CPSC and Health Canada Reporting Obligations

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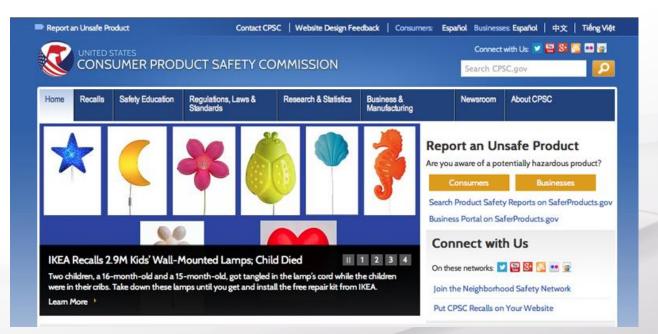
Overview

- CPSC Reporting Obligations
- Recent Civil and Criminal Penalties for Failure to Report
- Do's and Don'ts
- Health Canada's Reporting Obligations





• Is my product covered by the CPSC?





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The CPSC's Long Reach

- The CPSC asserts jurisdiction over millions of "Consumer Products"
 - The definition of "Consumer Products" is intentionally broad and rarely challenged in court
 - It has been interpreted to include any product or component used by or having an effect on consumers
 - Commercial products, drugs and motor vehicles are examples of products not covered



My Product is Covered - Do I need to Report?

A manufacturer must report if:

1. The product fails to comply with a consumer product safety rule or voluntary standard;



- 2. Contains a defect that could **create a substantial product** hazard;
- 3. Creates an unreasonable risk of serious injury or death; or
- 4. Fails to comply with any other rule, regulation, standard or ban under the Consumer Product Safety Act or any other act enforced by CPSA



Reporting Obligation Construed Very Liberally...

- One decision interpreting the reporting requirements, <u>United</u> <u>States v. Mirama</u>, 185 F. Supp. 2d 1148 (S.D. Ca. 2002), is extremely problematic for manufacturers
- <u>Mirama</u> sets a very low threshold for requiring manufacturers to report problems with their products



- Not what company believes
- Not what experts believe
- It is what "reasonable person believes"



Liberal Reporting Standard

- <u>Mirama</u> involved incidents of exploding juicers
- 22 people were injured
- 7 people required medical treatment. The court concluded that this was "overwhelming" evidence that the product was defective or unreasonably dangerous and that the manufacturer's failure to report the incidents violated the CPSA



What Happens If You Do Not Report?

Civil Penalties

- May be imposed for "knowing" violations of the CPSA:
 - \$10,000/violation
 - \$15 million max



Multiple Violations

- Following <u>Mirama</u>, courts will not consider a failure to report a single violation, but rather will consider the number of potentially defective or unreasonably dangerous products in the stream of commerce as individual violations
 - In <u>Mirama</u>, the court concluded that manufacturer had not committed 23 violations(one for each unreported incident), but 30,000 to 40,000 violations based on the number of potentially affected products in the stream of commerce
- This combination makes it relatively easy to maximize civil penalties



Criminal Penalties

- May be imposed for a "knowing and willful" violation of the CPSA
 - \$250,000 fine
 - Up to 5 years in prison





Prohibited Acts

- Among the prohibited and potentially criminal acts are the following:
 - Knowing and willful manufacture, sale, or distribution of a product that does not conform to the requirements contained in the CPSA; and
 - Knowing and willful failure to comply with mandatory reporting requirements





Criminal Conduct

A first-time knowing and willful violation of the Act is a criminal offense

• Places increased pressure on corporate actors to determine whether certain conduct violates the Act in the first instance





Who Could Be Affected?

- Reasonably likely to apply to:
- CEO
- President
- Officers
- Directors
- Managers
- In-house counsel
- Outside counsel?



Essentially, anyone with decision-making authority



So What Do You Do When Faced With Knowledge of Incident and Your Section 15(b) Reporting Obligation?

- Engage Product Safety Committee
- Seek legal opinion?
- Report problem and recall?
- Report problem but do not recall?
- How report?





Trump Administration

- Penalties took a "hiatus"
- CPSC imposed no significant penalties



Biden Administration

- Penalties returned
- Size of penalties increased significantly



2021 Civil Penalties

- \$12 million penalty against Walter Kidde Portable Equipment for failure to report 400incidents of fire extinguishers failing to discharge
- NEARLY 400 REPORTS OF MALFUNCTIONS 16 INJURIES 1 DEATH
- \$7.95 million penalty against Cybex International for failure to report over 100 complaints of defective exercise equipment





2022 Civil Penalties

- \$6.5 million penalty against Core Health and Fitness for failing to report 55 incidents of parts falling from exercise machines
- \$7.5 million penalty against Vornado Air LLC for failing to report incidents, including a death, relating to space heaters catching fire
- \$13 million penalty against TJX Companies for knowingly selling 1,200 recalled products from 21 separate recalls





2022 Criminal Penalties

- Gree Appliance Companies charged with failure to report dangerous dehumidifiers and agreed to pay \$91 million penalty in deferred prosecution agreement.
- Two Gree executives indicted for felony CPSC and wire fraud charges for their alleged roles in the failure to report defective humidifiers.



Important Lessons to be Learned

- Kidde \$12 million penalty
- Gree Appliance \$91 million penalty



Kidde \$12 Million Penalty

- Kidde self-reported to CPSC in 2014.
- Kidde told CPSC that "out-of-spec" value component was causing disposable fire extinguishers to fail to operate.
- Kidde told CPSC that problem limited to models sold for only 15 months.
- Kidde reported 12 incidents to CPSC.
- Kidde issued recall of 4.6 million units in February 2015.



However, . . .

- By November 2017, Kidde had received more than 400 reports of similar disposable fire extinguishers failing to work in fire emergency.
- In November 2017, Kidde issued a second recall of 37.8 million units in U.S. and 2.7 million units in Canada.
- CPSC: Kidde significantly underreported the scope and nature of the defect and risk.
 - Testing and incident data not disclosed
 - Kidde reported 12 incidents to CPSC; Kidde actually received 100 incidents of extinguishers failing to discharge, which resulted in 16 injuries and 1 vehicle fire fatality in 2014.



Lessons from Kidde

- Be careful about scope of your recall
- Do other products have same issue?
- Report all incidents related to issue
- Not over until it is over



Gree Appliance \$91 Million Penalty

- Gree, a large Chinese company, sold dehumidifiers in U.S. through U.S. affiliate.
- In July 2012, Gree U.S. CEO saw a video of burning Gree dehumidifier. Sent video to Gree Hong Kong with note:

"urgent"

"scary to just watch"

"very serious issue with Gree product quality"

"third reported instance of fire"

"could lead to lawsuits as well as recall costing millions"



- Gree Hong Kong Response: "We feel shocked. Will send to engineer.
- Gree U.S. tests dehumidifier inventory in August 2012. Gree U.S. CEO tells Gree Hong Kong:

"result is not like you were telling us"

"results show the units all can catch fire"

"material not according to UL"

"planning on having add'l testing done and informing CPSC about problem"



- Gree Hong Kong response: Do not report to CPSC
- Gree U.S. CEO replies:

"anyone who withholds info from CPSC about dangerous product could face severe punishment including criminal prosecution"



- Meeting in U.S. in September 2012. Gree Hong Kong:
 - Cannot replicate fires
 - Will modify future products
 - Decision about what to do should be "guided by the principle of minimizing the costs and reputation of Gree Companies"
 - Delay recall for 6 to 9 months to save existing sales
 - Delay justified because cooler fall weather will help prevent fires
 - Told Gree U.S. not to conduct further tests
 - We told you how to handle recall and hope you will follow our opinion



- October 2012 add'l testing confirms problem
- November 2012 attorney advises reporting
- January 2013 insurance company advises reporting
- March 2013 Gree finally reports (19 fires) and recalls 2.2 million dehumidifiers



Lessons from Gree

- Report, report, report
- Stop sales
- Internal communications are discoverable



Future Penalties?

- Industry should expect even larger penalties in future
- CPSC Commissioner: "wipe the slate clean and write next chapter in CPSC "work"
- Expect future penalties to be "multiples higher"





What Happens in Canada Does Not Stay in Canada

- Canada Consumer Product Safety Act
- In effect June 2011
- Mandatory incident reporting





- An incident that must be reported to Health Canada when a manufacturer becomes aware of:
 - An occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects to their health, including a serious injury;
 - A defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects to their health, including a serious injury;
 - Incorrect or insufficient information on a label or package—or the lack of a label or instructions—that may reasonably be expected to result in an individual's death or in serious adverse effects to their health, including a serious injury; or
 - A recall or other measure that was initiated for human health or safety reasons by another jurisdiction (including a foreign entity)

Conflicting Guidance from Canada

Very similar to U.S. reporting obligations (Health Canada Information Session (July 3, 2013))

Hudson Bay

BAFFIN SEA

Labrador

But risk assessment guidance is challenging

PACIFIC



Thank You!

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