Packaging Forensics

Package Failure in the Courts

Walter Stern, C.P.P., A.C.F.E.

Contributors:
Robert J. Bockserman, C.P.P.
Martin K. Brigham, Esq.
G.E. Campbell, C.P.P.
Patrick E. Carr, Esq.
Charles R. Goerth, Esq.
Peter Henningsen, Jr., C.P.P.
Matthew W. Loughren, Esq.
Robert A. Luciano, P.E., C.P.P.
Alfred H. McKinlay, P.E., C.P.-P/M.H.
Francis Patrick Murphy, Esq.
George A. Peters, J.D., P.E., C.S.P., C.P.E.
Grantges J. Raymus, M.E., M.S., P.E.
Barry S. Rope
Jack L. Rosette, Ph.D., C.P.P.
Paul Singh, Ph.D.
Suzelle M. Smith, Esq.
Eunice Trevor, Esq.
Nancy A. Zettler, Esq.

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Email: sales@lawyersandjudges.com

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Chapter 7
Ocular Injuries Caused by Institutional Food Packaging

Robert J. Bockserman, C.P.P.

7.1 Background

A law firm represented the plaintiff, a middle-aged woman, Mrs. Johnson, who came into contact with the food product, jalapeños packed in a vinegar-based juice. The liquid splashed into both of her eyes causing serious injury. The sequence of events that led up to this injury suffered by the plaintiff is as follows:

Mrs. Johnson was an employee of a restaurant, and worked as a cashier and at other periods in the restaurant kitchen preparing food. During one of the periods she worked in the kitchen, she was required to open various cans of food, many of the cans being institutional, No.10 food cans. On the occasion of the accident, she placed the food can on a metal table, used a restaurant can opener and pushed down on the can, turned the opener arm, which opened the lid. The plaintiff then removed the lid, and as she poured the contents out of the institutional can into another container, the jalapeños product and the vinegar-based juice it was packed in, splashed into both eyes of the plaintiff. Although she was an experienced food worker, Mrs. Johnson and the other kitchen and restaurant personnel were given no information as to the irritability and potential injury that this food product could cause to one's eyes.

Restaurant personnel heard Mrs. Johnson screaming, saw what occurred, took her into a back room where they proceeded to rinse her eyes with water and continued the rinse until security personnel took her to a local hospital emergency room. While in the hospital, the plaintiff claimed she could not open her eyes, and later claimed, "she could not see for a couple of days." The plaintiff stated that she had opened many institutional food cans, using the same procedure as with the can in this accident, without every having an accident or suffering injury from this product or any other food product.

The jalapeños packed in vinegar-based juice were processed, canned, labeled and distributed by XYZ Corporation, a large food processor with an extensive line of food products, and the company had been in existence for many years.

The label on the food can properly identify the product packaged within the can, the proper weight and the name of the processor. There was no information

on the label as to the high degree of irritability and corrosiveness that jalapeños juice can have to the human eyes. It was hard for me to comprehend why a warning statement on the harmful effects of jalapeños in vinegar-based juice was not included on the label. This food processor, having a large staff of technically-trained personnel in their analytical laboratories and product development areas, did not have the knowledge or did not research available data and literature as to the irritable chemical characteristics of and the damage that this vinegar-based juice could do to the human eye.

7.2 The Petition: (Key Paragraphs)

1. The liquid in the can was of such acidity as to cause conjunctival and corneal burns to both of plaintiff's eyes.
2. Defendant failed to use ordinary care to design the container so that when the contents were removed from the can, the liquid would not come into contact with an individual's body or splash causing injury such as that sustained by plaintiff.
3. Defendant failed to use ordinary care to adequately warn of the risk of harm from the liquid in the can if it came into contact with certain portions of one's body such as the eyes.
4. As the proximate result of defendant's failure to safely package this product, plaintiff suffered severe and permanent injury to both of her eyes.
5. Plaintiff has incurred substantial medical expenses for treatment of the injuries sustained as a result of this incident.
6. Plaintiff is required to use artificial tears and lubricants to maintain her eyesight and use of her eyes and will have to continue to do so for the rest of her life.
7. Plaintiff has endured and will continue to endure severe pain and suffering as a result of the burns to her eyes and the continued irritation she endures, causing her to require pain medication.
8. Plaintiff has been further damaged by her inability to enjoy many activities because of the irritations that certain activities and environments cause to her eyes.
9. Plaintiff has been further damaged in that the said injuries have affected and interfered with her marital relationship.
10. Plaintiff, Mrs. Johnson, has been further damaged by her inability to maintain steady employment and earn a livelihood and, as the proximate result, plaintiff has suffered a loss of income, which is continuing and will result in additional loss of income in the future.

7.3 One of the Defendant's Answers (Among Many) to the Petition

> For further answer and defense, defendant states that the carelessness and negligence of plaintiff in failing to exercise ordinary care for her own safety in emptying the contents of the can, in failing to use proper eye protection, in failing to keep a careful lookout directly caused, or in the alternative, directly contributed to cause whatever injuries and damages, if any, which plaintiff may have sustained and for that reason, any recovery by the plaintiff must be reduced by an amount representing her proportion of fault.

Note: There was no warning statement on the label that suggested or recommended the use of "proper eye protection," by the consumer, when using this product. The plaintiff knew nothing about the irritability of the product and its potential for injury.

7.4 Technical Background of Product Information for the Basis of Expert Testimony for the Case

The following information provided the background for the expert testimony in the case. Note: Jalapeños contain a varying percentage by weight of the compound capsaicin.

> Capsaicin is the active principle in hot peppers *Capsicum*, and as such it is an important ingredient of the spicy foods typical of tropical regions.
>
> Capsicum fruits contain about 0.1 to 1.0% of capsaicin. Capsaicin forms colorless platelets which have an intensely burning taste (threshold – 10 ppm), melt at 63 to 65° C, and boil at 210 to 220° C. It is only sparingly soluble in cold water and is more soluble in boiling water, but readily soluble in organic solvents such as petroleum benzene, alcohol, ether, glacial acetic acid, hot carbon disulfide, and fatty oils. Capsaicin has a maximum UV absorption at 227 and 281 nm.
>
> The chemical properties of capsaicin have been extensively investigated. It is weakly acidic and contains a phenol group. It is not precipitated, or only very slightly, by the usual reagents which precipitate alkaloids. The phenol group can be methylated to form methyl capsaicin, a derivative with much less pungency than the parent compound. Its pungency is not destroyed by heating with 2% NaOH solution, but is destroyed by oxidation with $KMnO_4$ or $K_2Cr_2O_7$. However, the synthetic capsaicin, having a saturated side chain, is not readily oxidized. Nelson and Dawson clarified the structural formula of capsaicin and found that it is the vanillylamide of dicilenic acid. Its empirical formula is $C_{18}H_{27}O_3N$ and its molecular weight is 305.40 daltons. In addition to capsaicin, four naturally occurring derivatives have been isolated and identified.

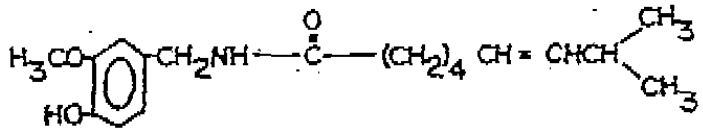
The peculiar pungency of red peppers is responsible for their widespread use as condiments in highly spicy dishes, especially in chili, curries, tabasco sauces, and in beverages such as ginger ale. The local irritating effect upon the nasal membranes which causes prolonged sneezing and coughing with allergic actions is well known to those who have worked with the pure capsaicin. Of similar common knowledge is the burning sensation of the skin produced by local application of capsicum. Capsaicin and therefore capsicum powerfully and locally stimulate heat receptors and may contribute to the lowering of rectal temperature as observed by Issekitz et al. When swallowed, capsaicin creates the sensation of warmth which, with more concentrated solution, increases to severe pain and intolerable burning, hereby leading to associated gastrointestinal disorders. Relatively high doses of powdered chilies given with cooked rice have been shown to increase the amount of saliva and its amylase concentration and to increase fibrinolytic activity of the plasma. There are also variable effects upon the cardiovascular and respiratory systems when capsaicin or capsicum is given either intravenously or orally.

The mechanism of capsaicin desensitization is not quite understood. Its long-lasting desensitization action apparently depends upon the precise molecular structure of the drug in which, in contrast to its pungent property, the presence of an alkyl side chain having an optimum length of 10 to 12 carbon atoms seems essential. Experiments with the cornea, the substantia gelatinosa, the spinal ganglion cells, and the somatosensory nerves of rats have demonstrated that, in the long-lasting (i.e., up to several months) specific desensitization induced by local and systemic capsaicin treatment, the cell bodies of the respective sensory neurons are also effected. Such ultrastructural changes consisted of characteristic swelling of mitochondria and a reduction in the number of microvesicles. The marked alterations in the fine structure of these cellular organelles may lead to changes in the cellular distribution of ionic calcium.[1]

Capsaicin has long been known to produce irritation of skin and mucous membranes upon acute topical application. However, chronic capsaicin treatment, either topically or parenterally, produces an insensitivity to almost all types of chemical irritation which persists for several months while responses to light touch and mechanical stimulation are unimpaired. Capsaicin has also been shown to markedly influence the phenomenon of neurogenic inflammation which can be induced by either chemical or antidromic electrical stimulation of sensory nerves and is independent of axon reflex mechanisms. These inflammatory responses to both topically applied capsaicin and structurally unrelated irritants (e.g., mustard oil) and to antidromic electrical nerve stimulation were completely abolished by either parenteral or chronic topical capsaicin desensitization. This inhibition of neurogenic inflammation produced by capsaicin has been attributed to the inhibition of release of some mediator or modulator of inflammation.[2]

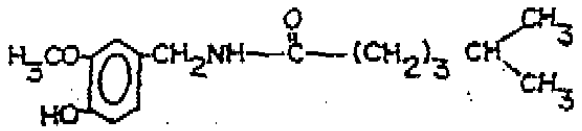
Capsaicin

(MW= 305) N-(3-methoxy-4-hydroxybenzyl)-8-methylnon trans-6-enamide



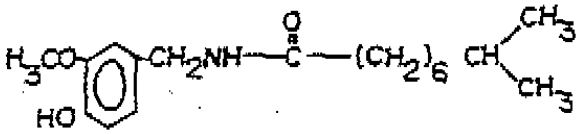
Norhydrocapsaicin

(MW=293) 7-methyl-octanoic acid vanillylamide



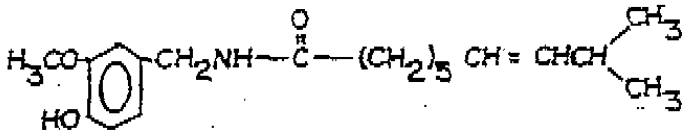
Dihydrocapsaicin

(MW=307) 8-methylnonanoic acid vanillylamide



Homocapsaicin

(MW=319) 9-methyldec-trans-7-enoic acid vanillylamide



Homodihydrocapsaicin

(MW=321) 9-methyl-decanonic acid vanillylamide

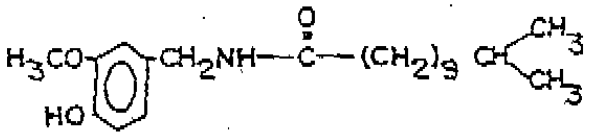


Figure 7.1 Structures of naturally occurring capsaicin and its derivatives

Following a single subcutaneous injection of capsaicin to neonatal mice, a high incidence of corneal lesions with opacity developed after a long latency. The intensity of the lesions progressed for about 1 month in animals which had received a high dose (50 or 100 mg/kg) of capsaicin. Although the intensity gradually decreased thereafter, 50% of animals still exhibited a visible opacity 6

months after treatment. Similar corneal lesions were also produced in neonatal rats which had been injooted with capsaicin. It is suggested that the corneal lesions induced by capsaicin may be due to destruction of the trigeminal nerve.[3]

Normal structure and function of corneal epithelium is known to be related to proper innervation. To investigate possible trophic actions of sensory neurons on corneal epithelium, corneal innervation and various physical parameters are studied in normal rats and in rats treated as neonates with intraperitoneal injections of capsaicin. Corneal lesions were noted in treated rats which varied from multiple punctate areas of corneal opacity to deep stromal opacity with ulceration and neovascularization. These lesions waxed and waned throughout the animal's life. In addition, mechanical threshold of the corneal reflux was higher in capsaicin-treated rats. The tear rate in response to a provocative test was diminished in treated rats, presumably due to reduced afferent trigeminal input to the brain stem; blinking rates were more frequent in these animals. Using fluorescent retrograde tracing techniques, the number of cells innervating the cornea in capsaicin-treated rats was found to be significantly less compared with control animals. Innervation in the cornea (examined using a gold chloride technique) demonstrated a decrease in the number of corneal large axons in treated rats with neurite sprouting from these axons yielding a higher density of nerve fibers compared with controls. Thus, sprouting of residual sensory neurons occurs in response to the partial corneal denervation produced by capsaicin, and this sprouting does not functionally compensate to prevent the development of chronic keratitis.[4]

Administration of capsaicin to neonatal rats is known to induce a chronic keratitis of varying severity. The etiology of observed corneal changes remains undefined. One potential cause of these changes might be increased susceptibility to direct trauma due to reduced corneal sensitivity. These animals have a threshold of corneal blink reflex which is higher than untreated rats. However, if this explained the observed keratitis, rats with lids sutured together before eye opening would not be expected to develop corneal lesions. As noted rats treated with tarsorrhaphy shortly after birth developed keratitis with an average intensity of lesions similar to what has been reported previously. Another potential source of corneal injury is phototoxicity. However, when animals were reared in the dark, they also developed keratitis. Thus, it appears that corneal injury alone does not account for observed corneal changes in capsaicin-treated rats. It may be that, despite an increased density of nerve fibers in capsaicin-treated rats, the remaining sprouted fibers are devoid of certain trophic factors supplied by capsaicin-sensitive neurons which are essential for normal corneal structure and function.[5]

The American National Standard for Hazardous Industrial Chemicals—Precautionary Labeling Handbook recommends the following statement to be added to a label, when the label must identify a product that is an irritant to the eyes:

HAZARD:
Irritant, Moderate Eye
CAUTION: MAY CAUSE EYE IRRITATION
Avoid contact with eyes.
Wash thoroughly after handling.
FIRST AID In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses, if worn.
Call a physician if irritation persists.

For additional information, see Material Safety Data Sheet (MSDS) for this chemical.[6]

The label statements required on hazardous substances are as follows:

1. The common or chemical name of the hazardous substance, or each of its hazardous ingredients.
2. One or more of these four "signal" words on the front panel:
   - DANGER if substance is highly poisonous, corrosive, or inflammable.
   - WARNING or CAUTION on all other hazardous products.
   - POISON (with skull and crossbones) on substances which are poisonous if swallowed.
   - POISON on substances formerly subject to the Caustic Poison Act, such as toilet bowl cleaners.
3. Instructions for any special handling or storage.
4. A description of the principal hazard.
5. Appropriate first-aid instructions.
6. The name and address of the manufacturer, packer, distributor, or seller.
7. The statement "Keep out of the reach of children" or its equivalent.

A hazardous substance in packaged form is considered misbranded if its label fails to include any of the above information. All warning statements and other user-protection information must be displayed in such a way that it may be easily read and understood.

The Federal Hazardous Substances Act defines substances which are hazardous, empowers the government to ban certain substances, and requires that marketed hazardous substances be labeled to caution the user. It may be contrasted with the Consumer Product Safety Act, which primarily regulates product composition.[7]

Note: The Food Labeling Guide distributed by the U.S. Department of Health and Human Services (F.D.A.) gives no information on any regulations that cover a product such as jalapeños, a product that could cause injury to human tissue.

Capsaicin is a pungent irritant substance from *Capsicum* (Hungarian red pepper). On the eyes of rats 50 micrograms/ml has caused obvious pain and blepharospasm. The blood vessels of the conjunctivae and lids became abnormally permeable to Evans blue dye injected intravenously. Application of local anesthetic prevented pain, but did not alter the vascular reaction. Local application of capsaicin is a selective method of activating sensory C-Fibers and causing sensory neuropeptide deliver.

Capsaicin opens neuronal calcium and sodium entry channels, resulting in depolarization of Type C nerve fibers, for which capsaicin is specific.

This irritating effect on the eyes has been utilized in pressurized dog-repellent sprays which incorporate capsaicin. One boy accidentally had his eyes sprayed with this material. His eyes immediately smarted, teared, and became red, but were normal by the next day. Treatment had consisted only of irrigating with water, then mineral oil. Capsaicin delivered postnatally in rats results in decreased corneal innervation and can result in corneal opacities due to axonal degeneration in mice and rats. Capsaicin also slows corneal epithelial wound healing in rabbits, perhaps by depleting neuropeptides from corneal sensory nerve endings.[8]

Ophthalmology

Contact of the substance with the eye results in severe pain and conjunctival inflammation. Ocular exposure to capsicum should be treated with 15 minutes of water irrigation. Topical anesthetics may be required for pain control.

Twenty-three percent of mice given chili extract daily in the buccal pouch until death developed ocular lesions characterized by shrunken eyeballs and closing of the eyelids. The etiology of this lesion is unclear; vitamin A levels are not implicated.

Rat cornea treated with 1% capsaicin develops neurogenic inflammation, swollen mitochondria and reduced numbers of microvesicles in nerve terminals. Substance P is depleted but the nerves do not degenerate. A loss of reaction to chemical stimuli ensues for up to a week.[9]

Oleoresin Capsicum (OC) is the concentrate containing the active compounds from capsicum peppers. The primary irritant activity is attributed to capsaicin. OC has been available as an aerosol chemical irritant used to transiently disable individuals since the 1970s. The sprays generally produce local inflammation, erythema, pain, a burning sensation, and temporary blindness. Although generally regarded as having minimal toxicity, significant pulmonary toxicity has been described. Two deaths have been temporally associated with exposure

to OC-containing products in the lay press. The prevalence and severity of toxicity after OC-spray exposure has not been described in emergency department (ED) patients. The objective of this study was to describe the toxicity associated with OC-spray exposure during law-enforcement actions.

While law enforcement reports indicate that there are no severe or permanent sequelae of OC when sprayed in controlled settings, there is no systematically collected, medically documented information available regarding its potential toxicity. Exposure without preexisting knowledge of the subject and concurrent disease states and health conditions, and use of the product in different settings at varying doses and distances, could result in different degrees of toxicity.

It is unclear what the etiology of the corneal abrasions was in this group of patients. All but one had a chief symptom that included eye pain. One patient also developed photophobia. Eye pain was not a specific finding associated with corneal abrasions, and was also present in most patients without abrasions. There was no consistent pattern of ocular findings such as conjunctival injection, erythema, or lacrimation concurrent with the abrasions.

Frequency of Clinical Presentations and Symptoms After Exposure to Oleoresin Capsicum Spray

SYMPTOM	NO. OF PATIENTS
Ocular	63
burning	45
conjunctival injection	36
erythema	32
lacrimation	13
altered vision	7
corneal abrasion	7
Dermal	26
burning	20
erythema	12
Respiratory	6
shortness of breath	3
wheezing	2
cough	1
throat irritation	1

CONCLUSIONS: The need for ED evaluation and treatment was infrequent after exposure to OC. A transient burning sensation, erythema, and localized irritation were the most common findings. While no patients had adverse outcomes attributed to OC exposure, practitioners assessing exposure should consider the potential for pulmonary and ocular toxicity.[10]

> The relative role of the warning specialist, the system safety specialist, and the company counsel may be dependent on the particular product involved, its packaging, the marketing process, the technical resources of the company, and the applicable regulatory and common law requirements. While the variations in implementation are infinite, the general principles and law are both finite and applied universally. Warnings are important because the failure to adequately warn or to provide appropriate safety instructions could result in serious bodily injury, extensive property or business interruption damages, or the loss of human life. Where the consequences can be severe, the attention given this technical area should be commensurate with the consequences.[11]

It was uncovered during my research and discovery phase of this litigation case that XYZ Corporation had notice of prior claims of injuries to individuals who complained of burns to the human eye as a result of the jalapeños and packing juice coming into contact with the human eye. There was also information on plant personnel whose eyes were injured when coming into contact with the product.

7.5 Deposition Data

I was deposed twice in this litigation case. I testified and presented the following information in my first deposition:

This litigation case involves a woman who opened and emptied an institutional #10 food can (six-pound) of jalapeños packed in juice. The jalapeños juice somehow splashed into both of her eyes and I would like to explain the source of jalapeños and why this food product, in its vinegar-based packing juice, can be so dangerous as to cause serious injury when it enters and contacts the delicate tissues of the eye.

The following are excerpts from my deposition:

1. Jalapeños come from the capsicum . . . family of peppers. Within that family of peppers there is an ingredient called capsaicin. This particular ingredient gives the bite and the heat to a product that contains jalapeños. Without the presence of capsaicin you would not have this biting, heat-producing property of peppers and especially jalapeños.
2. It is incomprehensible to me that XYZ Corporation that has existed for many years would market a product like jalapeños without a warning statement. And their name is on the can so it isn't that they are a distributor or it isn't that someone else has marketed it. It's their product. They sell it under a trade company name which they own.

3. So it's inconceivable to me that they would distribute a product like that with the high degree of acidity which is 3.6 pH (that was tested by a laboratory), and also with the irritability that capsaicin produces to the body without a warning statement. Capsaicin is also listed, and I have this in all my technical literature, as a rubefacient. This is a property of producing redness on the skin and heat and irritability to tissue.

4. Now, if you take jalapeños and put that on your skin you are going to get a tingling effect, and it affects people in different ways. I believe I read that older people are affected to a greater extent, because they have a greater sensitivity to these irritants and these heat-producing ingredients than younger people.

5. Capsaicin is also used in therapeutic uses. For instance they are used in creams, in ointments. One of the items is Zortex . . . cream and ointment that's used for aching muscles. It's used for pain. It has various uses in the body. And on their package and on their tube and on their leaflet, that's put into the carton with the tube of cream it specifically says, "Keep away from the eyes."

6. I can't understand how the XYZ Corporation with all their experience and all their scientists in the food area didn't—either didn't know that this could be an irritant to the eyes or did know and didn't address the issue for the potential injury that it could cause or didn't want to. I don't really know what the story is, the true story. But what I do know is there is a lack of a warning statement on that particular label.

7. Now, I have—I have no information on the master formula of this particular product. I would like to see the master formula to determine what all the ingredients are in percentage by weight and also to determine in that case the percentage of weight of capsaicin in the complete formula. That would give me very, very important information.

It is mandated by the Food and Drug Administration in their Good Manufacturing Practices to have a master formula available. (CFR title 21)

8. The capsaicin-containing product is an irritant and the low pH, which is 3.6, would be considered an acidified or an acidic food. Any

food product below 4.6 is listed in the CFR's as an acidic food. That can is very very difficult to control when you pour from it. By opening up the can you must open and remove the entire can lid which means that when you pour there is a great danger of splash. And where does the splash go? Unfortunately into a person's eye. And that was the injury that was caused to Mrs. Johnson.

9. I can't understand why XYZ corporation did not use for instance this glass jar we have in front of us which has a much—which has a screw cap, a metal screw cap with a liner and is much easier to pour. And there are many, many large containers like this in glass that also have handles on them which is part of the container which makes it very, very easy to pour and prevents in my opinion the splash factor that you have in an open fruit can like this where the entire lid is open and you've got the entire area exposed when you are ready to pour.

10. A warning statement I believe is necessary for a product such as this. Now, we're talking about a product, jalapeños, which contains the capsaicin irritant. That means in my opinion that that has to be—there should be a—there must be a warning statement to the person. And this happens to be in an institutional size food container. There's got to be and should be a warning statement on there so that the person who opens the can knows that they've got to protect their eyes either with goggles or in some way to make sure that that splash does not get into their eyes.

11. So the warning statement should include, and this is almost—in fact it's identical to a chemical that you see on the market: Caution; product is an irritant. That tells the person opening the can that there is a possibility of it causing injury and it's irritating to something, to the skin and especially to the eyes.

12. There are many items that are lightly irritating to the skin or to the palm of a hand, but with the eyes it's a completely different story. Because with the eyes, the eyes being so sensitive and the tissues of the cornea and the eyeball itself are so thin and multilayered that anything that is an irritant that could cause this injury, that was caused in this litigation case acts immediately even if you start flushing the person's eyes within seconds. Those few seconds are enough for that liquid to touch the tissue and start burning into the tissue and causing havoc in the eye area. Number two, there should be the state-

ment—the statement should also include: Open container carefully, because it is an irritant.

13. Number three, there should be a statement: keep liquid away from the eyes.

14. Keep out of reach of children. I don't see that anywhere on the label. One never knows when children are going to wander into an industrial area with their parents or a visit or something and come into contact with a can like that, that's opened or knock it over from a table. Children are very unpredictable as we all know.

15. Because that is an irritant and because that liquid contains the irritant capsaicin, there should be a statement on the label stating the emergency phone number of the manufacturer or the distributor. Now, in this case, I don't see a distributor name on the label, so I suspect—I feel that the distributor does not enter into the distribution chain and it was sold directly to retailers or institutions. But it should have the emergency phone number of the manufacturer and who to call if there is an emergency.

16. Now, let's get to the first aid statement. The first aid statement should be in bold letters, just as if it were a chemical. And it should say: "If liquid product comes into contact with the skin wash off immediately with water." That's the first part of the statement. The second part of the statement should say, "If liquid product comes into contact with the eyes—which is a separate entity and has to be handled separately—wash with running water immediately." It's not just putting some water in the eye. You've got to have running water to wash out that irritant immediately. And immediately seek medical attention.

17. That's how I feel on this particular product. I'm basing all this information on being a research chemist at Monsanto for six years and working with many, many different toxic products, with many toxic agricultural chemicals and we were very, very careful with everything, everything that we did especially when chemicals could come into contact with our eyes.

18. I have gotten chemicals on my fingers sometimes, not very often. I've had a few burns on my hands from chemicals spilling or a chemical maybe that was on the outside of a bottle that I didn't know about. But the eyes, I always protected myself with goggles and made sure

that I protected my eyes because damage to the eyes many times is not reversible. The damage is there and you might have to live with it the rest of your life and you probably do in case there is a serious injury to the eye. That is in essence my opinion on this product. I am looking at this product as a chemical, even though it is a food product.

19. My chemical background tells me that it has to be handled differently than if that can were with milk or that can was packaged with tomatoes or with corn on the cob or something like that. You've got a very, very dangerous product because of the capsaicin as one of the irritating ingredients in the product.

20. And I also base this opinion on the technical literature that I have reviewed on many studies that have been performed on small animals, rabbits, guinea pigs, mice, white rats, of capsaicin contact on the skin and also in the eyes. There are many studies that have been completed, and it shows the injuries to the cornea and to the eyes and to physiological changes that have occurred because of capsaicin in contact with the eyes and in contact with the skin. These were research projects that were conducted by various universities, chemical centers and medical centers to determine just how serious and how dangerous and how irritating the product and ingredient capsaicin really is.

I was asked by the opposing attorney if I have been trained as a physician which I immediately answered that, "I am not a physician." The opposing attorney asked, "Would you defer to a physician concerning matters pertaining to the injury to Mrs. Johnson in this case and what it is or is not caused by?"

I answered directly, "I believe so because I will not testify as a medical man. I am not a medical man."

I testified that, "The juice or the brine that is added intentionally contains vinegar for a certain technical purpose, as a preservative. If you did not have the vinegar in the juice, the peppers would spoil before the customer ever opened the can. It is my opinion because of everything that I've read on capsaicin that it is a dangerous irritant."

I was asked by the opposing attorney if the danger from the product was because it was an irritant or was it due to the acidity level of the product. My answer was as follows: "It's my opinion that it's both. There's a problem with low acidity, and the acidity has a pH of 3.6 on the pH scale, and the presence of

capsaicin. A food product that has a pH of less than 4.6, 4.6 or less is considered an acidic food. And that's very clearly spelled out in CFR title 21. The FDA must have this information on what the pH of a product is because of microbiological activity, because of the way it has to be thermally processed and other criteria. There's more criteria. There are nonacidic foods and there are acidic foods and they are handled differently and spelled out in the CFRs."

I was asked by the opposing attorney if it was my opinion that the six-pound XYZ Corporation #10 food can in any way, shape or form violates government regulations concerning labeling for a product of its kind. My answer to this question was: "To the best of my knowledge, no. I don't see any violation. The labeling, the food labeling regulations by the Food and Drug Administration are very broad. It's not on a product by product basis. They tell you the information that you require, the name of the manufacturer, the product, preferably a picture of the product, and now under the new nutritional labeling you must have a list of the ingredients and the nutritional values according to—for instance the calories and protein amount, the carbohydrate amount, some of these other ingredients, cholesterol, any sugar to protect diabetics."

I repeated a request many times during the deposition, that, "It's so important for me to get a copy of the master formula for this product."

The amount of Capsaicin would be important to know. In addition, "There are three other chemicals, organic chemicals that are closely related to capsaicin. There are, I believe, four different types of capsicums. It's like a family, and the family is called capsinoids . . . . And there are four or five different types of capsaicins. Capsaicin itself is the most irritating which is in this product. The other three are less irritating."

When asked by the opposing attorney what other foods am I aware of, that display eye irritants in them, whether or not the irritant is Capsaicin. My answer to this question is as follows: "Pickles would be one. Anything with vinegar would—could cause irritability. When we talk about irritability we have to define it. Either the irritability is just a mild irritability. It can be washed out very quickly with water and the eye recovers very quickly. You might have bloodshot eyes or you might have a little irritation for twenty-four hours. That's one thing. But when you are talking about capsaicin based on the animal studies that's a bad culprit."

When asked by the opposing attorney, "Have you ever been involved in other cases in which eye contact with food products caused or allegedly caused eye irritation or eye damage?"

My answer to this question was: "No. This is my first case that has contact of

a food product causing injury to the eye. Now, I have reviewed many studies involving chemicals in the eye, various types of chemicals, and damage to the eye. But this is the only case that I have had where a food product has caused serious injury and irreversible damage."

I explained my interpretation of the "splash" factor:

> You have a large opening and all of that material will want to eliminate itself because of gravity, to pull itself out of that can as soon as possible, hitting the secondary container that you are going to pour it into. And you've got a large amount of liquid. If you had a four-ounce bottle that's one thing. You've got a lot of liquid there. I haven't calculated the total amount of liquid but it's very easy using the formula $V = 3.14r^2h$. In five minutes you can calculate the total amount of liquid in that can. So you have a splash factor. Now, let me repeat. If you had corn packed in there and you have splash, the liquid—the corn is packed as corn cobs or creamed corn it's not going to be irritable to the eye. With a smaller opening it's much easier to control that liquid coming out of the container. The shoulders will help to control that liquid so you don't have that splash factor. I would be reluctant to pour anything out of a large can like that.

This six-pound, #10 institutional food can, because of the large opening, is very difficult to handle, when it is required to pour some of the contents from the can to another container.

> But what I'm basing it on is pouring chemicals for the last forty-three years. And I have received chemicals in large cans but these were liquid chemicals so you must puncture—make two punctures; one for the air to enter and one for the liquid to pour out. But I don't recall ever trying to pour something where there are solids and liquids in the same can with a sized can like that. It's very difficult to control a product with a size opening like that when you have solids and liquid. If it were only liquid there would be no problem. You wouldn't have to cut open the entire lid.

The opposing attorney asked me if I thought the can was defective. My answer was:

> No, I can't say that that can is defective. There's nothing defective about that can. When you say defective that means is there a hole in the can, is the seam busted, is there something wrong with the tinning, is there a wrong composition of tin, are there rust marks. That means a defective container. There's nothing defective about that particular container. It's just the wrong container in my opinion for jalapeños with a capsaicin percentage in there as an irritant.

Additional information that I believe was necessary for me to receive before I would present further opinions at trial:

1. A copy of the master formula.
2. Processing information on the product.
3. Packaging information on the product.
4. Specifications of the ingredients used, and the packaging components.
5. Steps in the formulation of the product, equipment used.
6. FDA complaint file—XYZ Corporation.
7. Copies of FDA inspection reports of the plant site.
8. Company information on XYZ Corporation employees that were injured by this product.
9. Company information on XYZ Corporation consumers that were injured by this product.
10. Any changes in the product formulation in the last ten years.
11. Any changes in the packaging of the product in the last ten years.
12. Copies of company quality control and testing data and test procedures.

The only statement I can make is something tells me because of experience, because of my educational background, that there may have been injuries by a jalapeño product to people in the past. Maybe it wasn't reported, number one. Number two, maybe there wasn't enough to get into a person's eye to really cause the damage that Mrs. Johnson has received. Maybe it was covered up by a company or companies. But I think there have been injuries. But I can't base that—I don't have any evidence, and I don't have the data. And I'm just saying that from experience that something tells me that there may have been injuries. On the hand and on the skin and on the face it probably wasn't reported. A little tingling, a little heat or something one receives to that effect. But damage to the eyes is something that many times in most cases is irreversible damage and causes permanent impairment of sight.

It would be very helpful to see—a copy of the FDA inspections of the plant that processed this particular product. Why? To see if there were any problems in

processing, to see if there were any problems in packaging, to see if the plant is running according to and complying with the regulations of the Federal Food and Drug Administration, GMPs, and comments on cleanliness and training of the people, and any other items. There is a long checklist that the FDA inspectors have.

I also added that it is important to know how it's formulated: "Something like this is probably formulated in two or three different steps where some ingredients are formulated in a batch and another batch of another two or three ingredients, and then after the batches are completed they are combined for the final batch."

If you are a manufacturing company, OSHA (Occupational Safety and Health Agency) requires a file on injuries to employees—incurred during employment. That would be complaints from the outside. It would be also helpful to know and very important, not only helpful, very important to know whether any of the workers in the plant processing and packaging this particular product had ever gotten this product into their eyes. And that's according to OSHA. I'm more than sure they must keep that record, if there were injuries. That's federal law. If there have been injuries to consumers or injuries to workers, there is a high probability that there is information in the literature, in technical literature available to the public on injuries to humans, to human eyes from this particular product.

7.6 Searching Technical Literature

From experience in searching, and I've been doing this all my life and still learn something new every time I do a search, that if there is any literature available on injury to the human eye on capsaicin I'll find it if it's been published. It's just a matter of time. If it's proprietary information that a company keeps and does not publish it and does not report it then you can't—that's it. You can't—it's there but you can't get to it. And I have seen many occasions where companies have proprietary information and do not disseminate the data to the scientific community or the general public.

The opposing attorney wanted to know what was my basis for stating that XYZ corporation was negligent in its packaging and/or labeling of the product. My answer was as follows:

Now, I'm not saying the word negligent in a legal sense because I'm not an attorney. I'm saying it from the standpoint that they missed the point. It was their responsibility. It was XYZ Corporation's responsibility if they knew that the product had an irritable ingredient, and they should have known because it is

their product, they should have had a statement on there at least to say Caution: Do not get this into your eyes; be careful, when handling this product. If the liquid comes into contact with the eyes, wash immediately with copious amounts of water and call a physician immediately—for necessary medical help.

There is no regulation at the present time from the FDA on warning statements that could cause injury, from food products. The one exception is a warning statement related to the handling of food products packaged in aerosol cans.

I was deposed a second time by the defense, because I had found new information on Capsaicin injury to humans. I testified and presented the following information in my second deposition:

I contacted five doctors based upon information given to me by my attorney and found three articles related to human injury from Capsaicin, which was an ingredient in a formulated product.

I contacted the one doctor in California that thought that there was another case involving Capsaicin injury to a person, outside of Mrs. Johnson's case, a different case completely, but he could give me no information. I could not obtain information from this doctor and he may have been prohibited from doing so.

I contacted the Ophthalmology Department at the University of Chicago . . . and they told me to look through MedLine. And then another doctor told me to check the *Archives of Ophthalmology* for the year 1997, which I did at Washington University Medical School Library (St. Louis, Missouri), which I have access to, and found nothing for the entire year of 1997 in these archives that pertains to any injury of Capsaicin to humans.

An index at the end of the year in the archives gives every article that has been written through the entire year of every month. I also contacted a doctor at the University of Illinois - Champaign, Illinois that suggested I research the 'medicine' database. The copies of the three articles were delivered to my attorney and also provided to the opposing law firm.

I was finally provided with information (based on the deposition of an XYZ Corporation employee) that there were prior injuries to some employed at the XYZ Corporation while filling and packaging the jalapeños product. I was also able to review plant regulations and the master formula of the product. The master formula stated that there were jalapeño peppers in the product, but the percentage of Capsaicin was not listed. Capsaicin is an inherent ingredient in the peppers.

The first article is from *The Annals of Pharmacotherapy,* and it describes toxicity from aerosol exposure. It is a case study from patients at the Truman

> Medical Center Emergency Department. The last paragraph of this article discusses the fact that this study reviewed 81 patients brought to an emergency department over a three-year period who had been exposed to these types of sprays that law enforcement policemen use, these sprays were of the hot pepper type sprays, which incapacitates the average person. And that those that did had effects most commonly seen described in the article as transient burning, erythema, and localized irritation. To the best of my knowledge, there is no FDA or any other governmental agency literature about the use of Capsaicin in food products.

I was asked by the opposing attorney, if: "In your work, Mr. Bockserman, have you ever looked at the issue of the use of Capsaicin in medicines, in therapeutic products?" My answer was:

> In my research and discovery for this litigation case, I have also looked at the issue of the use of Capsaicin in medicines and in therapeutic products. I uncovered articles involving the use of Capsaicin in arthritis ointments packaged in collapsible tubes. The heat produced by the Capsaicin is of medicinal value for pain from arthritis, rheumatism and aching joints. The amount of Capsaicin in the formulation is clearly stated on the ointment tubes of medicinals, that I investigated for the case. There was no percent of Capsaicin stated on the label of the XYZ Corporation jalapeños, therefore the consumer lacked knowledge as to how this food product compares to medicinal products.

What complicates the situation of trying to determine the Capsaicin strength (or %) in a given can of jalapeños is that the amount of Capsaicin in a particular pepper varies from pepper to pepper even among jalapeños and therefore, there is a certain amount of variation. One can pick a pepper from one field and pick a pepper from another field and they are both jalapeños and they are both three inches long and they are both green and they are both going to get identically packed and they can have different amounts of Capsaicin.

I would like to reiterate the FDA plant inspection process. Inspections are an integral part of the FDA for food, drugs and medical devices under the Food, Drug and Medical Device Act. Copies of inspection reports are very important. It is not that the product was defective in any way or below quality or out of spec or anything, we're not talking about a defect in the product or the package. This litigation case is primarily concerned with injury that was caused by the Capsaicin content in the formulation of jalapeños peppers packaged in an institutional can for food service use with apparently no warning statements on the label as to the irritability of the product and what precautions to be employed when opening and pouring the contents of the can.

7.7 Defendant's Motion for Partial Summary Judgment

The defendant's attorney raised the following points:

> Defendant's Motion for Partial Summary Judgment (the "Motion") seeks judgment on plaintiff's failure to warn claims and plaintiff's loss of consortium claim. The failure to warn claims fail because there is no evidence that an alleged failure to warn was the cause of plaintiff's accident. The loss of consortium claim fails because plaintiffs married after they knew of Mrs. Johnson's injuries. Plaintiff's response to defendant's Motion failed to raise a genuine issue of fact as to these claims. Defendant's Motion should, therefore, be granted.

The following points of law and cases were cited by the defense:

1. Plaintiff presented no evidence that an alleged failure to warn was the cause of the accident. *Arnold v. Ingersoll-Rand Co.*, 834 S.W. 2d. 192, 194 (Mo. banc 1992). In its Motion, defendant showed that an additional warning would not have altered plaintiff's behavior. That showing entitles defendant to summary judgment.
2. *Trotter's Corp. v. Ringleader Restaurants, Inc.*, 929 S.W. 2d 935, 939 (Mo. App. 1996). Defending party may establish a right to judgment by showing facts that negate any one of the elements of claimant's claim.
3. Arnold, 834 S.W. 2d at 194. Here, in order to avail herself of the heeding presumption, plaintiff had the burden to show she did not know that pepper juice exposed to the eye could be harmful. Plaintiff did not even attempt to meet this burden. She presented no evidence on the issue of her knowledge. Thus, the presumption does not arise.
4. Plaintiff failed to raise a genuine issue of fact as to the loss of consortium claim. Loss of consortium claims are precluded as a matter of law where either spouse is aware of the injury at the time of the marriage. *H.R.B. v. J.L.G.*, 913 S.W. 2d 92, 99 (Mo. App. 1995). Defendant showed that plaintiffs were aware of Mrs. Johnson's alleged injuries prior to their marriage. Plaintiffs admit this fact, but claim they were not "aware of the permanent nature of the injury" before their marriage.

7.8 The Order of the Court on Whether a Partial Summary Judgment Was to be Granted

> Counts I and II of Plaintiff's petition allege claims of negligence and strict products liability against Defendant, for defective design and failure to warn about the dangers of the characteristics of the liquid in the can and of the possibility of its splashing onto portions of one's body, including the eyes. Plaintiff contends that the can of jalapeños was then unreasonably dangerous when put to

a responsibly anticipated use without the knowledge of the characteristics of the liquid contained therein.

Defendant contends it is entitled to summary judgment on Plaintiff's *failure to warn claims, because Plaintiff testified in her deposition to the effect that if a warning had been placed on the can as to the acidity of the liquid therein contained and the harmful effects of its contact with the eyes, she probably would not have read it. Defendant cites* Klugesherz v. American Honda Motor Co., Inc. *929 S.W.2d 811, 816 (Mo. App. E.D. 1996) in support of his argument.*

Defendant contends that Plaintiff's speculation as to how a warning would have altered her behavior is not admissible evidence, and that inadmissible evidence cannot be considered by the Court in determining the outcome of this motion.

Defendant cannot use such speculative and immaterial testimony as a fact entitling it to summary judgment, just as Plaintiff cannot use it to create a disputed fact issue in opposition.

To establish causation in a failure to warn case, Plaintiff must establish two things. First, Plaintiff's injuries must be caused by the product from which the warning is missing. *Arnold, at 194; Klugesherz v. American Honda Motor Co.*, 929 S.W. 2d 811, 814 (Mo. App. E.D. 1996); *Tune v. Synergy Gas Corp.*, 883 S.W. 2d 10, 14 (Mo. banc 1994). Such a fact is undisputed in this case. Second, Plaintiff must show that a warning would have altered the printed message alleged to be a failure to warn. *Arnold v. Ingersoll-Rand Co.*, 908 S.W.2d 757, 763, (Mo. App. 1995).

Missouri, like several other states, aids plaintiffs in providing this second part of causation by presuming that a warning will be heeded. *Duke v. Gulf & Western Mfg. Co.*, 660 S.W. 404, 419 (Mo. App. 1983).

Plaintiff has made such a showing in her affidavit: If there was a warning on the can about potential injury from the pepper juice, I would have acted differently. I would have:

a. Been very careful when taking the lid off the can and emptying the peppers from the can, to prevent or minimize the amount of pepper juice that got on my hands that day;

b. Used tongs to remove the peppers from the container instead of turning the can upside-down to empty the peppers into another pan;

c. Gone to the hospital immediately after the pepper juice splashed in my eyes, instead of waiting for the security personnel to escort me to the hospital;

d. Wore eye protection to prevent the pepper juice from getting into my eyes.

Such testimony demonstrates that Plaintiff did not know of the potential injury the pepper juice could cause before her accident. The procedures that were put in place after Plaintiff's accident, namely the wearing of gloves,

goggles and the following of additional instructions when opening the can of jalapeños, which were not in place before Plaintiff's accident, are additional evidence that Plaintiff and her superiors did not know of the potential danger of opening and pouring out a can of jalapeños. The Court finds that Plaintiff has established causation by making an ample showing that she did not know of the potential danger of the pepper juice.

Defendant's Motion for Partial Summary Judgment was called, heard and submitted. The Court has considered the pleadings, arguments and authorities and now rules that the Motion is Denied.

7.9 My Conclusions in This Case

The following information is the author's opinion directly from the deposition:

Considering that there was no warning statement on the can and to exercise caution because the product is irritable especially to the eyes, there was no way for anyone to know what that product could do when it splashed into a person's eyes. If there is no statement, the average person will not know that there could be a problem or a potential for a problem.

Because it is an irritable mixture and contains an irritating product and has low acidity, the pouring of that product requires caution because you have solids and liquids that tend to splash. Therefore it is very difficult to pour from that particular can considering the dangerous nature of the product. It's difficult to pour. I would also have trouble pouring from that can.

The first aid statement should be listed as a separate statement. "First aid" has to stand out so that if anyone is injured because of a product, they have to be impelled to immediately go to the first aid section and the statement should give them information on procedures to undertake.

It is my opinion that XYZ Corporation was negligent in not putting a warning statement on its label that there is an irritable ingredient present in the jalapeño product, which could cause injury to the eyes.

If a prominent, conspicuous warning statement of product irritability to the eyes had been present on the can, I know to a reasonable degree of certainty that this accident may not have occurred to the Plaintiff.

It was my opinion that the defects in the package (which led to the eye injury sustained by Mrs. Johnson) were due primarily to a lack of a warning statement on the label, the container was not suitable because of its large opening which led to difficulty in pouring or removing of the product and the lack of a handle which required direct attachment to the can, which could have expedited the pouring process, from one container to another.

The warning statement should have contained the following information:

1. Caution, this product is an irritant to living tissue and could cause serious injury to the eye.
2. Open container carefully and use utmost care in removing product and pouring contents.
3. Keep liquid away from the eyes. This product in its liquid is highly irritable to the eye tissues and could cause serious, irreversible injury to the eyes. Seek immediate medical attention.
4. "Keep out of reach of children" in a contrasting type-face and color, surrounded by a separating border.
5. An emergency 800 phone number of the manufacturer or packager of the product should be displayed—in the event of injury whereby medical personnel can quickly contact the company distributing the product to obtain proper product information.
6. A separate and distinct first-aid statement to present necessary information on the need for immediate washing with cold water of any living tissue that has come into contact with the product or its packing juice.
7. To use protective devices such as goggles, a face mask, rubber gloves, rubber apron—to prevent the product from coming into contact with the human eye or other body tissue.

It is my opinion that there may have been other cases of people receiving eye injuries from jalapeños, but the record did not show the actual cases. In my research and discovery work on this litigation case, I was unable to uncover additional case information. I can offer one explanation; There may have been injuries and the injury was not reported by medical personnel or hospital emergency rooms. Another explanation I can offer is that consumers may have been injured and never sought medical attention, if the injury was not severe, the healing process was of short duration, or the consumer did not file a complaint with the CPSC.

This case was moving toward a court trial, but a settlement was made by the plaintiffs and defendants before it went to trial. I was not advised as to what the final settlement terms specified. I have not been able to obtain the facts of a settlement. It has been my policy to state to my clients that I am assisting on a case, that I hope that I have helped, that I did my very best to bring out the true facts of the case and that I hope we secured a good settlement for the client.

Notes

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2. Robert M. Virus and G.F. Gebhart, "Pharmacological Actions of Capsaicin: Apparent Involvement of Substance P and Sortonim," *Life Sciences*, Vol 25, No. 15, (1979), pages 1275–1276.

3. Tako Shimizu, et al., "Corneal Lesions Induced by the Systematic Administration of Capsaicin in Neonatal Mice and Rats," *Archives of Pharmacology* (1984), 326: p. 347.

4. Christopher S. Ogilvy, Karen R. Silverberg and Lawrence F. Borges, "Sprouting of Corneal Sensory Fibers in Rats Treated with Capsaicin," *Investigative Ophthalmology & Visual Science*, Vol 32. No. 1 (Jan-1991). p. 112.

5. Christopher S. Olgilvy and Lawrence F. Borges, "Changes in Corneal Innervation During Postnatal Development in Normal Rats and in Rats Treated at Birth with Capsaicin," *Investigative Ophthalmology and Visual Science*, Vol 31, No. 9 (Sept. 1990), p. 1814.

6. American National Standards Institute, Inc. ANSI-Standard Z 129.1-1994, New York: American National Standards Institute, Inc., p. 35.

7. Lawrence E. Hicks, *Product Labeling and the Law*, (1974), New York: American Management Associations, p. 20.

8. W. Morton Grant, M.D. and Joel S. Schuman, M.D., *Toxicology of the Eye*, 4th Edition, (1992), Springfield, IL: Charles C. Thomas, p. 311–312.

9. Rebecca L. Tominack RPh, MD and Daniel A. Spyker, PhD, MD., "Capsicum and Capsaicin—A Review," *Clinical Toxicology*, 25(7) (1987), p. 597.

10. William A. Watson, Katrina R. Stemel and Ellen J. Westdorp, "Oleoresin Capsicum (CAPSTUN) Toxicity from Aerosol Exposure," *The Annals of Pharmacotherapy*, (1996) July/August, Volume 30, pp. 733–735.

11. George A. Peters, "Warnings and Instructions," *Hazard Prevention*. Capistrano Beach, CA: Gallant/Charger Publishers, Jan/Feb-1986, pp. 16–17.

About the Contributors

Robert J. Bockserman, C.P.P. is President of Conatech Consulting Group, Inc., Creve Coeur, Missouri. His responsibilities include the management of product, packaging and engineering projects, and he serves as a technical consultant to the food, drug and medical device industries. Mr. Bockserman was a Research Chemist for Monsanto Company and the founder and president of Pharma-Tech Industries, Inc., a contract manufacturing and packaging corporation. He is a visiting lecturer at the University of Missouri-Columbia, conducting classes in Food Toxicology; University of Missouri-Rolla College of Engineering, conducting classes in Packaging Engineering, Federal Regulations, and Forensic Engineering; the University of Missouri-Graduate Extension Program, conducting classes in Food Litigation and a visiting lecturer at the Kellogg Graduate School of Management and Engineering-Northwestern University, conducting seminars in Environmental Auditing. He has completed numerous projects in the areas of product/package development and toxicological problems related to chemical, medical and pharmaceutical products, and serves as an expert witness in product liability, patent infringement and toxicology litigation. He is listed in various editions of *Who's Who in Science and Engineering, Who's Who in Finance and Industry* and in *Who's Who in the Midwest.* He has had many technical articles published in various magazines and is a technical reviewer for four journals. Mr. Bockserman earned a B.Sc. and an M.Sc. in Food Technology from the University of Missouri-Columbia and also attended the St. Louis College of Pharmacy and Bradley University, Peoria, Illinois.