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Coping with Proposed Rules, Proposed Guidance and the Growing Aggressiveness of the CPSC and Health Canada

C. S. Lewis famously wrote, "What you see and what you hear depends a great deal on where you are standing. It also depends on what sort of person you are." While written in the context of the magical land of Narnia in *The Magician's Nephew*, this quote also aptly describes the divergent and complementary nature of the relationship between regulators and those they regulate.

Balance can be difficult when regulators and industry are approaching things from different points of view. When the relationship between the regulator and the regulated is balanced, the company, the regulator, and society at large win. When the relationship is out of balance, it can foster an environment of mistrust that forces the parties to make extreme decisions that benefit no one.

Regulators have a responsibility to serve and protect the public. Companies, on the other hand, are in business to sell products at competitive prices. Cooperation, nevertheless, is essential to success in the regulatory environment. Companies are bound by consumer product safety laws and regulations and therefore must work with the regulators. Regulators have finite resources and depend on industry's cooperation to carry out their mandate effectively.

The balance of power in this uneasy but necessary relationship ebbs and flows depending on factors including the current political environment, resources available to either side, and even behavior of each side. When the relationship is at its best, both sides—and the public—benefit. Companies will produce products that are safe for consumers without the diversion of resources and distraction of regulatory investigation and product recalls. Regulators will have more resources to invest in more widely beneficial product safety initiatives if they can spend fewer resources investigating and overseeing product recalls.

This paper will explore recent regulatory proposals and activity by the United States Consumer Product Safety Commission (CPSC) and Health Canada that may present challenges to the delicate balance of the relationship between consumer product regulators and the consumer product industry.

United States: Consumer Product Safety Commission

In recent months, consumer product safety regulators in the United States have taken a more aggressive posture towards consumer product safety that changes and complicates the legal environments that consumer product firms and their attorneys must navigate. First, the CPSC has proposed new regulations that provide additional and potential hurdles to overcome in the event a recall is necessary and require firms to make difficult choices with serious legal consequences in a very short period of time as a condition to being permitted to recall their products. Second, the CPSC has chosen to pursue an administrative action against a corporate executive personally to implement a massive recall of an allegedly hazardous product despite the lack of clear legal authority to do so. Both of these developments place firms in a legally precarious position and threaten to alter the existing balance between the U.S. regulators and companies that produce consumer products.

CPSC Notice of Proposed Rulemaking: Voluntary Recall Notices

On November 21, 2013, the CSPC published a Notice of Proposed Rulemaking

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in the Federal Register. The proposed rules generated considerable concern in industry circles.

The notice stated that the new rule, an amendment to 16 C.F.R. 1115, would be "an interpretative rule to set forth principles and guidelines for the content and form of voluntary recall notices that firms provide as part of corrective action places under Section 14 of the Consumer Product Safety Act (CPSA)." Federal Register Vol. 78, No. 225, November 21, 2013 at 69793–69794. The "interpretive guidance" focused on clarifying the information that should "be included in a recall notice issued as part of a corrective action plan agreement." *Id.* at 69794. Furthermore, "the proposed rule would set forth the Commission's expectations for voluntary remedial actions and recall notices.…" *Id.* While billed as "interpretative," the proposed rule has the potential to substantively change the very nature of the current consumer product recall process.

Proposed Sections 1115.20(a)(1)(xv), 1115.20(b) and 1115.34(p)

Incorporating "compliance program requirements" as a condition of conducting a voluntary recall and publishing "compliance program requirements" in voluntary recall notices will discourage companies from engaging in process improvements and product improvements and will delay the announcement of product recalls, to the detriment of all. The proposed rule would permit the Commission to seek "compliance program requirements" as a condition of permitting a voluntary recall to take place and would permit the Commission to publicize "compliance program requirements" in a press release announcing a voluntary product recall.

In 1997, the CPSC adopted and implemented the award-winning Fast Track No Preliminary Determination Program (Fast Track Program). Prior to the adoption of the Fast Track Program, a firm would report to the CPSC when there was a potential safety issue with a product. The CPSC would then conduct an investigation and, after an evaluation, issue a preliminary determination as to whether the product was defective and presented a substantial product hazard. Having to wait for a "preliminary determination" that a product presented a substantial product hazard had the dual effect of delaying the process and potentially hurting companies in future product liability actions.

The Fast Track Program allowed a firm to conduct a product recall quickly without the inefficiencies and stigma associated with a preliminary determination. The Fast Track Program allowed companies to issue faster recalls—something that was considered a higher priority than the assignment of blame and something companies wanted to do anyway. Later, after the recall was underway or completed, companies and the CPSC staff could consider whether the firm reported the issue to the CPSC in a timely manner and could determine whether to pursue claims for civil penalties under 15 U.S.C. §2069, which permits the CPSC to seek civil penalties for violation of statutes and rules, including the statutes and rules that require companies to report safety issues to the CPSC.

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In some circumstances, where the CPSC staff sought to impose civil penalties for lack of timely reporting, as part of the negotiations that took place months and even years following the recall, companies would sometimes offer to change certain policies and procedures internally as a condition of settling the CPSC staff's civil penalty allegations. However, these changes were strictly voluntary and took place following the recall, not as a condition of the recall. The recall itself and the pursuit of civil penalties or agreed upon voluntary procedures relating to future reports to the CPSC were two different and distinct processes.

The new proposed rules could have the effect of merging the recall and civil penalties enforcement processes together, delaying the announcement and implementation of a product recall.

The proposal to incorporate "compliance program requirements" into voluntary recalls is antithetical to the letter and spirit of the Fast Track recall program. The CPSC's Fast Track-No Preliminary Determination program earned the CPSC the prestigious Innovations in American Government award in 1998. This program was adopted to permit a firm to quickly conduct a product recall without the inefficiencies and stigma associated with a Staff Preliminary Determination of product hazard.

The CPSC's "Fast Track/No Preliminary Determination" program's current brochure states:

> Traditionally, when a firm reported to the CPSC, the CPSC staff conducted any necessary investigation and, after careful evaluation, preliminarily determined whether the reported product was defective and presented a substantial product hazard.
>
> Some firms were concerned that the staff determination could hurt them in future product liability actions. Those firms that were already inclined to recall the product found that the formal evaluation process held them up. CPSC listened to the concerns and, in March, 1997, adopted the Fast Track Product Recall program.

Since 1997, therefore, the CPSC has recognized that the ability of a firm to quickly conduct a recall is paramount to the issue of assigning or accepting findings of wrongdoing.

A firm, therefore, may agree that a recall is in the best interest of consumers, but may strongly disagree that its reporting practices or manufacturing practices are flawed and must be changed. Negotiating additional issues regarding "compliance

program requirements" during the negotiation of the language of the press release announcing a product recall will undoubtedly delay the announcement of recalls, which will benefit no one. It would be in the best interest of both consumers and the recalling firm not to delay the announcement of a recall and the issuance of a press release based on controversy over whether "compliance related requirements" should be undertaken or should be included in the press release announcing the recall.

The proposal to incorporate "compliance program requirements" into recall announcements is without factual precedent and encumbers the recall process with the civil penalty process. The Notice of Proposed Rulemaking states, "Inclusion of compliance program requirements as an element of voluntary corrective action plans would echo compliance program requirements incorporated as part of recent *civil penalty settlement agreements*." (Emphasis supplied). There is no mention of any occasion in which the CPSC has incorporated "compliance program requirements" into any past *voluntary recall announcement*.

Firms enter into civil penalty settlement agreements to resolve CPSC claims that a firm failed to comply with reporting requirements and other requirements in a timely manner. These agreements are entirely different from, and resolve issues apart from, a firm's voluntary agreement to recall a particular product quickly.

Civil penalty allegations can be highly contested and the procedures to resolve such allegations can take months or years to resolve as there are numerous factual issues that must be evaluated. While some firms may wish to agree to engage in programs or processes approved by the CPSC in order to ensure that the CPSC will not seek civil penalties in the future, such agreements are, by their nature, voluntary, and should be entered into based on the firm's willingness to participate in such an agreement, rather than based on the CPSC's demand for participation as a condition of permitting the firm to conduct a voluntary recall. A firm's ability to conduct a safety related recall quickly and efficiently will be hampered if the CPSC also demands that the company must hastily agree to systemic changes in its reporting or other processes as a condition of being permitted to conduct the recall.

The proposal to include "compliance program requirements" in a press release announcing a voluntary recall has the effect of shortcutting and eviscerating the procedures and protections afforded to a firm in circumstances in which the CPSC seeks to impose civil penalties under 15 U.S.C. 2069 based on allegations that a firm failed to report a substantial product hazard in a timely manner or for other alleged violations. A firm should not be required to give up its rights to thoroughly address and contest allegations that it failed to report an issue to the CPSC in a timely fashion, and to conduct fair, arms-length negotiations with the CPSC if issues arise concerning a firm's compliance with reporting or other requirements, in order to obtain approval to conduct a voluntary recall.

A firm, therefore, may agree that a recall is in the best interest of consumers, but may strongly disagree that its reporting practices or manufacturing practices are flawed and must be changed.

The proposal to incorporate "compliance program requirements" into the recall process is without legal authority. The Consumer Product Safety Act permits the CPSC to order a company to recall a product; however, it does not permit the CPSC to order a company to undertake "compliance program requirements." 15 U.S.C. 2064(d) sets forth the procedures to be followed for the CPSC to determine if a product presents a substantial product hazard, and sets forth the actions the CPSC may order a company to perform, in the event action is determined to be in the public interest. The actions a company may be ordered to perform include repairing, replacing, and refunding the purchase price of the product, and notifying the public of the recall. This statute permits the CPSC to order a firm to "submit a plan, for approval by the Commission, for taking action under whichever of the preceding subparagraphs under which such person has been ordered to act." 15 U.S.C. 2064(d)(2).

The statute cited above contains no language, however, that would permit the Commission to order a firm to enter into a "compliance program" or to otherwise mandate that the recalling firm undertake any of the following actions, which are listed in the proposed rule at 1115.20(b) as potential elements of a voluntary "compliance program":

> Maintaining and enforcing a system of internal controls and procedures to ensure that a firm promptly, completely, and accurately reports required information about its products to the Commission; ensuring that information required to be disclosed by the firm to the Commission is recorded, processed, and reported, in accordance with applicable law; establishing an effective program to ensure the firm remains in compliance with safety statutes and regulations enforced by the Commission; providing firm employees with written standards and policies, compliance training, and the means to report compliance-related concerns confidentially; ensuring that prompt disclosure is made to the firm's management of any significant deficiencies or material weaknesses in the design or operation of such internal controls that are reasonably likely to affect adversely, in any material respect, the firm's ability to report to the Commission; providing the Commission with written documentation, upon request, of the firm's improvements, processes, and controls related to the firm's reporting procedures; or making available all information, materials, and personnel deemed necessary to the Commission to evaluate the firm's compliance with the terms of the agreement.

Thus, even if the CPSC followed the notice and hearing procedures described in 15 U.S.C. 2064, and issued an order

determining that a substantial product hazard existed, and that a firm must recall the hazardous product, the CPSC still would not have authority to order a company to take any of the actions that would comprise any of the components of a "compliance program" as described in the proposed rule.

The CPSC's authority under 15 U.S.C. 2064 is limited to that necessary to remove the hazardous product from the marketplace. The CPSC is permitted to seek civil penalties pursuant to 15 U.S.C. 2068 and 15 U.S.C. 2069 against the manufacturer of the product in the event required information was not timely reported, or in the event the product violated applicable regulations. Nothing in these statutes, however, authorizes the CPSC to order a firm to adopt any particular procedures or to otherwise undertake systemic corrective actions designed to ensure future compliance with reporting or other regulations.

The CPSC may not order a company to change its reporting procedures or manufacturing procedures as a condition of conducting a mandatory recall. The CPSC, thus, should not be permitted to require firms that are conducting voluntary recalls to agree to "compliance program related requirements" or to do more than what the CPSC would otherwise be authorized to order the firm to do. Permitting the CPSC the discretion to require such provisions as part of a voluntary recall or to refer to such provisions in a press release announcing a voluntary recall may suggest that the CPSC is permitted to exercise authority that was never granted under the CPSA.

If the staff believes that a company has not reported in a timely manner in the past, there are procedures that can be followed to seek civil penalties. Bypassing these procedures, and attempting to resolve them in the days leading up to the announcement of a recall by demanding "compliance program-related" requirements to be undertaken and to be included in the recall notice is unwarranted. This places a company that is attempting to recall a product voluntarily in the unenviable situation where it is simultaneously trying to recall the product quickly and to defend the propriety of its practices and actions.

Including "compliance program requirements" in a voluntary corrective action plan as a condition of conducting a voluntary recall and including "compliance program requirements" in a recall notice is antithetical to the goals of the CPSC's Fast Track program and confounds the goal of quickly recalling a product by rushing to a resolution of the issues surrounding the timeliness of the firm's report. This may have a chilling effect on a company's willingness to recall products and to change its reporting and manufacturing procedures.

> The Consumer Product Safety Act permits the CPSC to order a company to recall a product; however, it does not permit the CPSC to order a company to undertake "compliance program requirements."

Including language in the press release describing "compliance program requirements" will send an erroneous message to the public that the company has admitted wrongdoing in the activities leading up to the recall. This will have the dual effect of tarnishing the company and emboldening class action attorneys to commence baseless lawsuits. It may also be misconstrued as an official government finding of wrongdoing. It will do nothing to increase the efficiency or effectiveness of the recall.

Proposed Rule Section 1115.20

To permit the CPSC to bring an enforcement action for sanctions, a legal action for injunction, specific performance based on allegations that a firm is not complying with a voluntary corrective action plan, or a voluntary compliance program agreement goes beyond the statutory authority of the CPSA. The proposed rule at Section 1115.20(a) provides that, "A corrective action plan is a document, signed by a subject firm, which is legally binding and sets forth the remedial action which the firm will voluntarily undertake to protect the public." Section 1115.20(b) of the proposed rule provides that "Violation of a voluntary compliance program agreement may result in a formal Commission enforcement action, including all applicable sanctions set forth in the Consumer Product Safety Act. A violation may also result in legal action by the Commission to enforce the terms of a compliance agreement such as seeking an injunction or specific performance, as appropriate."

The proposed rule appears to grant the CPSC the power to seek sanctions for actions beyond the scope of what is permitted under the CPSA. 15 U.S.C. 2068 sets forth specified "Prohibited Acts" for which the CPSC may seek the imposition of civil penalties under 15 U.S.C. 2069. It is a prohibited act, for example, under 15 U.S.C. 2068(a)(2)(B), to sell a product that is subject to a voluntary corrective action. It is also a prohibited act under 15 U.S.C. 2068(a)(5) to fail to comply with an order requiring a company to recall a product, or to fail to issue a notification of an ordered recall.

Nothing in 15 U.S.C. 2068, however, gives the CPSC the authority to seek penalties or sanctions for alleged failure to comply with a voluntary recall or voluntary compliance program. The proposed rule would arguably serve to extend the authority of the CPSC to seek substantial multimillion dollar civil penalties based on a claim that a firm is not complying with the terms of a voluntary agreement. While the CPSC customarily reserves the right to monitor voluntary recalls and to request modification in the event the voluntary recall is not effective, the proposed rule effectively turns each voluntary recall in to an ordered, mandatory recall, with the same potential penalties in the event the CPSC alleges that the voluntary recall is not being performed properly, but none of the due process and appellate rights that would be afforded had the CPSC sought an order requiring the recall in the first place.

The stated rationale for this portion of the rule is:

> The Commission has encountered firms that have deliberately and unnecessarily delayed the timely implementation of the provisions of their correction action plans. Accordingly, proposed §1115.20(a) would provide the Commission with the necessary tools to compel a noncompliant or dilatory firm to carry out the terms of its voluntarily agreed upon corrective action plan.

The CPSA provides procedures to permit the CPSC to issue an order requiring a firm to recall a product that presents a substantial product hazard. These procedures would be available to be used in the circumstance of the noncompliant or dilatory firm the CPSC describes in the paragraph above.

A rule that would arguably permit the CPSC to seek sanctions against a firm, based on allegations that the firm "violated" a term of a voluntary recall or voluntary corrective action plan, goes beyond what is authorized under the CPSA, 15 U.S.C. 2068, and 15 U.S.C. 2069 and essentially creates a new Prohibited Act that does not appear in the statute itself, potentially subjecting a firm to substantial monetary penalties.

Proposed Section 1115.20(a)(1)(xiii)

Companies should continue to be allowed to include non-admission language in a voluntary corrective action plan: Forcing a company to admit a product defect as a condition of conducting a recall will benefit no one. Currently, 16 C.F.R. §1115.20(a)(1)(xiii) allows a firm recalling a consumer product to add the following disclaimer to the corrective action plan "if desired by the subject firm":

> The submission of this corrective action plan does not constitute an admission by (the subject firm) that either reportable information or a substantial product hazard exists.

This disclaimer provides a level of protection for a firm that wishes to recall consumer products that may present only a minor risk, out of an abundance of caution, without admitting a product defect exists, or at least without admitting that the recall constitutes an admission that a product defect exists, either of which could be problematic in subsequent legal proceedings. The proposed rule substantially eviscerates this right, and would allow the disclaimer only "if agreed by all parties." Federal Register, Vol. 78, No. 225, Thursday, November 21, 2013 at 69795. The rationale for the change is that the proposed rule "facilitates an opportunity for the Commission to negotiate and agree to appropriate admissions in each particular corrective action plan." *Id.* Requiring a company to "admit" that a product presents a substantial product hazard as a condition of permitting a voluntary recall to go forward, and refusing to permit a company to state its position regarding whether a hazard exists, and whether the recall constitutes an admission that a hazard exists, could have a chilling effect on the willingness of a company to enter into a voluntary recall in cases where a product defect is debatable and has substantial First Amendment implications.

> Nothing in 15 U.S.C. 2068, however, gives the CPSC the authority to seek penalties or sanctions for alleged failure to comply with a voluntary recall or voluntary compliance program.

Proposed Rule Section 1115.34(g)(3))

The requirement that the press release contain "a statement that the hazard 'can' occur" where there have been incidents or injuries associated with the recalled product" unfairly suggests a confirmed cause and effect relationship between a product and reports of incidents, when one may not exist. At times, firms will undertake a recall of a consumer product, even if consumer reports of incidents were the result of misuse or other factors and even if there are no verifiable occasions in which the product was the cause of an injury. Forcing a firm to make a statement in a press release that may constitute a tacit admission of a cause and effect relationship between its products and a consumer's report of an incident or injury could cause firms to be reluctant to conduct recalls under such circumstances. The language in a press release announcing a voluntary recall should be tailored to accurately reflect the data that led to the recall, without the constraints of mandatory language that may be inaccurate or misleading under the circumstances of the individual recall.

Proposed Section 1115.34(o)(4))

The requirement that any updated remedy information be transmitted to consumers "in a manner consistent with the communication of the initial voluntary recall notice" places an unfair burden on recalling firms. The proposed rules requires that, if a firm changes the recall process or nature of the remedy contemplated after the issuance of the voluntary recall notice, this should be communicated to the Commission and reflected in an agreed-upon update to the notice on the firm's website and the CPSC website. It also provides, however, that "[u]pdated remedy information also should be transmitted to consumers in a manner consistent with the communication of the initial voluntary recall notice." (Proposed Section 1115.34(o)(4))

While it would be appropriate for the CPSC and a firm, for example, to correct an outdated telephone number on their website versions of the press release, it would serve no purpose and create an unnecessary burden to require firms to personally re-notify consumers who are known owners of the product in the event the firm's telephone number has changed, or the remedy offered during the recall has been changed. Oftentimes, an original recall remedy, such as a repair kit or replacement product, may be changed to a voucher or cash refund because the product is obsolete, because repair kits are no longer available, or because the repair kits or replacement products may not meet current standards. In these instances, the recalled products may be old and far past

their useful lives. Requiring firms to re-notify consumers when they change the recall remedy, sometimes long after the recall has been announced and long after most of the products have been remediated, would be unduly burdensome and would do little to serve the needs of the consumer.

CPSC Administrative Action: Pursuit of Corporate Executive for Personal Liability for Recall Costs

Another example of recent regulatory action that raises some concern for firms and their attorneys is the highly publicized dispute between the CPSC and Craig Zucker of Maxfield & Oberton Holdings, the maker of Buckyballs. To briefly recap, Buckyballs were a desk toy that consisted of a collection of small, high-powered magnets that the user could use to create different shapes and objects. One issue of concern in this case was the CPSC's decision to add Craig Zucker, the former General Manager of Maxfield & Oberton Holdings LLC, as a respondent to an administrative action against Maxfield & Oberton and other companies that produced products with high powered magnets, seeking to require him to personally conduct a recall of the company's Buckyballs. Specifically, the CPSC is seeking to have an Administrative Law Judge hold Mr. Zucker personally financially responsible to conduct a recall that, by some estimates, could run over $50 million.

The CPSC, in seeking to hold Craig Zucker personally liable for the cost of recalling Buckyball products, relied, in part, on the *Park Doctrine*, which gets its name from the decision in *United States v. Park*, 421 U.S. 658 (U.S. 1975). In *Park*, the Supreme Court upheld the personal conviction of the CEO of a national retail grocery chain after the Food and Drug Administration found extremely unsanitary conditions in a warehouse owned by the retail chain. While the chain pleaded guilty, the CEO, Park, proceeded to trial and the jury convicted him. The Supreme Court noted that personal liability for corporate officers was built into the Food Drug and Cosmetic Act (FDCA) and that corporate officers had been held personally liable for violations under the Act since 1906. *Id.* at 668–69 citing to *United States v. Dotterweich*, 320 U.S. 277, 281-283 (U.S. 1943). Furthermore, the court noted that it was the "expressed intent of Congress to enlarge and stiffen the penal net and to discourage a view of the [FDCA's] criminal penalties as a license fee for the conduct of an illegitimate business." *United States v. Park*, 421 U.S. at 669 (internal citation and quotation marks omitted).

Requiring firms to re-notify consumers when they change the recall remedy, sometimes long after the recall has been announced and long after most of the products have been remediated, would be unduly burdensome and would do little to serve the needs of the consumer.

Fundamental to the *Park Doctrine* is that Congress has explicitly intended to apply liability to corporate officers on a personal basis in matters involving the FDCA. However, this is the exception, not the rule. For example, in *Meyer v. Holley*, the Supreme Court refused to permit personal or vicarious liability to be imposed on a corporate officer in a matter involving the Fair Housing Act in the absence of statutory language permitting this. 537 U.S. 280 (U.S. 2003). The Court noted,

> Congress said nothing in the statute or in the legislative history about extending vicarious liability in this manner. And Congress' silence, while permitting an inference that Congress intended to apply ordinary background tort principles, cannot show that it intended to apply an unusual modification of those rules.… Where Congress, in other civil rights statutes, has not expressed a contrary intent, the Court has drawn the inference that it intended ordinary rules to apply. *See, e.g.,* Burlington Industries, Inc., *supra*, 524 U.S. at 754-755 (deciding an employer's vicarious liability under Title VII based on traditional agency principles); *Meritor Savings Bank, FSB v. Vinson*, 477 U.S. 57, 72, 91 L. Ed. 2d 49, 106 S. Ct. 2399 (1986) ("Congress wanted courts to look to agency principles for guidance").

Id. at 286–287.

There are serious issues associated with the CPSC's invocation of the *Park* doctrine as it relates to pursuit of a claim that an officer of a legally dissolved corporation should be personally responsible for the cost of conducting a product recall. 15 U.S.C. §2064 codifies Section 15 of the CPSA that governs product recalls. Nowhere in this statute does Congress extend liability for a recall to an officer of a corporate manufacturer.

The current administrative law judge hearing the *Zucker* case, however, allowed the case to proceed against Zucker personally. Zucker, in turn, filed his own action for relief in the U.S. District Court for the District of Maryland challenging the CPSC's actions against him personally. (*Zucker v. U.S. Consumer Product Safety Commission and Robert Adler, in his official capacity as Acting Chairman of the U.S. Product Safety Commission*, 8:13-cv-03355-DKC). The CPSC has filed a motion to dismiss Zucker's action, centered in large part on the principle that, under the Administrative Procedures Act, specifically, 5 U.S.C. §704, and Supreme Court precedent, *e.g., FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232 (1980), a party facing administrative action cannot seek judicial review until the administrative determination is final.

In May 2014, the CPSC approved a settlement between the parties. Some of the terms included the following. Zucker agreed to acknowledge the jurisdiction of the CPSC over the product for purposes of the settlement. A Recall Trust was established and the parties would agree to a Corrective Action Plan. Zucker agreed to deposit $375,000 into an escrow account. The money would be used to fund the vol-

untary recall. Interestingly, the consent decree specifically called this deposit an "ordinary and necessary business expense" and "not a fine or penalty." *CSPC v. Zucker Consent Agreement* at ¶ 16(a). A website was also set up to assist in the voluntary recall and refund of the Buckyball product lines. After one year, Zucker would get back any funds that remained in the escrow account. Finally, Zucker agreed to dismiss his federal lawsuit challenging the CPSC's actions. In exchange, the CPSC agreed to release Zucker individually and in his capacity as a manager or officer. The Commission accepted this Consent Agreement by a vote of 2–1. The dissent objected on the grounds that the settlement did not do enough to protect consumers.

Practically speaking, if the administrative proceedings in the Maxfield and Oberton matter are predictive of things to come, company executives and their attorneys could face considerable and protracted litigation as the cases work their way through the administrative process, *i.e.*, initial determination by an ALJ, exhaustion of any administrative appeals, and then any judicial review and appeals. The threat of such protracted litigation could prove to be very powerful leverage for the CPSC to push parties into settlement with seemingly innocuous terms, especially considering the alternative. Furthermore, these settlements could keep a federal court from reviewing the legality of the CPSC's new strategy. This case should stand as a warning for any attorney or firm that deals with consumer product safety issues and product recalls.

Canada: Health Canada

Introduction

Over the past few years, Health Canada has indicated its continued commitment to regulate consumer products through the introduction of the Canada Consumer Product Safety Act (CCPSA) in 2011, and by imposing greater monetary penalties for those companies that fail to meet their obligations under the CCPSA. Increasing regulation of consumer products is undoubtedly part of the Canadian Government's promise to ensure safe products on store shelves. This is particularly true of products intended for use by children. Manufacturers, importers, and sellers of children's products should pay particular attention to the proposed changes under the CCPSA, as they will likely impose significant obligations.

Industry Guide

In 2012, Health Canada released the Industry Guide to Health Canada's Safety Requirements for Children's Toys and Related Products (**Industry Guide**). This document summarizes and clarifies the regulations under the CCPSA that address specific hazards of children's toys and related products. These include mechanical, flammable, toxicological, electrical, and thermal hazards. The primary regulation addressed in the Industry Guide is the *Toy Regulations*. Under the *Toy Regulations,* a toy is defined as "a product that is intended for use by a child in learning or play." Any product that falls within that definition is subject to stringent safety standards that specify particular measurements, construction requirements, and testing procedures.

This case should stand as a warning for any attorney or firm that deals with consumer product safety issues and product recalls.

Additional Proposed Regulatory Amendments

PlayPen Regulations

In April 2013, Health Canada circulated a draft proposal to amend the Playpen Regulations under the CCPSA and invited interested stakeholders to submit comments by June 29, 2013. Regulations relating to playpens have been in place since 1976; however, those regulations do not cover accessories attached to playpens, such as change tables, bassinets, mobiles, and canopies. The proposed amendments are in part to respond to emerging safety concerns relating to the use of playpens and sleep accessories and also to recognize concerns from manufacturers seeking greater alignment of Canadian standards to those of ASTM International. While these new standards will address safety concerns, the very nature of baby products is such that they are often passed down from one generation to another or sold at consignment stores and garage sales. Accordingly, there may be older products in use despite recalls.

If adopted, the amendments will result in stricter standards for side height, side and floor strength, and latching and locking mechanisms. The new standards relate to both construction and safety features. The changes will also require playpens to have bilingual warning labels regarding the use of both playpens and accessories. The proposed amendments are expected to bring Canadian rules more in line with international standards and U.S. requirements for playpens, play yards, bassinets, and cradles. The changes would be subject to a six month transitional period to allow industry time to re-design, test, and supply new product models.

Exemption Regulations

The proposed Exemption Regulations to the CCPSA were published in December 2013. The regulations exempt retailers from preparing and maintaining certain documents in respect of a consumer product that are obtained through donation. The regulation would exempt retailers, such as thrift stores, from maintaining documents indicating the name and address of who donated the product and relating to the location and period during which they sold the donated product. This proposed exemption does not apply to consumer products donated to a retailer by a manufacturer, importer, or seller.

CCPSA Reporting Requirements

Section 14 of the CCPSA sets out the duties of companies in the event of a potential health or safety incident with consumer products. The provision requires that any person who manufactures, imports, or sells a consumer product for commercial purposes report any incident related to a consumer product within two days after the day on which they become aware of

the incident. Additionally, the manufacturer or importer (if the manufacturer is located outside Canada) is required to provide Health Canada with a more detailed report within ten days after the day on which they become aware of the incident or as specified by the Minister. As noted below, actual injury does not need to occur for the reporting requirements to be triggered.

In March 2013, Health Canada circulated a revised "Draft Guidance on Mandatory Incident Reporting under the Canada Consumer Product Safety Act–Section 14 Duties in the Event of an Incident" ("**Draft MIR Guidance**"). The Draft MIR Guidance reinforces the importance of reporting consumer product related incidents, noting that the reports are "a key tool in the early warning and detection of potential health or safety issues related to consumer products on the Canadian market." Significant changes have been proposed in the draft guidance with regard to the scope of events that qualify as a reportable incident.

In defining what qualifies as an incident under section 14 of the CCPSA, the Draft MIR Guidance specifies that an event that *may* have reasonably resulted in death or a serious adverse effect on an individual's health is considered to be a "near miss." Specifically, it defines a near miss as "an event that could have resulted in harm, or in a greater degree of harm, under different circumstances." As an example, the Draft MIR Guidance provides that property damage resulting from a house fire that could have reasonably been expected to result in an individual's death or serious adverse effects on human health qualifies as a near miss.

Additionally, a "serious adverse health effect" now includes "a harmful effect that results in, or could have resulted in, a reversible or irreversible change to health requiring hospitalization or professional medical treatment." The draft guideline also defines a serious injury to include "the temporary or permanent impairment of a body function or temporary or permanent damage to a body structure, chronic health effects or any injury requiring hospitalization or professional medical treatment."

The Draft MIR Guidance streamlines the criteria to determine if an incident falls under section 14. An incident is determined by assessing two criteria: 1) whether the event is connected or related to a consumer product that is manufactured, imported, or sold in Canada for commercial purposes; and 2) whether the event meets one of the situations as outlined in subsections 14(1)(a)–(d) of the CCPSA.

> The proposed amendments are expected to bring Canadian rules more in line with international standards and U.S. requirements for playpens, play yards, bassinets, and cradles.

Under the first criterion, the product under consideration must not have only been involved, but it must have contributed to the incident.

The Draft MIR Guidance also articulates that the CCPSA is intended to protect against unreasonable dangers posed by products that are used in a normal or foreseeable manner. Therefore, in assessing whether a near miss or mild injury is reportable, companies need to consider whether the event poses an unreasonable hazard by normal or foreseeable use. What constitutes normal or foreseeable use depends on the product involved, the foreseeable users, and the circumstances surrounding the event. For example, the Draft MIR Guidance explains that a cut caused by use of a knife in a normal or foreseeable manner could be considered a reasonable hazard and would not be considered an incident. However, if during normal use the handle of the knife breaks causing a cut, this would be considered an unreasonable hazard and would need to be reported.

Health Canada also describes other specific examples of events that would be considered reportable incidents, including:

- A person replacing a light bulb in a normal manner when the light bulb catches fire, burning the person's hand;
- A child choking on a small part of a toy that broke off, and without intervention from his or her caregiver may have asphyxiated; and
- A recall of a lawnmower is initiated in another country due to a faulty ignition switch. The same lawnmower sold in Canada would be considered to be an incident as would any other product using the same faulty ignition switch.

The changes proposed in the Draft MIR Guideline suggest that Health Canada is attempting to broaden the scope of reporting under the CCPSA. By clarifying that an 'incident' under section 14 includes near misses, it is clear that events that have the potential to cause harm will need to be seriously deliberated. The broadening of incidents to include unreasonable injuries caused in the normal or foreseeable use of a product also increases the onus on manufacturers, importers, and sellers to fully investigate all incidents reported to them by consumers.

Health Canada has indicated that, as of March 2013, the number of reports received since the CCPSA came into force totals 2,984. Of this number, 1,997 reports have been received from industry and 1,007 from consumers. With respect to toys, between June 2011 and November 2013, Health Canada received 185 incident reports involving children under the age of 12, 10 of which related to children's jewelry and 37 of which related to children's sporting equipment.

The proposed changes also indicate that Health Canada is concerned about "under reporting." At a conference on March 21, 2013, Health Canada confirmed that they had not received the volume of reports that they had expected. They also expressed concerns about the quality of the reporting, stressing that it was important to include as much information as possible. In the event that a company proposes no corrective action is warranted in a 10 day report, this conclusion should be supported with the data the company is relying upon, in-

cluding test reports, technical data, and studies.

Draft Risk Assessment Framework

In November 2013, Health Canada released a draft Risk Assessment Framework to provide clarity and guidance on the principles and processes associated with risk assessment under the CCPSA and to determine where the Consumer Product Safety Program (the "Program") should focus its efforts. The Program is responsible for identifying, assessing, managing, and communicating risks posed by products and supporting compliance with the CCPSA. The framework is to provide a foundation for risk assessment to help prioritize risk in a systematic and structured manner that is based on the best available evidence. The Framework identifies six principles that are intended to guide the implementation of risk assessment.

The first principle is that "the priority and level of effort given to a risk assessment are determined by the potential danger to the health and safety of the Canadian public." Factors considered in reference to this principle include:

(a) the severity of the actual or potential injury (near-miss) or death;
(b) the age of the person affected;
(c) the extent of wear and age of the product in question;
(d) the number or pattern of reports related to the product; and
(e) a determination of whether the hazard is present when the product in question is used or misused in a reasonably foreseeable manner.

Other factors referenced may include (a) the availability of the product on the Canadian market; (b) risks identified by another authority outside Canada; and (c) elevated public concern or media attention. Emerging trends or reports involving specific vulnerable populations, such as young children, will receive higher priority.

The second principle is that risk assessments are based on evidence and professional judgment and should be independent of external expectations. Where the risk or hazard is serious, the absence of information will not prevent risk assessment.

The third principle is that the process will be transparent with respect to the principles that guide the assessment and the process by which they are conducted to ensure consistency.

The fourth principle is that the risk assessment will identify uncertainties, whether they arise from a qualitative or quantitative standpoint.

The fifth principle is that the risk assessment will appropriately consider population variability or vulnerability. The message is loud and clear—children are a priority. The Draft Framework notes: "young children constitute a vulnerable group that is of greatest concern for the Program due to their unique physiology and behaviors, as well as their lack of awareness of and/or control over hazards to which they could be exposed." The Program places a high priority on compliance in relation to children's products, and also in assessing hazards associated with products not necessarily intended for children, but to which there may be incidental exposure by children.

> Therefore, in assessing whether a near miss or mild injury is reportable, companies need to consider whether the event poses an unreasonable hazard by normal or foreseeable use.

The sixth and last principle is that the risk assessment must consider whether a hazard results from foreseeable use and/or misuse of a product.

Reports relating to a consumer product are prioritized and screened to determine their relative priority for risk assessment. Incidents involving children will generally result in a higher priority for review. Incidents involving products that are regulated are sent directly to risk management for consideration and are not prioritized. Incident reports that have been prioritized for risk assessment undergo preliminary screening, which may include a consideration of (a) whether it is reasonable to attribute the product use to an injury; (b) whether a user would have an awareness of the potential hazard with the product; and (c) whether harm would occur only if a user used the product in an unreasonable manner, which may include gross negligence or criminal activity.

Following the preceding analysis, there would be a preliminary determination if (1) risk management action can be considered without further assessment; (2) if the issue should be monitored and tracked; or (3) whether a more comprehensive risk assessment is warranted and the scope of any such assessment. The preliminary determination may include a level 1 report, which will outline a summary of the product and incident information, product history, applicable legislation and regulations, industry reporting, discussion on the potential hazard, product features that may influence the evaluation, and may include some discussion on the probability and foreseeable use/users of the product and identify any concerns a risk assessor has regarding the product. Hazard identification and characterization are undertaken concurrently with exposure assessment to estimate the probability and extent of exposure to the hazard, all of which seek to inform characterizing the risk.

Recalls of Children's Products

The first-ever mandatory recall under the CCPSA was issued in April 2013 in relation to a children's product. The Federal Minister of Health, Leona Aglukkaq, announced that action would be taken to remove magnet sets, commonly known as "Buckyballs," from the Canadian marketplace more than a year after similar action was undertaken in the United States.

Since the mandatory recall last spring, Health Canada has issued a number of recalls related to children's products. A number of these recalls relate to products that pose choking, laceration, and falling hazards. In most cases, Health Canada had not received any reports of incidents or injuries related to the use of the products. The recalls effectively serve as a precau-

tionary measure and signify that near-miss events are as much a priority as events actually causing injury.

Anecdotally, while WD-40 contains several warnings and is clearly not a product intended for use by children, a recall was issued in January 2014 relating to canisters of the product equipped with a Smart Straw because they were not child resistant. Health Canada expressed the position that since the recalled products contain ingredients that could pose an aspiration hazard, the product must be packaged in a child resistant container. Evidently, Health Canada will require action where there is potential injury to children even in respect to products that are clearly labeled poisonous and should not be kept within a child's reach.

The recalls effectively serve as a precautionary measure and signify that near-miss events are as much a priority as events actually causing injury.

Heavier Penalties

Following the mandatory recall in April, the government announced heavier fines under the CCPSA in June 2013. In her announcement, Leona Aglukkaq explained, "Canadian consumers expect the products they pick up on store shelves to be safe for them and their families" and the introduction of these fines will therefore ensure "that companies who break the law will pay the price." The *Administrative Monetary Penalties (Consumer Products) Regulations* ("**AMP Regulations**") signify the commitment of the Canadian government to penalize companies that fail to adhere to the requirements under the CCPSA.

The AMP Regulations and accompanying guidance detail the time and manner in which monetary fines under the CCPSA are calculated and the manner in which certain documents are to be provided. For example, monetary fines are issued when a company fails to comply with orders of the government to recall a product or stop the manufacture of a non-compliant product. Under the AMP Regulations, penalties are calculated to reflect the seriousness of the violation and past violations of the company or person. Penalties also differ depending on whether the violation is committed by an organization for a non-commercial purpose (such as a non-profit) or for a commercial purpose. The maximum fine under the AMP Regulations for a non-profit organization is $5,000; however, the maximum penalty in any other case is $25,000. The result is that companies like Mattel, Fisher-Price, and Hasbro will be subject to penalties that are five to ten times higher than organizations that manufacture, sell, or import consumer products for a non-commercial purpose. It is likely that Health Canada will vigilantly enforce these fines in relation to children's products.

The recent guidance documents and proposed regulatory amendments outlined above indicate that Health Canada is trending towards a stiffer regime of consumer product regulation. The Canadian government has clearly signaled that it will closely monitor products marketed to children and even those products not necessarily intended for children, but to which children may be exposed. The proposed guidelines clarify reporting requirements and emphasize that near miss events will be scrutinized with the same vigilance as those causing actual injury.

Conclusion

From the point of view of industry, these recent actions by the U.S. and Canada product safety regulators represent a difficult change in the delicately balanced relationship between the regulations and industry. If these regulations and guidance documents are issued in their present form and the practice of pursuing corporate officers in an attempt to involve personal liability for the cost of consumer product recalls become more prevalent, the balance of cooperative interaction between industry and the regulators will be disturbed and industry will be required to react.