# Product Recall

*Contributing editors*

**Jason Harmon, Alison Newstead and Devin Ross**

2019

GETTING THE DEAL THROUGH

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**Shook, Hardy & Bacon LLP**

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This article was first published in November 2018
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First published 2009
Tenth edition
ISBN 978-1-78915-057-5



Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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## Product Recall 2019

Tenth edition

**Getting the Deal Through** is delighted to publish the tenth edition of *Product Recall*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

**Getting the Deal Through** provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Colombia and Mexico.

**Getting the Deal Through** titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

**Getting the Deal Through** gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Jason Harmon, Alison Newstead and Devin Ross of Shook Hardy & Bacon LLP, for their continued assistance with this volume.

GETTING THE DEAL THROUGH

London
October 2018

# United States

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**Shook, Hardy & Bacon LLP**

## General product obligations

### 1 What are the basic laws governing the safety requirements that products must meet?

In the United States, product safety is largely regulated by federal agencies. Each federal agency regulates a specific category of products, with occasional overlapping authority among agencies with respect to a particular product.

Given the breadth and diversity of products regulated by the federal government, this chapter focuses on the following three agencies: the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA) and the National Highway Traffic Safety Administration (NHTSA). These three agencies regulate tens of thousands of different types of products, from prescription drugs and medical devices, to automobiles and more than 15,000 types of consumer goods. The products regulated by these agencies are often involved in the most well-publicised safety recalls and are at the centre of much of the product liability litigation in the United States. The three primary product safety laws administered by these agencies are the Consumer Product Safety Act (CPSA), title 15 of the United States Code (USC) sections 2051 to 2089, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 USC sections 301 to 399(f), and the Motor Vehicle Safety Act (MVSA), 49 USC sections 30101 to 30183.

The CPSA applies to a broad range of consumer products defined generally as any product distributed for sale to a consumer for personal use in or around a home, school or in recreation. In addition to the CPSA, the CPSC administers a variety of other product safety statutes including: the Federal Hazardous Substances Act (FHSA), 15 USC sections 1261–78(a), the Flammable Fabrics Act (FFA), 15 USC sections 1191 to 1204, the Poison Prevention Packaging Act (PPPA), 15 USC sections 1471 to 1477, and the Refrigerator Safety Act (RSA), 15 USC sections 1211 to 1214. The FFDCA regulates foods, drugs and devices intended for human or animal use, as well as any cosmetic or biologics intended for human use. While most foods (and food additives) are covered under the FDA's jurisdiction through the FFDCA, certain foods, such as meat, poultry and egg products, are regulated separately under the United States Department of Agriculture Food Safety and Inspection Service. For reference, the laws governing these specific food products include the Federal Meat Inspection Act (FMIA), 21 USC sections 601 to 695, and the Poultry Products Inspection Act (PPIA), 21 USC sections 451 to 472. Finally, the MVSA regulates motor vehicles and items of motor vehicle equipment. Through the MVSA, the National Highway Traffic Safety Administration establishes various federal motor vehicle safety standards.

### 2 What requirements exist for the traceability of products to facilitate recalls?

As a practical matter, the ability for a firm to trace its product at the various levels in the distribution chain is essential to effectively implement a recall. That said, there are few specific requirements regarding the traceability of a product with regard to a recall. Depending on the agency, however, there may be more generally applicable traceability requirements with which the firm must comply. The FDA, as part of its quality system regulation scheme, requires that a manufacturer 'establish and maintain procedures for identifying the product during all stages of receipt, production, distribution, and installation to prevent mixups' (21 Code of Federal Regulations (CFR) section 820.60). Additionally, the manufacturer of a device intended for surgical implantation into the body must maintain procedures to identify finished devices and components, if the failure of such device or component could cause significant injury (21 CFR section 820.65). The CPSA requires tracking labels for certain children's products in order to 'facilitate ascertaining the specific source of the [children's] product' (15 USC section 2063, as amended by section 103 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)). The CPSC has authority to grant exclusions to these tracking requirements where it determines that compliance would be impracticable.

### 3 What penalties may be imposed for non-compliance with these laws?

Both the CPSA and FFDCA provide for civil and criminal penalties. Criminal penalties are typically imposed only after repeated, intentional and fraudulent violations of the statutes. Civil penalties under both statutes may include a fine, administrative action or both. The CPSC said in its 2017 annual report, for example, that it had negotiated out-of-court settlements totalling US$29.4 million in civil penalties paid to the US Treasury. Two other significant administrative penalties include seizure and injunction. Under the CPSA and FFDCA, a violative product, which has been distributed in interstate commerce, may be seized by the agency, an injunction may be entered preventing sale of the product or both (eg, 15 USC section 2071 and 21 USC section 334).

In addition to administrative penalties, both statutes provide for fines and incarceration for violating a statutory or regulatory provision. Under the CPSIA, the maximum civil penalty per violation is US$100,000. The maximum civil penalty for a related series of violations is US$15 million (15 USC section 2069). Criminal penalties can be up to five years' maximum imprisonment for a knowing and willing violation. A criminal violation of a CPSC-enforced regulation may also result in forfeiture of the assets associated with the violation (15 USC section 2070). Under the FFDCA, the specific penalty available will be determined based on the alleged violation and violative product. Penalties can range from US$1,000 to US$1 million and one to 20 years' imprisonment. Penalties under the FFDCA are more severe if the violation was undertaken knowingly and if death resulted based on a violation (21 USC section 333).

## Reporting requirements for defective products

### 4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

A manufacturer of regulated products must notify the applicable regulating authority regarding substantial safety deficiencies in its products. Although each agency maintains different thresholds and reporting requirements, all agencies rely, in large part, on the self-reporting of firms in determining product safety issues.

Under the CPSA, for example, there are two basic reporting requirements. First, a manufacturer, importer, distributor or retailer of a consumer product is required to report under section 15(b) when a product does not comply with a safety rule issued under the CPSA, contains a defect that could create a substantial product hazard to

consumers, or creates an unreasonable risk of serious injury or death. Second, under section 37, a manufacturer of consumer products must report information about lawsuits or settlements if:

- a particular model of the product is the subject of at least three civil actions filed in a federal or state court within a 24-month period;
- each suit alleges death or grievous bodily injury; and
- at least three of the suits result in final settlement or judgment in favour of the plaintiff.

The FDA also requires regulated companies to notify the agency immediately once the company becomes aware that the company's product is violative of a statute or regulation enforced by the FDA. Food manufacturers, processors, packagers and holders are required to notify the FDA as soon as they become aware that there is a reasonable probability that an article of food is 'reportable'. An article of food is considered 'reportable' if there 'is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals' (21 USC section 350f(a)). The FDA also requires that companies report serious and unexpected adverse events associated with new drugs, approved drugs, non-prescription drugs and dietary supplements as soon as possible, 'but no later than 15 calendar days from initial receipt of the information' (21 CFR section 314.80(c) and 21 CFR section 310.305(c)).

Finally, under 49 USC section 30118(c), a manufacturer of a motor vehicle or an item of original or replacement equipment must report to the NHTSA within five working days from determining that a safety defect or non-compliance exists in the manufacturer's product (49 CFR section 573.6).

### 5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

A firm's reporting obligations typically begin once the firm becomes aware that its product poses a risk to the safety of a user or consumer, or is otherwise in violation of a statutory or regulatory requirement, such as a safety standard. The specific reporting criteria and requirements, including when the information must be reported, depend on the product at issue and corresponding agency's regulations.

For example, under section 15 of the CPSA, a firm must immediately report after obtaining information that reasonably supports the conclusion that a product does not comply with a safety rule issued under the CPSA, contains a defect that could create a substantial product hazard to consumers, or presents an unreasonable risk of injury or death. According to CPSC guidance documents, 'immediately' means 'within 24 hours'. The obligation to report commences upon receipt of the reportable information, although the CPSC does allow 10 days for the company to conduct 'expeditious investigation' in order to evaluate whether the information is reportable. Likewise, the FDA's reporting obligation for drugs, non-prescription drugs for human use, and dietary supplements arises upon notice of a 'serious adverse event'. Title 21 USC section 379aa(a) defines a serious adverse event as an adverse event that results in a life-threatening experience, death, hospitalisation, disability, birth defect or requires medical or surgical intervention to prevent death, disability or birth defects. A report of a serious adverse event must be made to the FDA no later than 15 business days after the report is received by the company. Facilities responsible for the production or packaging of food are required to notify the FDA 'as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food' (21 USC section 350f(d)).

The specific regulating agency for particular classes of products is discussed in question 6.

### 6 To which authority should notification be sent? Does this vary according to the product in question?

The particular authority to which notification should be sent – as well as the kind of information to be reported as part of the notification – depends on the kind of product at issue. A list of general product types and the corresponding regulating federal agency is listed below. Additional information about the specific types of products regulated by each agency can be located at the agency's website.

- Aircraft: Federal Aviation Administration: www.faa.gov.
- Alcohol: Alcohol and Tobacco Tax and Trade Bureau: www.ttb.gov.
- Boats: US Coast Guard: www.uscgboating.org.
- Consumer products: Consumer Product Safety Commission: www.cpsc.gov.
- Cosmetics: Food and Drug Administration: www.fda.gov.
- Drugs and medical devices: Food and Drug Administration: www.accessdata.fda.gov/scripts/medwatch/.
- Industrial, commercial or farm products: Occupational Safety and Health Administration: www.osha.gov/dep/index.html.
- Firearms and ammunition: Bureau of Alcohol, Tobacco, and Firearms: www.atf.gov.
- Food (meat, poultry and processed eggs): Department of Agriculture: www.fsis.usda.gov/wps/portal/fsis/home.
- Food (except meat, poultry and processed eggs): Food and Drug Administration: www.fda.gov.
- Motor vehicles (including tyres, car seats and parts): National Highway Traffic Safety Administration: www.safercar.gov.
- Pesticides, rodenticides and fungicides: Environmental Protection Agency: www.epa.gov.
- Tobacco and tobacco products: Alcohol and Tobacco Tax and Trade Bureau: www.ttb.gov.

### 7 What product information and other data should be provided in the notification to the competent authority?

Each regulatory agency will have its own requirements for what specific product information must be reported and what forms need to be completed as part of the notification process.

For example, the CPSC provides an online 'initial report' that companies can use to report potentially defective or hazardous products pursuant to section 15 of the CPSA. The initial report can be completed at www.saferproducts.gov/CPSRMSpublic/Section15/. The reporting should be done by a person with knowledge of the product and the reporting requirements of section 15. The initial report should include the following information:

- description of the product;
- name and address of the company and whether it is a manufacturer, distributor, importer or retailer;
- nature and extent of the possible product defect or unreasonable risk of serious injury or death;
- nature and extent of injury or possible injury associated with the product; and
- contact information for the person informing the commission.

Following the filing of an initial report, a 'full report', is required to be submitted by the reporting firm. The full report requires more detailed product information than the initial report, including, but not limited to, such information as technical drawings, test results and schematics; a chronological account of facts and events leading up to the report; and model numbers, serial numbers and data codes of the affected products. The complete list of information required by the full report is set forth in 16 CFR section 1115.13(d)(1)–(15).

The FDA requires that serious and unexpected adverse events be reported using FDA Form 3500A, which is available at www.accessdata.fda.gov/scripts/medwatch/. This form provides the required information necessary for the mandatory submission of serious adverse events. Some of the information required includes: name of the suspected product; description of the adverse event; relevant history associated with the specific adverse event; and other information regarding manufacturers, importers and users of the product. Reports regarding serious adverse health consequences or death from articles of food should include information concerning date and nature of food adulteration; product information found on packaging; contact information at the reporting facility; and the contact information for parties 'directly linked in the supply chain' for the reportable food (21 USC section 350f(e)).

Finally, the NHTSA requires a manufacturer to complete a 'defect and non-compliance information report' (also known as a '573 Report') once it determines there is a defect in its product (49 CFR section 573.6). Information that must be provided in this document includes, at a minimum: the manufacturer's name; identification of the product containing the defect with a description of the manufacturer's determination of the population subject to the defect; and a description of the defect or non-compliance, including a brief summary and a detailed description of the defect (49 CFR section 573.6(c)). The regulations recognise additional information that a manufacturer should submit as it becomes available.

**8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?**

In order to ensure the adequate completion of recalls and other safety notifications, most regulating agencies require firms to submit various reporting documents regarding the status of the recall and the ongoing risks presented by the violative product. The ongoing reporting requirements and obligations will vary depending on the agency and product involved. The NHTSA, for example, requires that a recalling manufacturer submit quarterly recall reports under 49 CFR section 573.7. The specific information submitted in these reports includes, but is not limited to:

- notification campaign number assigned by NHTSA;
- date the notification campaign began and was completed;
- the number of vehicles or items involved in the campaign;
- the number of vehicles inspected; and
- the number of vehicles determined to be unreachable for inspection.

These quarterly reports are due on or before the 30th day of each month following the end of each calendar quarter (ie, 30 April, 30 July, 30 October and 30 January) (49 CFR section 537.7(d)). The FDA typically requests recall status reports every two to four weeks that include specific categories of information from which the FDA can determine the effectiveness of the current recall procedures (21 CFR section 7.53). The CPSC monitors all consumer product recalls. This typically includes submission of monthly progress reports, recall verification inspections, and retail visits conducted by CPSC field staff and state investigators to confirm receipt of recall notification and assure that recalled products are no longer being sold. This monitoring can continue as long as the CPSC deems necessary for a particular product recall.

**9 What are the penalties for failure to comply with reporting obligations?**

The failure to comply with reporting obligations is typically considered a prohibited act and may subject the firm to civil penalties, criminal penalties or both (see, for example 15 USC sections 2069–72). A firm that intentionally fails to comply with the statutory reporting obligations may be deemed to 'knowingly' commit a prohibited act and be subject to more severe penalties under the appropriate regulatory framework. A motor vehicle manufacturer that fails to comply with the reporting requirements imposed by the MVSA can be fined up to US$105 million (49 USC section 30165(a)(1)). In addition to civil and criminal penalties, a drug manufacturer that fails to comply with its reporting requirements also risks having FDA approval of its drug withdrawn (21 CFR section 314.150 (b)).

**10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?**

The Freedom of Information Act (FOIA) allows for members of the public to access information controlled by the US government. A firm may seek to protect information submitted to a regulatory agency from the reach of the FOIA. For example, firms reporting under both the CPSA and FFDCA are, in certain situations, provided with protection from FOIA requests.

The CPSA prevents the public disclosure of proprietary and confidential information. However, information included in a section 15(b) report can otherwise be made available to the public, through an FOIA request, after remedial action is requested or if the submitting firm consents. The commission must notify the company prior to the release of any information to the public and allow the submitting company an opportunity to object. The CPSIA recently reduced the time within which a company may object to the release of information from 30 days to 15 days. Additionally, the CPSIA allowed for the CPSC to further shorten this period if it determines that 'the public health and safety requires public disclosure with a lesser period of notice' (15 USC section 2055).

A firm reporting under the FFDCA is protected from the disclosure of trade secrets and confidential commercial information (21 CFR section 20.61(d)). If the FDA disagrees with a firm's classification of the information as confidential, the FDA may determine that disclosure is appropriate. In such cases, the FDA will provide the submitting entity notice of the request and the opportunity to object to disclosure. The firm will have five working days from receiving the notice to object to the disclosure under these regulations (21 CFR section 20.61(e)(1)–(2)).

**11 May information notified to the authorities be used in a criminal prosecution?**

Generally no distinction is made between disclosure of information based on civil or criminal proceedings. The CPSC, however, expressly provides that information submitted pursuant to section 37 will be immune from disclosure except for an action brought against the manufacturer for failure to provide information required by section 37 (15 USC section 2055(e)(2)). Therefore such information could be used against the manufacturer in a suit brought against it by the commission (15 USC section 2070).

## Product recall requirements

**12 What criteria apply for determining when a matter requires a product recall or other corrective actions?**

The criteria for initiating a recall or other corrective action vary according to the governing statutes, regulations and agency. Generally, once a firm becomes aware that its product is in violation of a statutory or regulatory provision of the agency, presents a threat to safety or creates a substantial risk of injury to the public even though it is not in violation of any applicable rule, the implementation of a corrective action should be considered (see, for example, 15 USC section 2064). The decision to recall a product is an important one and can be made voluntarily, at the request of the regulating agency or both. If, however, the regulatory agency requests the product be recalled as an alternative to other administrative action, a firm should consider undertaking such action so as to avoid incurring harsher administrative penalties. To encourage prompt recalls of potentially dangerous products, the CPSA allows manufacturers to elect a 'fast-track' recall procedure that, if satisfactory to the CPSC, avoids the need for a formal determination by the CPSC that the product contains a defect that creates a substantial product hazard (www.cpsc.gov/en/Business-Manufacturing/Recall-Guidance/CPSC-Fast-Track-Recall-Program/). This approach should be a serious consideration for firms seeking to minimise potential litigation or prolonged CPSC action.

**13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?**

The requirements regarding publication of warnings and other information about a defective or dangerous product vary. For some products, statutes mandate that the manufacturer make specific notifications to all owners, purchasers and dealers of the product (see, for example 49 USC section 30118(b)). Most agencies provide guidance documents or product recall handbooks outlining suggested media for publishing such information. See also the discussion in questions 7 and 14. The CPSC is required by law to maintain a public online database containing any reports made by consumers or entities of harm or risks of harm related to products covered under the CPSA (CPSIA at section 212).

**14 Are there requirements or guidelines for the content of recall notices?**

All agencies provide guidelines regarding the content of recall notices and communications concerning products under their jurisdiction. Most recall or safety communications include information such as:

- the name of the recalling firm;
- the firm's contact information;
- the name of the product being recalled;
- a general description of the danger posed by the product; and
- specific instructions on what should be done with respect to the recalled product.

Additional information such as model numbers, photographs or line drawings may be helpful or required depending on the particular product and media used for the notification (15 USC section 2064(i)). The MVSA specifically mandates seven elements that must be included in notices for motor vehicle recalls (49 USC section 30119). The FDA requires that recall notifications be in writing, contain specific categories of information about the product and the reason for the recall,

**Update and trends**

There has been a significant number of outbreaks of illness and well-publicised food recalls in 2018. In April, the Center for Disease Control reported an E. coli outbreak that was eventually tied to romaine lettuce grown in the Yuma, Arizona region. More than 200 people from 36 states were infected in the outbreak, and five deaths were reported. In May, McDonald's stopped selling pre-made salads at 3,000 locations in 14 states owing to a cyclospora outbreak. In June, pre-cut watermelon, honeydew and cantaloupe were recalled in 26 states because of a salmonella outbreak that resulted in more than 75 illnesses. In July, various snack foods including Swiss Rolls, Ritz Bitz and Goldfish crackers were recalled because of the risk that the whey ingredient used to make these foods may have been contaminated with salmonella.

These well-publicised, multi-state recalls grabbed the attention of national media outlets, which noted the rise in food-related recalls and questioned the safety of the US food supply. In a report published in April 2018, the United States Department of Agriculture (USDA) looked at the trends in food recalls from 2004 to 2013 (Trends in Food Recalls: 2004-13, EUB-191, US Department of Agriculture, Economic Research Service, April 2018). It found that between 2004 and 2008, food recalls averaged 304 a year; between 2009 and 2013 that number had more than doubled to 676.

The USDA cautioned, however, that 'this upward trend should not be interpreted to mean that foods are becoming riskier'. Instead, the USDA attributed the rise in recalls to multiple factors, including 'an increasingly complex food supply system, improvements in health risk detection, increased regulatory oversight and enforcement, and the passing of two major food policy laws'. The report highlighted two important trends in particular.

First, a recall of an upstream ingredient – such as the whey used in the snack food recall – can have an exponential impact on downstream products that use the ingredient. Between 2004 and 2013, more than 22 per cent of recalls were the result of an upstream-ingredient recall. Second, undeclared allergens were the leading cause of recalls between 2004 and 2013, a trend likely caused by the passage of the Food Allergen Labeling and Consumer Protection Act (FALCPA). FALCPA came into effect in 2006 and requires that all the major food allergens (wheat, eggs, peanuts, milk, tree nuts, soybeans, fish, and crustacean shellfish) be properly declared on food products.

These food recalls have a significant financial impact on companies and the economy as a whole. More than 80 per cent of surveyed companies described the financial impact of a recall as either 'significant' or 'catastrophic' (Capturing Recall Costs: Measuring and Recovering the Losses, Grocery Manufacturers Association, October 2011). The direct costs of a recall include notifying consumers, regulatory agencies and the supply chain; product retrieval, storage, and destruction; and lost sales and profitability from the unusable product.

The indirect – but potentially more significant – costs include post-recall litigation, lost future sales, and negative impact to the company's market value and image. Given the massive expense of recalls and the fact that many could be prevented with an accurate label declaring all allergens, USDA suggests that companies implement procedures that will ensure compliance with all laws and regulations.

specific instructions on what should be done with respect to recalled products, a ready means for recipient of communication to report to recalling firm and not contain any promotional or irrelevant materials (21 CFR section 7.49).

**15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?**

No specific requirements exist as to the exact media that must be used in communicating warning or recall information to ultimate users or suppliers. Each regulatory agency provides its own guidelines and review of sent and proposed communications. However, a press release (submitted jointly or independently by the firm) is usually considered an initial step in communicating information to a wide range of consumers. Depending on the product, the degree of the risk posed and the specific distribution chain, other forms of media may also be appropriate or required, ranging from publication of notices in newspapers to direct contact with consumers via mailings, email or telephone.

**16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?**

In most product recalls, the number of products that must be retrieved and the time period for which the recall must be conducted is a subjective fact-specific determination made on a case-by-case basis by the appropriate regulatory agency.

For example, in a recall involving a CPSC-regulated product, the recalling firm may submit a final progress report and request that the file be closed once it has determined that its corrective action plan has been implemented to the best of its ability and as many of the recalled products as possible have been removed from the marketplace. The CPSC will then review the firm's progress and decide whether the file should be closed. If the CPSC determines the plan has not been effective, it may request that the firm implement broader corrective action measures.

Likewise, the FDA will terminate a recall when it 'determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product' (21 CFR section 7.55(a)). A firm may request that the FDA make such a determination by submitting to the district office a statement in writing that the recall has achieved the articulated goals and including the most recent recall status report (21 CFR section 7.55(b)).

**17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?**

Although not always mandatory, nearly all product recalls in the United States include some form of replacement, repair or other compensation mechanism. For example, the CPSC may not approve a firm's proposed corrective action plan without some form of consumer remedy. Similarly, the FDA has authority to order a manufacturer, importer or any distributor of a device intended for human use, which the FDA determines presents 'an unreasonable risk of substantial harm to the public health' to undertake the repair, replacement or refund of the device or a combination of all three (21 USC section 360h(b)). Before issuing such an order, the FDA must provide the firm with an opportunity for an informal hearing at which time the firm may object to the classification of the FDA. Finally, it should be noted that providing a consumer remedy, even when not required by statute, may help achieve the appropriate level of consumer participation required by the administrative agency. By contrast, the MVSA specifically mandates that motor vehicle manufacturers remedy any defects without charge to the consumer (49 USC section 30120).

**18 What are the penalties for failure to undertake a recall or other corrective actions?**

Most product recalls are conducted voluntarily by firms, which may obviate more burdensome administrative procedures provided by statute (eg, seizure, detention and injunction). Therefore, a firm that fails to voluntarily initiate a product recall, or does not undertake a requested recall, may run the risk of being subjected to these harsher penalties.

**Authorities' powers**

**19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?**

The authority to compel recalls or take other corrective action varies by product and agency. In most cases, manufacturers voluntarily initiate recalls and the agency merely provides oversight and assistance with developing a recall plan. However, in some instances, the regulating agency can override a manufacturer's decision regarding the need for a recall, and take corrective action of its own.

For example, the secretary of the NHTSA can issue recall orders to motor vehicle manufacturers requiring them to give notice to all owners, purchasers and dealers as well as remedy the defect (49 USC section 30118(b)). Additionally, the FDA has the power to initiate

recalls in four limited contexts: medical devices intended for human use (21 USC 360h(a)), biological products intended for human use (42 USC section 262), human tissue intended for transplantation (21 CFR section 1271.440) and misbranded or adulterated infant formula and interstate milk shipments (21 USC section 350a(e) to (g)). Furthermore, even where the FDA cannot otherwise compel a manufacturer to recall its drug, it may suspend or withdraw approval of the drug upon finding the drug presents an imminent hazard to public health (21 USC section 355(e)).

For most consumer products, the agency seeking to compel a recall must resort to filing an action in federal court for either an injunction or seizure of the defective products (16 CFR section 1115.21). The CPSA also authorises such actions to be brought by the attorneys general for states in which a defective product is sold (15 USC section 2073(b)).

**20 Can the government authorities publish warnings or other information to users or suppliers?**

In most situations, the administrative agency works with the recalling firm in drafting and approving all product safety or recall communications. The agency will then post recall notices or other pertinent safety information on the agency's website or specific recall websites such as www.recalls.gov. For example, the FDA publishes a weekly 'Enforcement Report' regarding recently initiated recalls. The Enforcement Report communicates the particular recall classification, whether the recall was voluntary or requested by the FDA and the action being taken by the recalling firm (21 CFR section 7.50). If an agency feels the recalling firm is lacking in its recall efforts, the agency may choose to publish information to consumers directly that is critical of the recalling firm and generally unfavourable. Under the provisions of the CSPIA, the CPSC is required to maintain a public online database for product incident reports. When a report is received, the CPSC transmits notice to the manufacturer of the product at issue. The manufacturer then has 10 days to challenge the accuracy of the report before it is made public. If material inaccuracies can be established, the CPSC is granted an additional five days to investigate before publishing the report (15 USC section 2055a). Both the FDA and CPSC have the authority to issue public health notices and other public warnings related to products within their jurisdiction, and they are more likely to issue such warnings when they perceive that the firm responsible for the products has failed to take sufficient action on its own.

**21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?**

Generally, product recalls are undertaken voluntarily by a firm, with the respective agency lacking authority to initiate a recall. Firms often choose to voluntarily conduct a recall that may obviate other possible administrative actions available under the respective agency's statutes, such as seizure or injunction. As discussed in question 19, there are certain products for which Congress has provided explicit recall authority. As a practical matter, even where an administrative agency lacks the specific authority to initiate a recall, a firm requested to do so should consider complying with this request in order to avoid the statutory alternatives.

**22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?**

A firm will usually not be responsible for costs relating to the government's actions regarding a safety issue or product recall. However, a court could, upon conviction, order payment of the agency's cost of investigation (28 USC section 1918(b)).

**23 How may decisions of the authorities be challenged?**

The decision by a firm to recall a product, in most cases, is voluntary and is undertaken with the assistance and input of the applicable regulatory agency. Many of the agency's decisions during the recall process are negotiated between the agency and the recalling firm. However, in situations where the agency may seek to pursue statutory remedies such as seizure or detention, a regulated firm may desire to challenge the decision of the regulating authority. In such situations, the firm will typically have a limited opportunity to present evidence that the product in fact complies with (or does not violate) the applicable statutes, standards or regulations. The regulatory authority will review the evidence and make a determination.

## Implications for product liability claims

**24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?**

When determining tort liability, the publication of a safety warning or the initiation of a product recall is generally not considered a per se legal admission that the product at issue is defective. The CPSA, for example, expressly recognises that the use and definition of 'defect' are 'not intended to apply to any other area of the law' (16 CFR section 1115.4). Likewise, the FFDCA has a similar provision that states that information submitted in connection with the safety of a product 'shall not be construed to reflect a conclusion by the [reporting firm] that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness' (21 USC section 379v).

It should also be noted that, in practice, lay jurors may find it difficult to grasp the concept that a product that was recalled or labelled defective by the governing regulatory authority should not, in turn, also be considered 'defective' or as a basis for liability under the applicable state law. To that end, companies do have the benefit of limited legal safeguards, such as pretrial in limine motions (which can be used to attempt to exclude or limit evidence of the recall) and proposed jury instructions (which can be used to focus the jurors on the correct legal standards).


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**25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?**

Companies can expect that evidence such as internal reports or planned corrective actions will be disclosed to an adverse party during the pretrial discovery process. There are, however, certain categories of potentially relevant evidence that may – depending on the situation – be protected from disclosure. These include: communications between client and counsel, attorney work product and documents created in anticipation of litigation. In such situations, the company will have to state the basis for its non-disclosure, which can then be challenged by the adverse party. It should be noted that information or documents disclosed, or testimony given during the pretrial process will not necessarily be admissible at trial. For example, documents and other evidence of the company's subsequent remedial measures may be considered 'discoverable' but not ultimately 'admissible' in court. Conversely, courts are likely to admit evidence that a product was recalled, but may impose certain limitations on the use of this evidence at trial.

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ISBN 978-1-78915-057-5