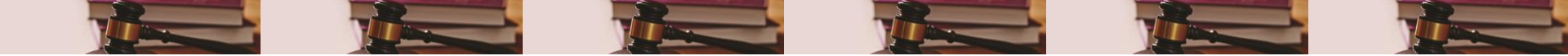

Managing a Recall: Preparing for Regulatory and Legal Implications

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FDA Recalls

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December 13, 2018

Recalls

Firm's removal of marketed product that the Food & Drug Administration considers to be in violation of the law it administers and against which the agency would initiate legal action; e.g., seizure.

Does not include a **market withdrawal** or a **stock recovery**.

21 CFR Part 7.3(g)

Market Withdrawals

Firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

21 CFR Part 7.3(j)

Stock Recovery

Firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, e.g., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

21 CFR Part 7.3(k)

Correction

Repair, modification, adjustment, re-labeling, destruction, or inspection of a product and/or the promotional literature which causes the product to be violative, without its physical removal to some other location.

21 CFR Part 7.3(h)

Recalls

May be undertaken voluntarily and at any time.

In response to a formal request by FDA.

Means of protecting the public health and well-being.

Retrieving products that present a risk of injury or gross deception or are otherwise defective.

21 CFR Part 7.40

Recalls

When a firm decides to initiate a product removal or correction, it should proceed with the action and not wait for FDA to determine whether that action is a recall, conduct a hazard evaluation, classify the recall, and review the strategy for that recall.

Recalls

- The recall of an FDA-regulated product is the responsibility of both FDA and the firm responsible for the manufacture of that product. This is essential to define not only FDA's role in product recalls, but industry's as well because ultimately the recall procedures that a firm follows actually determines the success or failure of a particular recall.

Recalls

- A voluntary recall does not preclude FDA from invoking any of its regulatory powers.

- Because a recall similar to seizure in basis and effect, injunction, criminal prosecution, and/or other sanctions may be also appropriate in a recall situations.

Recalls

- A firm can first make an initial decision whether an action is a recall; however, FDA makes the final decision as to whether the firm's removal or correction constitutes an FDA recall.

- FDA has the responsibility for deciding when a firm's action is or is not a recall.

The Different Types of Recalls

FIRM INITIATED (most common):

- Initiated by a firm independently and under any circumstances to remove or correct a distributed product.
- Initiated by a firm when informed by the FDA that the product in question violates the law, but the agency has not specifically requested a recall.

21 CFR Part 7.46

The Different Types of Recalls

FDA REQUESTED - The Commissioner of FDA or his designee may request a firm to initiate a recall when the following determinations have been made:

- Urgent situation;
- Risk of illness, injury, or gross consumer deception;
- Firm has not initiated a recall; and/or
- Necessary to protect public health and welfare.

21 CFR Part 7.45

Role of the Recalling Firm

The firm who initiates a recall, or in the case of an FDA-requested recall the firm that has primary responsibility for the manufacturing and marketing of the product to be recalled.

21 CFR Part 7.3(i)

Recall Strategy

A planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warning, and extent of effectiveness checks for the recall.

21 CFR Part 7.3(1)

Recall Strategy

- The planned course of action to be carried out by the firm in the achievement of its recall goals.

- The FDA will review and/or recommend changes to the firm's recall strategy, as appropriate.

21 CFR Part 7.42

Recall Strategy

- Results of firm's health hazard evaluation.
- Ease in identifying the product.
- Degree to which the product's deficiency is obvious to the consumer or user.
- Degree to which the product remains unused in the marketplace.
- Continued availability of essential products.

Evaluating Health Hazards

Evaluation by FDA scientists of the threat to health presented by a product, including its labeling and/or promotional literature, that is being recalled or considered for recall.

21 CFR Part 7.41

Evaluating Health Hazards

- Any disease or injury has occurred.
- Any contributing factors.
- Assessment of hazard to various segments of the population.
- Assessment of the degree of seriousness.
- Assessment of the likelihood of occurrence.
- Assessment of the consequences of occurrence.

Extent of Recall

- Level in the distribution chain to which the recall is to be extended.
- Depends on the product's degree of hazard and the extent of distribution.
- Consumer or user level.
- Retail level.
- Wholesale level.

Consignee

Anyone who received, purchased, or used the product being recalled.

21 CFR Part 7.3(n)

Recall Communications

- Should be brief and to the point.
- Clearly identify the product.
- Concisely explain the reason for the recall and the hazard involved.
- Provide specific instruction on what should be done with respect to the recalled product(s).

Recall Communications

- Convey the name of the recalled product.
- Further distribution or use of any remaining product should cease immediately.
- When appropriate, that the direct account should conduct a sub-recall.
- Instructions regarding what to do with the product.

21 CFR Part 7.49(a)

Recall Communications

Should not be diluted or camouflaged by irrelevant qualifications, promotional materials, or any other statement or information that may detract from the message.

21 CFR Part 7.49(c)(2)

Recall Communications

Provide a means for the recipient
to report back to the recalling firm.

21 CFR Part 7.49(c)(1)

Recall Enterprise System

- Automated system
- Track Recalls Nationwide
- Consistency in recall reporting
- Time efficient
- Real time agency awareness
- Real time public awareness (Internet)

Recall Classifications

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

21 CFR Part 7.3(m)(1)

Public Warnings

- Purpose is to alert the public health that the recalled product presents a serious hazard to health.
- Reserved for urgent situations where other means for preventing use appear inadequate.
- Issued through the general news media, and/or the specialized news media, or to specific segments of the population.

21 CFR 7.42(b)(2)

Public Warnings

- Purpose is to alert the public health that the recalled product presents a serious hazard to health.
- Reserved for urgent situations where other means for preventing use appear inadequate.
- Issued through the general news media, and/or the specialized news media, or to specific segments of the population.

21 CFR 7.42(b)(2)

Recall Classifications

CLASS II: A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse consequences or where the probability of serious adverse health consequences is remote.

21 CFR Part 7.3(m)(2)

Recall Classifications

CLASS III: A situation in which use of, or exposure to, a violative product is **not** likely to cause adverse health consequences.

21 CFR Part 7.3(m)(3)

Notifying the Public of a Recall

Weekly FDA Enforcement Report:

- Contains a descriptive listing of each new recall, its classification, and the specific action being taken by the recalling firm.
- Does not contain a firm's product removals or corrections, which are classified as market withdrawals or stock recoveries.

21 CFR Part 7.50

Effectiveness Checks

- Conducted by the recalling firm.
- Verify that all consignees have received notification about the recall and have taken appropriate action.
- If not done, the firm is not meeting its obligation and responsibility to the consumer.

21 CFR Part 7.42 (b)(3)

Recall Status Reports

- Recalling firm is requested to submit periodic recall status reports so that an assessment can be made of the progress of the recall.
- Frequently will be determined by the relative urgency of the recall.

21 CFR Part 7.53

Levels of Audit Checks

Percentage of total number of consignees contacted:

- Level A – 100%
- Level B – greater than 10% but less then 100%
- Level C – 10%
- Level D – 2%
- Level E – No effectiveness checks.

FDA Recall Audit Check Program

- Audit checks determine the adequacy of the firm's effectiveness checks.
- Audit checks are decided upon after evaluating the recalling firm's strategy.
- Audit checks are conducted by:

  - Personal visits

  - Telephone calls

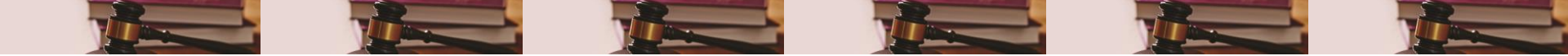
Termination of Recall

Occurs when FDA has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy and proper disposition has been made according to the degree of hazard.

21 CFR 7.55

Tips

- Get the basic facts first and fast (dates, lot numbers, suppliers, consignees, lot numbers, any remediation action taken)
- Contact FDA
- If you don’t know the answer to a question, tell FDA you don’t know but will find out
- Stay in close touch with FDA through the termination of the recall



Challenges and Opportunities

Looking at recalls through the eyes of the recalling firm

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Our World Today

- Widely publicized outbreaks of food-borne illnesses
  - In the United States,120 multi-state outbreaks over the last 5 years; romaine lettuce results in empty shelves
- External factors and fears drive heightened food anxieties
  - Fears of the Unknown: Globalization
  - Environmental Concerns: GMOs / Pesticides
  - Mistrust of “Big Food”
- “Information,” real and imagined, goes viral in minutes
  - Effective response demands new urgency, new thinking, new tools
- From government, increased scrutiny
  - Heightened inspectional activity / FSMA, new tools
- From customers, increasing oversight
  - Retailer requirements for food safeguards
  - Global auditing programs – a “shadow” government
- An ever-increasing focus on ***prevention***

Voluntary Self-Regulation

- Under FSMA, FDA can order a recall if there is a serious health threat and the company refuses to act
- Even though FDA has this new power, the voluntary recall remains a powerful tool of self-regulation and public health protection
- Taking voluntary action not only saves FDA the expense and effort of enforcement, but it can also
  - Quickly and effectively protect public health, and
  - Help a company maintain and even build its reputation with consumers

FDA’s Recall Policy

“Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

“Recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.”

21 CFR, Part 7

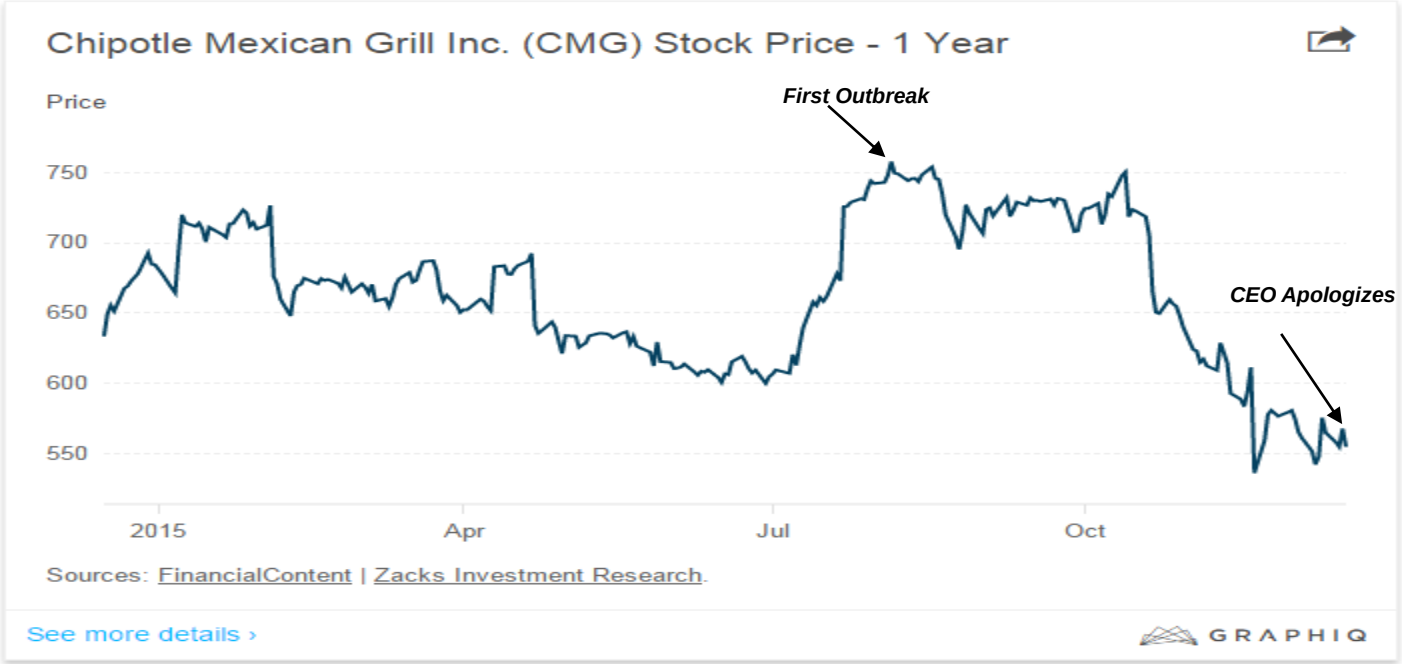
A Hobson's Choice?

- On becoming aware that it has put a hazardous or problematic product into the market, a food manufacturer can:
  - Do nothing and await an FDA seizure, prosecution, negative publicity and, in all likelihood, irreparable damage to its brand, or
  - Recall the product voluntarily, under FDA's supervision, warn the public, fix the problem and make sure it will never happen again
- This so-called "choice" is precisely why FDA's recall program has been so successful
  - It provides a clear pathway for a manufacturer to do the right thing and restore public trust
  - Handling a recall effectively can in fact enhance a company's reputation with consumers, e.g., the Tylenol scare;

Chipotle: A Case Study

- August 2015 – 200+ customers in CA fall ill from norovirus
- September – Salmonella sickens customers at 22 restaurants in Minnesota
  - October-November – 52 E.coli cases in nine states
- December – 120 customers get sick from norovirus in Boston
- Company apologizes and struggles to gain control
- February 2016 – U.S. Attorney opens inquiry, subpoenas records

Free Fall



Losses: $72M in sales, 10.3M burritos. Bloomberg Business, 02/02/16: Chipotle working on safety plan / testing for 2,000 restaurants.

Eye of the Storm

- In a crisis all eyes are on a company's leaders
- For responsible companies, a crisis management program provides the necessary tools to ensure a swift response and, most importantly, convey to the public that the situation is being handled properly
- This kind of program can actually have a *positive* impact on a company's financial value

Insurance Industry Study
Focus on 15 Catastrophes: An Upside?

Source: "The Impact of Catastrophes on Shareholder Value," Rory F. Knight & Deborah J. Pretty, Templeton College, University of Oxford, p. 3.

Leadership!

- Why would some catastrophes lead to an *increase* in shareholder value?
- Two elements to the catastrophic impact:
  - Immediate estimate of the associated economic loss, and
  - Management's ability to deal with the aftermath
- "Although all catastrophes have an initial negative impact on value, paradoxically they offer an opportunity for management to demonstrate their talent in dealing with difficult circumstances
- "Effective management of the consequences of catastrophes would appear to be a more significant factor than whether catastrophe insurance hedges the economic impact of the catastrophe."

The Necessary Tools

- To ensure a rapid response and effective resolution, every company should
  - Maintain a standing, cross-functional crisis management team
    - Legal, Food Safety, Communications, Sales, Security
    - Clear assignment of roles & responsibilities
  - Implement and update a crisis management plan
    - Clear lines of communication and decision-making
    - Contact info, 24-7
    - Communications plan
    - Integrate into food safety plans
  - Be prepared to act quickly and bring other resources to bear, e.g., R&D, toxicology, HR, etc.

Leverage Social Media!

- A tool to get in front of product crises:
  - Listen and monitor for product mentions
  - Quickly reach out
  - Create a credible consistent message
  - Build reputation based on transparency and trust
- Remember that the regulators are also listening
  - CDC, NYS searching sites to identify source of outbreaks of food-borne illness!

Thank You

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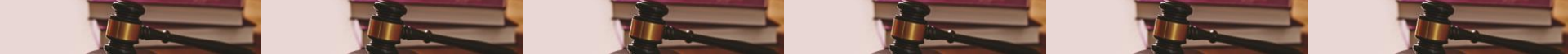

Specialty Recall Insurance Coverage for Accidental Contamination or Product Tampering

Enforcement, Litigation, and Compliance Conference

Washington, D.C. December 13, 2018

What is Product Recall Insurance?

- Insurance that generally covers expenses associated with recalling a product from the market.
- It typically covers costs such as customer warnings and notices of the recall, shipping costs and disposal costs.
- It may cover costs of repairing, reprocessing, and replacing defective products, as well as product refunds.
- It typically covers costs incurred by the manufacturer, but can also cover third-party costs.

Why Should Companies Consider Purchasing Product Recall Insurance?

- Government Oversight has Increased.
  - The Consumer Product Safety Improvement Act of 2008
  - The Food Safety Modernization Act of 2011
  - Between 2012 and 2017, yearly product recalls by the US Dept. of Agriculture rose 83.4%, while food recalls issued by the FDA increased 92.7%. "FDA, CDC Food Recalls Climb," *Becker's Hospital Review,* July 30, 2018.
- The costs for a recall are prohibitively expensive.
- Product recall insurance can be customized to fit your business.

What Events Trigger Product Recall Insurance?

- There are a number of common triggering events in most recall policies:
  - Accidental Contamination
  - Malicious Product Tampering
  - Adverse Publicity
  - Government Recall
  - Intentionally Impaired Ingredients
  - Product Extortion
  - Product Refusal

Accidental Contamination

- Policy language might require either (1) a demonstration of actual contamination or (2) only suspected contamination.
  - May be limited to substances that likely will result in actual bodily injury or sickness.
- Possible conflict between FDA Class I recall definition and policy requirements:
  - A Class I recall is a situation in which there is a "reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

Accidental Contamination (cont'd)

- If the FDA seeks a voluntary recall pursuant to the "reasonable probability" standard, a policyholder might have difficulty proving the existence of "actual contamination" to trigger coverage.
  - One policy defines "accidental product contamination" as: "any accidental or unintentional contamination, impairment or mislabeling . . .during the manufacture, blending, mixing . . . or processing" of the insured's product.

Accidental Contamination (cont'd)

- In *Foster Poultry Farms, Inc. v. Certain Underwriters at Lloyd's,* 2016 U.S. Dist. LEXIS 7629 (E.D. Calif. 2016), the court granted coverage for accidental contamination.
- A federal government Notice of Suspension had suspended the assignment of inspectors at a particular facility and withheld marks of inspection for the chicken produced there due to the insured's failure to remedy the high incidence of salmonella at that facility.
- The *Foster* court held that these events constituted accidental contamination under the policy as a matter of law.

Accidental Contamination (cont'd)

- The *Foster* court also held that the insured's destruction of its chicken product from the specific facility after receipt of the NOS constituted a recall under the terms of the policy's "Government Recall" provision because the term "recall" was ambiguous, requiring an interpretation in favor of coverage.

Accidental Contamination (cont'd)

- In *Foster,* "Accidental Contamination" was defined simply as an error in the production, processing, or preparation of any Insured Products "provided that" their use or consumption "has led to or would lead to bodily injury, sickness, disease or death." 2016 U.S. Dist. LEXIS 7629, at *11.
- As a result, the court rejected the potential application of a series of cases asserted by the insurer in which coverage was afforded only if "actual" contamination had taken place: *Ruiz Food Products, Inc. v. Catlin Underwriting U.S., Inc.,* 2012 U.S. Dist. LEXIS 131031 (E.D. Cal. 2012); *Wornick Co. v. Houston Casualty Co.,* 2013 U.S. Dist. LEXIS 62465 (S.D. Ohio 2013); and *Little Lady Foods, Inc. v. Houston Casualty Co.,* 819 F. Supp. 2d 759 (N.D. Ill. 2011). *Id.* at *16-*18.

Accidental Contamination (cont'd)

- Some policies require only that the policyholder have "reasonable cause to believe" contamination has occurred.
  - This definition affords broader coverage.
  - It is more in line with the FDA recall regulations and the execution of a product recall.
  - Policyholders must negotiate to obtain a more favorable coverage trigger where possible.

Product Tampering

- Another triggering event is malicious tampering:
  - Any actual or threatened, “intentional, malicious and wrongful alteration or contamination of the insured product(s), by any person (including an employee of the insured), so as to render the insured product(s) unfit or dangerous for its intended use or to create such impression to the public.”
  - Includes substances that merely are unfit for consumption (but which may not be injurious).

Product Tampering (cont'd)

- In one case, recovery under product tampering/malicious contamination coverage was denied where a vendor substituted a cheaper, unapproved pesticide to treat grain stocks, and the insured needed to destroy the lot, even in the absence of a human health risk.
  - The introduction of the unapproved substance was not undertaken for the purpose of harming the insured.
  - The court found that the policy, which covered "intentional, malicious and wrongful" tampering, did not apply because the tampering involved only ordinary malice and not actual malice.
  - *Gen. Mills, Inc. v. Gold Medal Ins. Co.,* 622 N.W.2d 147, 154-55 (Minn. Ct. App. 2001).

Product Tampering (cont'd)

- Product recall policies may also provide coverage for a **product extortion** claim, which is typically defined as a demand for money made in conjunction with a threat to tamper with the policyholder's product.
  - When such coverage is afforded, the insured must commit to keep its existence a secret.
  - A professional consulting firm identified by the insurer is often required to be involved to assist the policyholder in responding to such demands.
  - Extortion coverage also will indemnify the insured for ransom money and incidental travel and related expenses.

Adverse Publicity

- Adverse publicity coverage is associated with a contamination or tampering event, but the insured's product or brand name must be specifically identified.
- **"Adverse publicity"** means the reporting of an actual or alleged Accidental Contamination during the Policy Period in local, regional, or national media (including but not limited to radio, television, newspaper, magazines or the Internet), or any governmental publication provided that the insured product is specifically named."
  - Many policies include provisions affording coverage for reasonable expenses incurred in connection with a company's public relations response to the adverse publicity.

Adverse Publicity (cont'd)

- Adverse publicity could result from the listing of a product in an FDA enforcement or inspection report posted on the FDA website.
- But the coverage may not be triggered by an FDA advisory warning consumers not to consume a specific category of food regardless of the brand or producer.
- Also, the coverage may not respond as a result of adverse publicity about a competitor's product, when that publicity results in a decrease in sales of the policyholder's same type of product.
- Policyholders should review their policy wording carefully.

Government Recalls

- With the passage of the Food Safety Modernization Act of 2011, granting FDA mandatory recall authority, the potential need for this coverage grant has increased somewhat.
- The FDA has exercised its FSMA mandatory recall authority only once, however.
- Lost profits and expenses to rehabilitate the product's reputation following a recall may be covered.
  - Such policies often require that the recall be responsive to government requests or undertaken with the insurer's consent.

What Types of Losses are Covered?

- Policy wording differs, and policyholders must work with their insurance professionals to make certain that the expenses they are most likely to incur during a product recall will be covered.
- Those expenses are most often listed in the definition of “loss.”

What Types of Losses are Covered (cont'd)

- Typically covered recall-related expenses:
  - Transporting, storing and disposing of the recalled product.
  - Hiring and paying temporary staff to manage the recall.
  - Paying overtime to regular employees, including out of pocket expenses.
  - Inspection costs, including the costs of chemical analysis to identify the cause(s) or potential effect(s) of contamination.
  - Costs to redistribute any recalled or restored products.
  - Crisis management expenses.

Issues and Key Policy Terms

- As with all insurance policies, but especially with a specialty policy like a recall policy, the application process is critical.
- Insureds should work with their insurance professionals, including legal counsel, to make certain that all necessary and required information is provided during the application process.

Issues and Key Policy Terms (cont'd)

- Information about past recalls must be provided and explained.
- Whether the company has robust quality control practices is important.
- Notice provisions should be reviewed carefully.
- Alternate Dispute Resolution provisions must be reviewed and, potentially, revised.

Thank you.

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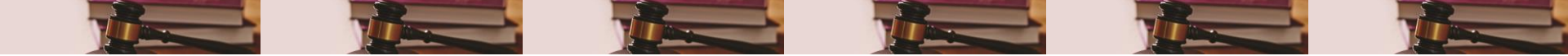

Recalls & Litigation

Victoria Calhoon

Faegre Baker Daniels

FDLI

Types of Litigation

- Individual lawsuits from affected consumers
- Multi-district litigation
- Class actions

Potential Legal Claims for Recalled Products

- Product liability law is state-specific and can vary widely
- Negligence and/or Strict Liability
- Failure to Warn
- Design Defect
- Manufacturing Defect
- Unfair Trade Practices
- Personal injury v. economic damages

Anticipate Possible Deposition Exhibits Before the First Suit is Filed

- Manage internal communications
  - "Dance like nobody is watching, but email like it may one day be read aloud in a deposition or at trial"
  - Company-wide or team emails
  - Assuming everyone reading the email "knows"
- Drafts of documents like recall notices or press releases
- Marketing & social media documents
- Documents will be viewed in hindsight & scoured for sound bites

Other Recall Document Considerations for Litigation

- Not only what a document says, but the who, when, where, and how could be relevant
- Company protocols & quality system documents – were these procedures followed?
- Consider issues like spoliation of evidence & duty to preserve

Privilege Considerations

- Some documents may be protected from discovery because of privilege:
  - Attorney-client
    - Copying an attorney is not a guarantee of privilege
    - Best practices:
      - Label the email/memo as Attorney-Client Communication and Privileged
      - Add a note that the purpose of the communication is to seek legal advice
      - Be careful when copying third-parties, e.g. communications consultants
  - Work Product

Evidentiary Rules Could Still Keep Evidence of the Recall Away From the Jury

- Recall evidence is not relevant to the product at issue
  - Not the same product
  - No evidence that the product at issue was defective
  - No evidence that the product at issue had the same defect
- The probative value of the evidence is substantially outweighed by the danger of unfair prejudice or misleading the jury
  - *Bizzle v. McKesson Corp.*, 961 F.2d 719 (8th Cir. 1992) (excluding evidence of recall of walking cane not shown to be same model as plaintiff's because it was misleading to jury & unfairly prejudicial)
- Subsequent Remedial Measures (sometimes)

Federal Rule of Evidence 407 – Subsequent Remedial Measures

When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:

- negligence;
- culpable conduct;
- a defect in a product or its design; or
- a need for a warning or instruction.

But the court may admit this evidence for another purpose, such as impeachment or — if disputed — proving ownership, control, or the feasibility of precautionary measures.

Exceptions to FRE 407

- Ownership/control of the product is in dispute – weigh admissibility of recall evidence when deciding whether to dispute ownership/control of the product
- Feasibility of a Precautionary Measure/Alternative Design
  - When the feasibility of other safety measures is in dispute
  - Broad view: *Anderson v. Malloy*, 700 F.2d 1208, 1213 (8th Cir. 1983) (feasibility of installing peepholes/chain locks at hotel where assault occurred was admissible)
  - Narrow view: *Gauthier v. AMF, Inc.*, 788 F.2d 634 (9th Cir. 1986) (can describe trade-offs with design changes without opening the door to the subsequent changes to the design)

Subsequent Remedial Measures – What is likely not covered by this rule

- Involuntary recalls
  - Involvement of a federal agency is not enough for a recall to be “involuntary” for the purposes of FRE 407

FDA Won’t Be a Party, But…

- What FDA did (or did not do) will be discussed
- What a company told FDA will be critiqued
- Regulatory experts will weigh in
- FDA Guidance documents could become exhibits
- Related 483s (and responses), warning letters, correspondence with FDA, and meeting minutes could be discoverable

Questions?