

#### Part 1 Agenda

- Recall & Lawsuit Trends
- Understanding the Full Realm
- The Role of the Design Review Team
- The Role of the Product Safety Team

#### **Today's Agenda**

- A brief Recap of some of the Key Points from Part 1
- Records Retention & Dangerous documents
- Supplier Control & Asian Suppliers
- Post Sale Duties & Recalls
- Entering into Litigation

### **Randall Goodden**

#### Manufacturing Background

- Interim President
- Corporate VP -
- New Product Development, Quality & Product Reliability, Field Services, Technical Support, Litigation Management 30+yrs



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Lets get started ...





### **U.S. Product Liability Statistics**

Over 80,000 product liability cases annually in the U.S.

(2013 study by Harvard Law School)













### Why So Many Recalls?

#### **Typical Causes**

- ➤Defects in Design
- Not complying with Regulatory requirements
- >Defective components/materials
- >Defects in manufacture

#### **Current Trends**

A number of U.S. Law Firms began opening new offices back in Nov in cities/states they weren't already in and hiring new PL attorneys, as they seen in 2017 that the largest Legal growth area is in Product Liability Lawsuits.

Product recalls continue to climb all around the world, and the insurance industry expectation is that it's going to get worse.

Understanding the full realm of

Product Liability Prevention





#### Review

- More than just Hazards Analysis or Warning Labels
- More than just an Engineering concern

A wide spectrum of concerns that needs to be understood by the entire management team.





#### **The Design Review Stage**

- Most important first stage in a products lifecycle.
- > Least expensive time to make a change.
- Viewed by the Legal community as an industry standard.







### Need for Test Data in PLP

- Need to have facts regarding product performance and reliability
- Need to be able to prove component supplier claims
- Need to see failure mode and effects first hand
- Need to have the ability to prove products could withstand extreme conditions
- Need to prove products will live up to expectation and last

### **Product Testing**

Ensure you can prove your products were adequately tested and assured to be safe, prior to releasing them into the marketplace.

Also ensure your suppliers are adequately testing component parts.

Governments and Courts Expect Manufacturers To Fully Test Their Products Before Marketing Them









#### Hazard Analysis and Risk Assessment

The Product Safety Team needs to analyze the new product and recognize any potential hazards.







#### **Standards for Instructions**

ANSI Z535.6 Compliance Standards for Collateral Materials

> RECORDS RETENTION & DANGEROUS DOCUMENTS

#### **Records Retention**

- In a lawsuit, records become paramount
- Being able to factually address issues concerning;
  - ✓ Design
    - ✓ Engineering
    - ✓ Marketing
    - ✓ Testing
  - And many other aspects

#### **Key Documents**

- Drawings & specifications
- Sales & Purchase Orders
- Contractual agreements
- Product correspondence
- Advertising materials
- Warranties
- Installation/Service instructions
- Warnings
- Test reports
  - More . . .

#### **Key Documents**

- Audit inspection records
- Design review verifications
- Product safety review verifications
- Receiving inspection records
- Customer complaints
- Shipping records
- Records of returns

#### **Engineering Records**

#### A major area of concern.

- Focus will be centered around;
- Blueprints at the time of production
- Instruction sheets or owners manuals
- Warnings provided
- Design reviews held
- Engineering changes made prior/since

### **Records Retention**

- Make sure procedures are in place and being followed addressing records retention
- Create a record retention schedule for every type of record, which is in compliance with any industry requirements
- Always assure the procedure is being complied with
- Dispose of old records per schedule

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| Dept Res     | Record Description                                | 1 Y al | 2 Y e8 | 3 Y ea | 5 Yea |  |
| Sales        | Oustomer Purchase Orders / Product Specifications |        |        |        | х     |  |
| Engineering  | Blueprints and Product Specifications             |        |        |        | х     |  |
| Engineering  | Design Review Minutes                             |        |        | ×      |       |  |
| Engineering  | Engineering Change Requests                       |        |        | x      |       |  |
| Safety Tean  | Hazards Analysis/Risk Assessments                 |        |        | ×      |       |  |
| Test Lab     | Product Test Reports                              |        |        |        | х     |  |
| sustomer Ser | ic Customer Product Complaint Forms               |        |        | х      |       |  |
| Purchasing   | Supplier/Subcontractor Purchase Orders            |        |        | х      |       |  |
| QA           | Obsolete Quality Procedures                       |        |        | х      |       |  |
| QA           | Obsolete Process Instructions                     |        |        | х      |       |  |
| QA           | Receiving Inspection Records                      | х      |        |        |       |  |
| QA           | Supplier Rejected Material Reports                | х      |        |        |       |  |
| QA           | Production Audit Inspection Records               | +      | -      | ×      |       |  |
| QA           | System Audit Inspection Records                   | +      | -      | ×      |       |  |
| QA           | Supplier Performance Evaluations                  | +      | -      | ×      |       |  |
| QA           | Corrective Action Reports                         | +      |        | х      |       |  |
|              |   |        |        |        |       |  |
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# DANGEROUS DOCUMENTS

Dangerous Documents also known as "The Smoking Gun"

#### **Dangerous Documents**

Records are critical elements in your defense.

You need to know how to write them . . .

And how not to write them!

### **Dangerous Documents**

- Sometimes internal memos that are initiated at the spur of the moment blaming other departments for part/product problems
- Could be documents that overstate capabilities, or part reliability (sales/marketing)
- Documents that prove that the manufacturer had prior knowledge of a potential defect, and failed to react

### **Dangerous Documents**

### Come in many forms

- Memos
- Letters
- •Engineering changes
- Meeting minutes
- Advertising & promotion

#### **Dangerous Documents**

### Some examples



The court awarded \$24M to the plaintiff



U.S. Magistrate Judge Paul Grewal also found that Samsung intentionally did not save other emails that were relevant and stated to the Jury "You also may presume that relevant evidence was destroyed after the duty to preserve arose, and the lost evidence was favorable to Apple".

The Jury awarded Apple \$1B

#### Takata

Takata secretly conducted tests on their air bags recovered from a junkyard and found they had the potential to crack in a way that could lead to a rupture and potentially harm passengers, yet the result was not reported to regulators

The 2004 tests came after Takata received a report that the inflator from one of its air bags had sprayed an Alabama driver with metal debris, says two unnamed former employees who were involved with the tests, During the test, inflators in two of the tests cracked. The result persuaded the company's engineers to start searching for a possible fix.

Takata executives ordered lab techs to delete data about the secret tests and throw away the air bag inflators used in the tests. All the testing was hush-hush," said one former veteran employee. "Then one day, it was, 'Pack it all up, shut the whole thing down.' It was not standard procedure."

Four deaths and more than 30 injuries linked to the defect. 34 million cars to be recalled. Largest auto recall in history. NHTSA is fining them \$70M.

#### Takata

As of Jan 1 2018 the airbags have been linked to 20 deaths worldwide.

With spiraling debts estimated at more than \$9 billion, Takata pursued bankruptcy protection in June of 2017 in Japan and the U.S. It's also selling its business to a U.S.-based rival Key Safety Systems, a Chinese-owned company based in Michigan, who is paying \$1.6 billion for nearly all of Takata's operations, but is staying away from the parts that deal with the airbeg inflators.

"We caused troubles for our supporters, those who cooperated with us and the creditors," Chairman Shigehisa Takada said at a news conference in June 2017 where he bowed before the cameras. "On behalf of Takata, I apologize deeply from the bottom of my heart."

Takata <u>admitted</u> to manipulating and withholding key information about the faulty inflators for years, even after they started exploding in people's cars. It <u>pleaded</u> <u>guilty</u> in the U.S. to a criminal charge of wire fraud for which it will have to pay \$1 billion, including a \$125 million fund to compensate victims and their families.

The automakers who used Takata airbags in their cars -- including Honda, Toyota and GM -- could end having to pick up the tab for most of the estimated \$5 billion that's needed to pay for replacing the tens of millions of Takata airbag inflators.

### Volkswagen

#### se Emissions Software (2015)

Volkswagen has said as many as 11 million cars were fitted with software that could cheat emission's tests. The group falsified U.S. pollution tests by installing software ("defeat devices") to make them appear cleaner than they were. Once on the road, the cars would pump out as much as 40 times the allowed level of nitrogen oxides. The German government said the company cheated in Europe too.

Six VW employees have been charged by the DOJ for their roles in conspiracy including the former head of Development; the former head of Engine Development; former head of Engine Development After-Treatment in Wolfsburg, Germany; former supervisor for Quality Management and Product Safety; former general manager of VW's Environment and Engineering Office in Auburn Hills, Michigan; and the VW Quality Management and Product Safety Group and liaison with U.S regulatory agencies

German prosecutors announced an investigation into former CEO Martin Winterkorn who lost his job with Volkswagen for possible fraud related to selling cars with falsified emissions data.

The company is being fined \$14.7B by NHTSA and \$4.3B by the DOJ.

#### **Electronic Discovery**

- Data Files are categorized into 4 types:
  - A. Active Data
  - B. Replicant Data
  - C. Residual Data
  - D. Backup Data

#### **Electronic Discovery**

Bottom line . . . when you think you've deleted documents, chances are you haven't, and plaintiff experts know how to find them, *so don't write them!* 

#### **Dangerous Documents**

## Educate the employees on how to properly write any type of document

- Avoid unnecessary documents
- Avoid exaggerations of a condition
- Avoid dealing with issues outside your area of expertise
- Avoid communication of liability issues

Legal Dept – Don't play word games (anomaly)

#### **Dangerous Documents**

#### Other ways to prevent:

- Teach them to recognize and react to potential dangerous documents, and stop them in their tracks
- Companies are going to face difficult situations and have to make tough decisions

Remember: you can't destroy such documents once in litigation

The Documents You Maintain Can Serve as You Best Defense, Or the Nails in Your Coffin!

#### How to Decide What to Write:

Don't Write Anything That You Wouldn't Mind Having Read Someday in a Courtroom!

### **SUPPLIER CONTROL**

and the use of Asian Suppliers

### **Supplier Problems**

Suppliers and Subcontractors can create serious problems for buyers and manufacturers by:

- > Not complying with your specifications
- > Changing materials w/o your knowledge
- > Not controlling their own suppliers or processes

And the worst part of it is that the customer (You) don't figure it out until it's too late.

### **Common In-House Problems**

- The areas where most companies go wrong include:
- Suppliers weren't adequately evaluated or qualified to begin with
- They were given the specifications and expected to comply, without any verifications
- Final products, or incoming materials, aren't ever checked
- Regardless of the contracts and agreements that are in place, it is your reputation that is damaged







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Wool testing: Australia Laser finesse tester meter











#### **Supplier Selection**

#### A Key List to Follow:

- Avoid selecting key suppliers without visiting their facility
- Inspect the locations to ensure they have apparent experience with the specific product lines
- Ensure the [candidate] supplier has a formal Quality system in place, then look for proof that it is being audited and followed

#### **Supplier Selection**

#### A Key List to Follow:

- Ensure the candidate suppliers are fully knowledgeable of any regulatory requirements and have the staff to support the effort
- Require that the candidate supplier have product liability insurance (with an international carrier)



### **Post Sale Duty to Warn**

"Although a product [may] be reasonably safe when manufactured and sold and involve no then known risks of which warning need be given, risks thereafter revealed by user operation and brought to the attention of the manufacturer or vendor may impose upon one or both a duty to warn."

Cover v. Cohen, New York Court of Appeals (1984).

#### Indicators of Trouble

In many cases, before a defective product actually injures someone or causes property damage, "flags" will begin to appear indicating the potential for such an incident.





Customer ServiceReturned GoodsBut is anyone paying attention?

### **Incident Reports**

### Are incidents of unusual product failure in the field forwarded to the right people?

- ✓ Can Sales, Account Management and Tech Support recognize potential product liability failures from everyday failures?
- Is there a procedure in place telling who such information should be taken to?
- ✓ Does someone monitor the nature and extent of warranty returns, field failures, customer service calls?

#### Having "Prior Knowledge" sets the stage for Punitive Damage awards.

### **Post Sale Duties to Warn**

In the end, many courts may leave the final decision of whether a manufacturer had a post-sale duty to warn up to the juries themselves.

### **Recall Readiness**

- Build-in product traceability
- Have Recall procedures in place
- Project Leader known
- Train employees to be alert
- Field options & resources known

### **Recall Readiness**

Important considerations:

- How will you handle a high volume of phone calls? Concerned customers can't receive busy sounds or be put into voice mail
- If you're not already conducting various recalls, schedule mock recall drills to ensure everyone is ready
- Keep in mind that there are companies that can handle the recall for you, such as

### **Internet Alternatives**

- Communicate by email to customers, distributors, retailers, etc.
- Video and text messages on website.
- Web based registration for returns
- Increase ID of customers
- Increase response rate

#### Internet Warranty Registration

| John Deere - Homeown  | ers - Warranty Registra   | ition   |  | Atha Dann - Monacowanti - Warta   | oty Registration  |                                      |
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### **Recall Readiness**

Always being able to react quickly!



#### **Statistics**

- Jury awards hit new \$billion highs, not seen in more that a decade
- Class action lawsuits have increased in the past 10 years by over 1000%
- The average median jury award in all product lines of product liability cases is over \$1.9M
- Plaintiffs win 37-53% of product liability trials in front of juries (Contingency basis)
- Roughly 96% of cases settle out of court, but there are indications that this is dropping

#### Interrogatories

A pretrial discovery device consisting of written questions related to the case, submitted by one party to the other. A court ordered questionnaire that is answered under oath.

#### **The Interrogatory**

#### Questions that could be asked;

- Identify each and every individual who may have a a role in the design and engineering of this product
- Identify each person who may have specific knowledge of the manufacturing process
- Describe all applicable government, independent agency, trade, industry standards, codes, or regulations which may pertain to this specific product.

#### The Interrogatory

#### Questions that could be asked;

- Identify any individual, consultant, company or laboratory that may have performed an evaluation of the product, and who may have had input into the design of the product.
- Identify all Quality Control documents that would have contained information pertaining to the manufacture of this product.
- Identify any reliability tests that may have been performed on the product, along with the names of the individuals that performed such tests.

#### **The Interrogatory**

#### Questions that could be asked;

- Identify the extent of all customer complaints that have been received regarding this product line
- Identify all individuals that have become involved in this incident, have detailed
- Involved in this incident, have detailed knowledge of the incident, or maintain certain facts or opinions regarding the incident.
  Identify all individuals who would be expected to testify on behalf of the defense, the nature of their testimony, their background and experience, and current positions.

#### **The Request for Documents**

#### Demand will likely include;

- The instruction manual supplied with the subject product.
- Written safety instructions and warnings supplied
- Photos and blueprints showing location of warnings
- Blueprints and/or design plans of product
- All memoranda reflecting optional equipment or safety devices offered

#### **The Request for Documents**

- > Could involve thousands of documents
- > 30 days to respond

### Depositions

Depositions primarily help counsel for the plaintiff gain more technical information and material about the product and the industry to help them with their case.

### Depositions

#### **Plaintiff Strategies:**

• To gain as much knowledge as possible about the company, the product, problems the company has had regarding the product, learn the names of other people within the organization that you might want to call to testify, to get as much information as possible to help them with their case.

#### "State of the Art"

- Product's design conforms to industry standard;
- Design reflects the safest and most advanced technology developed and in commercial use; or
- Design reflects technology at the cutting edge of scientific knowledge

### Final Questions?

### **Working Together**

- Consultation
- > On-Site Meetings/Reviews
- In-House Seminars
- > Other Executive Assistance

Let me know how I could help you out

