsi Produce, Inc.*, 130 F.3d 857, 861 (9th Cir. 1997) (absent "convincing evidence that the state supreme court would decide differently, a federal court is obligated to follow the decisions of the state's intermediate appellate courts").

Plaintiffs argue that *Kanter* is distinguishable because "[u]nlike the *Kanter* plaintiffs . . . Plaintiffs here have alleged that Defendants' products are not only ineffective, *but*

are affirmatively unsafe as well." Pls.' Opp'n at 15 (emphasis in original). As Defendants note, this is a distinction without a difference. No matter how unsafe Defendants' products are alleged to be, Plaintiffs nevertheless insist that "damages for personal injuries . . . are not within the scope of this case." *See, e.g., Carter* Compl. at 1.[26] Thus, their claims, including the warranty claims, are not actions for "product liability" as defined under at least California law.

Of course, §379r(e) speaks of "the product liability law of any State," not just California, but the extent to which the four Complaints at issue are brought under the law of other states is unclear. For instance, the first count of each Complaint is brought under the New Jersey Consumer Fraud Act, N.J. Rev. Stat. §56:8-1, for unfair acts and practices in the promotion and sale of Defendants' OTC medicines. *See also Carter* Compl. at 18 (requesting injunctive relief pursuant to consumer protection statutes of California, Illinois, Massachusetts, Minnesota, Missouri, New Jersey, North Dakota, Ohio, and Washington). However, it is Plaintiffs' burden to demonstrate that their actions fall within the product liability law of each of these states. Because Defendants have met their initial burden of demonstrating that the express preemption clause applies, the onus shifts to Plaintiffs to prove that their state law claims satisfy the savings clause. *Cf. BNSF Ry. Co. v. Swanson*, — F.3d —, 2008 WL 2609159 (8th Cir. July 3, 2008) at *3 (applying burden shifting to savings clause of express preemption provision in Federal Railroad Safety Act of 1970).

In fact, Plaintiffs have not demonstrated that product liability law in any state omits a requirement for injury to one's person or property. As a particularly relevant example, the New Jersey Supreme Court has held that claims under its Consumer Fraud Act are not "product liability" claims; that any such claims must be brought under New Jersey's Product Liability Act; and that product liability claims under that Act must allege actual injury. *See Sinclair v. Merck & Co., Inc.*, 948 A.2d 587, 595 (N.J. 2008); *see also* N.J. Stat. § 2A:58C-1(b)(2)-(b)(3) (New

[26] Plaintiffs also argue that *Kanter* and certain other cases that follow it, such as *Berenguer v. Warner-Lambert Co.*, Appellate Case No. 02-05242, 2003 WL 24299241 (Fla. Cir. Ct. July 31, 2003), are distinguishable because those cases did not "concern the general duty not to deceive," as here, but rather "the sufficiency of the products' labels." Pls.' Opp'n at 9 n.5. This appears to be another distinction without a difference, especially given Plaintiffs' heavy reliance on a purported duty to supplement labeling at oral argument. As explained above, §379r does not distinguish claims that relate to the general duty not to deceive from claims that do not.

Jersey Products Liability Act) (defining "harm" in a product liability action as physical damage to property or person, without including economic injury).

2. Implied Conflict Preemption

Defendants further argue that implied conflict preemption applies. As the Court has found express preemption under §379r, it is not necessary to decide the issue.

In any event, Defendants have not met the standard for conflict preemption here. They object that Plaintiffs' claims "collide directly with FDA's regulation of . . . OTC drugs." Defs.' Reply Mem. Supp. Mot. to Dismiss Pls.' Compl. ("Defs.' Reply") at 17. Yet the existence of the broad savings clause in §379r(e), which preserves all actions "under the product liability law of any State," suggests that Congress intended to allow at least "product liability" actions to coexist with FDA oversight. *See, e.g., Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1055-56 (W.D.Wis. 2006) (noting, in context of denying field preemption argument, that "Section 379r(e) leaves room explicitly for state product liability laws to supplement the drug labeling process"). Defendants point out that Plaintiffs' claims are not, in fact, brought under the "product liability law of any State," but this alone does not demonstrate that Plaintiffs' claims stand as an obstacle to the accomplishment and execution of the full purposes of federal law.

Nor have Defendants demonstrated an actual conflict, such that "compliance with both state and federal law is impossible," *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984). For example, the Supreme Court in *Geier v. Am. Honda Motor Co., Inc.*, held that a lawsuit that sought to force a manufacturer to install airbags in all its automobiles conflicted with a Department of Transportation regulation that permitted a "range of choices among different passive restraint devices" and thus provided for a nuanced, gradual introduction of airbags over time. 529 U.S. 861, 874-75 (2000) (finding conflict preemption of claims that alleged negligence in failing to equip the plaintiff's car with driver's side airbag). Defendants also cite *Gaeta v. Perrigo Pharm. Co.*, 2008 WL 2548813 (N.D. Cal. June 13, 2008), which involved a different kind of actual conflict. In *Gaeta*, the plaintiff suffered liver injuries allegedly caused by the defendant's nonprescription drug. *Id*. at *1. However, the FDA had already engaged in a

comprehensive review regarding the safety of that OTC drug at issue and specifically determined that a warning for risk of liver injury was "not scientifically supported by the available data." *Id.* at *5. In that instance, the plaintiff's lawsuit, brought in part on a failure to warn theory, would have conflicted with an express judgment of the FDA.[27]

The FDA has not yet made a similar judgment here. After receiving the Advisory Panel's recommendation in October 2007 that OTC cough and cold medicines were unsafe for children under the age of 6, the FDA adopted that recommendation only with respect to children under 2. It has not yet taken action with respect to children in the age group complained of by Plaintiffs. *See* OTC PUBLIC HEALTH ADVISORY ("FDA has not completed its review of information about the safety of OTC cough and cold medicines in children 2 through 11 years of age.") The FDA's actions in this respect do not unambiguously suggest the existence of an actual conflict that would trigger preemption.

B. Rule 9(b)

Finally, Defendants argue that Plaintiffs' consumer fraud claims must be dismissed for failure to satisfy Rule 9(b). *See* Defs.' Mot. at 23 (citing *Naporano Iron & Metal Co. v. American Crane Corp.*, 79 F. Supp. 2d 494 (D. N.J. 1999) (claims under the New Jersey Consumer Fraud Act "sound in fraud" and are subject to the Rule 9(b) standard)). A party must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).[28]

Here, Plaintiffs merely allege that Defendants "knew, or should have known" that the medications were ineffective and dangerous. This is the basis for virtually all their non-warranty claims: that Defendants actively concealed this material fact from the public; that they were

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[27] *Gaeta* also gives great weight to the dangers of "overwarning," which "just like underwarning, can similarly have a negative effect on patient safety and public health." 2008 WL 2548813, at *5. It reasons that "State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act." This is too broad and amorphous ground on which to base a finding of conflict preemption, especially when an actual conflict has already been identified.

[28] In California, the five elements of common law fraud are (1) a misrepresentation, (2) knowledge of falsity ("scienter"), (3) intent to defraud (i.e., to induce reliance), (4) justifiable reliance, and (5) damage. *See, e.g., Unterberger v. Red Bull North America, Inc.*, 162 Cal. App. 4th 414, 423 (2008) (citing 5 WITKIN, SUMMARY OF CAL. LAW (10th ed. 2005) Torts, §772).

unjustly enriched thereby; and their advertising, by omitting this fact, was rendered false and misleading and constituted one or more "unfair acts or practices in the promotion and sale" of their products. Yet Plaintiffs provide no details of the alleged fraud. For example, they do not explain when, or how, any individual Defendant learned that its statements were false. What did the Defendants know, for example, before the FDA Advisory Panel issued its report in October 2007? Similarly, Plaintiffs do not provide any facts relating to their reliance on Defendants' alleged misrepresentations. The Complaints do not suggest, for instance, that Plaintiffs saw or read any of the misrepresentations that allegedly gave rise to express or implied warranties. They are also unclear as to when (if at all) contrary information about the safety and effectiveness of OTC cough and cold medicines became widely available – information that might have affected the justifiability of Plaintiffs' reliance on Defendants' advertising and other public statements. Plaintiffs' fraud-based claims cannot survive the 9(b) standard.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is GRANTED as to all claims pursuant to express preemption under 21 U.S.C. §379r; and GRANTED as to Plaintiffs' consumer fraud claims pursuant to Rule 9(b). In accordance with the consolidated briefing, the Court DISMISSES WITHOUT PREJUDICE *Carter v. Novartis Consumer Health, Inc.*, CV 08-0334 MRP (JCRx); *Ostergard v. Wyeth*, CV 08-1817 MRP (JCRx); *Ostergard v. Adams Respiratory Therapeutics, Inc.*, CV 08-2574 MRP (JCRx); and *Kotler v. Johnson & Johnson*, CV 08-3023 MRP(JCRx).

At oral argument, Plaintiffs requested leave to amend in order to bolster their fraud allegations and claims for breach of express and implied warranty. Tr. at 44:12-22. Defendants, however, argued that granting leave to amend would be futile to the extent that Plaintiffs' breach-of-warranty theory would continue to rely upon FDA-approved labeling and advertising statements. The Court is inclined to agree with Defendants. However, the Court grants leave to

amend with respect to these claims. Accordingly, Plaintiffs shall file an amended complaint, if any, by Monday, August 25th, 2008.

IT IS SO ORDERED.

DATED: August 05, 2008

Hon. Mariana R. Pfaelzer
United States District Judge