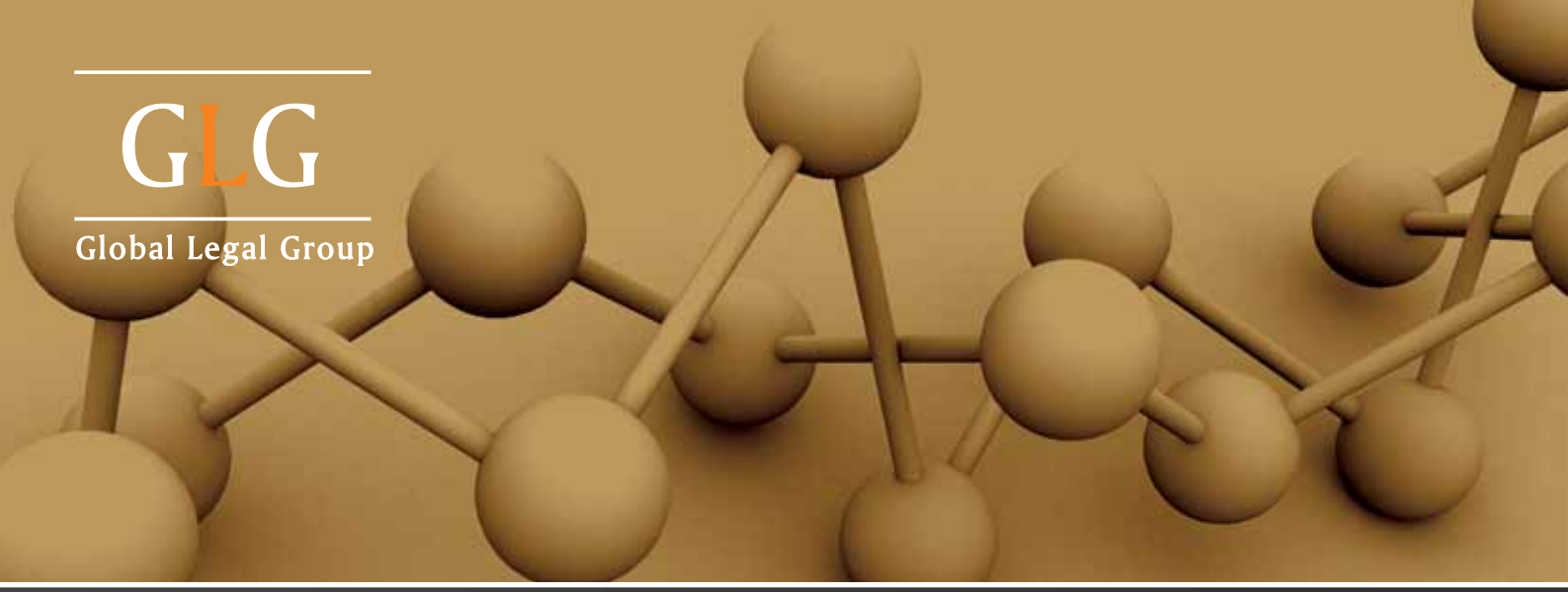

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The International Comparative Legal Guide to:
Class & Group Actions 2011

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A New Frontier: Health-Claims Class Actions

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I. Introduction

Recently, a new type of class action has emerged, the health-claims class action. These cases sound primarily in warranty and consumer fraud law, and they focus on marketing statements made by food and beverage manufacturers about potential health benefits that may be obtained from consuming their products. This chapter begins with an historical overview of the class action law underpinning health-claims class actions; examines some health-claims class actions pending in the United States; and explores potential legal defences to health-claims class actions.

II. Historical Background

In 1995 and 1996, five different federal appellate courts reached the same conclusion: mass tort products liability cases involving personal injury claims are simply not amenable to class treatment. [See Endnote 1.] These courts ruled that individualised alternative causes and medical histories must be examined to resolve whether a product may have injured a particular person, which precluded class-wide treatment of personal injury claims. In other words, it could not be said that "as goes the claim of the named plaintiff, so go the claims of the class". [See Endnote 2.]

These landmark decisions and the district court opinions that followed in their wake resonated with the plaintiffs' class action bar. Product-related class action complaints began to shift their focus away from personal injury claims to "pure economic" or "money back" themes. For instance, instead of alleging that a defective drug physically injured a class of individuals, the class complaint would disavow personal injury claims and seek reimbursement for purchases of the allegedly defective drug. [See Endnote 3.] And because a warranty claim alone could not provide a basis for punitive damages, creative plaintiffs' attorneys increasingly turned to state consumer fraud statutes as a means by which to maximise recovery. Indeed, a recent Northwestern Law School report provides an empirical analysis of private litigation under state consumer protection laws, finding a 119 per cent increase between 2000 and 2007 in the number of decisions involving consumer protection acts. [See Endnote 4.]

Against this backdrop, the health-claims class action has emerged. It is a new subcategory of consumer fraud class actions that arguably can be viewed as a hybrid of the personal-injury and money-back varieties of class actions. On the one hand, these cases rely on consumer fraud statutes and speak using breach-of-contract lingo. On the other, they call into question whether the plaintiff, in fact, received the advertised health benefit, which once again may require consideration of individualised medical evidence.

III. The Current Trend: Consumer Fraud Class Actions Focusing on Health Claims

Class action complaints focusing on health-related statements and omissions are on the rise. The products targeted in these lawsuits are often ones for which a governmental agency has simply raised a question.

Consider, for instance, a multidistrict litigation (MDL) pending in New Jersey involving Cheerios® cereal. [See Endnote 5.] In May 2009, a district office of the U.S. Food and Drug Administration (FDA) sent General Mills an advisory letter of possible technical noncompliance with federal drug labelling regulations in the advertising of Cheerios®. Specifically, FDA identified language on the cereal box and on General Mills' website stating that Cheerios® may help reduce the risks of heart disease and some cancers. The FDA letter claimed that General Mills' use of such language required the company to file a new drug application with the FDA, as Cheerios® cereal is not "generally recognised as safe and effective in preventing or treating hypercholesterolemia or coronary heart disease".

The FDA was *not* refuting the possibility that eating Cheerios® – the same cereal General Mills had sold for nearly 70 years – could actually reduce the risk of coronary disease and cancer. Rather, the FDA's position was that clinical trials specifically linking Cheerios® to lowered health risks should be required, as opposed to General Mills' reliance on broader studies that were not Cheerios®-specific but instead examined more generally the impact of eating whole grains on risk reduction. Once news of this FDA advisory letter broke, entrepreneurial class action lawyers all around the county began asserting consumer fraud and warranty claims using the precise language flagged by FDA. So many cases were filed that they were ultimately before a multidistrict litigation court.

Another recently filed class action targets POM Wonderful LLC. This civil class action was filed immediately following a letter from the FDA to POM Wonderful LLC alleging that it improperly marketed its pomegranate juices with health-related representations that, according to the FDA, required FDA approval. The *Giles v. POM Wonderful LLC* complaint expressly relies on these FDA allegations and targets advertising slogans that allegedly misled putative class members about POM Wonderful's ability to combat prostate cancer, cardiovascular disease, and other diseases and conditions, because the claims were not backed by clinical studies. [See Endnote 6.] Shortly after *Giles* was filed, POM Wonderful LLC filed its own case against the Federal Trade Commission (FTC) asserting a free-speech challenge in connection with a new policy requiring "competent and reliable scientific evidence" for

statements in advertising. [See Endnote 7.] Specifically, POM Wonderful LLC asserts that its speech, unless proven false, is protected by the First Amendment, and FTC has exceeded its jurisdiction under the FTC Act. FTC then sued POM Wonderful, including allegations mirroring those in *Giles*. [See Endnote 8.] The *Giles* plaintiffs, no doubt, hope to be the beneficiaries on the sidelines of this governmental dispute.

But not every health-claims lawsuit is the result of a governmental inquiry. Consider cases like *Williams v. Gerber Products Co*., [see Endnote 9] where plaintiffs claim they were duped by pictures of multiple fruits on boxes of Gerber's Fruit Juice Snacks®. Because the product contained grape juice only, the plaintiffs claim the other pictured fruits are misleading to consumers, despite full disclosure on the package's ingredient list. Though the trial court dismissed the complaint, the Ninth Circuit has reinstated the action, finding that the ingredient list was not dispositive and did not preclude a finding of deception. Two additional cases that echo *Williams*' theme are a proposed consumer fraud class action against Kellogg Co. for marketing Cocoa Krispies® and Rice Krispies® cereals as having immunity-boosting qualities, [see Endnote 10] and a proposed consumer fraud class action against Hostess Brands, Inc. for marketing certain products as containing "0 Grams of Trans Fat" despite containing artificial *trans* fat from partially hydrogenated vegetable oil. [See Endnote 11.]

IV. Defending Health-Claims Class Litigation

The fate of health-claims class actions should ultimately circle back to the fate of the relatively abandoned personal injury class actions. After all of the publicity and all of the court filings, what remains is still whether a given health claim was true as to a given individual. If, for instance, Dick ate Cheerios® and Jane ate Rice Krispies®, and their respective medical records show that Dick's cholesterol dropped after introducing Cheerios® into his diet and Jane has not been sick nearly as frequently as in her pre-Rice Krispies® days, then they have no fraud claim to assert. [See Endnote 12.] Thus, highly individualised inquiries should still preclude class certification.

Still, most product manufacturers faced with a health-claims class action will want to explore earlier possible defences to end the case before the question of class certification is reached. Numerous defences are currently being asserted in motions to dismiss health-claims class actions, albeit with varying levels of success.

a. Preemption

Articles abound on preemption law, and this chapter does not seek to compete. A basic overview of preemption, however, helps frame the discussion.

A federal law may preclude, or "preempt," a state law claim. Two major principles guide courts in determining if preemption applies, namely, (1) the purpose of Congress and (2) an assumption that a federal statute does not displace traditional state regulation unless Congress clearly and manifestly says so. [See Endnote 13.] Courts are to "start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress", [see Endnote 14] particularly so if Congress has legislated "in a field which the States have traditionally occupied". [See Endnote 15.] Given the focus of this chapter, it should be specifically noted that "[c]onsumer protection is quintessentially a 'field which the States have traditionally occupied'". [See Endnote 16.]

There are three forms of preemption: express preemption; field preemption; and implied preemption. [See Endnote 17.] Express preemption exists when Congress uses explicit preemptive language to express its purpose. [See Endnote 18.] Even if a federal statute contains an express preemption provision, it is not certain that the state law claim cannot proceed. Instead, the specific language of the preemption provision must be considered. [See Endnote 19.] Field preemption exists "where the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it'". [See Endnote 20.] "For field preemption to be applicable, congressional intent to supersede state laws must be 'clear and manifest'." [See Endnote 21.] Finally, conflict preemption exists "where a party's compliance with both federal and state law would be impossible or where state law would pose an obstacle to the accomplishment of congressional objectives". [See Endnote 22.]

In the context of health-claims class actions, an express, implied, or field preemption defence may exist, depending on the allegations in the particular case. To determine whether a preemption defence exists, the defendant must consider the specific food-related regulations to which the health claims are subject. [See Endnote 23.]

One possible basis for a preemption defence in a health-claims class action is the Federal Food, Drug, and Cosmetic Act (FDCA), [see Endnote 24] which authorises FDA to regulate food, drugs, cosmetic products, and medical devices. [See Endnote 25.] The FDCA does not contain an express preemption provision, so any preemption argument based on it must be of the implied or field variety.

The Nutrition Labeling and Education Act of 1990 (NLEA), which sets labelling standards for most food sold in the United States and establishes a regulatory scheme for nutrient content claims on food labels, [see Endnote 26] provides another basis for a possible preemption defence. The NLEA contains an express preemption provision that prohibits state requirements "not identical" to NLEA requirements. [See Endnote 27.]

Depending on context, other federal food-related regulations may provide a potential preemption defence. For example, the Organic Foods Production Act of 1990 (OFPA), which sets the standards for the sale and labelling of organically produced agricultural products, was the focus of a preemption argument recently considered by the Eighth Circuit Court of Appeals in a proposed class action alleging that some "organic" milk had been deceptively labelled. [See Endnote 28.] Nineteen class action complaints were filed (and eventually consolidated in an MDL) after the U.S. Department of Agriculture proposed revoking a milk producer's organic certification status for allegedly violating the OFPA by using nonorganic cows. [See Endnote 29.] The defendants successfully moved to dismiss on grounds of preemption, and an appeal to the Eighth Circuit ensued. [See Endnote 30.] Analysing OFPA's preemptive effect, the Eighth Circuit found preempted (via conflict preemption) all claims against the certifying agent and all claims that alleged the supplier and retailers sold non-organic milk. [See Endnote 31.] The court allowed, however, claims "unrelated to the decision to certify, and certification compliance", even if they might be based on the same facts underlying the certification decision, and it specifically allowed the consumer fraud claims alleging misrepresentations about how the cows had been raised to proceed. [See Endnote 32.]

Another preemption case of note is *Holk v. Snapple Beverage Corp*., [see Endnote 33] in which the Third Circuit reversed a finding that the FDCA impliedly preempted claims of falsity relating to Snapple's "All Natural" tea-based drinks. While the district court had been persuaded that the FDA's formal definition of the term "natural flavour" and its informal policy regarding the term "natural" illustrated an extensive FDCA regulatory scheme relating to use of these terms in labelling, the Third Circuit focused

on the fact that the FDA had not sufficiently commented upon and analysed the policy. [See Endnote 34.] The Third Circuit also considered but rejected a field preemption argument under the FDCA. [See Endnote 35.] *In dicta*, the court also addressed a potential NLEA express preemption defence, which it concluded applied only if the plaintiff sought to require additional specific language on the label, as opposed to faulting the manufacturer for failing to disclose additional, unspecified information on the label. [See Endnote 36.]

In short, a defendant facing a health-claims class action complaint should examine the federal regulations under which it operates to determine if it may have an express, implied, or field preemption argument.

b. Primary Jurisdiction

The Cheerios® litigation discussed earlier is currently stayed as a result of a motion to dismiss that argued, *inter alia*, that the FDA had jurisdiction over the dispute, not the district court. Specifically, General Mills successfully argued that: "(1) the core question of regulatory compliance involves technical and policy questions within the FDA's expertise; (2) adjudicating these issues through private litigation risks inconsistent regulatory determinations; and (3) there is an ongoing dialogue with the FDA". [See Endnote 37.] In the end, the same FDA action that spurred the class litigation provided the basis for holding it at bay.

c. *Iqbal/Twombly* Defence

While not limited to health-claims class actions, *Bell Atlantic Corp. v. Twombly* [see Endnote 38] and *Ashcroft v. Iqbal* [see Endnote 39] should not be forgotten. These two pleading-related decisions from the U.S. Supreme Court require a plaintiff to plead a claim that is at least plausible on its face. [See Endnote 40.] This should include a requirement that the plaintiff connect the alleged fraud to the decision to purchase the product. Thus, for example, a court dismissed a putative class action against The Coca Cola Company relating to its Enviga® beverage, which allegedly had been advertised as providing unsubstantiated weight-loss benefits, [see Endnote 41] because the plaintiff had not specified which particular health claims lacked substantiation and which ones she personally relied on when purchasing Enviga®.

d. Lack of Standing

"A plaintiff, in order to have standing in a federal court, must show more than a violation of law …." [see Endnote 42]. As such, a lack of standing defence should be evaluated. For example, one court recently dismissed a health-claims class action alleging that an ice cream manufacturer misled consumers about the nutritional quality of its ice cream based on the plaintiff's lack of standing. [See Endnote 43.] By not alleging that he had failed to receive what he paid for – an ice cream product – the court determined that the plaintiff lacked standing to assert a misrepresentation claim. [See Endnote 44.] Such an approach could be coupled with the *Iqbal/Twombly* defence to argue that unless a plaintiff alleges he relied on a health-claim in making his purchase *and* alleges that the health-claim was untrue as to him, then his case should not proceed. For instance, Dick's suit against General Mills should not proceed unless Dick alleges he bought Cheerios® because of the cholesterol-lowering statement on the box and further alleges that, since adding Cheerios® to his diet and making no other dietary changes, his cholesterol has increased.

V. Conclusion

The ultimate success of health-claims class litigation remains to be seen. What is clear, though, is that products marketed as providing potential health benefits are increasingly under attack by government agencies and targeted by the plaintiffs' class action bar.

Endnotes

1 *Castano v. American Tobacco Co*., 84 F.3d 734, 746 (5th Cir. 1996) (cigarettes); *Georgine v. Amchem Prods., Inc*., 83 F.3d 610, 628 (3d Cir. 1996), *aff'd sub nom, Amchem Prods., Inc. v. Windsor*, 521 U.S. 591 (1997) (asbestos); *In re American Med. Sys., Inc.,* 75 F.3d 1069 (6th Cir. 1996) (penile implant); *Valentino v. Carter-Wallace, Inc.,* 97 F.3d 1227 (9th Cir. 1996); *In re Rhone-Poulenc Rorer, Inc.,* 51 F.3d 1293 (7th Cir.), *cert. denied*, 516 U.S. 867 (1995) (blood products).

2 *Sprague v. General Motors Corp*., 133 F.3d 388, 399 (6th Cir. 1998).

3 *E.g., In re Digitek Prods. Liab. Litig.,* MDL No. 2:08-md-01968, 2010 WL 2102330, *5 (S.D. W. Va. May 25, 2010).

4 Searle Civil Justice Institute, *State Consumer Protection Acts, An Empirical Investigation of Private Litigation, Preliminary Report* xii (Northwestern Univ. School of Law Dec. 2009). The report discusses the class action provisions of state consumer fraud acts, although it does not limit its analysis of consumer fraud decisions to class decisions.

5 *In re Cheerios Mktg. & Sales Pracs. Litig*., No 2:09-cv-02413-PGS-ES.

6 *Giles v. POM Wonderful LLC*, No. 10-32192 (Fla. 17th Jud. Cir.) (filed Aug. 6, 2010). The targeted advertising slogans include: "Pure Science"; "Cheat death"; "Forever young"; "Health's Angel"; "Heart Therapy"; and "Saving Lives . . . one mortal at a time". *Id.*

7 *POM Wonderful LLC v. FTC*, Case No. 10-cv-01539 (D.D.C.) (filed 9/13/10).

8 *In the Matter of Pom Wonderful LLC et al*., Case No. 082-3122 (Federal Trade Commission).

9 552 F.3d 934 (9th Cir. 2008).

10 *Kammula v. Kellogg Co*., No. 2:09-cv-08102-MMM (C.D. Cal.) (second amended complaint filed 5/6/10).

11 *Guttman v. Hostess Brands, Inc*., No. 2:10-cv-02303-CBM (C.D. Cal.) (first amended complaint filed 5/26/10).

12 Similarly, not every person who bought Cheerios® or Rice Krispies® did so because of what was written on the box. Dick may like Cheerios® based on preferences he developed as a child, long before the health claim at issue appeared on the box and perhaps even before he could read.

13 *Wyeth v. Levine*, 129 S. Ct. 1187, 1194-95 (2009). *See also Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 516 (1992) (finding there is a presumption against preemption).

14 *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996). See also *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 449 (2005) (stating the presumption against preemption means courts "have a duty to accept the reading that disfavors preemption").

15 *Id.*

16 *Watters v. Wachovia Bank, N.A*., 550 U.S. 1, 35-36 (2007) (Stevens, J., dissenting).

17 *Hillsborough County, Florida v. Automated Med. Labs Inc.,* 471 U.S. 707, 713 (1985).

18 *Gade v. National Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98 (1992) (plurality opinion).

19 For example, in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), the Court applied a two-part test to determine whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prohibited state labelling or packaging requirements in addition to or different from those required by FIFRA. *Id.* at 443. First, the court considered whether the requirement was for "labelling and packaging", and, if so, whether it imposed a requirement "in addition to or different from those required" under FIFRA. *Id.* at 443-44. Applying this test, the Court concluded that FIFRA did not preempt design defect, manufacturing defect, negligent testing or

express warranty claims because the plaintiffs had not sought to mandate that the manufacturer label or package its product in any particular way.

20 *Gade*, 505 U.S. at 98.

21 *Holk*, 575 F.3d at 336 (quoting *English v. General Elec. Co*., 496 U.S. 72, 79 (1990)).

22 *Pet Quarters, Inc. v. Depository Trust & Clearing Corp*., 559 F.3d 772, 780 (8th Cir. 2009).

23 "In appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rule-making may also have a preemptive effect over state law." *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 243 (3d Cir. 2008).

24 Pub. L. No. 75-717, 52 Stat. 1040 (1938).

25 21 U.S.C. § 301 *et seq.*

26 Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 343, *et seq.*).

27 21 U.S.C. §§ 343-1(a)(4)-(5). The NLEA's express preemption clause provides: "[N]o State or political subdivision of any State may directly or indirectly establish under any authority . . . any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title . . . [or] any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." *Id*.

28 *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Pracs. Litig.,* No. 09-2762, 2010 WL 3564849, slip op. (8th Cir. Sept. 15, 2010).

29 *Id*. at *1.

30 *Id*. at *5.

31 *Id*. at *9-10.

32 *Id*. at *11-13.

33 575 F.3d 329 (3d Cir. 2009).

34 *Id*. at 342.

35 *Id*. at 337-39.

36 *Id*. at 329, 336 n.3 ("[Section] 343(k) is a disclosure requirement – i.e., it regulates only what companies must place on a label. Holk's claims go to what a company cannot put on a label for purposes of commercial marketing, an important distinction.").

37 *In re Cheerios Mktg. & Sales Pracs. Litig.,* No. 2:09-cv-02413-PGS-ES, Doc. #29, Mot. To Dismiss, at 2 (Apr. 28, 2010), and Doc. #4, Order, at 1 (Sept. 1, 2010).

38 550 U.S. 544 (2007).

39 129 S. Ct. 1937 (2009).

40 *See Iqbal*, 129 S. Ct. at 1940; *Twombly*, 550 U.S. at 570.

41 *Franulovic v. The Coca Cola Co*., No. 07-539, 2007 WL 3166953 (D.N.J. Oct. 25, 2007).

42 *Cronson v. Clark*, 810 F.2d 662, 664 (7th Cir. 1987) (citing *Allen v. Wright*, 468 U.S. 737, 754 (1984)); *accord Waste Mgmt. of N. Am., Inc. v. Weinberger*, 862 F.2d 1393, 1398 (9th Cir. 1988) ("Absent injury, a violation of a statute gives rise merely to a generalized grievance but not to standing.").

43 *Carrea v. Dreyer's Grand Ice Cream, Inc.,* No. 3:10-cv-01044-JSW, Doc. #32, Order, at 3 (Aug. 24, 2010).

44 *Id.*

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