

The importance of

DUTY OF CARE



By **LINDSAY MOORE**, PhD

Exaggerated marketing, false and overblown label claims, adulterated and misbranded products all violate the law, mislead or deceive consumers, and evidence a failure by manufacturers to fulfil the *duty of care* due consumers.

Duty of care is a legal term frequently used in personal liability and corporate law. It assigns to manufacturers a legal and moral responsibility, *quid pro quo* for the privilege and competitive-market benefit of offering products for sale.

Under the law, those who take products of any kind into the marketplace must brand and label their products in an accurate and truthful manner, making only substantiated claims and statements, ensuring product efficacy and the safety of those who use them.

Each year the FTC, the FDA and other regulatory agencies prosecute many cases against manufacturers for false advertising, deliberate misbranding, false ingredient statements, product adulteration, deceitful or unsubstantiated claims, and unsafe or inefficacious products.

In April, a death due to liver failure and at least 23 reports of significant adverse health effects associated with Hydroxycut diet products resulted in FDA warnings to consumers and product recalls by the manufacturer, Iovate Health Sciences.

In February, the FDA discovered that StarCaps weight-loss capsules, which were

being marketed as dietary supplements, actually contained a potent pharmaceutical drug called bumetanide, a diuretic that can be used to mask steroid use, which could have serious side effects upon users of the product. Since December, the FDA has issued a list of 70 brands of weight-loss products that contain undeclared and potentially hazardous prescription drugs and antiseizure medications.

Similarly, Tren Extreme and Mass Extreme athletic-performance and bodybuilding products, marketed as 'potent legal alternatives' to steroids and popular among high school athletes, were discovered to actually contain the very steroids they claimed not to have. Such products, which may contain synthetic steroids, 'designer steroids' and modified forms of testosterone, are illegal and constitute unapproved drugs that may put consumers at risk. The FDA has issued warnings not to buy products with 'code words' such as 'anabolic' and 'tren,' or phrases such as 'blocks estrogen' (in an effort to maximize testosterone). When the FDA finds that a supplement has an undeclared active pharmaceutical ingredient, it considers the product to be an illegal, unapproved drug.

Commerce that puts the public at risk, deceives the buyer, or unjustly claims an appellation or set of words that bestow a market benefit, falls under the jurisdiction of many federal and state laws. If the package contains undeclared ingredients, is unsafe or inefficacious, or makes an unsubstantiated claim, the company may be liable for 'false advertising,' 'misappropriation of an unfair competitive advantage' under the statutes enforced by the FTC, 'misbranding' under the FDA, and/or 'the introduction or delivery of adulterated products into

interstate commerce' under the DEA or the USDA, which also bears responsibility for the National Organic Program and the veracity of organic claims.

Importantly, some of these violations carry both civil and criminal penalties, including substantial fines and imprisonment, and can entail expensive product recalls and sizeable liability. Companies in the business of manufacturing and marketing products are responsible for the ingredients and processes they use and the claims they make.

The majority of dietary-supplements products are legitimate and manufactured by responsible companies, but clearly some companies are not motivated to act in good faith, or by a bona fide regard for the interests of their consumers.

Duty of care, then, is a formalization of the social contract that exists between a company and the public to whom it

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sells its products. By placing its product within the stream of commerce and enjoying the freedom to market its offerings, a manufacturer owes a *duty of care* to society to take reasonable care and to evidence attentiveness and prudence in its business operations.

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