

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

**JOHN O. SPENGLER,
DANIEL P. CONNAUGHTON
and ANGELA V. CONNAUGHTON**

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

John O. Spengler is an Assistant Professor, Department of Parks and Recreation Management, University of Florida, Daniel P. Connaughton is an Assistant Professor, Department of Exercise and Sport Science, University of Florida, and Angela V. Connaughton is a Resident, Department of Internal Medicine, University of Florida.

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=aeb9a1c7e09e0f90e6e0390511e20713, 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,

- 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.