Product liability and dietary supplements

THE MARKET FOR DIETARY SUPPLEMENTS in 2012 was estimated to be worth approximately £385m in the UK alone and is worth billions of dollars globally.[1] Sarah Croft, of Shook Hardy & Bacon International, assesses the regulatory environment for these products in Europe and the UK and considers the product liability issues for this sector.

Surveys have shown that over a third of adults in the UK take some kind of dietary supplement, with multivitamin tablets and fish oil capsules being the most popular. Vitamins and minerals are, of course, essential for good health and wellbeing, and many people feel it is convenient and beneficial to their health to take a supplement to obtain essential nutrients they may not be getting from their diet alone. Recently, there have been some scientific studies that have questioned just how beneficial certain dietary supplements might be to health. Some studies have found that certain supplements may actually be harmful in some cases, particularly when taken in very high doses. In 2012, for example, it was concluded in a study that the use of calcium supplements could increase the risk of a heart attack.[2] As is often the case, litigation may occur where there is a gap in regulation, so, in assessing future litigation risks in this sector, it is instructive to review the regulatory framework too.

REGULATION IN THE EU AND THE UK

Dietary supplements are classified as a food and are therefore subject to the regulations relevant to food safety. Products intended to treat illness or existing conditions are classed as medicines and are subject to separate regulation beyond the scope of this article. In the UK, the relevant legislation is the Food Safety Act 1990, which requires food products to comply with safety requirements, to be 'of the nature, substance and quality demanded', and correctly described and labelled.[3]

Where a supplement is sold in the form of a measured dose, for example a multivitamin tablet, the product is also subject to the provisions of the Food Supplements Regulations 2003,[4] which implemented Directive 2002/46/EC of the European Parliament and Council of 10 June 2002 on the approximation of the laws of member states relating to food supplements. This Directive came into force on 1 August 2005. The 2003 Regulations contain requirements regarding the ingredients and labelling of food supplements, including the vitamin and mineral substances permitted for use in food supplements. As regards to labelling, the Regulations require a food supplement to be labelled with the following:

1) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;

2) the portion of the product recommended for daily consumption;

3) a warning not to exceed the stated recommended daily dose;

4) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

5) a statement to the effect that the product should be stored out of the reach of young children; and

6) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

Food supplements are also subject to the general labelling requirements for food products under the Food Labelling Regulations 1996[5] and Regulation (EC) No 1924/2006 of the European Parliament

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Sarah Croft, partner, Shook, Hardy & Bacon International
E-mail: scroft@shb.com

and of the Council on nutrition and health claims made on foods, incorporated into UK law by the Nutrition & Health Claims Regulations 2007.[6] Part II of the Food Labelling Regulations 1996 gives detailed general labelling requirements for food products, which include a list of ingredients, information on durability, storage instructions and the manufacturer's details. Part III contains regulations regarding the making of nutritional claims and misleading descriptions, including prohibiting a claim in labelling or advertising that a food product has medicinal properties. The Nutrition & Health Claims Regulations 2007 require that any claims made regarding the nutritional value or benefit to health of a food product in its labelling or advertising must be clear, accurate and substantiated.

MARKETING AND ADVERTISING

With regards to marketing and advertising, manufacturers must comply with the codes of the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP), which are applied and ruled on by the Advertising Standards Association.[7] Chapter 15 of the CAP code contains specific provisions relating to the advertising of food supplements, requiring that nutrition or health claims must be supported by documentary evidence. Marketers must not state or imply that a balanced or varied diet cannot provide appropriate quantities of nutrients in general, and advertising must not claim that a product treats clinical vitamin or mineral deficiency.[8]

The Advertising Standards Association has frequently upheld complaints against manufacturers, finding that they have breached the provisions in Chapter 15 of the CAP code relating to the advertising of food supplements. In 2013, there have been three adjudications. In March, the ASA upheld a complaint against a manufacturer of multivitamins, holding that their advertisements implied that dietary supplements were necessary for obtaining nutrients which could not be obtained through eating a balanced diet.[9] Earlier this year it upheld complaints against two dietary supplement manufacturers, holding that one had made unsubstantiated health claims in advertising for their products[10] and the other had made medicinal claims for a food supplement.[11] Although the Advertising Standards Association's powers are limited to requesting that an offending advertisement be withdrawn, the resultant publicity from an unfavourable decision can be damaging for a manufacturer.

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LITIGATION

While product liability litigation related to dietary supplements has not yet arisen this side of the Atlantic, there have been cases in the US. The litigation there has fallen into two broad categories. First, there have been traditional personal injury cases, where plaintiffs have alleged that taking a supplement has directly harmed their health. For example, the family of a soldier who died after taking a dietary supplement called Jack3D that contained dimethylamylamine (DMAA) recently filed a suit in San Diego.[12] The family allege that the product was not safe and that the manufacturer had failed to warn consumers of the potential health risks. DMAA is thought to narrow the blood vessel and arteries in some circumstances, raising blood pressure which can lead to a heart attack. DMAA was banned in the UK in 2012, although products containing it are available to UK consumers from overseas websites. It was implicated in the death of a British runner during the London Marathon in 2012 who had consumed Jack3D. At the January 2013 inquest into the runner's death, the coroner held that the use of

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1) See http://www.telegraph.co.uk/health/healthnews/9656077/Millions-fewer-taking-vitamin-supplements.html.
2) MJ Bolland, A Grey, A Avenell, GD Gamble, IR Reid. 'Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women's Health Initiative limited access dataset and meta-analysis', BMJ 2011; 342 (apr19 1): d2040 DOI: 10.1136/bmj.d2040.
3) See http://www.legislation.gov.uk/ukpga/1990/16/contents.
4) http://www.legislation.gov.uk/uksi/2003/1387/contents/made.
5) See http://www.legislation.gov.uk/uksi/1996/1499/contents/made.
6) See http://www.legislation.gov.uk/uksi/2007/2080/contents/made.
7) See http://www.cap.org.uk/Advertising-Codes/Broadcast/BCAP-Code.aspx.
8) See http://www.cap.org.uk/Advertising-Codes/Non-broadcast-HTML/Section-15-Food,-food-supplements-and-associated-health-or-nutritional-claims.aspx.
9) See http://www.asa.org.uk/Rulings/Adjudications/2013/3/Pfizer-Consumer-Healthcare-Ltd/SHP_ADJ_212962.aspx.
10) See http://www.asa.org.uk/Rulings/Adjudications/2013/1/Good-Health-Naturally/SHP_ADJ_210719.aspx.
11) See http://www.asa.org.uk/Rulings/Adjudications/2013/2/Dulwich-Health-Ltd/SHP_ADJ_210679.aspx.
12) See http://www.nytimes.com/2013/02/14/business/death-after-use-of-jack3d-shows-gap-in-regulation.html?pagewanted=all&_r=1&.
13) See http://www.bbc.co.uk/news/uk-england-london-21262717.
14) http://www.reuters.com/article/2013/03/27/us-usa-court-comcast-classaction-idUSBRE92Q0MS20130327.

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the supplement containing DMAA was a factor in her death from cardiac failure.[13] In the US, a different approach has been adopted. A warning was issued in April 2012 by the Food and Drug Administration warning of the risk to health, but DMAA has not been banned.

Secondly, the US has recently seen an increasing number of claims focusing on alleged misrepresentations in the marketing and labelling of dietary supplements. In a number of cases, plaintiff's lawyers have filed class actions making these allegations shortly after a manufacturer has received an adverse decision from the Federal Trade Commission relating to an advertising claim. While a traditional personal injury case would require a plaintiff to overcome the significant hurdle of proving that the product was the cause of their injury, a claim alleging deceptive labelling avoids this difficulty and is therefore more attractive to plaintiff's lawyers in the US, although plaintiffs would need to prove that the deceptive labelling had caused them to purchase the product. Also, in class action claims, plaintiffs' lawyers may view class certification as being more straightforward as issues relating to injury causation for individual class members are avoided, although as the recent decision in the *Comcast Corp v Behrend* [2013]class action shows, US courts do appear to be tightening up on class certification.[14] Class certification significantly increases the potential liability exposure for a manufacturer.

In the UK, litigation funding reforms which came into force in April 2013 may make group litigation a much more attractive option than low-value individual claims to entrepreneurial claimant lawyers. To pre-empt the liability risks from these types of claims, manufacturers of dietary supplements must ensure compliance with all regulations relating to the marketing and labelling.

CONCLUSION

Although it remains to be seen whether the product liability litigation relating to dietary supplements which has developed in US will spread to Europe and the UK, manufacturers of products classed as food supplements should ensure that these products comply with the regulations in force governing their composition and that the products are correctly labelled and marketed. Compliance with the legal requirements will make it harder for plaintiffs to prove tortious conduct by the defendant companies in the event that any product liability litigation is considered.

By Sarah Croft, partner,
Shook, Hardy & Bacon International LLP.
E-mail: scroft@shb.com.

Comcast Corp et al v Behrend et al [2013] No 11-864 (US Supreme Court)