RISK CONTROL BULLETIN

Product Liability Risk Control

Let the Seller Beware!

Until the mid 1800s, manufacturers, wholesalers, and retailers were relatively protected from product liability under the prevailing legal rule of *"caveat emptor."* Loosely translated this means, "let the buyer beware." If injured by a defective product, there was little chance a buyer could successfully sue and recover damages. In essence, society and the courts generally took the position that customers had to look out for themselves. Most goods were agricultural products or uncomplicated manufactured goods and generally the buyer could easily discover defects.

Another barrier that provided protection against product liability suits was the prevailing legal doctrine known as *"privity of contract."* Under this doctrine, persons injured by a defective product could only bring suit against the one who actually sold the product to them. If an injured customer purchased a defective product from a retailer, he would have no *"privity of contract"* with either the manufacturer or wholesaler and no legal basis to sue them. If the person injured by a defective product was anyone but the buyer he would have no legal basis to sue the manufacturer, wholesaler or retailer.

Today, the pendulum has almost swung entirely in the opposite direction. The prevailing legal climate is more that of *"caveat venditior"* or "let the seller beware." The doctrine of *"privity of contract"* in product liability suits is largely irrelevant under current law. Under implied warranty of merchantability theory, a general condition of a sale is an implied warranty of merchantability. The implied warranty is that the goods sold are reasonably fit or safe for the ordinary purposes for which such products are used.

Under strict liability theory, injured parties do not even need to prove negligence. They only need to show that a product was in a "defective condition unreasonably dangerous" to the user, that injury or damage resulted from the defect, and that the defect existed while the product was under the control of the manufacturer. The party seeking damages can be the buyer, bystander or any foreseeable user. It's not only the manufacturer who is at risk, but also any "commercial supplier" (i.e. someone in the business of selling goods versus the casual seller such as the housewife who sells a jar of jam to a neighbor). Strict liability applies to the manufacturer (including a component part manufacturer), or anyone else in the distribution chain including wholesalers and retailers.

Seven Keys to Product Liability Risk Control

There are at least seven key risk control measures that you can implement to help minimize your product liability loss potential as follows:

1. Management Leadership and Support

Product liability risk control measures have little chance of long lasting success unless everyone throughout your organization believes that the measures have top management's firm and unwavering support. Top management must "walk the talk" and lead by example. This means that top management must:

- Allocate time and money to develop and implement solutions.
- Foster a culture in which all employees understand that production and sale of safe, reliable products is critical to continued success.
- Promote open communication channels among all organizational levels, as well as with suppliers, subcontractors, distributors and other external "partners."
- Establish accountability for achieving total quality management (TQM) objectives that integrate product safety and product liability prevention considerations.
- Document and update policy, procedures, goals, accountability, and all product safety program activities.

In addition, management must understand current legal concepts associated with product liability, use this knowledge to shape effective policy, and effectively communicate this policy to employees.

2. Safe Design

Remember that today, under strict liability theory, plaintiffs do not even need to prove negligence to be successful in product liability suits. They only need to show that the product was "defective", i.e. was not fit for its intended use, or for reasonably foreseeable misuse. To successfully defend against suit based on alleged design defect some of the key factors to consider when making design decisions are:

- Mandatory and voluntary, codes, standards and regulations
- Reasonably foreseeable product use and misuse
- Environmental conditions in which a product may be used
- Physical or mental limitations of foreseeable users
- Cultural and language differences among expected users
- Anticipated product life cycle
- Disposal or storage requirements
- Interface with other products or use with non-compatible chemicals
- Advances in technology
- Adequacy of warnings

If critical hazards cannot be eliminated by design or controlled via warnings and safe operating procedures, it may be best to keep the product off the market.

3. Legal Review and Counsel

Being prepared in the product liability arena requires that you employ the services of qualified legal counsel well before you ever bring a product to market. This individual or firm should have considerable experience in product liability law if they are to help you avoid the many legal pitfalls that confront a manufacturer today. If your first contact with qualified legal counsel is with the insurance company's attorney after suit has been brought against you; you will likely be in for a difficult time!

Depending on the size and complexity of your company and your line of products, you will probably only need the services of a quality legal counsel on a part-time or retainer basis.

However, keep in mind that in this era of consumer activism, new laws and regulations having a significant impact on product liability and product safety requirements are common. Court decisions are being made that can have important ramifications for your company. One wrong word or misrepresentation in advertisements, sales presentations, or other product literature can create an "express warranty" that you didn't intend to make but may be held liable for.

Should you purchase, or merge with, another company, you could be liable for harm or injury arising from any defective product they ever sold. Some key areas of concern that require legal review and counsel before a suit include:

- Preparation of contracts, hold harmless agreements, warranties, guarantees, and disclaimers
- Staying informed regarding laws, regulations and court decisions
- Evaluating product liability implications arising from acquisitions or mergers
- Reviewing advertising and sales literature for statements that may unintentionally create "express warranties"
- Evaluating product labels and warnings for adequacy and compliance with codes and regulations
- Reviewing records for usefulness in defending suits

Naturally, this list isn't intended to be all-inclusive. It's intended to demonstrate that there is much that needs to be done, and this is not an area that you "do it yourself" (i.e. without the services of qualified legal counsel).

4. Quality Assurance and Control

Manufacturing and quality control are focal points for assuring that products are manufactured in conformance with design criteria and specifications. People, equipment, material and the work environment must function effectively as a system so that nothing degrades product safety during the production process.

Controls are required to prevent unauthorized modification in design and to insure that only prescribed materials are used. Care must be taken so that the product is not damaged by overstressing, temperature extremes, falling impacts, or adverse storage conditions. Coding or polarizing may be necessary to prevent misassembly, particularly when differences between component parts are not visually easy to discern. Procedures are needed to insure that a product can not escape a quality control checkpoint. There should be a written Quality Assurance Program that is revised periodically, and at a minimum, includes provision for:

- Testing and inspection of raw materials, component parts, and finished product
- Inspection of packaging, manuals, labels, and customer service work
- Engineering drawing, and change control procedures
- A system for controlling, inspecting, and evaluating procedures
- Detailed records of all quality assurance activities
- Validation of quality standards and size of test samples
- Control of non-conforming materials and rejects
- Calibration of testing and measuring equipment

The following organizations publish information on quality assurance, including ISO 9000 registration requirements that can help you develop a system suited to your needs:

- American National Standards Institute (ANSI)
  (212) 642-4900
  Fax: (212) 398-0023
  www.ansi.org

- The American Society for Quality
  (414) 272-8575
  (800) 248-1946
  Fax: (414) 272-1734
  www.asq.org

ISO 9000 standards are worldwide, quality-system standards first published in 1987 by the International Organization for Standardization, Geneva Switzerland. More than 90 countries have adopted ISO 9000 standards including U.S., Canada, Japan, and the European Union. The standards define a product in broad terms as "the result of activities or processes." This simple definition would include something tangible such as assemblies or processed materials; something intangible such as information, or a combination of both, such as service.

Understand, that the ISO 9000 series is a set of five individual, but related, international standards on quality management and quality assurance. They provide quality management guidance with regard to generic quality system elements essential to effective quality assurance. They are generic, not specific to any particular products, and can be used by manufacturing and service industries alike. They are not product standards per se and do not substitute for distinct product technical requirements, they are also voluntary.

However, U.S. courts can, and do, use voluntary standards for establishing a manufacturer's "duty of care." By codifying procedures necessary to produce safe products and, given ISO 9000s ever increasing recognition as a "global quality assurance standard," manufacturers are in a tenuous situation if their quality assurance program does not measure up.

5. Product Labels, Packaging, and Warnings

When deciding if a product is defective, has been negligently manufactured or designed, or if it lives up to a warranty, the courts will generally apply a broad definition to the word "product." They will not only examine the functional product (i.e. what the customer uses or consumes), they will also consider product labels, packaging, warnings, advertising, manuals, and instructions for use and maintenance. Essentially, they will review anything that affects user expectations about the functional product itself. Virtually anything that affects the ability to safely use a product in a reasonably foreseeable manner is also fair game.

Because of this, product labels and product packaging must be considered part of the product or even viewed as products themselves. Likewise, there may be applicable mandatory and voluntary codes, regulations, and standards regarding labels and packaging those manufactures must be familiar with.

Improper disposal of some packages or containers can result in pollution or serious physical injury (i.e. hazardous chemicals, exploding aerosol cans); inadequate design can lead to damage during shipment or storage, which in turn can result in serious physical damage or personal injury (i.e. leakage of flammable liquids, gases, etc.). Inadequate warnings on labels or instructions for use can lead to misuse with serious consequences to the user.

Some important product labeling, packaging and warning risk control considerations to keep in mind are that:

- Wording on labels must be accurate, brief, and easy to understand
- Warnings must be conspicuous, and designate the degree of hazard (i.e. CAUTION or DANGER)
- Warnings and instructions should be repeated in the various languages of primary users
- Warnings must convey consequences of failure to heed (i.e. causes burns, dizziness, may be fatal etc.)
- Labels should describe proper method of disposal, if contents of container are toxic, corrosive, caustic or flammable
- Labels must be firmly attached so they remain in place and are legible for the life of the product
- Packaging should have its own labels and warnings as appropriate
- Packaging should be designed to minimize harm to contents or handlers during shipment, handling, and storage
- Packaging must meet standard requirements of DOT, US Postal Service, etc.

6. Marketing and Customer Service

Current law recognizes that any promise or representation of fact made about a product in advertising, on labels, during sales presentations or otherwise will normally constitute an "express warranty." This holds true whether or not you intended to make an express warranty and whether or not you actually use the word "warranty" or "guaranty." The statement can be made by a sales clerk, service representative, or anyone affiliated with or representing your company.

While an expression of an opinion or belief (i.e. this is the best of its kind) is not normally considered a warranty, it may be construed as such in cases involving serious personal injury and/or sympathetic plaintiffs (i.e. children). It's best to avoid sales puffery or exaggerations about your products.

Anyone in your organization who has contact with customers should be well versed in product application and limitations and the consequences that can result from over statements or misinformation they provide. Any statements made in advertisements, sales literature, oral sales presentations, etc. must be factual. You should be able to substantiate them with documented test results and other data. Naturally, the same holds true for actual, or intended, warranties or guarantees.

A manufacturer also has the obligation to inform customers about the proper use and maintenance of products so they will be safe for use throughout the anticipated life cycle. If a warranty or guarantee is limited in time or scope this must be spelled out. The customers must also be advised of service requirements and proper use requirements that must be met for the warranty or guarantee to remain in effect.

Service or repair functions performed by the manufacturer, or on the manufacturer's behalf, are in the realm of "completed operations exposure" rather than "product liability." Use of improper or inadequate replacement parts or materials, modifications that increase hazard or reduce safety, poor workmanship, inadequate training, incomplete records, and making statements not supported by data, can do the same harm here that they can for product liability exposure. This area also requires the same integrated approach to safety as does Product Liability.

7. Product Recall Planning and Implementation

To paraphrase Robert Burns, the famous Scottish poet, man's best laid plans often go wrong. Despite the best product design, quality controls, manufacturing practices etc. there is always the possibility that products you sell may be defective and cause harm to others. Contingency plans are needed to deal with this possibility no matter how small you consider the probability. If you do not have a well thought out plan to remove defective products from the market or to retrofit them with needed safety improvements, the consequences can be severe for your company. Product recalls may be needed when:

- You learn a product is defective as a result of hazard analysis, or reports by users, consumers, employees, suppliers, or others in the product distribution chain;
- An accident or claim reveals an unforeseen product defect;
- A product is in violation of a government act, standard, regulation or other mandatory requirement; and
- Product specifications or characteristics are incompatible with advertised claims for safety.

Essential elements of a product recall and retrofit plan include at least the following:

- Management support and leadership
  - Establish a policy statement that describes purpose, objectives, and functional accountabilities
  - Establish a recall procedure manual with written procedures for each operating unit, including criteria and procedures for deciding if and how a recall will be initiated
- Establish a strategy and criteria for communicating with the media
  - Establish a procedure for communicating with, and working with government agencies that may either mandate recalls or require notification of voluntary recalls
  - Establish a procedure for notifying all customers, other users and other potentially affected parties in the manufacturing/distribution chain
  - Establish a method for funding recalls and allocating recall expenses
  - Include legal counsel in all aspects of recall planning
- Product traceability and record keeping
  - Determine recall potential and product liability loss potential of all products sold
  - Determine how products will be located and removed from the stream of commerce or modified in the field
  - Establish a procedure for tracking products that are resold and/or have a plan in place to notify such users through media and/or trade publications
  - Estimate the cost of traceability
  - Identify critical parts and components and establish records and procedures to be able to track them from suppliers throughout the distribution chain
  - Maintain comprehensive and detailed records of all design, quality assurance/manufacturing data, testing, shipping and distribution, etc.
  - Maintain back-up records at a second location should there be loss due to fire, flood or other perils
  - Establish a records retention policy, typically based on anticipated life of the product, plus 30 years, for critical records
  - Periodically review records to be certain current system meets company needs
- Decision making criteria for voluntary recalls
  - Moral and ethical considerations are critical and consequences of ignoring these can result in adverse publicity, loss of reputation, product litigation and risk of government intervention and regulation.
  - Legal, statutory and regulatory requirements such as recalls mandated by the Consumer Product Safety Commission, Department of Transportation, Food and Drug Administration and others.
  - Financial considerations should only come into play when the product defect does not affect safety and the decision is one of weighing a recall against potential loss of customer goodwill
- Performance audit
  - Provide for periodic review, evaluation and updating of the product recall and retrofit plan
  - Review and update plan when new products are added to product line
  - Preferably use outside auditors

FCCI has a Product Recall Preplanning Checklist that is available should you need additional help with developing your product recall plan.

Conclusions

Mitigating your product liability loss potential requires genuine commitment by senior management and the active involvement of all segments of an organization. Manufacturers, wholesalers, and retailers all have duties and may be liable if a defective or unreasonably dangerous product results in harm to the person of property of others. Product liability risk control must be an integral part of your total quality management process. Have a product recall and retrofit plan in place as a contingency for the possibility that despite your best efforts, defective and potentially dangerous products may still enter the stream of commerce.

References

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