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Consumer Product Safety Improvement Act of 2008

The U.S. Consumer Product Safety Commission has long used the duty of companies to notify CPSC of potential safety hazards and the threat of civil penalties for late reporting as a key enforcement tool. The recently enacted Consumer Product Safety Improvement Act of 2008 expands this reporting requirement, increases the maximum civil penalties for late reporting, and also opens the door for criminal penalties. This Analysis and Perspective article by attorney Eric A. Rubel provides a detailed discussion of the Section 15 notification requirements and addresses related changes implemented by the CPSIA.

This article is the fifth in a series on the CPSIA that examine the law from different perspectives. Previously, John B. O'Laughlin Jr. addressed the preemptive effect of the act (36 PSLR 1037, 10/20/08). On Oct. 6, professor James T. O'Reilly examined the statute's effect on small business and foreign companies (36 PSLR 974, 10/6/08). On Sept. 29, attorneys David Arkush and Graham Steele discussed the law's impact on product safety (36 PSLR 940, 9/29/08). An analysis of the CPSIA, by attorney Kerrie L. Campbell, appeared Sept. 22 (36 PSLR 908, 9/22/08).

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Consumer Product Safety Notification Requirements: Section 15 of the Consumer Product Safety Act

BY ERIC A. RUBEL

The U.S. Consumer Product Safety Commission (CPSC) has jurisdiction over the safety of a broad array of products. With a budget for fiscal year 2008 of $80 million (up from about $63 million in 2007) and fewer than 450 employees, the agency is responsible for helping to protect consumers from unreasonable risks of injury from more than 15,000 types of products. Particularly given the agency's limited resources and the enormous investment of staff time required to adopt new regulations, CPSC relies heavily on enforcement of the mandatory notification requirements under Section 15 of the Consumer Product Safety Act (CPSA) to carry out its mandate. Further, as discussed in this article, the notification requirements have now been expanded by the Consumer Product Safety Improvement Act of 2008 (CPSIA), and the penalties for non-compliance have been increased dramatically.

CPSC is an independent[1] federal agency that Congress created in 1972 under the Consumer Product Safety Act (CPSA). CPSC's statutory mandate is to protect the public against ''unreasonable risks of injury associated with consumer products.''[2] As discussed below, the CPSA defines the term ''consumer product'' broadly, and CPSC has asserted jurisdiction over a wide range of products. Moreover, under the CPSIA, the statutory reporting requirement has been extended to articles other than consumer products over which CPSC has jurisdiction.

This Analysis & Perspective first explains the statutory notification requirements under Section 15 of the CPSA, and then discusses two routes to consumer product recalls. The article then addresses the CPSA penalty provisions for late reporting under Section 15. Finally, the article describes CPSC's ''working model'' for Section 15 reporting, which provides a safe harbor from civil penalties through the use of objective reporting criteria for firms that voluntarily participate in the program.

[1] CPSC does not report to any other department or agency in the federal government. The agency's chairman and commissioners are appointed by the president for seven-year terms with the advice and consent of the Senate.

[2] 15 U.S.C. § 2051(b)(1).

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I. Duty to Report to CPSC Under Section 15 of the CPSA

Under Section 15 of the CPSA, a manufacturer, distributor or retailer of a consumer product or any other product over which CPSC has jurisdiction (other than motor vehicle equipment),[3] distributed in commerce, must notify CPSC ''immediately'' upon the receipt of information that reasonably supports the conclusion that such product:

(1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under Section 2058 of this title;[4]

(2) fails to comply with any other rule, regulation, standard, or ban under [the CPSA] or any other Act enforced by the Commission;[5]

(3) contains a defect which could create a substantial product hazard . . . ; or

(4) creates an unreasonable risk of serious injury or death.[6]

There are no objective standards in the statute or CPSC's interpretive regulations as to when a duty to notify CPSC is triggered with respect to sub-parts (3) and (4), above. Rather, the requirements are relatively subjective, and the thrust of the CPSC's regulations is to urge companies to report early and often.[7]

A. *Definition of 'Consumer Product'*

The CPSA defines a ''consumer product'' as:

[3] The CPSIA expanded Section 15 beyond consumer products to include other products regulated by CPSC, other than motor vehicle equipment. Pub. L. No. 110-314, § 214(a)(2), 122 Stat. 3016, 3054 (2008). The Motor Vehicle Safety Act, enforced by the National Highway Traffic Safety Administration, contains a separate notification requirement applicable to manufacturers of motor vehicles and motor vehicle equipment. 49 U.S.C. § 30118(c).

[4] The only voluntary standards upon which CPSC has so relied are provisions of (i) ANSI B1715.1 (gasoline-powered chain saws), and (ii) ANSI Z21.11.2 (gas-fired room heaters). *See* 16 C.F.R. Part 1115, App.

[5] This provision was added by the CPSIA. Pub. L. No. 110-314, § 214(a)(2), 122 Stat. 3016, 3054 (2008).

[6] 15 U.S.C. § 2064(b). The ''unreasonable risk'' clause was added to the CPSA in 1990 through the Consumer Product Safety Improvement Act of 1990. Pub. L. No. 101-608, § 112(a)(2), (3), 104 Stat. 3110, 3115 (1990).

[7] Two other notification requirements are beyond the scope of this article but should not be ignored: (i) manufacturers of consumer products must notify CPSC upon settling or receiving adverse judgments in three or more lawsuits in state or federal court alleging ''death or grievous bodily injury'' from the same model of a consumer product during designated 24-month periods (*e.g.*, 1/1/2001 thru 12/31/2002 etc.), *see* 15 U.S.C. § 2068; 16 C.F.R. §§ 1116.3(b)-(c); and (ii) manufacturers, importers, distributors and retailers must notify CPSC within 24 hours of receiving a report that a child choked on a marble, small ball, latex balloon, or small part and died, suffered serious injury, ceased breathing for any length of time or was treated by a medical professional. *See* Pub. L. No. 103-267, 108 Stat. 722 (1994); 16 C.F.R. § 1117.4(a)).

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> any article, or component part thereof, produced or distributed (i) for the sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation or otherwise.[8]

Excluded from this statutory definition of ''consumer product'' are certain products under the jurisdiction of other federal agencies, such as automobiles, aircraft, tobacco, firearms, pharmaceuticals, and medical devices.[9] The CPSA also excludes ''any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer.''[10] In addition, buildings or structures do not qualify as ''consumer products'' under the statute.[11]

Companies rarely have challenged CPSC's assertion of jurisdiction in court, and only a few decisions have addressed the meaning of the statutory term ''consumer product.'' In one case, an administrative law judge considered whether CPSC has jurisdiction over allegedly defective fire sprinkler heads.[12] The judge in *In re Central Sprinkler Corp.* found that CPSC had jurisdiction over the sprinklers even though they were installed in commercial and industrial buildings; they were marketed primarily to professional contractors; and consumers did not actively use the product.

The judge focused on the fact that the sprinkler heads were produced and sold as distinct articles of commerce,[13] and found that a ''consumer product'' need not be available ''off the shelf'' at the retail level or used in consumers' homes.[14] The judge further found that ''products which are primarily or exclusively sold to industrial or individual buyers would be included within the definition of consumer product so long as they were produced or distributed for use of the consumers.''[15] Finally, the judge found that the ''weight of judicial opinion'' determined that the ''focus of the Act is directed towards consumers' exposure to hazards associated with products.''[16] And, in fact, courts have focused on the exposure of consumers to harm in finding that CPSC has jurisdiction over aluminum branch circuit wiring systems,[17] aerial tramways at state fairs,[18] refuse bins,[19] and amusement park rides.[20]

The decision in *Central Sprinkler* is consistent with CPSC's historically broad interpretation of the term ''consumer product'' to include virtually any article, or component of an article, used by or having an effect on consumers. For example, CPSC has asserted jurisdiction over escalators and elevators. Although it may be counterintuitive to consider escalators and elevators as consumer products, CPSC has exerted jurisdiction because consumers could be exposed to risks associated with those products. As CPSC explained in a 1978 Advisory Opinion, ''Congress' overriding concern in enacting the CPSA was to provide one agency with jurisdiction over products which could expose consumers to unreasonable risks of injury, regardless of where that exposure occurred.''[21] Under this logic, CPSC has asserted jurisdiction to reach many seemingly ''commercial'' products, such as vending machines,[22] cement-asbestos wallboard used in construction,[23] blown-in fiberglass insulation,[24] and fire alarm equipment.[25]

The expansion of Section 15 to cover other products over which CPSC has jurisdiction addresses what had been an unsettled issue in the law. As noted, food, drugs and cosmetics are excluded from the CPSA's definition of ''consumer product.''[26] CPSC's authority with respect to such substances is limited to certain packaging issues—e.g., mechanical hazards from food packaging with sharp edges, which CPSC addresses under the Federal Hazardous Substances Act (FHSA) or the CPSA, and child resistant packaging, which CPSC regulates through the Poison Prevention Packaging Act

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[8] 15 U.S.C. § 2052(a)(1).

[9] *See id.*

[10] *Id.*

[11] *See CPSC v. Anaconda Co.*, 593 F.2d 1314, 1320 n.19 (D.C. Cir. 1979) (CPSC concedes that it lacks jurisdiction over housing).

[12] *In re Central Sprinkler Corp.*, CPSC Docket No. 98-2 (Apr. 6, 1998). Note, however, that the decision was not appealed to the Commission.

[13] *See id.* at 11-12.

[14] *See id.* at 10-12 (discussing *Anaconda*, 593 F.2d at 1319 and *Kaiser Aluminum & Chem. Corp. v. CPSC*, 574 F.2d 178 (3d Cir. 1978)).

[15] *See id.* at 14 (quoting *Anaconda*, 593 F.2d at 1322).

[16] *See id.* at 14.

[17] *Kaiser Aluminum*, 574 F.2d at 181-82 (finding that CPSC has jurisdiction over aluminum branch circuit wiring systems); *but see Anaconda*, 593 F.2d at 1320 (explaining that the term ''consumer product'' was designed to include the various ways ''through which consumers acquire products and are exposed to the risks of injury associated with those products,'' but remanding for a determination of whether CPSC has jurisdiction over aluminum branch circuit wiring systems).

[18] *See State Fair of Tex. v. CPSC*, 650 F.2d 1324, 1329 (5th Cir. 1981) (finding a fixed site amusement ride is a ''consumer product,'' and ''a critical factor [in the determination] is the consumer's exposure to a product, not the legal relation to it'').

[19] *See United States v. One Hazardous Prod. Consisting of a Refuse Bin*, 487 F. Supp. 581, 584 (D.N.J. 1980) (stating that refuse bins found in apartment complexes, supermarkets, motels, retail businesses and other locations are ''consumer products'' since their distribution ''results in a significant number of consumers being exposed to the hazard associated with the product'').

[20] *See CPSC v. Chance Mfg. Co.*, 441 F. Supp. 228, 231, 233 (D.D.C. 1977) (jurisdiction depends upon the extent to which consumers were exposed to the risks associated with the product) *but see Robert K. Bell Enterprises v. CPSC*, 645 F2d 26 (10th Cir.1981).

[21] *See* Adv. Op. No. 262, 2 (Feb. 27, 1978), *available at* http://www.cpsc.gov/library/foia/advisory/262.pdf.

[22] *See* Adv. Op. No. 125 (Oct. 23, 1973), *available at* http://www.cpsc.gov/library/foia/advisory/125.pdf.

[23] *See* Adv. Op. No. 55 (Dec. 21, 1973), *available at* http://www.cpsc.gov/library/foia/advisory/55.pdf.

[24] *See* Adv. Op. No. 205 (May 21, 1975), *available at http://www.cpsc.gov/library/foia/advisory/205.pdf*. *See also* 16 CFR § 1209 (interim standard for cellulose insulation).

[25] *See* Adv. Op. No. 181 (Feb. 12, 1975), *available at* http://www.cpsc.gov/library/foia/advisory/181.pdf.

[26] 15 U.S.C. § 2052(a)(1)(H).

(PPPA).[27] However, neither the FHSA nor the PPPA contains a notification requirement analogous to Section 15 of the CPSA. Thus, arguably there was no duty to notify CPSC where the ultimate risk was from the contents of the packaging—e.g., spoiled food in a can that was not properly sealed, or drugs or cosmetics that lacked required child-resistant packaging—rather than from the packaging itself.[28] Yet, the staff has contended that packaging is itself a consumer product, and thus that there was a duty to notify CPSC of packaging defects even where the risk of injury was presented by the contents of the packaging and not by the packaging.[29] The issue has now been resolved, in part, through the expansion of the notification requirement to cover all products, other than motor vehicle equipment, over which CPSC has jurisdiction under any act enforced by CPSC.

B. *Failure to Comply With a Rule, Regulation, Ban or Standard Under Any Act Enforced by CPSC*

Effective Oct. 13, 2008, the CPSIA expanded the Section 15 notification requirement to apply to the failure of any product (other than motor vehicle equipment) over which CPSC has jurisdiction and that is distributed in commerce to comply with ''any . . . rule, regulation, standard, or ban'' under any act enforced by the Commission.[30] This change has important consequences. *First,* as noted above, it clarifies that the duty to notify CPSC applies to items other than consumer products over which CPSC has jurisdiction (e.g., drugs and cosmetics that lack required child-resistant packaging).[31]

Second, in the past, absent evidence that a product presented a substantial product hazard or an unreasonable risk of serious injury or death, the only rules that triggered mandatory notification were the narrow class of ''consumer product safety rules''—those described in Section 7(a) of the CPSA, and rules under the CPSA declaring a consumer product to be a banned hazardous substance. Now, however, the violation of any rule, regulation, ban or standard—regardless of type and regardless of whether it was enacted pursuant to the CPSA or another act that the Commission enforces—automatically triggers a duty to notify CPSC under Section 15.

In addition, the CPSIA has added a number of standards under the CPSA (e.g., a ban of certain phthalates in toys and child care articles; provisions of the industry toy standard, ASTM F963; and advertising requirements for certain toys and children's products) and under the FHSA (e.g., decreased limits on lead in paint and surface coating; limits on lead in the substrate of children's products). The failure to comply with these new standards will trigger mandatory notification under Section 15 (as well as potential enforcement actions for the underlying violation). Similarly, the CPSIA directs the Commission to adopt a number of new standards and rules (e.g., standards and consumer registration requirements for durable infant and toddler products). Again, a manufacturer, importer, distributor or retailer will be required to notify CPSC under Section 15 of the failure to comply with these new standards once they become effective.

C. *'Substantial Product Hazard'*

The CPSA defines a ''substantial product hazard,'' in relevant part, as ''a product defect'' that ''creates a substantial risk of injury to the public.''[32] The Act, as amplified by CPSC's interpretive regulation on Section 15 reporting, identifies the following factors that may be considered in assessing whether a product defect or noncompliance ''presents a substantial risk of injury.''[33]

- ''[p]attern of defect'';
- ''[n]umber of defective products distributed in commerce'';[34]
- ''[s]everity of the risk''; and
- ''[o]ther considerations.''[35]

CPSC's regulations provide that, as in the product liability context, a product can be defective with respect to its design, manufacture or warnings.[36] Factors to be considered in assessing whether a product is defective include, ''as appropriate:''

- ''the utility of the product involved'';
- ''the nature of the risk of injury which the product presents'';
- ''the necessity for the product'';
- ''the population exposed to the product and its risk of injury'';
- ''the obviousness of such risk'';
- ''the adequacy of warnings and instructions to mitigate such risk'';

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[27] 15 U.S.C. §§ 1471-76.

[28] *See, e.g.,* Adv. Op. No. 229 (December 15, 1975), *available at* http://www.cpsc.gov/library/foia/advisory/229.pdf (opining that CPSC has jurisdiction over packaging for food or cosmetics that presents a ''mechanical hazard,'' but not over such packaging where the ''ultimate harm is . . . related to the properties of the ingredients'').

[29] The Commission had asserted that ''manufacturers (including importers), distributors, and retailers of *consumer products* which are subject to regulation under provisions of the FFA, FHSA, and PPPA must comply with the reporting requirements of Section 15(b).'' 16 C.F.R. § 1115.2(d) (emphasis added). However, this begged the question whether food, drug or cosmetic packaging is itself a ''consumer product,'' particularly where the ultimate risk of harm is from the contents of the packaging.

[30] 15 U.S.C. § 2064(b)(2); *see* Pub. L. No. 110-314, § 214(a)(2), 122 Stat. 3016, 3054 (2008).

[31] It remains to be seen how far CPSC will attempt to stretch the scope of the expanded notification requirement. For example, while medical devices are excluded from the definition of a ''consumer product,'' they are not excluded from the scope of the FHSA. *Compare* 15 U.S.C. § 2052(a)(1)(ii)(H) (excluding drugs, devices and cosmetics, as those terms are defined under the Federal Food, Drug and Cosmetic Act, from the definition of a ''consumer product'' under the CPSA) *with* 15 U.S.C. § 1261(f)(2) (excluding drugs and cosmetics, but not devices, from the definition of a ''hazardous substance'' under the FHSA).

[32] 15 U.S.C. § 2064(a).

[33] 16 C.F.R. § 1115.12(g).

[34] CPSC's July 2006 amendments to the interpretive regulations clarify that it is the number of units ''remaining with consumers,'' rather than the number initially distributed, that may be relevant to determining the severity of the risk. *See* 71 Fed. Reg. at 42,030. However, the Commission cautioned that a company ''may still have a reporting obligation'' even if ''the number of products being used by consumers decreases'' over time. *Id.* According to the Commission, firms that delay reporting ''in anticipation of, or because of, a decrease in the number of products in use . . . will be subject to civil penalties.'' *Id.*

[35] 16 C.F.R. § 1115.12(g).

[36] *See* 16 C.F.R. § 1115.4; *see also, e.g.,* Restatement (Third) of Torts: Prod. Liab. § 2 (1998).

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- ''the role of consumer misuse of the product and the foreseeability of such misuse'';
- ''the Commission's own experience and expertise'';
- ''the case law in the area of products liability'';

and

- ''other factors relevant to the determination.''[37]

Three of these factors were formalized during 2006 when CPSC amended the interpretive regulation. Specifically, CPSC added ''the obviousness of the risk,'' ''the adequacy of warnings,'' and ''the role of consumer misuse'' to the litany of factors.[38] Further, in revising the reporting regulation, the Commission cautioned companies that ''[r]eliance on one factor alone cannot negate a reporting obligation if other factors, as applied, reasonably support the conclusion that a defect exists.''[39]

CPSC instructs companies to consider all reasonably available information to determine ''whether it suggests the existence'' of a product defect or unreasonable risk.[40] Examples of such information include engineering, quality control, or production data; information about safety-related production or design change(s); information from an independent testing laboratory; product liability suits and claims for personal injury or property damage; consumer complaints; information received from CPSC; and information received from other firms.[41]

CPSC has also addressed the relevance of voluntary and mandatory standards in determining whether a product presents a substantial product hazard. CPSC may consider compliance or non-compliance with such standards as relevant factors in determining whether a substantial product hazard exists. However, the Commission does not view compliance with such standards as necessarily precluding the need to notify CPSC under Section 15.[42] Further, according to the Commission, ''[c]ompliance with a voluntary standard does not preclude a determination that a substantial product hazard exists.''[43] With respect to hazards addressed by mandatory standards, the Commission strikes a somewhat softer tone, stating that, while compliance does not ''provide [a] safe harbor for the failure to report, ... the Commission appreciates that it is generally inappropriate to hold firms to a higher standard for products retroactively.''[44]

Neither Section 15 nor the interpretive regulations specify the geographic scope of the information to be considered in determining whether there is a duty to notify. CPSC has taken the position in a policy statement that firms should evaluate not only information about products sold in the United States, but also information about the same or substantially similar products sold outside of the United States ''that may be relevant to defects and hazards associated with products distributed within the United States.''[45]

D. *'Unreasonable Risk of Serious Injury or Death'*

With respect to reporting an ''unreasonable risk of serious injury[46] or death,'' CPSC's regulations provide that the duty to notify is triggered by information that reasonably supports the conclusion that such a ''risk'' is presented, even if ''no final determination of the risk is possible.''[47] Thus, ''[t]he Commission expects firms to report if a reasonable person could conclude given the information available that a product creates an unreasonable risk of serious injury or death.''[48] Moreover, CPSC has stated that companies ''should not wait for such serious injury or death to actually occur before reporting.''[49]

Determining whether a risk is ''unreasonable'' involves a balancing of factors, including the product's utility, the nature and extent of the risk, and the availability of alternative designs or products that could eliminate the risk.[50] Information that may indicate the presence of an unreasonable risk includes ''reports from experts, test reports, product liability lawsuits or claims, consumer or customer complaints, quality control data, scientific or epidemiological studies, reports

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[37] 16 C.F.R. § 1115.4.

[38] 71 Fed. Reg. 42,028, 42,029 (July 25, 2006).

[39] *Id.* at 42030.

[40] 16 C.F.R. § 1115.12(f).

[41] *Id*.

[42] *See* 16 C.F.R. § 1115.8.

[43] 71 Fed. Reg. 42,030.

[44] *Id. But see* Adv. Op. No. 317 (Sept. 12, 2008), *available at* http://www.cpsc.gov/library/foia/advisory/317.pdf (opining that the new lead limits imposed by the CPSIA apply to inventory). It should also be noted that companies have paid civil penalties for allegedly failing timely to notify CPSC about products that evidently complied with mandatory standards that addressed the very risk at issue. In 2004, Battat Inc. agreed to pay a civil penalty of $125,000 to settle allegations that it failed timely to notify CPSC about a choking risk associated with a drum set. 69 Fed. Reg. 56,202, 56,202-03 (Sept. 20, 2004). CPSC acknowledged that the product complied with the small parts standard in testing, but alleged that Battat failed timely to notify the agency that the product could produce small parts in actual use. *Id.* Similarly, in 2007, Fisher-Price agreed to pay a civil penalty of $975,000 to settle allegations that it failed to report that a nail fastener in the Little People® Animal Sounds Farm could separate from the toy and pose a choking or aspiration hazard to young children, despite the absence of any suggestion that the product failed to comply with the small parts standard. 72 Fed. Reg. 10,713, 10,713-15 (Mar. 9, 2007).

[45] 66 Fed. Reg. 30,715, 30,715, 30,717 (June 7, 2001).

[46] CPSC considers the term ''serious injury'' to include not only grievous injuries, e.g. mutilation, amputation, severe burns and/or electrical shock, loss of important bodily functions, and debilitating internal disorders, *see* 16 C.F.R. § 1115.12(d), but also injuries requiring hospitalization for medical or surgical treatment, ''fractures, lacerations requiring sutures, concussions, injuries to the eye, ear, or internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day,'' *id.* § 1115.6(c). In addition, CPSC advises that chronic or long-term health effects, as well as immediate injuries, should be considered. *See id.*

[47] *Id.* § 1115.6(a); *see also Mirama Enters.*, 387 F.3d at 988 (concluding that ''[i]nformation about a possible defect triggers the duty to report, which in turn allows the Commission either to conclude that no defect exists or to require appropriate corrective action'').

[48] 16 C.F.R. § 1115.6(b). CPSC has asserted in civil penalty matters that a ''reasonable person'' may refer to an ordinary person who does not necessarily have expertise in any given subject, and the court in *Mirama* agreed. *See Mirama Enters.*, 185 F. Supp. 2d at 1158-59 (stating that ''[t]he standard is a 'reasonable person' standard, not a 'reasonable expert' standard'' and finding that, based on the evidence Aroma had received, ''a reasonable person could conclude that the juicer contained a defect which created a substantial risk of injury to the public . . . and . . . 'an unreasonable risk of serious injury or death' '').

[49] 16 C.F.R. § 1115.6(a).

[50] *Id.* § 1115.6(b).

of injury, information from other firms or governmental entities, and other relevant information.''[51]

E. *Timing of the Reporting Obligation*

As noted, companies are required to notify CPSC ''immediately'' upon receiving information that triggers a reporting obligation. CPSC interprets ''immediately'' to be within 24 hours after a company obtains the requisite information.[52] If a company is uncertain about whether information is reportable, it may investigate the matter. CPSC takes the position that a company may not take longer than 10 days to conduct an investigation, unless a longer period is reasonable.[53] Moreover, according to the Commission, companies may not wait until a defect is established scientifically before reporting under Section 15. Rather, CPSC ''urge[s]'' companies to ''report if in doubt as to whether a defect could present a substantial product hazard'' or ''as to whether a defect exists.''[54]

F. *Who Must Notify CPSC Under Section 15 and What to Report*

The duty to notify CPSC under Section 15 applies to manufacturers, importers (who are included within the definition of ''manufacturer'' under the CPSA), distributors and retailers—essentially all entities in the chain of distribution.[55] An entity need not report, however, if it has ''actual knowledge that'' the CPSC ''has been adequately informed'' of a potential hazard.[56]

CPSC's interpretive regulation identifies information that should be included in an ''Initial Report'' under Section 15(b)—identification of the product; name and address of the manufacturer, if known; nature and extent of the possible defect; nature and extent of the risk of injury; and the name and address of the person notifying the Commission.[57] A more extensive list of information is then specified for the Full Report—e.g., how and when the company learned of the issue; the total number of units at issue; the number of units in possession of the manufacturer, distributors, retailers and consumers; when the product was manufactured, imported, distributed and sold at retail; any pertinent changes that have been or will be made to the product; details of any planned recall; and a description of how the product was marketed and distributed.[58] If a company does not propose to conduct a recall, the Full Report should explain why no corrective action is warranted.

Retailers and distributors may provide less information than is required of manufacturers and importers. A retailer/distributor that is not also the manufacturer or importer of a product may satisfy its Section 15 notification obligation by submitting to CPSC only the Initial Report information, and sending a copy of the report to the product's manufacturer or importer.[59] The Commission staff may then request additional information from the product's manufacturer or importer, and may also follow up with the reporting retailer/distributor.

In practice, CPSC typically pursues recalls through a U.S. manufacturer or importer, rather than through a retailer or distributor that did not also import the product. This approach generally is more efficient—both for the government and companies—and less confusing for consumers than having each retailer of a product develop and implement a separate corrective action plan for the product. However, civil penalties have been assessed against retailers for alleged late reporting under Section 15.[60] In addition, CPSC has required retailers and distributors to recall products when, for example, the retailer imported the product directly or the manufacturer was insolvent or was not located in the United States.[61]

F. *Confidentiality*

Under Section 6(b)(5) of the CPSA, information submitted to the Commission under Section 15 is exempt from disclosure by the agency under the Freedom of Information Act or otherwise, absent one of the following exceptions:

(1) CPSC files an administrative complaint seeking to require a recall;

(2) CPSC accepts ''a remedial settlement'' (*i.e.*, a voluntary recall) in writing;

(3) The person who submits the information agrees that it may be disclosed; or

(4) CPSC publishes a finding that the public health and safety requires public disclosure with less than 15 days notice.[62]

Confidentiality also does not apply if CPSC files a complaint in federal district court alleging that a consumer product presents an ''imminent hazard'' under Section 12 of the CPSA, or if the Commission has ''reasonable cause to believe'' that a product violates a ''consumer product safety rule or provision under [the CPSA] or

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[51] *Id.* § 1115.6(a).

[52] *Id.* § 1115.14(e).

[53] *Id.* §§ 1115.14(c), (d).

[54] 16 C.F.R. § 1115.4(e); *see also United States v. Mirama Enters. Inc.*, 185 F. Supp. 2d 1148, 1159-60 (S.D. Cal. 2002) (noting that ''[c]ertainty is not the reporting threshold'' and that ''[c]ompanies are specifically advised to over-report rather than under-report'' (citing Statement of Enforcement Policy, 49 Fed. Reg. 13820, 13822 (Apr. 6, 1984)), *aff'd*, 387 F.3d 983 (9th Cir. 2004).

[55] 15 U.S.C. § 2064(b).

[56] *Id.*; *see* 16 C.F.R. § 1115.10(f); *Mirama Enters.*, 185 F. Supp. 2d at 1163 (finding that CPSC was not adequately informed under Section 15 when the agency knew of 7 of 23 incidents of which the company had knowledge).

[57] *See* 16 C.F.R. § 1115.13(c).

[58] *See* 16 C.F.R. § 1115.13(d). The staff frequently asks the reporting company for additional information, such as copies of consumer complaints and lawsuits, test reports and samples of returned products that demonstrate the potential defect that is being reported.

[59] *See* 16 C.F.R. § 1115.13(b).

[60] *See, e.g., United States v. Wal-Mart,* Case No. PJM 01-1521 (D. Md. April 23, 2003) (Stipulated Judgment and Order), *available at* http://www.cpsc.gov/CPSCPUB/PREREL/prhtml03/03118.pdf ($750,000 civil penalty settlement for alleged late reporting under Section 15).

[61] *See, e.g., Consolidated Electrical Distributors Inc., Provisional Acceptance of a Settlement Agreement and Order,* 64 Fed. Reg. 43,990 (Aug. 12, 1999) (distributor of a recalled heater paid $1.5 million under a Consent Agreement with CPSC to help fund a recall where the manufacturer had declared bankruptcy after negotiating a corrective action plan with CPSC).

[62] 15 U.S.C. § 2055(b)(5). The fourth of these exceptions was added by the CPSIA, thereby expanding CPSC's ability to disclose publicly information about a potential safety hazard that a company reports under Section 15(b). *See* Pub. L. No. 110-314, § 21, 122 Stat. 3018, 3048 (2008).

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similar rule or provision of any other Act enforced by the Commission.''[63]

Thus, absent one of these exceptions, a Section 15 report that does not result in a recall remains confidential. In addition, even if a recall is conducted, confidential commercial information is exempt from disclosure.[64]

II. Routes to a Recall

The two most common routes to a consumer product recall are through (a) CPSC's preliminary determination process, and (b) the agency's Fast Track recall program, both of which are described below.

A. *Preliminary Determination Process*: Companies frequently notify CPSC, either to satisfy the Section 15 reporting obligation (discussed above) or in response to a request for information from the CPSC staff, but do not believe that a recall is warranted. In such cases, CPSC staff, acting under authority delegated by the agency, conducts an investigation to assess the hazard and the need for a corrective action. CPSC classifies risks as follows:

> **Class A Hazard:** Exists when a risk of death or grievous injury or illness is likely or very likely, or serious injury or illness is very likely.
>
> **Class B Hazard:** Exists when a risk of death or grievous injury or illness is not likely to occur, but is possible, or when serious injury or illness is likely, or moderate injury or illness is very likely.
>
> **Class C Hazard:** Exists when a risk of serious injury or illness is not likely, but is possible, or when moderate injury or illness is not necessarily likely, but is possible.[65]

If the CPSC staff determines that the risk is Class A, B or C, the staff then sends the company a letter stating the agency's ''preliminary determination'' that the product presents a substantial product hazard, and requesting that the company conduct a recall.[66] The company may then agree ''voluntarily'' to do so, as occurs in most cases upon receipt of a preliminary determination letter, or continue to oppose the need for recall. If the staff concludes instead that no further action is required—either because it concludes that the product contains a defect that does not rise to the level of a substantial product hazard (informally known as a Class D hazard), or that there is insufficient information to conclude a defect exists—the staff typically sends the company a letter stating that, based on the available information, the staff has concluded that action under Section 15 is not required.

Absent an agreement by the company to conduct a recall, the staff may seek Commission approval to initiate an administrative proceeding under Section 15 of the CPSA to require a manufacturer, importer, distributor or retailer to provide public notice that a product presents a substantial product hazard, or to require a company to repair, replace or refund the purchase price of the item at issue.[67] Such cases, although rare, are initiated by the filing of an administrative complaint against the company.[68] Notably, the confidentiality provisions of Section 6(b) do not apply to such complaints,[69] which thus are publicly available and typically announced by CPSC through issuance of a press release.[70] Proceedings are held before an administrative law judge, who serves as the Presiding Officer.[71] Following discovery and the opportunity for a hearing in accordance with 5 U.S.C. § 554, the Presiding Officer files an Initial Decision with the Commission.[72] The Initial Decision becomes final 40 days after issuance absent either (a) an appeal to the Commission, or (b) issuance of an order by the Commission to review the Initial Decision.[73]

In lieu of filing an administrative complaint, CPSC also has authority to proceed directly to a federal district court under Section 12 of the CPSA to seek such ''temporary or permanent relief as may be necessary to protect the public'' with respect to a product that the court determines presents an ''imminent and unreasonable risk of death, serious illness, or severe personal injury.''[74] Although CPSC invoked that provision during the 1970s and 1980s, it has not done so since that time.[75] However, a change in the law effected by the

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[63] *Id.* The CPSIA expanded this exception to cover acts other than the CPSA.

[64] *See* 15 U.S.C. § 2055(a)(2); 16 C.F.R. § 1015.16(d). *See also Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871 (D.C. Cir. 1992) (en banc) (protecting from disclosure information submitted voluntarily to the government). Further, before disclosing information through which the product's manufacturer or private labeler ''may be readily ascertained,'' CPSC must take reasonable steps to ensure that the information ''is accurate, and that such disclosure is fair in the circumstances and reasonably related to effectuating the purposes of this Act.'' *See* 15 U.S.C. § 2055(b)(1); 16 C.F.R. §§ 1101.31 - 1101.34. In practice, CPSC has applied this same standard to the disclosure of information through which a retailer or distributor can be identified.

[65] *See* Recall Handbook (May 1999) at 12, *available at* http://www.cpsc.gov/BUSINFO/8002.html.

[66] The determination is ''preliminary'' because the Commissioners will not yet have made a formal determination, through the process described below, that the product presents a substantial product hazard. *See* 15 U.S.C. §§ 2064(c), (d).

[67] *See id.* §§ 2064(c), (d).

[68] *See* 16 C.F.R. 1025.11(a). Once the Commission has filed such an action, it may also seek a preliminary injunction in a federal district court to restrain the distribution of the product pending the completion of the administrative proceeding. 15 U.S.C. § 2064(g). In addition to the *Central Sprinkler* case, discussed above, the CPSC staff filed only three administrative complaints in the 10 years from 1998 through 2007. *See Daisy Manufacturing Company*, CPSC Docket No. 02-2, 66 Fed. Reg. 56082 (Nov. 6, 2001) (air rifles); *In re Chemetron Corporation,* CPSC Docket No. 02-1 (Oct. 9, 2001), *available at* http://www.cpsc.gov/LIBRARY/FOIA/FOIA02/fedreg/sprinklr.pdf (sprinkler systems); *In re Cadet Manufacturing Company,* CPSC Docket No. 99-1, 64 Fed. Reg. 3932 (Jan. 26, 1999) (heaters). Further, none of these matters were litigated to judgment; each was settled during the course of the proceedings.

[69] *See* 15 U.S.C. § 2055(b)(5)(A).

[70] *See, e.g.,* Press Release, CPSC, CPSC Files Lawsuit Against Daisy Manufacturing Co. To Recall Two Models of Daisy's Powerline Airguns Due to Defects (Oct. 30, 2001), *available at http://www.cpsc.gov/CPSCPUB/PREREL/prhtml02/02029.html*.

[71] *See* 16 C.F.R. § 1025 (CPSC rules of practice for adjudicative proceedings).

[72] *See* 16 C.F.R. §§ 1025(d)-(f).

[73] *See* 16 C.F.R. §§ 1025.51-.54.

[74] *See* 15 U.S.C. § 2061(b)(1).

[75] *See, e.g.,* Memorandum and Order, *United States v. Am. Honda Inc.*, Civ. A. No. 87-3525 (Apr. 27, 1988) (consent decree under Section 12, including a ban of three-wheel ATVs) (reproduced in *United States v. Am. Honda Inc.*, 143 F.R.D. 1, App A (D.D.C. May 28, 1992)); Order, *CPSC v. A.K. Electric Corp.*, No. 74-1206 (D.D.C. Sept. 9, 1974) (granting injunction

CPSIA may encourage more use of Section 12: If CPSC determines that a product presents an imminent hazard and files an action under Section 12, the Commission may now order the product's manufacturer, importer, distributor or retailer to cease distribution, provide public notification of the hazard, and recall the product, even without first providing the company with an opportunity for a hearing.[76]

B. *Fast Track Program*: Under CPSC's Fast Track program, companies agree to announce publicly a corrective action program acceptable to the staff within 20 business days after notifying CPSC. In exchange, CPSC does not send the company a ''preliminary determination'' letter, as described above.[77] The program benefits reporting companies by avoiding receipt of a preliminary determination letter, which plaintiffs would seek to use in product liability or consumer protection litigation, as well as by providing a means to implement recalls more quickly and efficiently. And, CPSC benefits by not having to devote its limited resources to conducting a more detailed investigation of a potential safety hazard. Indeed, the program has become so popular that, in recent years, roughly half of all Section 15 reports (other than those made pursuant to the ''working model'' reporting program, discussed below) were made under the Fast Track program, and Fast Track recalls have far outpaced recalls conducted through the Preliminary Determination process.[78]

III. Civil Penalties for Late Reporting

The CPSA provides for civil penalties against manufacturers, distributors and retailers who ''knowingly'' fail to notify CPSC under Section 15(b).[79] Adding to the risk of being second-guessed for alleged late reporting, the CPSA defines ''knowingly'' as having ''actual knowledge'' or ''presumed . . . knowledge deemed to be possessed by a reasonable man who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations.'' [80] Particularly when combined with the language in Section 15 requiring notification upon receipt of information that ''*reasonably supports the conclusion*'' that a product ''contains a defect which *could* present a substantial product hazard,''[81] the government has ample opportunity to second-guess decisions about whether, and, if so, when a duty to notify arises under Section 15.

The current maximum civil penalty is $8,000 per violation and $1.825 million for a related series of violations.[82] However, under the CPSIA, those authorized penalty amounts will be increasing dramatically to $100,000 per violation and $15 million for a related series of violations, effective the earlier of one year after enactment of the CPSIA (i.e., Aug. 14, 2009) or upon publication of regulations by CPSC interpreting the factors in Section 20 of the CPSA that the Commission is directed to consider in determining the amount of a civil penalty to seek against a company.[83] CPSC treats each unit of a product as a separate violation,[84] so the potential penalty for a related series of violations can easily reach the statutory maximum.

A five-year statute of limitations applies to actions seeking a civil penalty for failure to timely report to CPSC under Section 15(b).[85] Further, the government argues that the statute of limitations does not start running until the manufacturer, distributor or retailer either reports to CPSC or has actual knowledge that CPSC has been adequately informed.[86]

Virtually all CPSC civil penalty assessments for alleged reporting violations have been resolved through settlement rather than litigation. To date, only one such case has been decided by a court on the merits. In that case, *United States v. Mirama Enterprises Inc.*,[87] the court granted the government's motion for summary judgment, holding that, as a matter of law, the defendant manufacturer had a duty to notify CPSC after receiving the first three (of 23 total) reports that a juice

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under Section 12 barring manufacture, distribution and sale, and ordering recall, of a ''mechanic's light'' that was found to pose an imminent danger of serious or fatal electric shock).

[76] *See* 15 U.S.C §§ 2064(c), (d). While the elements of a corrective action plan are beyond the scope of this article, it is important to note that the CPSIA has implemented significant changes in this area as well. For example, previously, under Section 15 of the CPSA, a company that was ordered to recall a product could choose to either repair, replace or refund the purchase price of the item. The CPSIA has now given the Commission authority to choose the appropriate remedy in such mandatory recalls. *See* 15 U.S.C. § 2064(d); Pub. L. No. 110-34, § 214(b), 122 Stat. 3018, 3054 (2008). In connection with voluntary recalls, the remedy has been and likely will continue to be a negotiated point between the staff and the company conducting the corrective action.

[77] *See* 62 Fed. Reg. 39,827-39,828 (July 24, 1997).

[78] On February 20, 2008, John G. Mullan, Director of CPSC's Office of Compliance & Field Operations, reported the following data on Section 15 reporting during the Annual Meeting of the International Consumer Product Health and Safety Organization:

Section 15 Reporting Trends:

Fiscal Year	All Reports	Fast Track
2005	545	261
2006	482	236
2007	571	308

Disposition of Section 15 Reports:

Fiscal Year	Fast Track	Closed - No CAP*	CAP*	Open
2005	240	159	124	22
2006	228	124	104	26
2007	257	191	63	60

* CAP = Corrective Action Plan

[79] *See* 15 U.S.C. §§ 2068(a)(4), 2069(a)(1).

[80] 15 U.S.C. § 2069(d).

[81] 15 U.S.C. § 2064(b).

[82] *See* 69 Fed. Reg. 68,885 (Nov. 26, 2004).

[83] *See* Pub. L. No. 110-314, §§ 217(a)(1), (4), 122 Stat. 3016, 3058 (2008). The civil penalty factors are discussed below in Section III A.

[84] *See United States v. Mirama Enters. Inc.*, 387 F.3d 983, 988 (9th Cir. 2004); *see* 15 U.S.C. § 2069(a)(1).

[85] 28 U.S.C. § 2462.

[86] *See United States v. Advance Machine Co.*, 547 F. Supp. 1085, 1091 (D. Minn. 1982) (concluding that ''a manufacturer, possessing information that its product contains a defect which could create a substantial product hazard, has a continuing duty to inform the Commission unless the Commission has been adequately informed of such defect'').

[87] *United States v. Mirama Enters. Inc.*, 185 F. Supp. 2d 1148 (S.D. Cal. 2002), *aff'd*, 387 F.3d 983 (9th Cir. 2004). Other courts have denied the government's motions for summary judgment in Section 15 cases. *See* Order, *United States v Wal-Mart*, Civ. No. 01-1521 (D. Md. July 22, 2002); *United States v. Dynamic Classics Ltd.*, Civ. No. 94-397, slip op. at 7 (D.N.J. June 2, 1995).

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extractor's filter basket had ''exploded'' while in use, posing a risk to consumers of being cut by sharp pieces of plastic and metal. The court imposed a civil penalty of $300,000. The Court of Appeals for the Ninth Circuit affirmed, finding that a penalty for late reporting may be assessed even if the product ultimately is determined not to be defective, and that each unit of a product (rather than each model or product line) constitutes a separate violation.[88]

CPSC can be undoubtedly be aggressive in seeking civil penalties for late reporting, and the assessment of penalties for late reporting can be expected to have a spill-over effect on private litigation. However, the risk of a private cause of action under Section 15 is less significant. The only federal appeals courts that have addressed the issue have held that there is no private right of action to enforce Section 15 reporting violations.[89] In addition, although the CPSIA granted state attorneys general authority to enforce certain provisions of the CPSA, that authority does not include enforcement of the Section 15 reporting obligation.[90]

A. *Factors in Size of Penalty*

Apart from the maximum penalty amounts provided for in the CPSA and drawing on information from prior penalty settlement agreements (which tends to be incomplete), there is only limited guidance on the factors CPSC will consider in determining the amount of a civil penalty to seek. The statute instructs CPSC to consider:

> the nature, circumstances, extent, and gravity of the violation, including the nature of the product defect, the severity of the risk of injury, the occurrence of absence of injury, the number of defective products distributed, the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses, and such other factors as appropriate.[91]

In July 2006, CPSC proposed a new interpretive regulation that identifies the following additional factors that Commission and staff may consider, ''as appropriate,'' in determining the ''appropriateness and the amount'' of a civil penalty:[92]

- ''Previous record of compliance'';
- ''Timeliness of response'';
- ''Safety and compliance monitoring'';
- ''Cooperation and good faith'';
- ''Economic gain from non-compliance'';
- ''Product failure rate'';

and

- ''Any other pertinent factors''[93]

Although the regulation has not been finalized, the agency already has the flexibility to consider these and other factors it deems relevant in deciding the amount of a civil penalty to seek and in settling such cases. Further, CPSC will be revisiting this issue, as the Commission has been directed under the CPSIA to issue a regulation by August 2009 interpreting the statutory civil penalty factors.[94]

Civil Penalty Case Study: During 2006, CPSC entered into a $975,000 civil penalty settlement with Fisher-Price to resolve allegations that the company failed timely to notify CPSC about a potential choking and aspiration hazard with a toy. A review of this case helps demonstrate the risk of civil penalties that companies confront under Section 15. The staff alleged the following timeline of events:

- During September 2002, Fisher-Price first learned of an incident in which a nail fastener disengaged from one of the toys.
- By mid-November 2002, Fisher-Price had learned of nine reports of nail fasteners coming loose from the toy, including one report from a consumer that her child placed a nail fastener in her mouth.
- By early February 2003, Fisher-Price had received two telephone calls in which consumers expressed concern that this problem posed a choking hazard to children.
- On Feb. 14, 2003, Fisher-Price learned that a 14-month-old child aspirated a nail fastener from the toy into his lung, requiring emergency surgery to remove the fastener. The consumer told Fisher-Price that she had notified CPSC of the incident.
- On March 14, 2003, Fisher-Price submitted a Full Report to CPSC notifying the Commission of the potential hazard. By that time, Fisher-Price knew of 33 reports the nail fastener had come loose from the toy, including four reports that children put a fastener in their mouths (one of whom cut the inside of her mouth).
- On April 23, 2003, Fisher-Price announced a voluntary recall under CPSC's Fast Track program.

CPSC alleged that ''[a]lthough Fisher-Price had obtained sufficient information to reasonably support the conclusion that the [toy] contained a defect which could create a substantial product hazard, or created an unreasonable risk of serious injury or death, *it failed to immediately inform* the Commission of such defect or risk. . . .''[95] Although Fisher-Price denied that the toy contained any such defect, denied that it violated any reporting requirements, and believed that the toy complied with all applicable CPSC regulations regarding small parts, it nonetheless chose to settle CPSC's allegations for the substantial sum of $975,000 in civil penalties.

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[88] *Mirama Enters., Inc.*, 387 F.3d at 986-89.

[89] *See Daniels v. Am. Honda Motor Co.*, 980 F.2d 729, 1992 WL 361271, at *4 (6th Cir. 1992); *In re All Terrain Vehicle Litig.*, 979 F.2d 755, 757-58 (9th Cir. 1992); *Kloepfer v. Honda Motor Co.*, 898 F.2d 1452, 1457-57 (10th Cir. 1990); *Benitez-Allende v. Alcan Aluminio de Brasil S.A.*, 857 F.2d 26, 33-34 (1st Cir. 1988), *cert. denied*,489 U.S. 1018 (1989); *Drake v. Honeywell Inc.*, 797 F.2d 603, 609-10 (8th Cir. 1986); *but see Kelsey v. Muskin Inc.*, 848 F.2d 39 (2d Cir. 1988) (not resolving whether a cause of action exists, but indicating that even if there were a cause of action, plaintiff would have to establish causation between non-disclosure and injury); *Young v. Robertshaw Controls Co.*, 560 F. Supp. 288 (N.D.N.Y. 1983) (allowing a private right of action for violation of Section 15).

[90] *See* Pub. L. No. 110-314, § 218, 122 Stat. 3016, 3060 (2008).

[91] 15 U.S.C. § 2069(b).

[92] 71 Fed. Reg. 39,248 (July 12, 2006).

[93] *Id.* at 39,249.

[94] *See* Pub. L. No. 110-314, §§ 217(b)(2), (4), 122 Stat. 3016, 3059 (2008).

[95] 72 Fed. Reg. 10,713, 10,714 (Mar. 9, 2007) (emphasis added).

It is instructive to review the factors in CPSC's proposed regulation in light of the allegations against Fisher-Price:

(1) *The firm's previous record of compliance with CPSC requirements*: During June 2001—about 15 to 18 months before the CPSC staff claims that Fisher-Price should have notified the Commission in this case—the company paid a $1.1 million penalty for allegedly failing to notify CPSC about a fire hazard associated with Power Wheels ride-on toys.[96]

(2) *Timeliness of a firm's response to relevant information*: Fisher-Price notified CPSC six months after receiving the first report of a product failure, four months after Fisher-Price had learned of nine product failures, and four weeks after learning of the only serious injury. While not discussed in the settlement agreement, the staff may have believed that if Fisher-Price had notified CPSC sooner and conducted a recall before the end of 2002, the injury could have been avoided.[97]

(3) *Safety and compliance monitoring*: Although the settlement agreement does not mention Fisher-Price's internal controls, in announcing the 2001 penalty, then Chairman Ann Brown ''applaud[ed]'' the company for strengthening its ''product integrity organization.''[98]

(4) *Cooperation and good faith*: There is no suggestion that Fisher-Price failed to cooperate with CPSC. To the contrary, Fisher-Price notified CPSC without the staff first opening an investigation, and announced a voluntary Fast Track recall within about five weeks after submitting its Full Report to CPSC.

(5) *Economic gain from any delay or noncompliance*: Fisher-Price imported and sold a total of 67,000 units of the product. According to the press release announcing the corrective action, retail sales of recalled units ended in December 2002. Thus, even assuming that Fisher-Price should have notified CPSC and stopped sales during the Fall of 2002, the company cannot have made a significant profit through the alleged delay in notifying CPSC.

(6) *The product's failure rate*: The product failure rate was 0.049 percent (33 reports out of 67,000 units). It is unclear how that rate compares with other toys.

(7) *Any other pertinent factors*: Although we do not know what other factors, if any, were considered here, two merit discussion:

- *When is CPSC adequately notified of a risk?* A company's duty to notify CPSC under Section 15 of the CPSA is excused if the company has ''actual knowledge that the Commission has been adequately informed'' of the potential safety hazard.[99] In this case, the consumer who notified Fisher-Price of the only serious injury also told the company that she had already reported the incident to CPSC. Yet, the staff likely took the position that CPSC had not been ''adequately informed'' because it did not know how many reports Fisher-Price had received that the product had broken.
- *What is the significance of compliance with applicable safety standards?* Fisher-Price asserted that the toy complied with applicable safety standards, presumably including mandatory and voluntary standards that bar toys for children under three years of age from having small parts even after use and abuse testing. However, CPSC has asserted that compliance with mandatory or voluntary standards—even those that address the risk in question— does not ''relieve a firm of the requirement to report when a substantial product hazard may exist'' or ''provide a safe harbor for the failure to report.''[100]

B. *Civil Penalty Data*

In the past decade (Fiscal Years 1999-2008), the maximum civil penalty allowed by law increased from $6,000 for each violation and $1.5 million for any related series of violations, to $7,000 for each violation and $1.65 million for any related series of violations in 2000; to $8,000 for each violation and $1.825 million for any related series of violations in 2005; and finally to $100,000 for each violation and $15 million for any related series of violations, effective not later than August 2009.[101] During Fiscal Years 1998-2007, the median civil penalty for a Section 15 reporting violation was $338,000, the average such penalty was approximately $514,000, and the average annual total for such penalties was $3.1 million.[102]

Through fiscal year 2008, the highest annual total for Section 15 reporting penalties was $8.8 million, which also included the single largest civil penalty in CPSC's history.[103] In particular, during 2005, CPSC announced

[96] *See* 66 Fed. Reg. 32,328 (June 14, 2001).

[97] However, such an argument would be highly speculative. Even if Fisher-Price had notified CPSC in September 2002, upon receiving the first report that the toy had broken, it is unlikely that a recall would have been announced by mid-December unless Fisher-Price had opted to participate in *CPSC's* Fast Track program. Otherwise, it often takes CPSC months to conduct a technical analysis of a product and to issue a preliminary determination requesting that a company recall a product. And, given that the Fast Track program is voluntary, it would be unfair to penalize a company for not utilizing the program (or, in this case, not using the program sooner).

[98] *See* Press Release, CPSC, CPSC Fines Fisher-Price $1.1 Million for Not Reporting Defective Power Wheels: Largest Fine Against a Toy Firm in CPSC's History (June 7, 2001), *available at* http://www.cpsc.gov/cpscpub/prerel/prhtml01/01167.html.

[99] 15 U.S.C. § 2064(b).

[100] 71 Fed. Reg. 42,028, 42,030 (July 25, 2006).

[101] *See* 59 Fed. Reg. 66,523 (Dec. 27, 1994); 64 Fed. Reg. 51,963 (Sept. 27, 1999); 69 Fed. Reg. 68,885 (Nov. 26, 2004); Pub. L. No. 110-314, §§ 217(a)(1), (4), 122 Stat. 3016, 3058 (2008).

[102] The CPSC provides a listing of each civil penalty by fiscal year with links to additional information. Find Civil Penalties by Fiscal Year, http://www.cpsc.gov/cgi-bin/civfy.aspx. Fiscal year 2008 was excluded from the median and mean figures because those calculations would otherwise have been skewed by a group of 17 late reporting penalties that year for amounts from $25,000 to $70,000, all relating to drawstrings at the hood or neck area of children's garments. *See* http://www.cpsc.gov/cgi-bin/civfy.aspx. Those penalties coincided with the lack of a quorum at CPSC, during which time the Director of the Office of Compliance & Field Operations, with the concurrence of the General Counsel, had authority to accept civil penalty settlements of up to $100,000. *See* Interim Delegation of Authority in the Absence of a Quorum (Feb. 1, 2008), *available at* http://www.cpsc.gov/LIBRARY/FOIA/ballot/ballot08/quorum2-1.pdf.

[103] *See* U.S. Consumer Product Safety Commission, 2005 Performance and Accountability Report, Nov. 2005, at 11 (noting that CPSC ''obtained the largest total civil penalties in a single year'' for reporting violations), *available at* http://www.cpsc.gov/about/gpra/05perfrpt.pdf; Press Release, CPSC, Record Civil Penalty Levied Against Graco Children's Products

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a $4 million penalty against Graco Children's Products Inc. for allegedly failing timely to notify the agency under Section 15 concerning 16 different products, including infant carriers, high chairs, strollers, and toddler beds.[104] Similarly, many of the larger civil penalties for reporting violations—including the three largest—have involved multiple product cases involving different alleged defects and risks.[105]

Once the maximum civil penalty for Section 15 violations increases to $15 million, CPSC may be expected to seek a penalty in that range only in the most egregious cases. It remains to be seen, however, what impact the new ceiling will have on the civil penalty amounts that CPSC seeks in more typical cases.

C. *Criminal Penalties for Section 15 Violations*

Prior to the 2008 amendments to the CPSA, criminal penalties were available under the CPSA only if a person willfully violated the statute after having received notice of noncompliance from CPSC.[106] Thus, for all practical purposes, the failure timely to notify CPSC of potential safety hazards carried only civil penalties. However, the CPSIA removed the prior notice requirement as a prerequisite for criminal penalties, and allows for felony prosecutions.[107] Thus, knowing and willful violations of the Section 15 reporting requirements can now be the basis for criminal sanctions—including by directors, officers and agents—of imprisonment for not more than five years and a fine to be determined in accordance with 18 U.S.C. § 3571.[108]

Further, the penalties available for a ''criminal violation'' of the CPSA (or other Acts enforced by the Commission) now include the ''forfeiture of assets associated with the violation.''[109] And, for these purposes, a ''criminal violation'' means a violation ''for which the violator is sentenced to pay a fine, be imprisoned, or both.''[110]

IV. The Search for Objective Reporting Standards: 'Working Model'

In early 2005, CPSC staff announced a ''working model'' through which companies can satisfy the Section 15 notification requirements by reaching agreement with the staff on objective reporting criteria. By reporting specified information on an ongoing basis, companies gain a safe harbor from civil penalties for alleged failure to meet § 15(b) notification requirements based upon information submitted under this program. The program can also help CPSC to identify emerging product hazards sooner than would otherwise be possible.[111]

The program was developed in the aftermath of Wal-Mart's settlement of a civil penalty case for an alleged late reporting violation.[112] To avoid future penalties, Wal-Mart began to flood CPSC with consumer complaint information. CPSC and Wal-Mart then developed a program through which Wal-Mart notifies CPSC and suppliers each week of certain incident reports, regardless of whether such complaints and claims have been verified.

Wal-Mart provides CPSC with a spreadsheet of incident reports from a number of sources, including its toll-free customer hotline, consumer correspondence, stores, claims and lawsuits, and CPSC Clearinghouse. For each incident, Wal-Mart provides electronically to CPSC a number of categories of data, including, among others, product-, consumer- and supplier-identifying information; the date of purchase, incident, notice to Wal-Mart and tender to the supplier; the claimant's assertions, including whether there was an alleged injury; the age and sex of the consumer; product sales and inventory information; the number of claims if Wal-Mart was the importer; and actions taken by Wal-Mart's

Inc.: CPSC, Graco Announce New Recall of 1.2 Million Toddler Beds (Mar. 22, 2005), *available at* http://www.cpsc.gov/cpscpub/prerel/prhtml05/05138.html (noting that Graco civil penalty was a record).

[104] *See* 70 Fed. Reg. 15,842 (Mar. 29, 2005) (provisional acceptance of settlement with Graco).

[105] *See id;* 69 Fed. Reg. 64,035 (Nov. 3, 2004) (provisional acceptance of a $1.4 million civil penalty against Dynacraft BSC Inc. for alleged Section 15 reporting violations concerning various models of mountain bicycles), *available at* http://www.cpsc.gov/BUSINFO/frnotices/fr05/dynacraft.pdf; 66 Fed. Reg. 18,450 (April 19, 2001) (provisional acceptance of a $1.3 million civil penalty against Cosco for alleged Section 15 reporting violations concerning infant and toddler products, including cribs, strollers, and high chairs), *see* Press Release, CPSC, CPSC Fines Cosco/Safety 1st $1.75 Million for Failing to Report Product Defects: Largest Fine Against Children's Product Manufacturer in CPSC's History (Apr. 4, 2001), *available at* http://www.cpsc.gov/cpscpub/prerel/prhtml01/01119.html.

[106] 15 U.S.C. § 2070 (2008).

[107] *See* Pub. L. No. 110-314, § 217(c), 122 Stat. 3016, 3060 (2008).

[108] *See* 15 U.S.C. §§ 2070(a), (b) (providing criminal penalties for knowing and willful violations of Section 19 of the CPSA; *id.* § 2068(a)(4) (failure to furnish information required by Section 15(b) is a violation of Section 19).

[109] 15 U.S.C. § 2070(c)(1).

[110] *Id.* § 2070(c)(2).

[111] CPSC's Director of Compliance & Field Operations, John G, Mullan, announced the ''working model'' at the Annual Meeting of the International Consumer Product Health and Safety Organization on February 23, 2005. *See* U.S. Consumer Product Safety Commission, A Working Model for Retailer Reporting Under Section 15 (Feb. 23, 2005), *available at* http://www.cpsc.gov/BUSINFO/retailer.pdf. The program has not been voted on or formally adopted by the Commission.

[112] *United States v. Wal-Mart,* Case No. PJM 01-1521 (D. Md. April 23, 2003) (Stipulated Judgment and Order), *available at* http://www.cpsc.gov/CPSCPUB/PREREL/prhtml03/03118.pdf ($750,000 civil penalty settlement for alleged late reporting under Section 15).

safety group.[113] Wal-Mart also notes whether each incident meets any of the following automatic or cumulative ''trigger'' criteria, and thus may be of particular interest to the Office of Compliance:[114]

(1) Automatic triggers

(a) all injury allegations in which a consumer asserts that he or she either sought medical attention or missed more than a day of work/school, and all deaths; and

(b) all reported incidents, regardless of whether an injury was alleged, that involve any of the following potential hazards: electrocution/shock; entrapment/strangulation of a child; choking of a child; or drowning of a child;

(2) Cumulative triggers

(a) three reports of a recurring hazard in specified categories for the same product,[115] or

(b) five reported injuries from the same product.

Wal-Mart reports weekly, but it also notifies CPSC within 24 hours when it learns of an incident that results in a death or if a product is withdrawn from the market for safety reasons.[116]

Upon receiving information from retailers, CPSC may follow up through either the Office of Epidemiology, which tracks data for trends, and/or the Office of Compliance. Thus, for example, the Office of Compliance may launch an investigation of an incident, ask either the retailer or the manufacturer to submit a Full Report, or potentially seek a corrective action.

As of February 2008, several retailers and at least two manufacturers were participating in the program. However, the program is not ''one size fits all.'' Each company that wants to participate must determine in advance with the Office of Compliance the types of incidents, data on each incident, and sources of incident reports that will be reported to CPSC. And, the safe harbor applies only to the information submitted under this program.

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Helping to protect consumers and guarding a company's brand reputation remain as powerful incentives for companies to identify and address potential safety issues quickly and effectively. Further, particularly given the expansion of the Section 15 reporting obligation and the risk of substantial civil and even criminal penalties for late reporting, it is more important than ever for companies to ensure that they understand the scope of Section 15 and have internal controls in place to capture, track and analyze complaints and other information that may trigger a duty to notify CPSC.

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[113] *See* U.S. Consumer Product Safety Commission, A Working Model for Retailer Reporting Under Section 15 (Feb. 23, 2005) at 6-9, *available at* http://www.cpsc.gov/BUSINFO/retailer.pdf.

[114] *See id.* at 14-17.

[115] The categories are structural failure/breaks/ruptures/leaks; fire/burn potential/electrical incident; entrapment/caught in object/pinch/crush; unsafe operation/assembly/ malfunction; unstable/tipping hazard; choking/suffocation potential; chemical exposure/poisoning/skin irritation; sharp edge/point; and unknown/other. *See id.* at 18.

[116] *See id*. at 22.

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