Product Recalls

The 2008 Amendments drew their energy from the failures of imported products and product recalls. Every prudent maker of consumer products worries about product recalls. Recalls serve a social benefit, which is to avoid further injuries from a defective product, but they have an economic cost that is borne by the responsible firm, occasionally with insurance or with cost shifting to a supplier who promised to indemnify the recalling company. Recalls have been performed for decades; the FDA formalized the process in the seventies.¹

The many problems that occur during poorly managed recalls are well publicized. The CPSC has long realized that consumers are also constituents and voters who complain to Congress about the agency when a recall is badly handled by the product sponsor. These consumers tend to hold the federal government responsible when a regulated firm fails to adequately protect the consumer by executing an effective recall.

Recall failures adversely influenced congressional perceptions of the CPSC, as the primary federal agency that was tasked with oversight of the recall function in the consumer products field. The fallout of publicity about injuries from a failed recall would hit the CPSC in the form of congressional hearings and news media criticism. To an extent that cannot be quantified, the inadequacies of the currently funded CPSC have caused the public pressure for change of the statute.

Q 3.2 CONSUMER PRODUCT SAFETY REGULATION

The Basics of Product Recalls

Q 3.1 What is the CPSC’s role in product recalls?

Originally, recalls were intended to be only an ancillary function of the CPSC. Congress had set up the CPSC in 1972 to adopt many detailed technical standards on consumer products; much of the original legislation reflected details of the standards writing process. But Congress in the eighties lost interest in this expensive technical mission, accepted the Reagan Administration’s planned starvation of the CPSC budget, and failed to fund that sophisticated standard setting role. So the CPSC’s scientific strength atrophied and its work became reactive, responding when it learned from news media sources that consumer products had failed and consumers were injured. But small agencies with small budgets and a very broad constituency tend to languish in the appropriations process. Congress failed again during the nineties to fund the depth and quality of technical staff needed for excellence in the recall function, and the results were evident in the media reports of failed recalls. The stage was set for the 2008 wave of reform legislation proposals that strengthen the CPSC’s recall powers.

Q 3.2 What enhancements to the CPSC’s recall powers were effected under the 2008 Amendments?

Congress has revisited the topic of recall adequacy in 2008, and those failings were the sources of congressional support for the following enhanced recall powers in the 2008 Amendments:

- Section 15 modification giving a mandatory effect to the CPSC’s chosen remedies;
- Increased notification and content requirements for product recalls;
- Creation of an Internet Recalls Database; and
Permanent markings are required on any children’s product and its packaging to facilitate identification of products that will be subject to recalls.

Q 3.3 What section 15 provisions were modified by the 2008 Amendments?

Section 15 of the CPS Act, which deals with the “substantial product hazard” response, was modified in several ways by the 2008 Amendments. Principal among these was the substitution for “may . . . elect” with “shall,” giving a mandatory effect to the remedial actions that the CPSC has chosen to respond to the potential hazard. What had been voluntary choices became mandatory directives.

The key changes to section 15 include:

• Broader reach of the section 15 powers, beyond only a violation of final CPSC standards, now to be triggered by virtually all forms of violations of statutes, rules, or product bans in which there is arguably a substantial hazard result;
• Reducing administrative hearing delay options for respondents, to hasten the execution of an order;
• Making corrective action plans mandatory, not elective for companies;
• Mandatory upgrades of the company’s recall plan to do more active outreach, if the CPSC finds recall plans inadequate;
• “Death penalty” or an immediate halt to distribution of the product, not just one lot suspected of a defect, if the voluntary plan fails;

Q 3.4 CONSUMER PRODUCT SAFETY REGULATION

- Wider remedial authority for what the CPSC may include in mandatory orders for "corrective action";
- Uniform content of all recall notices is now specified in the Act;
- Recall notices must describe the date of the reported injuries, and details of harms caused by the product, and so the notice might scare more consumers into litigation;
- Internet database and multi-language notification to the public about recalled products;
- Involvement of and notification to state and local officials about the product recall, since state health officials receive notice of each recall and state attorneys general might become involved in penalty cases for inadequate actions;
- Strengthened import and distribution controls on products that may have a potential safety concern; and
- Bans on the export of recalled products, with narrow exceptions.

The novice reader may miss the impact of these very subtle wording changes if the sections are read too quickly. Careful parsing of the statute as amended will be essential to corporate survival in the company’s negotiations with CPSC compliance officials over a mandatory corrective action order.

Q 3.4 Were there any limitations imposed on the CPSC’s recall powers under the 2008 Amendments?

There are two limitations in the 2008 Amendments that restrict the CPSC’s flexibility in construing this section. First, if the CPSC sues under section 12 powers (pursuing court, rather than administrative, remedies) but the federal district court denies the injunction, then the CPSC must dissolve any administrative order on the same issue relating to that product; it cannot use both court and administrative weapons in hopes that one will remain in place. Second, a corrective action cannot be one that changes the “functionality” of the product. In the House Report, sponsors stated that a plan to deal with a crib’s problems by immobilizing the drop sides of the crib “would not be an appropriate remedy
because it changes the crib’s functionality.” If the CPSC staff applies this norm to their negotiations, then the company wishing to make a quick fix will need to show appropriateness of the repair in light of functionality. This is a significant limitation on potential claims by companies that a danger can be avoided simply by notifying consumers to stop using a part or an aspect of the product. For example, letters saying “to avoid fire, do not use the vacuum cleaner on shag carpets” would not be a sufficient remedy since it reduces the expected functionality. A redesign or a replacement part would be needed to have both a reduction of hazard and continued functionality.

**Q 3.5 What is the legislative history of the provisions dealing with product recalls under the 2008 Amendments?**

As a direct effect of the news media alarm over product defects and inadequate product recalls, the provisions on product recalls became more extensive and robust as the bills moved through the congressional process. The House committee held five days of hearings in 2007. The original section 209 of the House bill was far shorter in November 2007 than the text that was eventually adopted; the original section would have increased the CPSC recall authorities, but was not as substantial a change to section 15 as the Senate version.

The Conference Report on H.R. 4040 produced relatively few surprises; it gave “greater recall authority and created requirements for recall notices in order to better inform the public of potential product harms.” There were numerous product-specific items that were not carried into the final bill from the House passed bill. The one exception arose when conferees took note that child car seats are used in non-

---

4. H. REP. NO. 110-501, at 40 (2007) (while the House bill was not dominant, this language survived into the text as a requirement that CPSC “shall consider whether a repair or replacement changes the intended functionality of the product”); 15 U.S.C. § 2064(d)(3)(B).
automotive settings as well as in vehicles. The CPSC shares jurisdiction over car seats with the National Highway Traffic Safety Administration ("NHTSA"), and the 2008 Conference Report makes clear that car seat-related infant injury accidents that occur outside of vehicles are subject to (1) reporting of noncompliance, and (2) CPSC remedies, such as recalls. (In-car failures are reportable to NHTSA, and may be subject to NHTSA recalls.)

**Reporting Obligations of Regulated Companies**

**Q 3.6** What is the section 15 reporting requirement?

A regulated company is responsible for its product that is sold in interstate commerce. The CPS Act section 15 imposes a reporting duty for two primary types of problems: (1) a violated standard (with or without harm), or (2) a product that has a defect that could cause a substantial product hazard. Each of these is independent of the other grounds for reporting. The law presumes that if the product fails to meet a standard (or, after 2008, any product regulatory rule or any section of the selected statutes), then the "defect" finding can be presumed. This is more significant than the novice reader may recognize. The reporting to the CPSC of violations of the few existing final product safety standards have been relatively infrequent; that number will expand greatly. The reporting of actual or potential harm from defects found in products, apart from noncompliance with a standard, was very frequent. In the future, assuming that a responsible industry firm wishes to avoid penalties, more reports will be filed and more of the reports will be of noncompliance (typically from laboratory testing) than of "substantial hazard" or actual injury situations.

Q 3.7 What information must a company include in its section 15 report?

Section 15 reporting companies should include the following information in their reports:

- 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;
- Name, address, and telephone number of the person informing the CPSC;
- If available, the other information specified in section 1115.13(d) of the CPSC’s regulations interpreting the reporting requirements; and
- A timetable for providing information not immediately available.

In the alternative, retailers and distributors may send a letter to the manufacturer or importer of the product describing the risk of injury or death associated with the product or its failure to comply with an applicable regulation, with a copy of such a letter sent to the CPSC’s Division of Recalls and Compliance. The recipient manufacturer or importer must report to the CPSC, unless the manufacturer or importer is aware that the CPSC has been adequately informed of the defect.9

---

Q 3.8 When must a company file its report under section 15?

Amended section 15 requires that a company that becomes aware that its product either violated a standard or has a defect that could cause a substantial product hazard must make a timely report ("shall immediately inform") to the CPSC. According to the CPSC, they should receive notification "within [twenty-four] hours of [the company] obtaining reportable information."[1]

Q 3.9 Is intentional defectiveness required under section 15?

No. There is no culpability or intent required on the part of the company responsible for the product. The focus is on the product in comparison to the norms set by the terms of an existing rule, regulation, standard, or ban.

Q 3.10 How are mistakes treated under section 15?

Mistakes are events that could trigger a section 15 analysis. Examples of mistakes include mislabeling a flammable product without a Federal Hazardous Substances Act warning, marketing a blouse that fails the adult flammability standard of the Flammable Fabrics Act, or using sharp instead of rounded edges on a child toy box.

To illustrate, the maker of a household liquid product that failed the flashpoint flammability test of the Federal Hazardous Substances Act, but did not have a "flammable" warning, could previously try to escape filing a report by asserting the lack of "substantial" hazard effects. Under

11. Id.
the old two-step alternative approach, an importer could react to the news of a test result that shows a failing grade against a standard or norm by rationalizing (in the absence of coverage by a final CPS Act mandatory standard for that product) that the result of the failure would not be a “substantial product hazard.” Under the 2008 Amendments, the product’s failure of that CPSC mandated test probably means the product will be considered to be covered by section 15 reporting obligations; the violation of rules occurred from noncompliance with the labeling rule. Assuming that some evidence suggests that a hazard could result from the failure, the product marketer has less leeway in deciding not to make a report. So more notifications and more recalls are likely, with less subtle rationalization, under the 2008 Amendments.

**Q 3.11** What are the consequences of making misleading or false statements to the CPSC?

The 2008 Amendments added a special prohibition. Companies can be heavily fined if they misrepresent to agents of the CPSC the “scope of consumer products subject to” a recall or make “material” misrepresentations to the CPSC in the course of an investigation. The civil penalties for misleading or false statements are significant, but the FBI could also be brought in to prepare indictments for false official statements to a government agent. It is much smarter for the company to call in experienced lawyers early in the company’s decisional process, after a complaint or after an adverse test result. For three decades the question has always been, “Are we required to do this recall?” The answer to a situation with product defects or mandatory-testing failures is now a “yes.”

13. For thirty years, lawyers have been studying the potential defect report against the parameters set by the CPSC in 16 C.F.R. § 1115.12, see 43 Fed. Reg. 34,998 (Aug. 7, 1978).
Q 3.12 **CONSUMER PRODUCT SAFETY REGULATION**

### Corrective Action Plans

**Q 3.12 Are corrective action plans mandatory under the 2008 Amendments?**

Yes. Under the 2008 Amendments, after a company makes a timely report to CPSC, the company may negotiate with the CPSC about the terms of a corrective action plan, but there is no question that the company must carry out such a plan.\(^ {17}\) The CPSC decides what the remedy will be, what the announcement will include, and whether TV and radio dissemination of the recall notice will be required. The corrective action plan must be completed by the company at its expense. If the voluntary plan fails to adequately protect consumers, the CPSC could make a mandatory order imposing its view of an adequate plan.\(^ {18}\) The bargaining power of the small number of employees on the CPSC compliance staff is greatly enhanced.

**Q 3.12.1 What was the status of corrective action plans before the 2008 Amendments?**

Section 15 regulations prior to 2008 were rather open ended to allow these negotiations on corrective actions and recalls to proceed. Part 1115 of the CPSC rules had been in place for three decades.\(^ {19}\) Section 15 remedies were part of the original 1972 legislation, in a form that was far less stringent than the 2008 version. For decades, the CPSC compliance staff group handled the incoming reports and negotiated the terms of recalls and notification. In order to avoid the products liability consequences of an official finding of “substantial product hazards,” companies and their counsel grew familiar with negotiating the Voluntary Corrective Action Plans (“VCAPs”) with the CPSC staff.

\(^ {17}\) The passage of expanded H.R. 4040 was praised by the American Association for Justice, see www.justice.org.


Recalls under the negotiated VCAPs have been conducted for years, with a series of "carrot and stick" informal inducements and occasional confrontations that stimulated agreements. The content of notices during recalls had followed an informal template, including a standard format for a press release, which CPSC compliance staffs had created. That was more flexible and friendly to companies than the 2008 Amendments system is likely to become.

**Q 3.13 What happens when a company’s plan is deemed inadequate by the CPSC?**

After 2008, the downside of a CPSC finding that the company’s plan is inadequate would be potentially devastating to the company: an order that prevents further distribution unless the CPSC accepts an improved corrective action plan. What had been a voluntary "election" by a willing company is now a mandate fixed by the CPSC compliance staff. So any violation of the corrective plan that occurs after such an order is in place will carry heavy penalties.

**Q 3.14 What is the Product “Death Penalty” Risk?**

The 2008 Amendments raise the ante of a failed product recall. The "death penalty" of a CPSC order banning movement of the entire stock of this product is possible, if the corrective action plan failed to meet its objectives. The loss of markets, and civil penalties in the millions, could cause a smaller firm to collapse. This far higher cost of failure is on top of the products liability consequences of a poorly implemented recall.

Such a recall will trigger liabilities under state tort laws, which would increase the likelihood of a plaintiff’s substantial victory if a "recall gone bad" had exposed the plaintiff to harm. Pressure to settle with the CPSC is likely to come from distributors and retailers; prudent legal counsel with experience in dealing with the CPSC is essential to getting a reasonable settlement.

---

Q 3.15  CONSUMER PRODUCT SAFETY REGULATION

Q 3.15  What happens to companies that do not cooperate with the CPSC?

Prior to the 2008 Amendments, those companies that did not cooperate were given adverse publicity by a “Preliminary Determination of Substantial Product Hazard” that carried some publicity and product liability concerns.\textsuperscript{21} The worst recalcitrant firms were taken to court for injunctions or penalized for not having made “immediate,” that is, not sufficiently prompt, reports to the CPSC as required.\textsuperscript{22}

After 2008, if the company balks at full cooperation with the corrective action, the CPSC can issue a section 15 administrative recall order, or could go to court for a section 12 injunction. The CPSC can punish a company (retailer, distributor, manufacturer, Internet marketer, etc.) that sells a product that is subject to but is not in conformity with an order under section 15, a court order under section 12, or a corrective action plan “if the seller, distributor or manufacturer knew or should have known of such voluntary corrective action.”\textsuperscript{23} A similar ban applies to exporting such products. Connect this risk with the size of the expanded penalties, and the decision to fight against a recall becomes a very high stakes gamble.

\textsuperscript{21} These were part of the process for handling incoming reports under 16 C.F.R. \textit{1115.12(g)}.
\textsuperscript{22} 16 C.F.R. \textit{pt. 1115}.

44
Recall Notices

Q 3.16 What information must recall notices contain under the 2008 Amendments?

The era of benign euphemisms in consumer recall notices is over. After 2008, a recall notice that a company must send to its consumers will include, among other items, a more disturbing statement with an expanded impact on the reader. The company must tell the consumer:

The number and a description of any injuries or deaths associated with the product, the ages of any individuals injured or killed, and the dates on which the Commission received information about such injuries or deaths.24

The new recall notice content requirement has a bite. For example, it puts in front of the consumer who is the parent of an infant, the news that six infants have died, allegedly from using the recalled product, and that the CPSC had received news of these deaths ten days before (or, more controversially, had received news for months or years before, without compelling a recall as of that time). The impact of the specifics cannot be underestimated; consumers who were lulled by past euphemistic letters are not going to remain passive when these notice letters arrive.

Q 3.17 Will plaintiffs’ lawyers benefit from the notice letters?

For plaintiffs’ lawyers, the content of the expanded notice appears to be ideal; it is an implicit invitation for those who were injured to seek a litigator’s help to gain compensation for the injuries experienced with

Q 3.19 **CONSUMER PRODUCT SAFETY REGULATION**

that product. Companies cannot take a wait-and-see approach, waiting to see whether the defective product design produces more injuries; reporting of the actual violation of the regulation, rule, ban, or standard is enough. Because the timing of section 15(b) reports is a subject for potential civil penalties, there are likely to be more penalties issued for belated reports, and more attention by the media and activist groups to recall letters disclosing the delay between news of a product-related death and public notice of the recall.

Q 3.18 **What are the recall notice requirements for online sales?**

The “Amazon clause” applies. An Internet posting of the product warning is required on the maker’s website, and notice must also be given to Internet sales agents such as Amazon.com, walmart.com, craigslist.com, and other service providers, through whose websites the product had been sold. These Internet sales agents, in turn, must place such warning information where the consumer can read it before purchasing the product.

Q 3.19 **Can the CPSC order television and radio messages?**

Yes. If the CPSC staff determines that the product maker did not adequately reach customers with conventional print notices or posters, then the product maker can incur additional expenses. The 2008 Amendments allow the CPSC to compel the responsible firm to make television and radio spots to notify consumers “where the Commission determines that a substantial number of consumers to whom the recall is directed may not be reached by other notice.”

The Recalls Database

Q 3.20 What is the recalls database?

One of the farthest-looking provisions of the 2008 Amendments was the database of product problems proposed by consumer advocates, and that was strongly opposed by industry and the Bush Administration.26 The 2008 Amendments create a newly expanded Safety Database for consumer products that is "publicly available, searchable, and accessible through the Internet website of the Commission."27 The database must include all reports of harm that are not duplicative28 or otherwise excluded. This “early warning” for consumers builds on the longstanding injury database that has been maintained by the CPSC for decades to capture injury data from selected hospital admissions.29

Q 3.21 What information will be available on the database?

The database entries will include:30

- Product descriptions;
- Manufacturer or private labeler identification;
- Description of the “harm relating to the use of the consumer product”;

26. The final language of this provision was negotiated closely in the Conference Committee. An even stronger database proposal by Rep. Markey in the House was voted down 35–14 in Committee, with every Republican voting “no.” H. REP. NO. 110-501, at 25.
Q 3.22 CONSUMER PRODUCT SAFETY REGULATION

- Contact information for the person making the report;
- A statement verifying that the information is "true and accurate to the best of the person's knowledge";
- Consent of the submitter to inclusion of the data in the database; and
- Any additional information the CPSC finds to be in the public interest.

A disclaimer is required that the CPSC "does not guarantee the accuracy, completeness or adequacy of the contents of the database."³¹ Whether database results are admissible into evidence will be debated in future tort cases.

Q 3.22 Do companies receive advance notice of inclusion in the database?

Congress included, as industry requested, a provision for ten days' advance notice to the company of the critical report concerning its product before it is included in the database (and will be posted along with the company's rebuttal statement). The CPSC can decide to exclude from the database "materially inaccurate" information, and it can remove prior postings or place additional corrective information on the database when rebuttal data is later received.³² The Bush Administration "strongly opposed" this provision because it said, in echoing comments by industry, that it would be of "limited public safety benefit" and "will result in a significant increase in wasteful litigation, especially if there are no controls for the quality of the data, in addition to placing signifi-

cant, unnecessary burdens on the CPSC.”[^33] Final passage included authorization for $25 million to be spent on the new database.[^34]

### Tracking Labels

**Q 3.23** What permanent markings are required under the 2008 Amendments?

Makers of children’s products will need to alter their plastic mold, metals stamping tools, and package printing cylinders before August 2009. A “permanent, distinguishing” mark must be “on the product and its packaging” to facilitate identification of products that will be subject to recalls. The markings will allow identification of the source of the product, its batch or lot information, and date of production.[^35]


Q 3.24 What actions can the CPSC bring against regulated companies in Federal court?

“If you’re in court, you’ve already lost!” may be the experts’ response to the 2008 changes in the CPS Act. Under the 2008 Amendments, section 15 remedies are expanded and there are many more non-judicial weapons available to the administrative compliance staffs. In the past, court injunctions were available under section 12 of the CPS Act but were very rarely sought. Negotiations with the CPSC compliance staff should be pursued in hopes that the federal courts will not become involved. Under section 12, a district court can decide to enjoin further distribution of the product, and the CPSC may ask for a temporary injunction to freeze the further dissemination of the product in commerce.

Q 3.25 What is the role of the courts in product recall cases?

The 2008 Amendments clarify what has been implicit: if the situation is so bad that the CPSC seeks a court order against an “imminent hazard,” then the CPSC has no obligation to also hold an administrative hearing. The CPSC staff has independent litigating authority because the CPSC is an independent agency. Presumably, however, the local U.S. Attorney will act as co-counsel in filing the action sought by the CPSC. The Justice Department’s Office of Consumer Litigation may also be involved.
Regulated Persons

Q 3.26 What product recall-related training programs must companies consider offering to their employees?

First and foremost, each consumer products company needs to study where its own obligations fit into the new and more highly regulated product recall system. Ask not what the CPSC will do for you, ask what the law now requires you to do for the consumer.

After identifying the impacts, prudent managers should invest in sound and practical training for their employees. Training that is related to specific job functions in the product recall context include:

- training the retail backroom and distributor warehouse clerks about quarantine of returned stocks of a recalled product;
- training the customer call center team to be vigilant for customer comments that trigger a potential section15 report;
- training import companies’ managers at the bonded warehouse where incoming containers are unloaded; and
- training customer service to monitor returns that assert injury or the potential for injury.

During training for potential recall duties, companies should emphasize to workers the reasons behind product safety activities. Explain the reason for upgrading systems, giving a plastic product durable product codes, preparing for potential recalls, examining complaint trends, getting back more units, disseminating more bulletins, calling more retail outlets, and so on. Avoiding harm to consumers is the primary reason, of course. The bottom line is that early warning is the remedial purpose of the 2008 Amendments.
Q 3.27 How can companies prepare for potential recalls?

Now that a legal minefield of new obligations and higher penalties has been established, planning is absolutely essential. Companies must focus on integrating an automated goods tracking and retrieval system. There is no question that the 2008 Amendments will expose firms to harsher punishment, and no question that prudent companies must train for their new responsibilities.

Q 3.28 How will companies comply?

*Distributing and manufacturing companies.* Distributors and manufacturers must get ready to pay more in customer restocking and overhead charges in the event of a recall.

*Company finance officers.* The finance officers of companies involved with consumer products must become fully aware of the charge-backs and additional costs that downstream participants will pass along to the owner or responsible party.

*U.S. agents acting as “importers of record.”* If you are a U.S. agent acting as the “importer of record” and the manufacturer of the consumer product is a foreign company, it will be timely to revise the contract to spell out who will have to bear which costs of the recall.

Q 3.29 Will importers bear losses?

In rare cases, the actual manufacturer of the failed component or toy is so remote in geography and in economic capacity to pay that the cost of the recall is borne by the importer. No one will be surprised if recall costs drive some importers to drop certain product lines or even into bankruptcy. The 2008 Amendments, like the existing CPS Act, do not excuse product defects on the basis of company size. The law will not allow an excuse or escape that asserts the costs of a complete recall will lead to a company’s financial ruin.