

Commentary:

Herbal Remedies and Dietary Supplements: Surveying the Landscape of Litigation Trends

By *Eric M. Kraus and Caroline E. Ohl*

In this analysis, Eric M. Kraus and Caroline E. Ohl of Sedgwick, Detert, Moran & Arnold in New York discuss the litigation trends involving herbal remedies and suggest that manufacturers of dietary supplements may soon face lawsuits similar to those that have confronted the pharmaceutical industry.

I. Introduction

The biblical dictate "man cannot live on bread alone" foretold the end of the millennium explosion of consumer purchases of dietary supplements and herbal remedies. This increasing popularity of herbal remedies and dietary supplements evinces the high consumer demand for alternative natural treatments for traditional ailments. However, manufacturers of dietary supplements may soon find themselves facing many legal issues similar to those that have confronted the pharmaceutical industry, especially those arising from complaints about their products. Supplement manufacturers should be especially vigilant, in light of the recent flood of negative media coverage regarding the dangers of supplements, and the increased public outcry questioning the government's effectiveness as a regulatory watchdog. As complaints mount, even seemingly modest problems can trigger the appetite of an ever-hungry plaintiffs' bar for new and relatively untapped litigation targets. This article offers a broad overview of the impact of the federal regulation on the industry, a look at the current state of dietary supplement litigation and some predictions about future litigation trends. This article particularly focuses on the experience of pharmaceutical products liability and deceptive-trade-practices lawsuits as a window into the future of dietary supplement litigation.

II. Regulatory History Concerning Herbal Remedies and Dietary Supplements

In 1938, Congress placed dietary supplements within the Food and Drug Administration's regulatory authority, and

so began a tumultuous relationship between the FDA and the dietary supplement industry. The passage of the 1938 Federal Food, Drug and Cosmetic Act marked the beginning of many regulatory oscillations of power to come between manufacturers and the FDA. It specifically provided labeling requirements and afforded the FDA authority to regulate dietary foods and declare them, under certain circumstances, misbranded.²

In 1958, the Food Additive Amendments to the Federal Food, Drug and Cosmetic Act were passed and the FDA was empowered to assess the safety of all new ingredients, including those used in dietary supplements,³ by regulating herbal substances as food additives.⁴ Consequently, the onus was now on the manufacturers to establish the safety of their products before selling them.⁵

In 1990, Congress enacted the Nutrition Labeling and Education Act of 1990, which placed limitations on the health claims that could be made on food and dietary supplement labels.⁶ The FDA would only authorize a claim if there was significant scientific agreement among qualified experts that such a claim was supported by the totality of publicly available scientific evidence.⁷

In the face of pre-market approval requirements for safety and efficacy, and explicit labeling requirements, opponents made efforts to prevent the FDA from implementing these regulations regarding health claims appearing on the labels of dietary supplements. The result was the Dietary Supplement Act of 1992,⁸ which called for a one-year delay on the implementation of the Nutrition Labeling and Education Act and mandated that the FDA submit documentation on the issues regarding dietary supplements.⁹

III. The Regulatory and Litigation Landscape Today

To preserve consumers' right to purchase dietary supplements, Congress enacted the Dietary Supplement Health and Education Act of 1994.¹⁰ While food and drugs may otherwise be subject to stringent regulations and testing by the FDA, the DSHEA exempts dietary supplement manufacturers from many of these regulations. Three salient changes under the DSHEA provide supplement manufacturers with a more liberal regulatory framework. First, the statute crafted a broad definition of "dietary supplement." Second, the requirements regarding the labeling of dietary

supplements were modified. Lastly, the burden of proof regarding a product's safety was shifted from the manufacturer to the FDA.

In an effort to make dietary supplements more accessible to American consumers, the DSHEA now broadly defines dietary supplements, creating a new category distinct from food and drugs. This expanded definition explicitly includes products intended to supplement the diet that, for example, contain herbs or other botanical substances; products labeled as "dietary supplements"; and even products approved as new drugs that, prior to approval, were marketed as dietary supplements or as food, unless there is an FDA waiver of this provision.¹¹ The manufacturers' response has been an explosion of supplements.

Another change implemented by the DSHEA deals with labeling. Although the DSHEA does not permit dietary supplement labels to make claims that the product could treat, diagnose, cure or prevent a disease, it does allow certain health claims without an FDA petition. Such claims include statements asserting a benefit related to a classical nutrient deficiency disease, claims about the role of a nutrient or dietary ingredient with respect to the structure or formation of the human body, and declarations of general well being from consumption of a nutrient or other dietary ingredient.¹² A manufacturer is entitled to make these claims by substantiating that the assertion is truthful, and by expressly stating on the label that the FDA has not evaluated the claim and was notified within 30 days of marketing of the product.¹³ A supplement manufacturer that is compliant with DSHEA labeling requirements can be secure that its merchandise will not be regulated as a drug, but as a supplement.¹⁴

The third significant change that the DSHEA effectuated was shifting the burden of proving safety from the manufacturer to the FDA. In fact, a product is considered "safe" if the new ingredient does not present a significant or unreasonable risk of illness or injury under conditions of use recommended in the product labeling.¹⁵ Moreover, if the FDA wishes to remove a supplement from the market, it must "affirmatively prove that the product would be harmful if taken as recommended."¹⁶ This separate threshold for dietary supplements has made it significantly more difficult for the FDA to remove a dietary supplement from the consumer market.

Despite government action and even industry responsiveness, litigation has already made its presence felt for dietary supplement manufacturers. L-Tryptophan, a sleep and depression aid, was one of the first to cause a litigation stir,¹⁷

when the media began reporting that individuals taking the product were becoming ill and dying.¹⁸ In particular, some L-Tryptophan consumers allegedly developed eosinophilia myalgia syndrome, a multi-systemic disorder characterized by severe muscle and joint pain, swelling of the arms and legs, skin rash, fever, and sometimes neuropathy resulting in paralysis.¹⁹ Other herbal supplements and remedies have been under fire as well.²⁰ For instance, a woman allegedly died after imbibing Super Dieter's Tea, which contained senna and other diuretic/laxative herbs that purportedly draw electrolytes from the body, prompting cardiac arrest.²¹

Presently, cases of death and illness attributed to ephedra, a naturally occurring stimulant derived from the Chinese herb ma huang, are on the rise. Some claim ephedra can cause conditions ranging from hypertension, palpitations, neuropathy and myopathy to psychosis, stroke, seizures and death.²² In 1994, a woman in Austin, Texas, died and 100 other Texans became ill allegedly after ingesting "Nature's Nutrition Formula One," leading to at least 21 lawsuits. In 1996, a 20-year-old college student died in Florida allegedly after taking "Ultimate Xphoria," resulting in a lawsuit and a settlement of \$2.5 million.²³ In April 2000, a 15-year-old high school student died during soccer practice after taking the dietary supplement "Ripped Fuel"; this matter, too, was settled.²⁴ In July 2000, the CEO of Chemins Co., one of the country's largest manufacturers of other ephedra products, was sentenced to 21 months in prison and fined \$4.7 million for spiking his supplement product with synthetic ephedrine. In Florida, plaintiffs claiming they suffered cardiovascular injuries after consuming ma huang have a class action suit pending against a manufacturer and distributor of the herbal supplement. Metabolife (an ephedra-containing product), boasted of \$900 million in sales in 1999 and no lawsuits. It currently faces 13 pending lawsuits, including two that are seeking certification as class actions.²⁵

IV. Potential Claims Against Dietary Supplement Manufacturers

Courts are likely to look to traditional products liability law and federal trade law to help define the parameters of this new area of litigation. Products liability cases involving prescription and over-the-counter pharmaceutical products provide some insight into the types of claims that supplement manufacturers may face from consumers.

A. Products Liability Claims

In general, a plaintiff may bring various claims against a commercial seller or distributor of a pharmaceutical product for personal injury. A drug is considered defective if it

contains a manufacturing defect, is not reasonably safe because of a defective design or is not reasonably safe because of inadequate instructions or warnings.²⁶ These types of claims are a useful template for projecting the litigation landscape facing herbal remedy and dietary supplement manufacturers.

1. Manufacturing Defects

Pharmaceutical companies may be subject to strict liability for harm suffered as a result of a manufacturing defect.²⁷ A prescription drug contains a manufacturing defect when it departs from its intended design even though all possible care was exercised in the preparation and marketing of the drug.²⁸ Thus, a manufacturer will be liable even if the plaintiff cannot prove that a manufacturer was aware of the defect or should have discovered it.²⁹ Strict liability puts pressure on supplement manufacturers to maintain uniformity in processing and manufacturing, and compliance with FDA dietary supplement regulations will not provide supplement manufacturers with a defense for a manufacturing defect claim. Therefore, when manufacturers develop design specifications for their products, they must institute and follow adequate quality control measures to ensure that compliance to those specifications is strictly maintained.

2. Design Defects

Drug manufacturers may also be liable if their products are not reasonably safe due to defective design. However, pharmaceutical manufacturers often are protected from liability for this kind of claim since some risks are deemed necessary if the larger benefits of partial drugs are to be enjoyed by the public. Supplement manufacturers will not necessarily benefit from the same shield enjoyed by prescription drug manufacturers with regard to design defects. The foreseeable harms tolerated in certain prescription drugs may not receive similar treatment when courts consider dietary supplements. Moreover, the risk/benefit analysis in a design defect claim is even less likely to be resolved in a supplement manufacturer's favor in the absence of the doctor-patient relationship, one that is always present regarding prescription drugs, in which risks and benefits can be explained by a health care professional.

3. Failure to Warn

Inadequate warnings or instructions to consumers are the classic defects that are raised in products liability litigation.³⁰ Although cases involving dietary supplements have attempted to assert claims for "nutritional malpractice,"³¹ traditional learned intermediary concepts are not likely to

present viable defenses in supplement litigation. First, supplements allow individuals to self-medicate without the need for prescriptions and consultations with medical professionals. Second, intervention by a nutritionist, a diet advisor or a personal trainer does not create the same sacrosanct relationship that arises between a physician and a patient. Moreover, even participation of a physician in recommending a particular supplement may not permit a manufacturer to find comfort in the learned intermediary defense; the looser regulatory framework governing supplements arguably limits even the physician's access to data about specific products.

Supplement manufacturers are likely aware that there is ordinarily no participation by a medical professional with dietary supplements and that it must directly issue warnings to patients. Thus, supplement manufacturers would likely fall outside the learned intermediary rule and potentially be subjected to liability if warnings to consumers are not adequate.

Absent the participation of a medical professional, dietary supplement manufacturers should consider failure-to-warn cases involving non-prescription drugs as more informative for potential litigation. Much like non-prescription-drug manufacturers, dietary supplement manufacturers may also wish to consider providing direct warnings about any ingredients generally known to cause adverse effects and any dangers associated with those ingredients.

Supplements have their own labeling obligations pursuant to FDA regulations. In addition, a supplement label must include directions for use.³² However, even complete compliance with all applicable FDA regulations does not necessarily insulate manufacturers from plaintiffs' claims. Recent cases suggest that FDA regulations set minimum standards; while regulatory compliance is admissible, it is not conclusive of the issue of due care.³³ Although jurisdictional trends differ, dietary supplement manufacturers should be aware that there is room for common-law claims despite compliance with FDA regulations.

B. Unfair or Deceptive Acts or Practices

Pursuant to a long-standing liaison agreement, the Federal Trade Commission and the FDA share responsibilities with regard to dietary supplements.³⁴ The FDA's responsibilities include claims regarding product labeling, packaging, inserts and other promotional materials distributed at the point of sale.³⁵ The FTC's responsibilities include claims in advertising, including broadcast and print ads, infomercials, catalogs and other direct marketing material.³⁶ The FTC produces an advertising guide that specifically

addresses the dietary supplements industry³⁷ and provides advertisers with an overview of pertinent issues. In general, the truth-in-advertising law is based on two propositions. First, the advertising must be truthful and not mislead consumers acting reasonably under the circumstances to their detriment. Second, the advertiser must sufficiently substantiate all objective product claims by a standard of competent and reliable scientific evidence. Therefore, dietary supplement advertisers must be careful about the accuracy of the claims they make with regard to their products and about consistency with available scientific data.

Although many states have truth-in-advertising laws,³⁸ this article only examines federal standards.

1. Interpreting Advertisements

Under FTC regulations, an advertiser is equally liable for claims that are expressly deceptive as well as those that are impliedly deceptive.³⁹ Thus, advertisers should consider their ad as a whole, assessing all of the elements such as the text, the product name and any depictions that it may contain, to determine whether it is expressly or impliedly deceptive. Disclosure of relevant safety risk information must be conspicuous and comprehensible to the average consumer. One way to assess this aspect of advertising and labeling is to use objective surveys to determine how an ad is actually interpreted by potential product consumers.

2. Substantiating Claims

In addition to marketing products clearly and accurately, manufacturers must have a reasonable basis to substantiate any claims made to the Federal Trade Commission. Generally, factors that are considered in determining whether a claim is adequately substantiated include the type of product, the type of claim, the benefits of a truthful claim, the cost or feasibility of developing substantiation, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable.⁴⁰ Specifically, efficacy and safety claims must be supported by "competent and reliable scientific evidence."⁴¹

In assessing the sufficiency of scientific support for a particular claim, an advertiser should ensure that the amount and type of evidence would be considered adequate by experts, are relevant to the product claims being made, and are evaluated in their totality and the surrounding body of evidence.

V. Other Litigation Issues

Supplement litigation will likely involve a variety of complex issues, including expert witness concerns and dealing with the potential of multiple claims through such mechanisms as class action suits, claim aggregation and multidistrict litigation. Dietary supplement manufacturers would be well advised to consider these issues before they are actually faced with a claim.

A. Excluding Plaintiffs' Experts

Because exclusion of an expert may mean the end of a plaintiff's claims, Daubert hearings can be the forum for the real "trial," and drug manufacturer defendants have taken advantage of this whenever possible. *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993). Supplement manufacturers should do so as well. Since the data on herbal remedies in peer-reviewed medical journals is far less available than for traditional pharmaceutical products, plaintiffs have a large hurdle when it comes to meeting the criteria under Daubert.⁴² As gatekeepers, judges take various approaches in determining whether scientific evidence is reliable and admissible. In any event, early assessment of any post-marketing scientific studies will leave supplement manufacturers better equipped to deal with potential claims. Such steps as pre-litigation retention of experts may be a worthwhile cost to help manufacturers appreciate the state-of-the-art of science concerning their particular products. Such retention through counsel may help preserve the confidentiality of any communications with an expert as attorney work product, but likely will not be accorded the greater protections of attorney-client privilege.⁴³

B. Mass Tort Actions

Just as manufacturers of prescription drugs and medical devices are today's mass tort targets,⁴⁴ dietary supplement manufacturers may soon be as well. Pharmaceutical litigation provides an excellent example of the many distinct issues that mass tort litigation poses for dietary supplement manufacturers.

1. Class Action Suits

Class actions were designed to offer individual claimants with small claims the opportunity to obtain judicial relief without bearing the expense of individual litigation.⁴⁵ Dietary supplement manufacturers are already facing class actions and the same special issues that such actions bring with them. Tactically, supplement manufacturers should know that class certification can occur relatively quickly⁴⁶ and the time prior to class certification is crucial for case assessment. Additionally,

early case assessment is especially important for dietary supplement manufacturers to assess the potential for settlement and to prepare adequately for a certification hearing.

2. Consolidation, Aggregation and Multidistrict Litigation

Consolidation and multidistrict litigation treatment are distinct from class action suits. Their purpose is to streamline discovery and decrease transaction costs: the actions are combined and transferred to a single judge or special master to oversee the discovery process.⁴⁷ Once discovery is completed, however, all actions are usually remanded to their respective originating jurisdictions for separate trials, if the MDL or coordinating judge does not achieve a pretrial global resolution.

Consolidation and MDL are likely to be the most common methods of adjudication of mass torts involving the dietary supplement industry. In fact, manufacturers and distributors of herbal remedies and dietary supplements already have some experience in multidistrict litigation. The U.S. Court of Appeals for the Fourth Circuit approved granting broad powers to the MDL panel to simplify the massive number of L-Tryptophan cases.⁴⁸

C. Punitive Damages

Punitive damages are intended to punish the wrongdoer and deter such conduct. If punitive damages trends in drug products liability cases are any indication of the course of punitive damages in herbal supplement litigation, herbal supplement manufacturers should be wary. Punitive damages awards have markedly increased in the past few years, as have products liability and mass tort litigation.

A telling example is the recent Alaska case where the court awarded a record \$13.3 million, including \$12 million in punitive damages to a plaintiff who allegedly suffered a debilitating stroke after taking the ephedra-based weight-loss product AMP II Pro.⁴⁹ Such increases have even prompted some states to enact legislation limiting recovery of punitive damages in drug products liability cases.⁵⁰ Also, some states like New York have adopted the complicity rule for punitive damages, which limits a corporation's punitive damage liability to outrageous conduct that superior officers ordered, participated in or ratified.⁵¹

D. RICO Claims

Herbal supplement manufacturers should also be aware that plaintiffs might attempt to apply the federal Racketeer Influenced and Corrupt Organizations Act in a civil action against a manufacturer. This usually involves allegations of some form of fraud and may include industry trade organizations as co-defendants as a means to satisfy

RICO's "enterprise" requirements. A plaintiff may also allege that an herbal supplement manufacturer intentionally misrepresented its products in advertisements or labels and this constitutes the requisite RICO acts of mail or wire fraud.⁵² The danger of RICO lies in treble damages afforded by the statutory scheme. Fortunately, as with class certification, there are numerous legal barriers that plaintiffs must hurdle for their RICO claims to be sustained.

VI. Corporate Policies Affecting Litigation

In light of the current trends of litigation in the dietary supplement industry, manufacturers should take preventive measures to guard against the threat of litigation and establish corporate policies that will withstand the harsh light of litigation scrutiny.

A. Corporate Document Retention Policy

Implementing a comprehensive document retention policy can be a great benefit to supplement manufacturers that find themselves buffeted by litigation. A document retention plan can generally limit exposure to pre-litigation spoliation penalties if it is reasonably designed, enforced and managed. With potential litigation in mind, a good document retention policy for the supplement industry includes retaining detailed records of testing and product development to document compliance with dietary supplement regulations. Such documentation is especially helpful if the manufacturer exceeded FDA standards and tested its products even more extensively than required by the FDA.

B. Good Manufacturing Practices

Another important concern is the applicability of "good manufacturing practices" to dietary supplements. The articulated role of GMP regulations regarding pharmaceutical products is "to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."⁵³ Although the FDA has not instituted GMP regulations for dietary supplements, there is some indication that such regulations are in the making. In 1997, the FDA considered rulemaking to develop GMP regulations for the dietary supplement and dietary supplement ingredients, and made a submission to the industry for its public comment.⁵⁴ However, to date, these regulations have not been adopted.

Dietary supplement manufacturers should be conscious of the purpose of GMPs and tailor their practices accordingly. Improvements in sanitation and record-keeping can aid in

meeting GMP standards. Although supplement manufacturers harbor legitimate concerns about the cost of implementation,⁵⁵ conforming to GMP standards may be a wise risk-management decision. Whether or not the FDA weighs in on this issue with formal regulation, self-regulation would have the salutary effect of garroting off certain claims that plaintiffs might make as part of manufacturing defect claims or generally about company conduct.

VIII. Conclusion

The increased popularity of dietary supplements in the United States will inevitably lead to increased litigation, especially in the wake of intense media coverage of cases of alleged adverse effects and deaths. Before the potential for litigation develops into lawsuits, supplement manufacturers should consider possible plaintiff claims, examine their trade practices, and be aware of legal and strategic issues that can arise in potential litigation. Establishing sound corporate protocols regarding scientific support for their products, establishing clear labeling, adhering to good manufacturing practices and following sensible document retention policies will help defend and ultimately defeat claims against manufacturers.

¹ Eric M. Kraus is a partner and Caroline E. Oh is an associate in the New York office of Sedgwick, Detert, Moran & Arnold. Amber Rye, a summer associate in the San Francisco office of Sedgwick in 2000, also assisted in the preparation of this article.

² See 21 U.S.C. § 403(j) (1998).

³ See 21 U.S.C. § 321 (prior to 1994 amendments).

⁴ See S. REP. NO. 103-410 (1994).

⁵ FDA Statement on Street Drugs Containing Botanical Ephedrine, April 10, 1996.

⁶ See Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. §§ 301 note, 321, 337, 343, 343 notes, 343-1, 345, and 371).

⁷ 21 C.F.R. § 101.14(c) ().

⁸ See Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (codified in scattered sections of 21 U.S.C. §§ 301 et seq.).

⁹ See Dietary Supplement Act of 1992, Pub. L. No. 102-571, §202(a), (b), 106 Stat. 4501 (1992) (FDA was prohibited from issuing regulations about dietary supplements until at least Dec. 15, 1993).

¹⁰ The Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.) (hereinafter DSHEA).

¹¹ See 21 U.S.C.A. § 321(ff) (2000).

¹² See 21 U.S.C. § 343(r)(6)(A).

¹³ *Pearson v. Shalala*, 164 F.3d 650, 334 U.S.App.D.C. 71 (D.C.

1995).

¹⁴ See 21 U.S.C. § 343(r)(6)(C), 321(g)(D) (noting in part that a dietary supplement "for which a claim, subject to [the provisions regulating misbranding under the FDCA], is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim").

¹⁵ See 21 U.S.C. § 342(f).

¹⁶ *Laura A. W. Khatcheressian, Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 628 (1999). See also, 21 U.S.C. § 342(f)(C) (If the FDA concludes that a product poses an "imminent hazard to public safety," the agency may immediately remove it from the market but must hold a proceeding to evaluate that decision.)

¹⁷ See *Vaught*, 37 Fed. R. Serv. 3d (Callaghan) 134 (5th Cir. 1997); *Martinez v. Showa Denko K.K.*, 964 P.2d 176 (1998); *Kramer v. Showa Denko K.K.*, 929 F. Supp. 733 (S.D.N.Y. 1996); *DiRosa v. Showa Denko K.K.*, 52 Cal. Rptr. 2d 128 (Cal. 1996); *Barela v. Showa Denko K.K.*, 1996 WL 316546 (D.N.M. 1996); *Bell v. Showa Denko K.K.*, 899 S.W.2d 749 (Texas 1995).

¹⁸ See General Accounting Office, report on FDA Management of Dietary Supplements (HRD-93-28R, July 2, 1993), reprinted in 5 FDLI FOOD & DRUG REPORT 4, at 566 (1994) (L-Tryptophan was said to have caused 37 deaths and between 1,500 and 10,000 illnesses from 1989 to 1990).

¹⁹ See *Vaught v. Showa Denko K.K.*, 37 Fed. R. Serv. 3d (Callaghan) 134, *5 (5th Cir. 1997).

²⁰ See Bruce A. Silverglade, *Regulating Dietary Supplement Safety Under the Dietary Supplement Health and Education Act: Brave New World or Pyrrhic Victory?*, 51 FOOD & DRUG L.J. 319, 320 (1996) ("There have been reports that: germanium caused fatal liver damage; comfrey when used internally, caused liver damage; ma huang, also known as ephedra, produced amphetamine-like side effects; jin ba huan provoked life-threatening reactions in children; kombucha mushroom tea killed at least one person who suffered from severe acidosis; royal jelly caused fatal asthma attacks in sensitive individuals; and diet teas containing stimulants and laxatives caused severe dehydration and death.")

²¹ *Porter v. Laci Le Beau*, No. 531430-7, filed (Cal. Super. Ct., San Francisco County, Mar. 29, 1995).

²² What is Ephedrine? (visited Jan. 8, 2001) <http://www.ephedrine-ephedra.com/pages/what_is_ephedrine_1234.html>.

²³ *Schlendorf v. Alternative Health Research Inc.*, No. 3:97-CV-104-RV(SMN), settled (N.D. Fla. May 20, 1998).

²⁴ See Steve Chawkins & Dawn Hobbs, *Death of 15-Year-Old Fuels Concern Over "Energy Pills" Health: Food Supplement is Not Regulated as a Drug Despite its Chemical Similarity to Methamphetamine*, L.A. TIMES, April 16, 1998, at A3.

²⁵ *Guy Gugliotta, Ephedra Lawsuits Show Big Increase*, WASH. POST, July 21, 2000, at A1.

²⁶ RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 6(b) (1998).

²⁷ See RESTATEMENT (THIRD) OF PRODUCTS LIABILITY *supra* note xx, § 2 cmt. A, at 14-17 (1998). See, e.g., *Henningsen v. Bloomfield Motors Inc.*, 32 N.J. 358, 161 A.2d 69 (1960) (holding both manufacturer of a defective automobile and the dealer who sold it liable for product defect on a strict liability theory); *Heaton v. Ford Motor Co.*, 248 Or. 467, 435 P.2d 806 (1967) (same).

²⁸ RESTATEMENT (THIRD) OF PRODUCTS LIABILITY, *supra* note xx, § 2(a) (1998).

²⁹ See, e.g., *Werner v. Upjohn Co.*, 628 F.2d 848 (4th Cir. 1980), cert. denied, 449 U.S. 1080 (1981) (plaintiff merely needs to show that the defendant placed the drug on the market).

³⁰ See RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 6 cmt. d. (1998). See also M. Stuart Madden, *The Duty To Warn In Products Liability: Contours and Criticism*, 89 W. VA. L. REV. 221, 224 (1987) ("The duty to warn is perhaps the most widely-employed claim in modern products liability litigation.").

³¹ Paul D. Rheingold, *Herbal Supplements May Be Dangerous: Supplements May Look Like Magic Bullets for Health Problems But Users May Be Playing Russian Roulette*, 35-NOV TRIAL 42, 46 (1999) (The author describes a case where a gym convinced the plaintiff to pay for a "trainer-nutritionist" who gave her a list of herbal supplements and vitamins to take, and instructed her on where to purchase them. She informed him that she suffered from high blood pressure and was taking prescription medication, but he told her that the exercise should reduce her blood pressure. The plaintiff thereafter suffered intracranial bleeding because of her elevated blood pressure. Such an unused fact pattern may permit a successful assertion of the learned intermediary defense or some deviation.)

³² *Id.*

³³ See FDA, *FDA Talk Paper: FDA Publishes Final Dietary Supplement Rules* (visited Jan. 8, 2001) <<http://vm.cfsan.fda.gov/~lrd/tpsapp2.html>> (discussing revisions to dietary supplement labeling requirements). Other requirements under these rules include: (1) product must be labeled as a dietary supplement and bear the "SUPPLEMENT FACT" panel listing serving size, amount and active ingredients; (2) products containing botanical ingredients must identify the part of the plant used; (3) label must indicate other ingredients in descending order of predominance; and (4) name and place of business or manufacturer, the packer or distributor.

³⁴ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

³⁵ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

³⁶ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

³⁷ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

³⁸ See, e.g., *General Business Law* § 349 (N.Y. statute); *Cal. Bus. & Prof. Code* § 17500 (Calif. statute).

³⁹ An example of an impliedly deceptive claim is an advertisement for a supplement that claims that 90 percent of cardiologists regularly take the product. The literal claim is the percentage of consuming cardiologists while the implied claim is that the supplement offers benefits for the heart. Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

⁴⁰ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

⁴¹ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (visited Jan. 8, 2001) <<http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>>.

⁴² Virginia M. Buchanan, *Study Supplements Before You Take The Case*, 35-NOV JTLATRIAL 44, 44 (November 1999).

⁴³ See *Hickman v. Taylor*, 329 U.S. 495, 508 (1947); *United States of America v. Ackert et al.*, 169 F.3d 136 (2d Cir. 1999).

⁴⁴ See James M. Wood, *The Judicial Coordination of Drug and Device Litigation: A Review and Critique*, 54 FOOD DRUG L.J. 325, 325 (1999).

⁴⁵ See *Amchem*, 512 U.S. at 615-17.

⁴⁶ Many federal and state court rules set a time for filing motions for class certification. See, e.g., U.S. Dist. Cts. R. 23.1 (must file class certification motions within 90 days after the filing of the complaint).

⁴⁷ See *id.*

⁴⁸ See *In re: Showa Denko K.K. L-Tryptophan Products Liability Litigation II*, 953 F.2d 162, 164 (1992).

⁴⁹ See Guy Gugliotta, *Woman Wins \$13.3 Million Against Dietary Company; Jurors Find Product Containing Ephedrine Caused Stroke*, THE WASH. POST, Feb. 8, 2001, at A8.

⁵⁰ See L. Frumer & M. Friedman, *Products Liability*, ch. 14, *Punitive Damages* (Matthew Bender).

⁵¹ See Frank C. Woodside, *Drug Product Liability*, ch. 17, *Damages*, § 17.04 [4] (Matthew Bender).

⁵² See Joseph A. Tate, *Application of RICO to False Advertising Claims*, 766 PLI/Corp 413, 415 (1992).

⁵³ 21 U.S.C. § 351(a)(2)(B)().

⁵⁴ *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements*, 62 Fed. Reg. 5700 (to be codified at 21 C.F.R. Ch. I) (proposed Feb. 6, 1997).

⁵⁵ See Terselic, *Inflationary Impact Assessment of the Proposed Revisions of Current GMP Regulations* (FDA Report, Dec. 29, 1975). This report was criticized by industry members as making unrealistic cost assumptions and was revised before the final drug GMP rules were issued in 1978. See 43 Fed. Reg. 45015 (Sept. 29, 1978).



Eric M. Kraus
Sedgwick, Detert, Moran & Arnold
New York
Eric.M.Kraus@sdma.com

Eric M. Kraus is a partner in SDM&A's New York office. Mr. Kraus concentrates his practice on complex civil litigation matters, with an emphasis on pharmaceutical product and medical device liability. His practice also includes medical malpractice defense of physicians and hospitals. Among the clients he has represented are Bristol-Myers Squibb Co., Pharmacia Corporation, Hewlett-Packard Company, Central Hudson Gas & Electric Corp., PRI and the Federation of Jewish Philanthropies. Mass tort litigation has also been a focus of Mr. Kraus's practice, ranging from DES and asbestos litigation to asbestos and repetitive stress injury claims. He has authored an article on "Junk Science" in the courtroom, which appeared in the April 1994 issue of the *International Insurance Law Review*. Mr. Kraus received his B.A. degree, *cum laude*, in 1976 from Hamilton College in Clinton, New York. His J.D. degree was conferred by Boston University School of Law in 1979. Following graduation from law school, Mr. Kraus joined the Kings County District Attorney's Office in Brooklyn, New York. During the course of his 11-year career with the District Attorney's Office, he prosecuted organized crime, corruption, and murder cases, and served as Deputy Chief of the Rackets Bureau. Mr. Kraus joined SDM&A in 1990.



Caroline E. Oh
Sedgwick, Detert, Moran & Arnold
New York
Caroline.E.Oh@sdma.com

Caroline E. Oh, an associate in SDM&A's New York office, practices in the Mass Tort & Complex Litigation Group. She recently assisted on the Blue Cross Blue Shield v. Philip Morris et al tobacco case. Ms. Oh is a member of the American Bar Association and the Phi Alpha Delta Law Fraternity International - La Guardia Chapter. She speaks Korean fluently. Ms. Oh received her undergraduate degree from Binghamton University (B.A., 1997) and her law degree from Brooklyn Law School (J.D., 2000). During law school, she was a member of the Moot Court Honor Society, on the Dean's List and a CALI Excellence for the Future Award recipient.