

*Interventions***Fair Notice: Reflections on *R v. Lake Estates Watersports Ltd, Michael Ely and Stuart Ely***

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This case concerns a prosecution under the Health and Safety at Work etc Act 1974. Two brothers, Michael and Stuart Ely were the operators of a water-sports centre, Lake Estate Watersports Ltd, based in Oxfordshire. The company and the two brothers were prosecuted following a fatal accident in August 1997. They were convicted at the Crown Court in Northampton in November 1999 and immediately appealed. On 19 July 2002 the Court of Appeal overturned all three convictions as unsafe.

It may be tempting for employers to see the Appeal decision as a victory for the small business in the face of aggressive enforcement of health and safety legislation. That would be a mistake. It is worth looking in some detail at the circumstances leading to the prosecution and the Appeal Court's decision.

All three were charged with breaches of section 3 of the Health and Safety at Work etc Act 1974. Section 3 is in the following terms:

General duties of employers and self-employed to persons other than their employees

- 3 (1) It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby, are not thereby exposed to risks to their health and safety.
- (2) It shall be the duty of every self-employed person to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that he and other persons, not being his employees, who may be effected thereby are not thereby exposed to risks to their health and safety.
- (3) In such cases as may be prescribed, it shall be the duty of every employer and every self-employed person, in the prescribed

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circumstances and in the prescribed manner to give to persons, not being his employees, who may be affected by the way in which he conducts his undertaking, the prescribed information about such aspects of the way in which he conducts his undertaking as might affect their health and safety.

In the early 1990s the Elys had set up the water sport centre with a water-ski club and a jet-ski club both operating on the lake. The brothers identified the need to separate both sides of the lake and had used a line of buoys. There is some ambiguity about exactly what was present but there were at least three large white buoys spaced regularly along a 300-metre division with two smaller coloured buoys between two of the openings. On one side of the division there was a course set up for jet-skiers and on the other a course set up for water-skiing.

On 9 August 1997 a novice jet-skier, Anthony Gee, with his 17-year-old niece, Faye Grundy, riding pillion, crossed the line of buoys from the jet-ski zone into the water-skiing area. Faye was knocked into the water and was run over by one of the water-ski powerboats. She was fatally injured by the propeller of the powerboat.

Mr Gee had not used a jet ski before the day of the accident. He appears to have received around 10 minutes' instruction on the use of the jet ski, during which the importance of keeping to the correct side of the separation line was emphasised. He and the other novices were also taken around the lake by Michael Ely on a tour of the novice circuit, although Mr Gee claimed that he had difficulty seeing where they were being taken because he was not first in line behind Mr Ely. He had made several circuits of the lake prior to the accident and on one earlier occasion, also with Faye Grundy on the jet ski, he had crossed the separation line into the water-ski area. Michael Ely spotted what happened on that occasion and chased after Mr Gee in a powerboat to alert him and emphasise the importance of staying on the correct side of the division. Despite this, a short time later Mr Gee failed to make an essential turn in the novice circuit and again crossed through into the water-ski area where the fatal accident occurred.

The Prosecution's main criticisms of the defendants were as follows:

- a) failing to ensure an effective form of separation either by allowing the activities to use the lake at different times or by way of a neutral buffer zone;
- b) permitting white markers buoys to be used as the means of separation;
- c) permitting the novice jet-ski course to be laid out in a form which made it difficult to steer safe passage (hexagonal form);

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- d) permitting spectators in an area which would be a distraction to the jet-ski users;
- e) failing to ensure that there was effective supervision and monitoring of the activities on the lake; and
- f) failing to ensure that there was an effective warning device audible to the users of the lake.

The first two aspects of the offence were seen as the most important and the Crown required to lead evidence in order to demonstrate that the marker buoy system of division employed by the Elys was not in accordance with good practice at similar water-sports facilities.

At the trial the Crown relied upon a document which, they claimed, illustrated the practice at other water-sport facilities. The Crown argued that this demonstrated that good industry practice dictated a proper separation between areas of a lake dedicated for personal water craft and for water-skiing. Separation was required to be either in time, with the two activities being conducted at different hours in the day, or physical with an effective barrier. The document had been prepared by the Crown's expert witness from the results of questionnaires. The questionnaires had been completed by local authority officials after approaching the operators of a number of facilities for information. In some cases this was simply by telephone. Although the questionnaire had been disclosed to the defence prior to the trial it was on the basis that it would not be used in evidence. Partway through the trial the Crown changed its position and decided to use the document to support the evidence of its expert witness. Counsel for the Defence objected, but the trial Judge ruled that it was admissible. The appeal turned upon whether the trial Judge was correct in allowing this evidence to go before the jury and, if he was not, whether that error made the subsequent convictions unsafe. The Appeal Court decided that the answer to both questions was yes. They held that by allowing the summary of questionnaire results to be admitted to evidence the defence were unfairly prejudiced. They could not verify the information at such a late stage in the trial and, since those actually providing the information on the practices, the operators of the facilities, were not called as witnesses there was no opportunity to challenge the evidence.

The use of the questionnaire was not of itself misconceived. The main problem for the Crown was that their expert witness did not visit any of the sites personally. He claimed to be too busy. Accordingly, when the questionnaire was produced in evidence and there was a dispute over the accuracy of the information, the Crown expert could not confirm that the results of the questionnaire were accurate. It was a basic error.

It is interesting to note that the Appeal Court took into consideration the effect of section 40 of the Health and Safety at Work etc Act 1974. This places the onus on the defendants to prove in any prosecution that it was not reasonably practicable to do more than was in fact done by them to satisfy their health and safety duties. In such circumstances any unfair advantage to the Crown was compounded and of even greater prejudice to the defence than in the usual case where the burden is wholly on the Crown.

The Appeal Court did not uphold the substantive defence on the merits. On the contrary, there is little doubt that if the Crown had provided fair notice that the questionnaire was to be used in evidence and there had been an opportunity to cross-examine on accuracy of the information contained therein, the document would have been admissible and the convictions would have been upheld.

What is of interest in this case is the Court's timely reminder of the importance of ensuring the availability of best evidence and fair notice in a case where, as a result of section 40 of the 1974 Act, the onus of proof is on the accused. It may be equally important to recognise the successful outcome for these defendants for what it is: not so much a victory for the defence as a defeat for the prosecution. The 1974 Act and subordinate regulations impose onerous duties to risk assess activities, implement proper precautions and carry out effective supervision and monitoring to ensure compliance. Whilst the size of a business and its resources may be relevant to the steps that it is reasonably practical to take it does not effect the absolute nature of the duties. One might argue that in this case, the Elys had a fortunate escape.

Facial Injuries and Football Before School

ANNE RUFF

Introduction

Sir Alex Ferguson may be grateful that David Beckham did not seek legal redress for the injury caused to his left eyebrow by a flying football boot. In *Kearn-Price v. Kent County Council* [2002] EWCA Civ.1539, a 14-year-old pupil suffered a serious eye injury when he was struck by a football while standing in the school playground. The Court of Appeal dismissed the local education authority's appeal against the decision of the county court that the school had been negligent in failing to prevent the injury to the pupil.

The case is concerned with the liability of a school for injuries incurred by pupils on school premises outside school hours. It also illustrates the arguably capricious approach by the courts to the meaning of 'negligence' in the school context. In addition, a number of broader issues emerge. These include the adequacy of school safety policies and their enforcement, as well as the legal implications for school football of research into the effect of heading the football on the brain. The increasing recognition of children's rights and presumably concordant responsibilities raises the question whether the courts are justified in adopting a protective attitude towards teenage pupils.

The Facts

In July 1998 the claimant, a 14-year-old Year 10 pupil, was struck in the eye by a full-size leather football while he was standing in the lower playground with friends before the start of the school day. As a consequence he has lost all useful vision in his left eye. The school day began at 8.45am. Thirty to 40 teachers would be in the staff room between 8.30 and 8.45am preparing for the school day. Pupils were expected to arrive 'at least five minutes before the school begins', and most pupils started to arrive at about 8.30am. However, in common with many schools, there was no supervision of pupils in the playground before 8.45am, although they were supervised during break periods. The lower playground, which was used by the pupils in Years

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9–11, was visible from the staff room but it was difficult for a member of staff to see what size or type of football was being used by the pupils. There were 5-a-side football posts in that playground, and up to eight games of football could be played at any one time, both before school started and during the school breaks.

There was a school policy banning the use of full-size leather footballs in the playground, although foam footballs were permitted. In March 1998 another pupil was hit in the face by a leather football in the playground, and the school reiterated the ban on the use of leather footballs. There was a series of incidents involving relatively minor facial injuries in May and June 1998. The judge found that the staff did not properly enforce the ban, and that pupils played with leather footballs in the playground on a daily basis. In particular teachers did not pay ‘flying visits’ to the playground or check the pupils’ bags on arrival at schools to see whether leather footballs were being used or brought to school. Footballs were occasionally confiscated during break time but never during the pre-school period. The judge also found that ‘apart from occasional reminders of the ban no positive steps were taken to ensure that the ban was enforced in the lower playground during the pre-school period’. The judge stated that the teachers must have known that football was being played regularly, and if they had visited the playground ‘it would have been obvious that the banned balls were being used’.

The Decision

The Court of Appeal in *Kearn-Price* rejected the proposition that a school never owes a duty of care towards children who are in the playground before or after school hours, and held that *Ward v. Hertfordshire County Council* [1970] 1 WLR 356 was not authority for that proposition. Dyson L.J. approved the decision of the High Court of Australia in *Geyer v. Downs and anr* [1977] ALR 408. In this case a pupil suffered severe injuries when she was struck on the head by a softball bat by a fellow pupil who was playing in a softball game in the school playground before school started. The High Court held that the question whether a school owes a pupil a duty of care depends upon ‘the nature of the general duty to take reasonable care in all the circumstances’. Dyson L.J. in the Court of Appeal considered that, ‘a school owes to all pupils who are lawfully on its premises the general duty to take such measures to care for their health and safety as are reasonable in all the circumstances’.

Dyson L.J. stated that:

The real issue is what is the scope of the duty of care owed to pupils who are on school premises before and after school hours. It may be

that it is not reasonable to expect a school to do as much to protect its pupils from injury outside school hours as during school hours ... Moreover, it may be unreasonable to expect constant supervision during the pre-school period, but entirely reasonable to require constant supervision during the break periods.

The Court of Appeal held that the school was in breach of its duty of care in failing to enforce the ban on leather footballs more effectively, in particular by not having a more rigorous policy of enforcement and spot-checking during the pre-school period. Such steps were reasonably required having regard to the fact that (a) the ban on the use of full-size leather footballs was known to be regularly flouted, (b) they were known to be dangerous, and (c) the additional steps would not impose an undue burden on the school. The judge was entitled to hold that the scope of the duty of care owed by the school to the boys encompassed a duty to take reasonable steps to enforce the ban on full-size leather footballs, and to carry out spot checks during the pre-school period to that end.

Dyson L.J. considered that it was important to emphasise that the claimant was not playing football; he was merely a bystander in a crowded playground where a number of games were being played, and he was behaving entirely reasonably in being where he was and what he was doing. The school appreciated that full-size leather footballs were dangerous and that the ban on their use was being flouted daily. The attempts to enforce the ban during school breaks was desultory, and during the pre-school period non-existent.

Discussion

There are a number of interesting issues raised by this case. First, both the English and the Australian courts have rejected Lord Denning's view in *Ward*, that there was no duty on the school to supervise pupils before the start of the school day as the staff were indoors preparing for the day's work and could not be expected to be in the playground as well. In *Ward* an eight-year-old pupil was injured while playing in the playground five minutes before the start of school. Salmon L.J. considered that liability might have arisen were the pupils engaged in 'some particularly dangerous game' that should have been stopped had a teacher been present. Cross L.J. considered that increased supervision would have been 'useless' in the circumstances.

The Court of Appeal's decision in *Kearn-Price* means that schools must supervise pupils whenever they are lawfully on the school premises, not just during school hours. The degree of supervision may be less before and after school than in break times during the school day, but this will depend upon

the particular circumstances. Secondary schools, which are often spread over a large area including playing fields, may find this an onerous task.

Second, *Kearn-Price* illustrates the difficulty of predicting whether particular facts amount to a breach of the duty of care. In *Etheridge v. Kitson and East Sussex County Council* [1999] Ed CR 550, the High Court dismissed the claim brought by a teacher who was injured by a basketball thrown by one pupil to another during change-over time between classes. There was a basketball craze at a school and a number of pupils carried basketballs around with them. A basketball weighs over one pound and is slightly larger and heavier than a conventional football. There was no rule that basketballs had to be kept in the lockers while pupils were in the school. The claimant was injured when a pupil passed the basketball to another pupil further down the staircase. That pupil either did not see the basketball or ignored it, and in consequence the ball bounced and struck the plaintiff a glancing blow to the head.

The High Court dismissed the plaintiff's claim for damages against both the pupil who passed the ball and the Local Education Authority (LEA) employer. The court held that the first defendant, as an ordinary prudent and reasonable 13-year-old, would not have realised that what he did gave rise to the risk of injury or the significant risk of the likelihood of injury; and that the second defendants, the LEA, had kept the school premises reasonably safe for the purpose for which persons were permitted to be there and had a proper system of working.

Both these conclusions seem surprising. First, a pupil aged 13 is surely aware that someone may be hit by a basketball that is thrown or passed down a staircase at changeover time. Second, passing or throwing of balls within the school building would seem to constitute a safety risk and such activity should have been banned. If the ball had injured another pupil would the court have been so forgiving? Were the facts of *Etheridge* to arise again, the teacher may well be successful.

Third, the case highlights the inadequacy of school safety policies and in particular their enforcement. Researchers from Hull University are reported to have found that six out of ten headteachers and governors said that not all their staff responsible for health and safety had been given formal instruction.¹ A similar proportion admitted that their health and safety policies were 'not very workable', but more than a third believed that they would not be personally liable if anything went wrong. Forty per cent of schools had not set money aside for health and safety training for staff, while 20 per cent had not checked that they had the right arrangements in place for after-school clubs.

The Health and Safety at Work etc Act 1974 places overall responsibility for health and safety with the employer. Who is the employer varies

according to the type of school. In the case of community schools, community special schools, voluntary controlled schools, maintained nursery schools and pupil referral units, the employer is the LEA. For foundation schools, foundation special schools and voluntary aided schools, the employer is usually the governing body. For independent schools, the employer is usually the governing body or proprietor.

The Department of Education and Skills (DfES) has issued guidance on health and safety to LEAs and schools.² The guidance states that school employers must have a health and safety policy and arrangements to implement it. It is good practice for community, community special and voluntary controlled schools where the LEA is the employer to draw up their own more detailed health and safety policies based upon their LEA's general policy. The LEA is required to monitor how its schools are complying with the LEA policy. An LEA may give a warning notice to any maintained school (community, community special, foundation, foundation special, voluntary aided or voluntary controlled) in its area where the safety (not the health) of staff or pupils is threatened by, for example, a breakdown in discipline.³

The guidance provides that school employers must assess the risks of all activities, introduce measures to manage those risks, and tell their employees about the measures. The guidance goes on to state that the LEA must provide health and safety guidance to those schools and services where it is the employer. It must ensure that staff are trained in their health and safety responsibilities as employees and that those who are delegated health and safety tasks (such as risk assessment) are competent to carry them out. If an LEA risk assessment shows that training is needed, the LEA must make sure this takes place.

Bearing in mind that leather footballs have not been used in professional football since the 1970s, having been replaced by polyurethane with a maximum weight of 16oz, it is surprising that in *Kearn-Price* there are repeated references to 'leather' footballs. Probably, the term is used by the court to distinguish a 'proper' football from the foam footballs that were permitted in the school playground, and with which no self-respecting teenage footballer would dream of playing. There is considerable evidence that heading footballs can cause injury to the head and the brain. In November 2002 a coroner ruled that Jeff Astle, who played for West Bromwich Albion and England in the late 1960s and early 1970s, died of an industrial disease after 20 years of heading heavy leather footballs.⁴ A consultant neurologist gave evidence that a scan revealed a brain injury consistent with 'repeated minor trauma'.

Suggestions have been made that other professional footballers are suffering from dementia, although it is not clear to what extent heading

footballs was a contributory factor.⁵ The Minister for Sport has recently commented that, 'the effect of heading on former professional footballers is a complex matter ... There is evidence documenting subtle brain injuries among people who have played football for many years, while other studies have suggested there is no significant risk'.⁶ He concluded that, 'what is clear is that most experts agree that the data collected so far are inconclusive and that further longer-term studies are required'.⁷

The government established a cross-departmental Accidental Injury Task Force, which published its report in 2002.⁸ The task force based its report on the findings of three expert working groups, one of which was chaired by a consultant neurosurgeon and was concerned with preventing the incidence of serious injury, illness, disability and death in organised sport. One of the priority areas identified by the task force was the need to 'produce guidelines for safety in children's sports', and in the longer term to 'create a sports injury database'. The Minister for Sport has confirmed that UK Sport will issue guidance on health and safety issues for sport including health and safety policies for different types of sport.⁹

Despite the Minister's view that the data so far is inconclusive, a US study found that Dutch soccer players suffered the same number of concussions as American footballers.¹⁰ Fifty-three Dutch footballers were monitored, and 45 per cent of them were found to have some form of brain injury. In Australia guidelines on the prevention of head injuries in Australian rules football were published in 2001.¹¹ In the same year the Football Association and the Professional Footballers Association began a joint ten-year project to learn about how heading a football affects the brains of young players. The study involves 33 professional footballers, who will be given regular MRI scans and neurological assessments. The Wellcome Trust is funding a study which is expected to report in September 2003, involving participants from youth and university football teams.¹² Dr David Williams, a psychiatrist at a Swansea hospital, noted an excess of footballers with dementia among his patients. A study was undertaken of eight patients who had previously been amateur or professional footballers. The authors reported in March 2002 that the results of the study added to the emerging evidence that repetitive mild head trauma over the course of an amateur and professional footballer's career may heighten an individual's risk of increasing dementia in later life.¹³ Dr Williams is also reported to have stated that children should not head a football because of this risk.¹⁴

US research tends to support the view that children should not head footballs.¹⁵ The American Association of Neurosurgeons estimates that approximately five per cent of soccer players sustain head injury as a result of head-to-head contact, falls or being struck on the head by the

ball. Heading a ball is the riskiest activity in the Association's view. Children aged 5–14 account for nearly 40 per cent of sports-related injuries, and of those 75 per cent are boys, with soccer being one of the sports associated with such injuries.¹⁶ Modern footballs may be lighter than leather footballs, but evidence is accumulating that they may also cause an unacceptable level of head injuries and brain damage, particularly to players of school age.

The decision in *Kearn-Price*, together with the accumulating research on the effect of heading the football on the brain, has implications both for playground football and for official games of school football. In order to avoid liability in negligence, LEAs and schools should ban the use of 'proper' footballs other than on the football pitch. Second, schools must properly police the ban whenever pupils are lawfully present on the school premises. At the very least schools should check on a daily basis the type of footballs being played with by pupils, and these checks should occur both before and after school as well as during lunch and other breaks. During the break-times schools should consider whether constant supervision is necessary to enforce the ban.

Local education authorities and schools should also consider whether to ban all playground football. This is likely to prove difficult to enforce and unpopular with pupils. One possibility is to ban playground football but introduce more formal sports within the school day. The government is reported to be looking favourably on a pilot scheme that is to be introduced in the London Borough of Brent from September 2003.¹⁷ The scheme will extend the school day in five secondary schools and will involve two hours of sport each afternoon. Pupils in Year 7 will start school at 8am and will finish at 5.30pm or 6pm.¹⁸ The initiative has been proposed by the MP for Brent North, and has the support of the School Standards Minister and the Minister for Sport.

Although, neither UK Sport, the Football Association, nor the government has published guidance banning headers by pupils or recommending the wearing by pupils of a helmet or other protection for the head or face, this may not be enough to absolve LEAs and schools from liability where a pupil suffers such an injury on the football pitch. Clearly football cannot be risk-free. However, where the risk of serious injury to vision or the brain could be minimised by the introduction of a relatively simple measure, the courts may consider that the failure to introduce such a measure amounts to a breach of the duty of care owed by the LEA or the school to the pupil. In order to minimise the risk of eye injury, England Squash has from 1 September 2000 made it mandatory for under-19 junior players to wear eye protection (goggles) at specified events. These include all junior-graded tournaments and county-closed tournaments. Middlesex

County also requires goggles to be worn at all inter-club junior matches. At the very least, LEAs and schools should formulate and properly implement a policy on safety on the football pitch that takes into account current good practice and medical research.

Fourth, the court arguably adopted a protective attitude towards the teenage claimant. The judge rejected the defendant's plea that the claimant was contributory negligent because he stood in the playground where football was being played rather than in an adjacent football-free picnic area which was infrequently used by the pupils. This finding was not appealed. The defence of consent to the risk was not raised. Dyson L.J. considered that it was important to emphasise that the claimant was not playing football; he was merely a bystander in a crowded playground where a number of games were being played, and he was behaving entirely reasonably in being where he was and what he was doing. Arguably, he was more vulnerable than a participant in the game because he was probably not watching the ball. What difference would it have made had the claimant been injured while participating in a casual football game in the playground? The defendant may have argued that the claimant consented to the risk of injury. However, if the school was in breach of its duty of care by allowing pupils to play with a 'proper' football in the playground, that defence may not be available. Similarly the defence may not be available where a spectator is injured by the football at a football match.¹⁹

Lord Denning's approach in *Ward* reflects an earlier and more robust attitude. Even eight-year-old pupils were expected to look after themselves 30 or more years ago. In an era of developing children's rights, it is ironic that a 14-year-old pupil may be *Gillick* competent and capable of obtaining contraceptive advice and entering into an unlawful sexual relationship, yet is not perceived as being competent and capable of recognising the risks of standing in a crowded playground where a number of football games are being played, nor the risks of passing a basketball down a busy staircase.

Finally, despite Dyson L.J.'s concern about 'the ever increasing pressures piling upon the teaching profession', the Court of Appeal's decision has placed an additional duty on schools and their staff.

The court's decision perhaps reflects the understandable sympathy it felt for the pupil. It also reflects a society that no longer accepts that accidents happen, and considers that 'someone' must be to blame and made to pay. The argument for a system of no fault liability in the maintained education system is strengthened by this decision.

NOTES

1. *The Times Education Supplement*, 30 October 2002.
2. Health & Safety: Responsibilities and Powers, DfES Guidance 0803/2001, December 2001.
3. School Standards and Framework Act 1998, s.15(2)(iii).
4. *The Times*, 21 November 2002.
5. For example, Hansard, 18 December 2002, col.979 (Dr Gibson, MP for Norwich North).
6. Hansard, 18 December 2002, col.980.
7. Hansard, 18 December 2002, col.981.
8. Accidental Injury Task Force, 'Preventing Accidental Injury: Priorities for Action', October 2002.
9. Hansard, 18 December 2002, col.981.
10. BBC News, 21 September 1998 (report of a study published in the scientific journal of the American Academy of Neurology).
11. National Health and Medical Research Council, 'Head and Neck Injuries in Football: Guidelines for Prevention and Management'.
12. Dr Andrew Rutherford, Keele University; and A. Rutherford *et al.*, 'Neuropsychological Review' (forthcoming), a major review of the football heading literature.
13. Abstract from a meeting of the Faculty of Old Age, in collaboration with the British Geriatric Society, Royal College of Psychiatrists Press Release, 8 March 2002.
14. *The Times*, 12 November 2002.
15. For example, 'Heading the Ball in Soccer', a list of sources provided by the National Youth Sports Safety Foundation, Boston, MA (www.nyssf.org) on heading the ball and brain injury.
16. 'Fact Sheet Head Injury – What is the significance of sports-related injuries?', September 1999.
17. *Observer*, 29 September 2002.
18. Schools are normally permitted to change the times of school sessions from the beginning of the school year, but under the Education Act 2002, s.2(1), it is now possible for a school to apply to the Secretary of State to vary the school sessions from, for example, the start of the Spring Term.
19. See, for example, *Wooldridge v. Sumner* [1963] 2 QB 43.

Young Athletes and Sports Participants at Risk: Ephedra Regulation and Legal Issues in the United States

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Introduction

How does a 16-year-old die of myocardial infarction? It wasn't just a mild myocardial infarction. I had to ask the pathologist what that meant. Troponin, which is an enzyme specific marker to the heart, was at 100 level, the number 100. You and I as adults are at one or two on a normal day's level. The troponin in your heart tells it to keep beating. When you're having a heart attack at 50, 60 years old, 70 years old, it would be marked at four to five. Think about it. You're at 100. The heart was racing so fast it just kind of couldn't do anything. It couldn't pump the blood fast enough and that's why he had a heart attack.¹

This was the testimony of the Logan County Coroner to the Senate Governmental Affairs Committee in response to the death of Sean Riggins, a 16-year-old high school football player, who died after taking a dietary supplement know as a 'Yellow Jacket' that contained ephedra. According to the coroner and forensic pathologist, the cause of Sean's death was consistent with the effects of ephedrine.²

The issue of ephedra use in sports has gained increasing attention both nationally and internationally.³ In the United States, the deaths of young athletes who have taken ephedra prior to sport participation have brought much attention to the use of dietary supplements for performance enhancement. These fatalities have also garnered substantial media coverage during the past several years.⁴ Even so, there is evidence that

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ephedra use among college athletes is growing, particularly among athletes during the competitive season.⁵ Additionally, ephedra is often taken immediately before practices or games.⁶ Compounding the problem, supplements containing ephedra are often advertised as a way to increase performance, build muscle, lose weight or increase energy, and are targeted to young people who participate in active sports.⁷

The regulation of ephedra and the legal issues surrounding the adverse consequences of its use are complex. This comment seeks to address these issues in the sport context. A description of ephedra as a dietary supplement will first be examined. Second, the regulation of ephedra will be discussed, looking in particular at the role of the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), sport organisations, and US state and federal legislative bodies, followed by a brief discussion of international response to the issue. Last, related legal issues in sport and fitness will be discussed.

Ephedra as a Dietary Supplement

Ephedra alkaloids are derived from several different branching shrubs in the *Ephedraceae* family. The dried stems and branches of the 1.5–4 foot shrub are typically harvested in the autumn, and the resulting extracts are commonly known as ephedra, *ma huang*, desert herb, or Chinese joint fir. These plants are grown in arid regions throughout the world, but are most common in Mongolia and the bordering regions of China.⁸

In China, the medicinal use of ephedra dates back to 2800 BC. Over the centuries, it has been used to treat a number of medical conditions, including the common cold, bronchitis, fever, low blood pressure, asthma, hay fever, and itching and swelling. Western medicine began to take an interest in ephedra in 1923 when it was discovered that the isolated ephedrine alkaloid possessed a number of sympathomimetic (that is, fight-or-flight) effects. This compound was later chemically synthesised and used for its pharmacologic actions.⁹

The two primary active ingredients in ephedra are ephedrine and pseudoephedrine. These compounds have been studied extensively and are available in many prescription and over-the-counter medications used to treat asthma, the common cold, hay fever and rhinitis, or as an appetite suppressant. However, when produced in herbal or extract form, ephedra can be sold as a dietary supplement without the more strict FDA regulations for drugs, and marketed as a 'natural' product.¹⁰

The clinical effects of ephedra are primarily due to ephedrine, whose pharmacology is similar to that of epinephrine or amphetamines. These effects include stimulation of the sympathetic nervous system and the

resultant dose-dependent effects on blood vessels, heart, respiratory tract, eye, gastrointestinal tract, central nervous system (CNS), metabolism and a variety of glands. The metabolic effects include the accelerated use of calories and the breakdown of fat. Since it can accelerate the body's use of calories (metabolism) and depress appetite, ephedrine is often a component of weight-loss products. Due to its stimulating effect on the CNS, ephedrine has been also been marketed as an energy enhancer.

Athletes typically use ephedra for one of two goals. One goal is to decrease fatigue and increase energy for training and competition. A second goal is to improve muscular definition. This is accomplished by reducing body fat through increased metabolism.¹¹ Research regarding ephedrine and athletic performance is limited, but most studies do not support ergogenic (performance enhancing) claims. Instead, adverse effects have been regularly observed during these studies, including those that involve both healthy and obese participants.¹²

The adverse effects of ephedrine range from psychosis, heart attack, stroke and death, to less serious but still troublesome effects including nervousness, headache, dizziness, insomnia, gastrointestinal distress, skin flushing and tingling, and irregular heartbeat. Increases in both heart rate and blood pressure are common. While the minor side effects may not be serious to most users, they can have serious consequences when consumed by those who are pregnant or with heart disease, hypertension, thyroid disease, diabetes and/or other medical conditions. In certain individuals, serious adverse reactions can occur with low doses. Additionally, the toxicity of ephedrine can be increased by physical activity, dehydration and increases in body temperature, all commonly experienced in athletic training and competition.¹³ Combining caffeine (from coffee, Green tea, Guarana, Yohimbe or Kola nut) and/or aspirin with ephedrine, or consuming larger than recommended doses, greatly increases the potential for adverse effects.¹⁴

More than 80 deaths and over 1,400 adverse reactions from people ingesting nutritional supplements that contained ephedrine and associated alkaloids have been reported to the FDA.¹⁵ The use of ephedra has been linked to severe cardiac and central nervous system adverse effects, including arrhythmias and strokes.¹⁶ Ephedra is found in at least 25 over-the-counter dietary products, and several of them do not identify ephedra by name. Even consumers who are aware that ephedra is a potentially dangerous supplement may not know that products marketed to boost energy or lose weight contain ephedra.¹⁷

Ephedra Regulation

Federal Regulatory Controls

The primary US federal regulatory agencies with the authority to regulate ephedra as a dietary supplement are the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA). The mission of the FTC is to prevent unfair competition and to protect consumers from unfair or deceptive practices in the marketplace. As part of this mission, a priority of the FTC is to challenge misleading advertisements or unsubstantiated claims (for example, health benefits or safety) used in the advertisement of dietary supplements.¹⁸ The authority of the FTC to accomplish this mission is derived from the Federal Trade Commission Act.¹⁹ Under the FTC Act, an advertiser is required to have competent and reliable scientific evidence supporting claims made in their advertisements.²⁰ When companies make unqualified health and/or safety claims about ephedra products in their advertisements, those claims may be challenged as deceptive and the FTC can bring enforcement actions against those companies.²¹ However, the FTC does not pre-screen advertising claims for dietary supplements and must address deception in the marketplace primarily through post-market enforcement.²²

The FTC works closely with the FDA, the agency with principal statutory authority to oversee the safety of dietary supplements. While the primary role of the FTC is to regulate advertising, it is the primary function of the FDA to monitor labelling.²³ Both agencies derive authority to regulate dietary supplements from the Dietary Supplement Health and Education Act of 1994 (DSHEA).²⁴ The DSHEA regulatory framework for dietary supplements is primarily a post-market programme.²⁵ Therefore, as with the FTC, the FDA cannot take enforcement action until the product is on the market. Additionally, since passage of the DSHEA, manufacturers of dietary supplements no longer have to prove that their products are safe. Rather, the FDA has the burden to prove they are unsafe.²⁶ Therefore, the burden of proof is on the FDA to prove that a dietary supplement presents a safety risk after a product is on the market. If safety problems occur after marketing, the adulteration provisions of the DSHEA apply. A dietary supplement is considered 'adulterated' if the product, or one of the product's ingredients, poses a 'significant or unreasonable risk of illness or injury' when used as directed on the label or under normal conditions of use when there are no directions.²⁷

The American Medical Association (AMA) contends that dietary supplements in the United States containing ephedrine alkaloids present a significant or unreasonable risk of injury and therefore should be removed from the market.²⁸ The AMA, however, also recognises that it is difficult to

prove a cause-and-effect relationship between ephedra use and adverse health consequences based on voluntary adverse event reports acquired by the FDA.²⁹ Additional scientific research on the health consequences associated with ephedra use is forthcoming. The Department of Health and Human Services recently funded the RAND Corporation to conduct a comprehensive review of the existing science on ephedrine alkaloids.³⁰

Regulation in Sports

Due to the potential health risks associated with taking dietary supplements containing ephedra, the National Collegiate Athletic Association (NCAA), the National Football League (NFL)³¹ and the International Olympic Committee (IOC) have banned the use of ephedra among athletes under their authority. The NCAA is tasked with protecting the health and safety of US student athletes. To that end, the Committee on Competitive Safeguards and Medical Aspects of Sports was formed to advise the NCAA and member institutions on health and safety matters. Additionally, the NCAA has implemented drug and supplement testing programmes, programmes on drug and supplement prevention,³² and guidelines and recommendations regarding educating athletes about dietary supplements, and has conducted a national survey (initiated in 1985 and replicated every four years) to study drug and supplement use and abuse habits of college athletes.³³ In replicated studies conducted between 1985 and 1997, survey evidence suggested that ephedra use among college athletes was growing.³⁴ Therefore, in 1997, the NCAA banned the use of ephedrine by college athletes.³⁵ The most recent survey data (2001) indicated a further rise in ephedrine use among college athletes (3.5 per cent in 1997 to 3.9 per cent in 2001).³⁶ Data also suggests that approximately half (50.8 per cent) of student athletes who used ephedrine did so with the hope of improving their athletic performance. Additionally, the use of ephedrine was highest during the competitive season, taken immediately prior to practice or competition, with use often beginning in high school.³⁷

US State and Federal Legislation

On 9 October 2001, Representative Susan Davis (D-CA) introduced a bill entitled the Ephedrine Alkaloid Consumer Protection Act (House Bill 3066).³⁸ The bill's key provisions sought to amend the Federal Food, Drug and Cosmetic Act by establishing labelling and advertising requirements for dietary supplements containing ephedrine alkaloids, and to prohibit the sale of these supplements to individuals under the age of 18. The bill addressed section 403 of the Federal Food, Drug and Cosmetic Act,³⁹ and, if passed, would have required warnings and the listing of possible adverse health effects on labels.⁴⁰ The bill would have also prohibited the sale of products

containing ephedra to those under the age of 18 where the sale was made directly to an underage purchaser, or where the underage purchaser had direct access to a supplement containing ephedra (for example, the supplement was on the counter at a gas station food store).⁴¹

State legislation currently exists that provides regulations for ephedra-based supplements.⁴² Ohio law provided the first comprehensive set of rules for ephedra-based supplements and other states have followed suit.⁴³ For example, California law requires that labels explicitly state the amount of ephedrine (in herbal form) present in supplements sold over the counter, provide warnings to pregnant women and individuals under the age of 18, and clearly state the possible adverse health effects of ingesting ephedra-based supplements.⁴⁴ Proposed federal legislation is modelled after California law.

International Response

Canada and several other countries have taken action to protect their citizens from the potential harmful consequences of taking ephedra-based supplements.⁴⁵ On 8 January 2002, Health Canada requested a voluntary recall and an advisory to Canadian citizens regarding products containing ephedra due to concerns that these products posed a serious public health risk.⁴⁶ Currently, the Canadian Food and Drugs Act does not include a special category for regulating herbal remedies.⁴⁷ Therefore, Health Canada has decided to initiate a voluntary recall until specific regulations for herbal remedies are in place.⁴⁸

Legal Issues in Sport and Fitness

Personal injury and wrongful death lawsuits involving products containing ephedra have increased in the United States. Class action lawsuits against supplement manufacturers (selling ephedra-based products) are pending.⁴⁹ Additionally, lawsuits have been brought that involve death or injury in the sport or fitness context. For example, in 1999, a high profile case against Crunch Fitness Centers alleged that a personal trainer had instructed a fitness club member (while on prescription medication for hypertension) to take several supplements, one of which contained ephedrine.⁵⁰ The suit alleged that several of the supplements (including the one containing ephedrine) caused the deceased to suffer a hypertensive stroke.⁵¹ Compensatory and punitive damages in the amount of \$320m were sought against the health club chain, the personal trainer employed by the chain, a vitamin store where the supplements were purchased, and the manufacturers of the supplements.⁵²

The case is currently on appeal in the state of New York.⁵³

Negligence

The aforementioned case, as well as future cases brought in the United States against sport or fitness providers will apply the principles of negligence in assessing whether a defendant's conduct failed to meet the legal standard designated to protect against unreasonable risks. The cause of action for negligence has four elements.⁵⁴ The first is a legal duty owed by a defendant to conform to certain standards of care to protect others. The second element is a failure by the defendant to conform to these standards. The third element is a causal connection between the defendant's conduct and the resulting injury or loss by the plaintiff. The final element is actual loss or injury to the plaintiff.⁵⁵

With respect to the duty owed a plaintiff by a personal trainer or coach, a possible claim might be that a defendant had a duty to warn, or instruct, about the dangers of ephedra use. The issue would hinge, in part, on the existence of an industry standard for coaches or personal trainers regarding their role with athletes or clients and dietary supplements. With the NCAA ban on ephedra use by athletes, a coach recommending or instructing a college athlete on using ephedra would certainly be suspect in meeting the standard of care. The line becomes less clear, however, with fitness trainers and high school coaches, for example, whose schools or places of business are not under the direct authority of a governing body. A related issue in cases where ephedra-based supplements have been recommended involves the training of sport or fitness personnel in the field of nutrition and dietary supplements.⁵⁶ If recommendations are given by untrained individuals, the argument that the defendant failed to meet the standard of care is strong.

A second key issue in cases where dietary supplements are recommended is causation. It has proven difficult to establish a cause-and-effect relationship between the use of ephedra and the resulting injury or death. One difficulty in determining causation arises from the fact that multiple supplements are often taken and the source of the culpable product is typically not readily apparent. Second, causality may be difficult to determine given a variety of other health factors that may be associated with the injury or death of an individual. Overcoming issues of causation would likely be accomplished by introducing sound medical opinion.

Conclusion

In the United States, the financial interests of ephedra manufacturers, the product's marketing and promotional claims and advertising, along with athletes' and coaches' desire to win at all costs can be a deadly combination.

Exercise, sport and healthcare professionals must rely on current scientific data, stay abreast of ergogenic supplement trends, and realise that there is no shortcut to athletic success.⁵⁷ The possible ergogenic benefits of ephedra are highly debatable and the health risks associated with its use are well documented. Therefore, a proper diet and sound training programme should be presented as a sensible alternative. Sport and fitness personnel should be highly alert to the dangers of recommending ephedra products to athletes or clients. Additionally, educational programmes should be made available to young people involved in sports to empower them to make informed decisions regarding supplements.

Self-regulation by manufacturers of ephedra-based products is a recent development. Some companies are now taking proactive measures to address the potential adverse consequences of taking dietary supplements containing ephedra. For example, Twinlab Corp., one of the nation's leading manufacturers of vitamins and other dietary supplements, has announced that it will no longer sell products containing ephedra. The company will shift to a line of ephedra-free products they have tested and claim are effective weight-loss aids. Additionally, General Nutrition Centers now require customers at each of its 5,300 stores worldwide to show proof-of-age identification 'when purchasing products intended only for use by adults, including products containing ephedra'.⁵⁸

Where sound judgement, education and industry self-regulation do not suffice, regulatory controls present an additional option. As mentioned, regulatory controls include powers granted to the FDA and the FTC under the DSHEA, proposed federal legislation, state law, and sport association bans. The regulation of ephedra-based products in the United States is arguably in need of additional refinement. For example, even with state laws that prohibit the sale of ephedra based supplements to those under the age of 18, this fails to account for some 360,000 college athletes, most of whom are between 18 and 22 years of age, who can legally buy ephedra. The tragic death of Sean Riggins, a promising young athlete, has put us on notice of the dangers associated with ephedra. Future attention to the issue will hopefully provide a silver lining to the storm.

NOTES

1. See United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, Charles Fricke, Logan County Coroner, Lincoln, IL, 31 July 2002, p.7, retrieved 7 January 2003 from the LexisNexis Congressional database.
2. Ibid.
3. See Associated Press, 'Restrictions on ephedra urged, Adverse reactions to dietary supplement studied', *Houston Chronicle*, 3 February 2003, <http://www.chron.com/cs/>

- CDA/story.hts/health/1763460, accessed 10 February 2003; D. Caruso, 'Study recommends limits for ephedra, an herb linked to deaths', *Associated Press*, 3 February 2003, http://web.lexisnexis.com/universe/document?_m=372211ae495d064e12f04721d761b02e&_docnum=8&wchp=dGLbVlz-lSIAI&_md5=aeb9a1c7e09e0f90e0e0390511e20713, accessed 10 February 2003; and 'Ephedra caused many poison calls', *United Press International*, 3 February 2003, http://web.lexisnexis.com/universe/document?_m=372211ae495d064e12f04721d761b02e&_docnum=12&wchp=dGLbVlz-lSIAI&_md5=ca8477dfcbb27c4a74046544cf925c4c, accessed 10 February 2003.
4. In addition to the death of Sean Riggins, another incident that sparked substantial media attention involved the death of Rashidi Wheeler, a Northwestern University football player, in August 2001. This case brought national attention to the dangers of ephedra-containing products when he collapsed and died during a workout. Wheeler drank the ephedra-based sports mix Ultimate Punch and used Xenadrine with teammates prior to practice.
 5. The NCAA conducts a survey every four years on ephedra use by college athletes. Survey results are available at www.ncaa.org.
 6. *Ibid.*
 7. United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, Frank D. Uryasz, President, The National Center for Drug Free Sport, Inc., 8 October 2002, retrieved 7 January 2003 from the LexisNexis Congressional database.
 8. Clinical Reference System, *Patient Education Handout*, 'Ephedra (Ma-Huang) Natural Remedy', <http://home.mdconsult.com/das/patient/body/149485276/10002/7310.html>, accessed 17 December 2002. See also M. Murray and J. Pizzorno, *Textbook of Natural Medicine*, 2nd edn. (London: Churchill Livingstone, 1999), 719–22.
 9. *Ibid.*
 10. J. Congeni and S. Miller, 'Supplements and Drugs Used to Enhance Athletic Performance', *Pediatric Clinics of North America* 49/2 (2002), 435–61.
 11. *Ibid.*
 12. M. Powers, 'Ephedra and Its Application to Sport Performance: Another Concern for the Athletic Trainer', *Journal of Athletic Training* 36/4 (2001), 420–4.
 13. *Ibid.*
 14. P. Clarkson, E. Coleman and C. Rosenbloom, 'Risky Dietary Supplements', *Gatorade Sports Science Institute, Sports Science Exchange Roundtable* 13/2 (2002), 1–4. See also E. Wooltorton and B. Sibbald, 'Health and Drug Alerts: Ephedra/Ephedrine: Cardiovascular and CNS Effects', *Canadian Medical Association Journal* 166/5 (2002), 633.
 15. P. Steinbach, 'Supplemental Restraint', *Athletic Business* (December 2002), 14.
 16. C. Haller and N. Benowitz, 'Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids', *New England Journal of Medicine* 343/25 (2001), 1833–8.
 17. Powers (note 12), 13.
 18. United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, J. Howard Beales III, Director, Bureau of Consumer Protection, 8 October 2002, retrieved 7 January 2003 from the LexisNexis Congressional database.
 19. The FTC's authority to regulate advertising is derived from section 5 of the Federal Trade Commission Act. See Federal Trade Commission Act, ch.311, 38 Stat. 717 [1914] (codified at 15 U.S.C. 52–55 [1994]).
 20. *Ibid.*, 17.
 21. *Ibid.* FTC enforcement actions challenging unqualified safety or no side effect claims for supplements containing ephedra include body-building and energy supplement claims. The FTC issued orders prohibiting unsubstantiated safety claims in these cases and required a strong disclosure warning about safety risks in all future advertising.
 22. *Ibid.* The justification for post-market enforcement is an attempt to balance the risk of allowing false or misleading commercial speech with the risk of banning or delaying commercial speech that might prove to be true.
 23. In addition to labelling, the FDA monitors product information, package inserts,

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- accompanying literature and voluntary dietary supplement adverse event reporting.
24. Pub. L. No.103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note [1994]).
 25. The DSHEA also grants authority to the Secretary of the Department of Health and Human Services to stop immediately the shipment of a dietary supplement by declaring it to 'pose an imminent hazard to public health or safety'. Successful application of this provision is extremely rare.
 26. J.A. Levitt, 'Regulation of Dietary Supplements: FDA's Strategic Plan', *Food and Drug Law Journal* 57/1 (2002), 1-13.
 27. United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, 31 July 2002, retrieved 7 January 2003 from the LexisNexis Congressional database.
 28. United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, Ron Davis, M.D., Board of Trustees, American Medical Association, 8 October 2002, retrieved 7 January 2003 from the LexisNexis Congressional database. The AMA finds additional authority for their stance under section 402(f)(1)(A)(i) of the Federal Food, Drug and Cosmetic Act.
 29. *Ibid.* The FDA is charged with monitoring adverse event reports and has a programme in place to collect consumer complaints related to dietary supplements.
 30. *Ibid.*, 26. The results of the RAND were not available at the time of writing.
 31. In May 2001, the NFL was the first professional sports league to ban the use of ephedra. Players that fail a random drug test for ephedra are suspended for four games.
 32. The NCAA's prevention efforts regarding ephedra include the establishment of the Dietary Supplement Resource Exchange Center. The Center provides a valuable resource for NCAA athletes and member institutions. Prevention information is provided online at www.drugfreesport.com.
 33. United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, Frank D. Uryasz, President, The National Center for Drug Free Sport, Inc., 8 October 2002, retrieved 7 January 2003 from the LexisNexis Congressional database.
 34. *Ibid.*, 6. Athletes who test positive for ephedrine lose their eligibility to compete for at least one year.
 35. The ban on ephedra/ephedrine was the result of survey data that suggested ephedra use was linked with the athlete's desire to improve their athletic performance.
 36. Survey results are available online at www.ncaa.org.
 37. *Ibid.*
 38. H.R. 3066, 107th Cong. (2001). House Bill 3066 was referred to the House Committee on Energy and Commerce. It received no further action. However, in conversation with a representative from Congresswoman Davis's office, it was said that the bill would be reintroduced in the 108th Congress. The bill models current California legislation on the control of ephedra for use by consumers.
 39. 21 U.S.C. 343.
 40. See H.R. 3066, section 2(t)(1)(A-E) (listing information to be included on labels containing ephedrine alkaloids).
 41. See H.R. 3066, section 2(b)(1)(2).
 42. As of 8 October 2002, approximately 20 states had legislation regulating ephedra-based dietary supplements. See United States Congress, Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, 8 October 2002. Testimony, Senator Richard Durbin (D-IL), 31 July 2002, retrieved 7 January 2003 from the LexisNexis Congressional database.
 43. See Ohio Rev. Code Ann. § 3719.44(K)(2)(a)(b)(c).
 44. Cal. Health and Safety Code § 110423(a)(b)(c) (2003). Section 110423(c) also requires labels to provide a toll-free number for the reporting of adverse events related to the ingestion of dietary supplements containing ephedrine alkaloids.
 45. In addition to Canada, other countries that have issued warnings or taken action to regulate ephedra-based supplements are Great Britain and Germany. Germany, for example, requires

- that all plant herbals be approved by the Federal Health Agency prior to sale.
46. G.S. Jepson, 'Regulation of Natural Health Products in Canada', *Food and Drug Law Journal* 57/59 (2002), 59–75.
 47. Food and Drugs Act, R.S.C. ch.F-27 (1985) as amended (Can.).
 48. *Ibid.*, 27. Despite the fact that the recall was voluntary, Dr Davis testified that such recalls are almost universally respected, making more rigorous regulatory action and enforcement unnecessary.
 49. Recently, a class action lawsuit was filed against Metabolife International Inc. in the state of Florida. The company manufactures the ephedra-based weight-loss product Metabolife 356. In November 2002 defence attorneys for the company asked a federal court in Miami to dismiss the class action suit, arguing that the plaintiffs had failed to properly support their product's liability claim with evidence that Metabolife 356 is 'unreasonably dangerous'. See *Perez v. Metabolife International Inc. et al.*, No.02 CV 22850, motion to dismiss filed (S.D. Fla., Miami Div. 14 October 2002).
 50. D.L. Herbert, 'Health Club Sued for \$320 Million', *Fitness Management* (October 1999), 68.
 51. K. Reinig, 'The Gym Killed My Wife', *Fitness Management* (September 1999), 40–1.
 52. *Ibid.*, 49.
 53. *Capati v. Crunch Fitness International, Inc., et al.* [N.Y. App. 2002] 295 A.D.2d 181.
 54. *Restatement (Second) of Torts* (St Paul, MN: West Publishing Co., 1965).
 55. I.M. Burnstein, 'Liability for Injuries Suffered in the Course of Recreational Sports: Application of the Negligence Standard', *University of Detroit Mercy Law Review* 71 (1994), 993–1023.
 56. See note 49.
 57. For additional supplement information see: Food and Drug Administration Center for Food Safety and Applied Nutrition, 'Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information', available at <http://www.cfsan.fda.gov/~dms/ds-savvy.html>.
 58. 'Vitamin Maker to Halt Sale Of Ephedra-Based Products', *Drug Recall Litigation Reporter* 6/5 (2002), 14.