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May 15, 2006

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**Re: Analysis of Proposed Legislation on Mandatory Adverse Event Reporting**

To Whom It May Concern:

We have been asked to provide the perspective of a product liability defense firm with respect to the potential legislation under the Federal Food, Drug, and Cosmetic Act placing mandatory adverse event reporting requirements on manufacturers, packers, distributors, and retailers<sup>1</sup> of dietary supplements. Among other things, placing mandatory reporting requirements on the dietary supplement industry will create an unreliable body of evidence that will have the potential for a significant negative impact on manufacturers, marketers and retailers of dietary supplement products in product liability cases and likely will increase the total number of cases to which they are exposed.

**SUMMARY OF CONCLUSIONS**

- Mandatory adverse event reports will contain little information of reliable quality and will be misleading based on existing conditions of patients and intake of other substances.
- The unreliable adverse event reports will be used to vest manufacturers with knowledge of potential product risks which may be unsubstantiated.
- The proposed amendment contains ambiguities that will result in difficult and varied compliance among manufacturers, packers, distributors, and retailers.
- Any perceived noncompliance with the mandatory reporting requirements can and will be used against manufacturers, packers, distributors, and retailers to establish product defectiveness.
- Mandatory adverse event reporting requirements will force these parties to produce the reports in litigation, which will be time-consuming, expensive, and will subject manufacturers to undue criticism and unreachable standards of performance.

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<sup>1</sup> The potential legislation's provisions regarding retailers apply only to a retailer whose name appears on the product's label as a distributor.

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- The adverse event reports will be used against manufacturers, packers, distributors, and retailers as a substitute for reliable causation evidence.
- There is a real potential for abuse of the underlying data contained in the adverse event reports.

## BACKGROUND OF THE FIRM

Rumberger, Kirk & Caldwell was founded more than 25 years ago as a products liability litigation firm. Throughout the firm's history, it has played a leading role in the defense of product manufacturer's strict liability and negligence claims. Some of the firm's clients include General Motors, Outboard Marine Corporation, Nissan, Dow, and Tyco. Our partners are leaders in product liability litigation and have been recognized in the National Law Journal, Florida Trend, and in other publications. Our trial teams have been called upon to represent manufacturers in serious claims from Maine to California. The firm has grown from four lawyers in Orlando to more than 70 lawyers in Orlando, Tampa, Miami, Tallahassee, and Birmingham.

## BACKGROUND ON PRODUCT LIABILITY LAW

The doctrine of strict liability is premised on various policy objectives, including encouraging greater manufacturer investment in product safety, reducing the litigation transactional costs associated with proving manufacturer fault or negligence, and recognizing that manufacturers are in a better position to insure against such losses. The emphasis is on creating incentives for manufacturers to achieve optimal levels of product safety in designing and marketing products. Most courts apply a balancing of risks and benefits to determine reasonably foreseeable risks for defective design and defects based on inadequate instruction or warning.

A product defect claim may be based on claims of a design defect, a manufacturing defect, or inadequate warnings or instructions. As to design defects, the issue is whether reasonable manufacturers, possessing the knowledge that a reasonable manufacturer had or should have had about the risks and benefits attendant to the use of the product, would sell or manufacture the product. Failure to warn claims typically point to the manufacturer to supply the consumer with such information so that the consumer can make an informed choice as to whether to consume the product. These duties arise only with respect to risks of harm that are reasonably foreseeable at the time of sale.

Injured plaintiffs may also pursue product liability actions under a negligence theory, which requires the following elements: 1) defendant owed plaintiff a duty of care; 2) defendant breached the duty of care; 3) plaintiff was injured; and 4) defendant's breach of duty proximately caused plaintiff's injury. As compared to strict liability, a plaintiff must demonstrate the defendant's failure to meet a reasonable standard of care in a negligence action. Regulatory guidance or policy, voluntary industry standards, and performance standards establish the duty of

care. A manufacturer may be liable for negligence if it does not exercise a reasonable standard of care in manufacturing a dietary supplement.

#### ANALYSIS OF MANDATORY ADVERSE EVENT REPORTING

In the strict liability context, mandatory adverse event reporting will unjustifiably be emphasized to juries to demonstrate the risks associated with dietary supplements. Litigants will argue that manufacturers had knowledge of potential risks based on the number of reports alone, despite the fact that the adverse event reports themselves do not sufficiently demonstrate a risk of an event associated with the product. As product benefits or favorable outcomes are not reported in a nationally maintained database with the imprimatur or the government standing behind it, there is a likelihood that any jury tasked with conducting a risk-benefit analysis will give greater weight to risks reported through AERs over benefits which are typically not reported.

In negligence cases, a litigant must prove that a manufacturer, packager, distributor or retailer breached its duty of care. Any analysis of whether this duty was breached can and will likely include an inquiry by the plaintiff into whether efforts were made by the manufacturer to establish and maintain appropriate manufacturing protocols, including compliance with current good manufacturing practices and other statutes governing dietary supplements. Similar inquiries may be made with regard to other parties in the chain of distribution. Undoubtedly, whether a "responsible person" complied with the mandatory reporting requirements will factor into a jury determination of whether that party took reasonable efforts to insure that dietary supplements were safe and presented no increased risk of harm or injury to the public. For example, a person suing a manufacturer or retailer will investigate that party's system for classifying calls into reportable AERs or non-reportable events. No matter what the system, there is a strong possibility that any minor criticism of the system for reporting AERs will lead to a jury finding of negligence against that party, even without negligence in the product's design, manufacture or warnings.

Mandatory adverse event reporting data will also be used to impute knowledge of a product defect to manufacturers, packers, distributors, and retailers and despite the fact that the reports contain little information of reliable quality and are misleading based on existing conditions of patients and intake of other substances. For example, the reports almost always contain double hearsay: the person receiving and evaluating the reports at one level, and the consumer/interviewee at yet another level. Further, most of the data contained in the reports will simply be a paraphrasing of versions of events given by the consumers, who surely cannot be regarded as trained observers. AERs in other contexts have proven to be often anecdotal, coincidental, and unverifiable. These reports can and will be used by litigants to support their claims of product defect or negligence against manufacturers, packers, distributors, and retailers by imputing to them a level of knowledge of potential risks associated with the product based on these reports.

Aside from the issues associated with proof at trial, the most demanding aspect of products liability defense is associated with discovery. Litigants will focus on AER contents during discovery and the adverse inferences which could be drawn from the failure to report even the most spurious claims. Litigants will also focus on what steps the "responsible person" took following receipt of the AERs to update or revise caution statements and to discontinue or continue selling products. Each AER will in effect create a decision point and in order to defend against future accusations of negligence, a "responsible person" may find itself in a situation where, in order to justify its ongoing marketing and sales of a particular ingredient or product following an AER, it must obtain an opinion from a third-party expert or doctor.

Discovery in litigation will also focus on the system for obtaining, prioritizing, analyzing, and ultimately reporting or not reporting an event as an AER. This discovery will be time-consuming, expensive, subject manufacturers to undue criticism and unreachable standards of performance. Invariably, even if the "responsible person's" intention is to report all events and no matter how conscientious the behavior of such party, an adverse event may slip through the cracks, leading to an adverse inference at trial that evidence was hidden from regulators or litigants. An "adverse inference" instruction from a court often dooms a legitimate product liability defense.

Another issue raised in litigation is whether litigated issues are considered adverse event reports. In litigation involving a pesticide manufacturer subjected to AER requirements, the issue has arisen as to whether events subject to litigation are subject to reporting requirements. These issues persist even after a judge or jury has concluded that no adverse event was caused by the alleged offending substance. The AER remains in the manufacturer's "file" and cannot be removed, leaving an impression that the AER accurately reports an adverse event. If a "responsible person" decides against including a clearly disputed event in the AER file and opts instead to classify the event as not subject to reporting requirements, there is a possibility that later agency action to review or investigate non-inclusion of those events will raise a question with litigants, judges, and perhaps juries that a duty to report was violated, leaving them with another false impression about the product and/or the manufacturer, packer, or distributor.

The *Restatement (Third) of Torts: Products Liability* concludes that a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, although such compliance does not preclude as a matter of law a finding of product defect. By contrast, when a party *fails* to comply with a product safety statute or regulation, the product is to be regarded as per se defective. The proposed amendment as written will result in difficult and varied compliance among "responsible person". For example, the vagueness of certain terms used in the definition of "serious adverse event," such as "life-threatening," "disability" and "incapacity," will undoubtedly lead to some disagreements between these parties as well as the FDA about the reach of the reporting requirements. Because the "mandatory" reporting requirements are ambiguous, litigants can and will find a way to argue that "responsible persons" had violated the statute, which can surely be taken to import

responsibility as a matter of law. Any comment from a “responsible person” that a health related event report was not reported as an AER will be used to demonstrate non-compliance with the statute no matter if there is no statutory duty to report rumor, suspicion and speculation that an adverse incident was caused by the product. The fear of negligence per se claims may, therefore, encourage defensive or cautious parties to err on the side of over-reporting, creating a false impression of risks. Those parties which interpret the statute more conservatively will be accused of “covering up” health complaints.

Another problem with the proposed legislation is that the responsible person’s obligation to file adverse event reports may be used against them and others as a substitute for reliable causation evidence. In order to prevail in a products liability action brought under a theory of either strict liability or negligence, a plaintiff must always demonstrate that the injuries complained of were caused by the product in question, and the courts have consistently required expert witness testimony to establish this element. One of the most problematic aspects of the proposed required reporting system is the lack of causality assessment. There is simply no process of determining whether a particular event arises from supplement usage, some other medication, an underlying disease, or some other, extraneous cause, such as diet or alcohol intake. Where no proof of causation is needed to trigger the obligation to report, an assumption can be made that causality exists; otherwise, the event would not have been reported. These reports may then be used to overcome an otherwise substantial causation burden imposed on plaintiffs.

In litigation, there is no simple way to prove that any single AER or set of AERs was not reasonably associated to the product in question. Consider an AER directed to a supplement manufacturer, packer, distributor, or retailer reporting high blood pressure as an adverse event suffered by “Customer Doe.” The limitations of practicality, time, and expense prevent a supplement manufacturer, packer, distributor, or retailer or any other manufacturer, packer, distributor, or retailer from determining whether this event or a set of similar events can be truly attributed to diet, overall health, congenital conditions, or another product. Manufacturers, packers, distributors, and retailers cannot compel the non-litigant consumer to submit to tests to determine whether the blood pressure increased for any other reason. Manufacturers, packers, distributors, and retailers cannot review Doe’s past medical history to evaluate information on alternate causation. In a trial for personal injuries brought by “Customer Smith,” manufacturers, packers, or distributors, will not be able to disprove the inference created by Doe’s AER because “mini-trials” within a trial on alleged similar incidents are disfavored. A set of AERs leaves an un rebuttable record of alleged injury and notice, which disrupts the common law burdens of proof imposed in a trial.

Nothing in the proposed legislation prevents the AERs from being utilized at trial. Moreover, adverse event reporting data, if relied upon by a litigant’s experts, are admissible under Rule 703 of the Federal Rules of Evidence. That Rule states that expert witnesses may rely on facts or data otherwise inadmissible in forming their opinions so long as the data is a type reasonably relied upon by experts in that particular field. Expert witnesses may seek to rely on

the adverse event reports in forming their opinions as a means of circumventing any rule against their inadmissibility.

Many of the mandatory reports that will be generated under this proposed legislation are likely to contain the confidential medical and background information of consumers. Even with the privacy controls contained in the proposed legislation, nothing prevents the reports from being made public or from disclosure of the underlying data contained in the reports. There is a real potential for abuse of this data. For example, attorneys may seek to obtain consumer information to generate additional cases against manufacturers, packers, distributors, or retailers and to bolster public mistrust of the dietary supplement industry. Manufacturers, packers, distributors, and retailers will be subjected to these types of discovery abuses simply because they have complied with the mandatory reporting requirements.

In sum, the proposed “mandatory” system of serious adverse event reporting will not achieve its intended purpose—that is, to presumably estimate accurately the incidence of safety problems associated with dietary supplements. The proposed legislation creates a system of reporting that yields unreliable and unsubstantiated data that will subject manufacturers, packers, distributors, and retailers if they strictly comply with the statute, to additional product liability.

Sincerely,



Daniel J. Gerber

DJG/jrv