A Product Supplier's Liability Exposure for Noncompliance With its Obligations Under the Consumer Product Safety Act and Related Alternative Statutory Authorities

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Manufacturers, importers, distributors and retailers have the obligation to place only those products that are safe for use into the stream of commerce. In addition to those obvious duties, these entities also face significant duties under the Consumer Product Safety Act (CPSA) [i] and other legislation and regulations enforced by the Consumer Product Safety Commission (CPSC). Whether prosecuting or defending a product manufacturer, it is critical to appreciate the various CPSA obligations that provide powerful liability hooks. For example, a manufacturer's product liability exposure frequently involves breach of post-sale duties of disseminating appropriate and updated warnings, safety bulletins, and installation and operating instructions, as well as implementing corrective actions, including product recalls, where necessary to avoid foreseeable dangers, risks and hazards from a recognized product defect.

The Consumer Product Safety Commission — Broad Regulatory Authority

The CPSC regulates the safety of more than 15,000 products in the United States on an annual basis. The Commission's Web site, www.cpsc.gov, provides detailed lists of product-related hazards, recalls and corrective measures undertaken. CPSC's 2005 annual report identifies 397 product recalls, affecting 67 million consumer products that presented a significant risk to the public or violated mandatory safety standards. The CPSC collected $8.8 million from manufacturers that knowingly failed to report potential hazards, failed to report lawsuits or settlements regarding product hazards, or knowingly imported or sold products that did not meet mandatory safety requirements. Additionally, there were 975 corrective actions taken by manufacturers to correct potentially hazardous conditions in products. From 1990 through 2005, the CPSC and industry members developed 304 voluntary safety standards and 35 mandatory rules.

The CPSA grants the CPSC broad authority to protect the public against unreasonable risks of injury from consumer products. Under the CPSA, a company is required to immediately notify the CPSC of information that reasonably supports the conclusion that its product has a reportable noncompliance or a defect that may create a substantial hazard or unreasonable risk of serious injury or death.[ii] This reporting is mandatory unless the company has investigated and determined that the information is not reportable. All available information should be evaluated to determine whether the information received suggests the existence of noncompliance, a defect or an unreasonable risk of serious injury or death, including, for example, information about engineering, quality control, production data, safety-related production or design changes, product liability suits and/or claims for personal injury or damage and other consumer complaints or warranty claims.[iii]

CPSC Recall Handbook — Practical Insights

There is no bright-line test to determine if a substantial product hazard exists. The CPSC Office of Compliance has issued a *Recall Handbook* to assist manufacturers, importers, distributors and retailers on understanding the obligatory reporting requirements under Sections 15 and 37 of the CPSA, and to aid in initiating and implementing product safety recalls.[iv] The 1999 revised edition also includes a "Fast Track" program for companies willing and able to move quickly with a voluntary recall of their product.[v] As suggest-

ed in the *Recall Handbook*, any entity involved in the manufacture, sale or distribution of a consumer product should have a system for handling consumer complaints, warranty returns, product liability lawsuits, etc…, as well as a designated person within the company to handle these issues who has knowledge of the product and of the reporting requirements.

Under Section 15(b) of the CPSA, manufacturers, importers, distributors and retailers of consumer products are required to notify the Commission "immediately [upon obtaining] information which reasonably supports the conclusion that a product distributed in commerce fails to meet a consumer product safety standard or banning regulation; contains a defect which could create a substantial product hazard to consumers; creates an unreasonable risk of serious injury or death; or fails to comply with a voluntary standard upon which the Commission has relied under the CPSA."[vi] Section 15's requirement that firms report "immediately" to the Commission has been interpreted as meaning the company *must* report within 24 hours of obtaining reportable information described in the *Recall Handbook* under the "When to Report" subsection.[vii] Federal regulatory provisions indicate that companies "should not delay reporting in order to determine to a certainty the existence of a reportable noncompliance. The obligation to report arises upon receipt of information from which one could reasonably conclude the existence of a reportable noncompliance, defect that could create a substantial hazard, or unreasonable risk of serious injury or death. Thus, an obligation to report may arise when a subject entity received the first information regarding a potential hazard, noncompliance or risk."[viii] Under subsection (d) of that regulatory provision, a company must report "information indicating that a noncompliance or defect in a consumer product has caused, may have caused, or contributed to the causing, or could cause or contribute to the causing of a death or grievous bodily injury (e.g., . . . severe burns, severe electrical shocks, and injuries likely to require extended hospitalization)," "unless the subject firm *has investigated and determined* that the information is not reportable."[ix]

Enforcement Actions

The Office of Consumer Litigation of the Department of Justice pursues enforcement actions on the CPSC's behalf[x] and represents the CPSC in federal court when a party seeks to invalidate its actions or compel action contrary to the CPSC's intended course of actions. Commonly, challenges are made to labeling or performance requirements promulgated by the CPSC under the statutes it administers.[xi]

Potential Civil Penalties

The CPSA authorizes the CPSC to go onsite at regulated firms for inspections to aid in enforcement actions.[xii] Failing to follow CPSC guidelines and report such information immediately can result in substantial civil penalties and criminal prosecution.[xiii] Knowing violations of CPSC-administered statutes can be sanctioned through civil penalties.[xiv] One of the civil penalties available for a knowing failure to report (and for the knowing distribution of an unsafe product) is monetary sanctions — the amount being guided by criteria specified by statutory provisions including limits on the amounts that may be recovered for individual violations and for related series of violations.[xv] Other sanctions include product bans, removal of violative goods from the market through *in rem* seizures, halts of distribution, and product recalls.[xvi] A company can institute a self-imposed recall but may face liability for negligence if the recall is later determined to be too narrow or insufficient by the CPSC.

Potential Criminal Punishment & Monetary Sanctions

Criminal prosecution can result in incarceration that does not exceed one year for conviction under the CPSC authorized statutes[xvii] (a misdemeanor) or under other criminal statutes, including felony provisions, procecution for conspiracy, fraud, obstruction of justice, false statement and other related federal offenses that may surface during a CPSC enforcement action. Persons knowingly and willfully violating the CPSA who are criminally prosecuted may also be subject additionally, or in lieu of incarceration, to a fine of not more than $50,000.[xviii]

Strategic Litigation Insights

Whether developing or defending a product defect case, it is important to be mindful of these CPSA requirements. Throughout discovery, counsel should look, depending on their perspective in play, to either develop or counter expected charges of a target defendant's lack of quality control, adequate warnings, and product stewardship as evidentiary support for proving product defect and deficient post-sale corrective actions (i.e., recall, retrofit, warnings, product hazard notice, cease distribution and sale, press release, etc...). The CPSC has developed an official policy by which it makes official CPSC records available to private litigants to the fullest extent possible.[xix] However, the CPSC has also expressed through regulatory provisions that use of CPSC employees in private litigation is discouraged because it is contrary to the Commission's policy, the employees' responsibilities and could impair the effectiveness of CPSC employees as witnesses in litigation in which the CPSC is directly involved.[xx] Private litigation has been defined by the CPSC as "any legal proceeding which does not involve the United States government, or any department or agency of the U.S. government, as a party."[xxi]

The CPSC's Wide-Ranging Power

The CPSC has been directed by Congress to act through more targeted legislation that addresses risks presented by defined categories of consumer products rather than under the authority of the broad-sweeping CPSA.[xxii] These alternative authorities are conferred by the Flammable Fabrics Act,[xxiii] the Federal Hazardous Substances Act (FHSA),[xxiv] the Refrigerator Safety Act[xxv] and the Poison Prevention Packaging Act of 1970 (the "PPPA").[xxvi]

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The "Packaging" Liability Hook

The PPPA is of specific interest because unlike other alternative authorities, the PPPA applies to household substances within both CPSC and Food and Drug Administration (FDA) jurisdiction. The PPPA authorizes the CPSC to set standards for labeling and packaging to protect children from serious potential harms caused by misuse and ingestion of household substances, vitamins and drugs.[xxvii] In administering the PPPA, the CPSC has required that a number of household products and drugs be sold in child-resistant packaging.[xxviii] The PPPA and FHSA were amended by the Child Protection and Toy Safety Act, which ultimately transferred the responsibility for enforcing the PPPA from the FDA to the newly-created CPSC in 1973.[xxix] The movement toward child protection was prompted by the introduction of child-resistant closures in the early 1970's and information gathered by poison control centers in the mid-1970's. This information was analyzed to determine that the second-leading cause of childhood poisoning, behind accidental ingestion of potentially toxic parts of plants, was accidental ingestion of soaps, detergents and cleaners, with accidental ingestion of vitamins and mineral preparations coming in third.[xxx] The National Center for Health Statistics, which analyzes mortality files, reports that since 1972, the number of deaths for children under age five attributed to or involving medicines and household chemicals has decreased from 216 in 1972 to only 29 in 1999.[xxxi]

The majority of veterinary drugs prescribed are administered by veterinarians and are not required to be in child-resistant packaging; however, the CPSC, recognizing that many of the drugs prescribed for small animals were generic equivalents of human prescription drugs and are often kept in or around the home, have strongly urged veterinary medical practitioners to use child-resistant packaging.[xxxii] The CPSC has published a handbook entitled *Poison Prevention Packaging: A Guide for Healthcare Professionals* that could be followed by both human healthcare and veterinary medical practitioners in order to ensure the safety of children.[xxxiii]

Enforcement actions by the CPSC for failure to meet the PPPA standard cross-reference and proceed under the authority of the FHSA because if a household substance is within the CPSC's jurisdiction subject to the PPPA standard and fails to meet that standard, it is deemed improperly labeled under the FHSA.[xxxiv]

FDA/CPSC Interplay

Many household items have been closely examined to determine whether they should be under the jurisdiction of the FDA or the CPSC. For example, infant pacifiers are generally regulated by the CPSC; however, if they are marketed with health claims, they are under the FDA's jurisdiction. Further, some other infant and child items that many would consider common household items, such as baby bottle nipples, ceramic ware intended for food use, coffee mugs and eye charts are under the FDA's jurisdiction as food-contact articles and medical devices. Also, the decision of which agency would regulate home canning equipment necessitated a memorandum of understanding between the FDA and CPSC — the equipment was ultimately assigned to the jurisdiction of the CPSC. The FDA's federal Food, Drug & Cosmetic Act (FDCA) specifically excludes soap from the definition of cosmetics to avoid stepping over into the CPSC's regulation of soap products. Although the CPSC was granted authority under its portion of the PPPA to regulate child-proof packaging, tamper-resistant packaging, required for certain over-the-counter drugs, cosmetics and medical devices, has remained the FDA's responsibility.[xxxv]

Special Packaging Criteria and Subject Substances

The CPSC follows a formulaic process to determine whether a household substance requires special packaging. First, the CPSC must find that the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using or ingesting such substance; and that the special packaging to be required by such standard is technically feasible, practicable and appropriate for such substance. In establishing a standard, the CPSC considers the reasonableness of such standard; available scientific, medical, and engineering data concerning special packaging and concerning childhood unintentional ingestions, illness and injury caused by household substances; the manufacturing practices of industries affected by the PPPA; and the nature and use of the household substance.

Substances regulated at 16 CFR § 1700.14 include aspirin, controlled drugs, furniture polish, turpentine, kindling and/or illuminating preparations, prescription drugs, iron-containing drugs and dietary supplements, solvents for paint or similar surface coatings, acetaminophen, glue remover containing acetonitrile, permanent wave neutralizers, ibuprofen, mouthwash, naproxen, ketoprofen, over-the-counter drug products (which contain active ingredients formerly available only by prescription), and those substances containing defined amounts of wintergreen oil (methyl salicylate), sodium and/or potassium hydroxide, methanol (methyl alcohol), sulfuric acid, ethylene glycol, diphenhydramine, loperamide, lidocaine, dibucaine, fluoride, minoxidil, methacrylic acid, and hazardous substances and drugs and cosmetics containing low-viscosity hydrocarbons.[xxxvi]

Conclusion

To effectively handle a product liability claim, it is imperative that counsel fully appreciate the broad breadth of the CPSA

and PPPA's obligations imposed on product manufacturers and related entities in the chain of distribution. These duties provide powerful liability hooks — post-sale warnings and updated product information, product recalls, and other corrective actions — to minimize product hazards. Accordingly, informal investigation and litigation discovery activities should cover, whether in an offensive or defensive posture, the manufacturer's corporate knowledge on its product risks, management of those risks, and interfacing with the CPSC, industry groups, and its product consumers and end-users.

In light of the manufacturer's significant CPSA and PPPA (through the FHSA) liability exposure, it is crucial to appreciate the product manufacturer's CPSC-driven obligations in order to get the competitive edge in the typically hard-fought product liability litigation.

References

[i] 15 U.S.C. §§ 2051 et seq. (1994 & Supp. 2004).
[ii] *Id.* § 2604(b).
[iii] 16 C.F.R. § 1115.12(f)(1-7) (2005).
[iv] U.S. CPSC Office of Compliance, *Recall Handbook* (May 1999).
[v] U.S. CPSC Office of Compliance, *Recall Handbook- Foreword* ¶ 3-4.
[vi] U.S. CPSC Office of Compliance, *Recall Handbook- Reporting Requirements I.A. Section 15 Reports* ¶ 1; *see also* 15 U.S.C. § 2064(b) (1994).
[vii] U.S. CPSC Office of Compliance, *Recall Handbook- Reporting Requirements I.A.2. When to Report* ¶ 1-2 (emphasis in original); *see also* 15 U.S.C. § 2064(b).
[viii] Substantial Product Hazard Reports, 16 C.F.R. § 1115.12(a) (1992).
[ix] 16 C.F.R. § 1115.12(d) (emphasis added).
[x] *See* In re Establishment Inspection of Skil Corporation, 846 F.2d 1127 (7th Cir. 1988), for an illustration of the kind of court intervention the Office of Consumer Litigation pursues on the CPSC's behalf.
[xi] O'Keeffe's, Inc. v. U.S. Consumer Product Safety Comm'n, 92 F.3d 940 (9th Cir. 1996), is representative of the Office of Consumer Litigation's defense of the CPSC.
[xii] 15 U.S.C. § 2065.
[xiii] *Id.* §§ 2069-2070.
[xiv] *Id.* § 2070 (CPSA); *Id.* § 1264(c) (FHSA).
[xv] *Id.* § 2069.
[xvi] *Id.* §§ 2069, 2071(a) & (b).
[xvii] *Id.* § 2070.
[xviii] *Id.*
[xix] 16 C.F.R. 1016.1(a) (2004); *see also* 16 C.F.R. 1016.3 (wherein it is stated that documents are released under the Freedom of Information Act and the Freedom of Information Act sections of the CPSA; further the Secretary of the CPSC must certify the authenticity of CPSC records and the Secretary's office will handle any subpoena *duces tecum* served on CPSC employees, with General Counsel or the Department of Justice stepping in to quash subpoenas or request protective orders to prevent improper disclosure of documents).
[xx] 16 C.F.R. 1016.1(b); *see* 16 C.F.R. 1016.4 (detailing how CPSC employees *may* testify in private litigation).
[xxi] *Id.* at 1016.2.
[xxii] 15 U.S.C. § 2079(d).
[xxiii] *Id.* §§ 1191 et seq.
[xxiv] *Id.* §§ 1261 et seq.
[xxv] *Id.* §§ 1211 et seq.
[xxvi] *Id.* §§ 1471 et seq.
[xxvii] *See* 16 C.F.R. 1700 et seq.; *see also* U.S. CPSC Office of Compliance, *Requirements under the Poison Prevention Packaging Act, 16 C.F.R 1700* (Jan. 2001).
[xxviii] *See* U.S. CPSC Document 5018, *Use Child-Resistant Containers, at* http://www.cpsc.gov/cpscpub/pubs/5018.html.
[xxix] 15 U.S.C. § 2079.
[xxx] *See* U.S. CPSC, Office of Information and Public Affairs, News Release # 78-018 (March 17, 1978), *at* http://classification.findlaw.com/recall/cpsc/files/1978mar/78018.html (last visited Apr. 12, 2006); *see also* U.S. CPSC Document 5051, *Prevent Poisoning and Death from Iron Containing Medicine, at* www.cpsc.gov/cpscpub/pubs/5051.html.
[xxxi] *See* U.S. CPSC Document 386, *National Poison Prevention Week 2003, at* http://www.cpsc.gov/cpscpub/pubs/386.html; *see also* U.S. CPSC Document 5019, *Child Resistant Packaging Saves Lives, at* http://www.cpsc.gov/cpscpub/pubs/5019.html; *see also* Rodgers, G., "The Safety Effects of Child-Resistant Packaging for Oral Prescription Drugs," Two Decades of Experience, JAMA 275: 1661-1665, 1996.
[xxxii] U.S. CPSC Document 5104, *Child-Resistant Closures and Veterinary Drugs Dispensed by Veterinarians to the Consumer, at* http://www.cpsc.gov/cpscpub/pubs/5104.html
[xxxiii] U.S. CPSC Document 384 - Revised 2005, *Poison Prevention Packaging: A Guide For Healthcare Professionals, at* http://www.cpsc.gov/cpscpub/pubs/384.pdf.
[xxxiv] 15 U.S.C. § 1261(p).
[xxxv] U.S. Food and Drug Administration, *How Much Do You Know About FDA?*, FDA CONSUMER MAGAZINE (Dec. 1995), *at* http://www.fda.gov/fdac/features/095_quiz.html.
[xxxvi] U.S. CPSC Document 384 - Revised 2005, *Poison Prevention Packaging: A Guide For Healthcare Professionals*, pp. 5-9, *at* www.cpsc.gov/cpscpub/pubs/384.pdf

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meaning it should not be used in combination with other immune system modifying drugs, the FDA said. Tysabri is designed for patients who have not responded adequately to, or cannot tolerate, other treatments for MS, the agency said.

Novartis Recalls Triaminic Vapor Patch

PARSIPPANY, N.J. — Novartis Consumer Health said it is conducting a voluntary nationwide recall of its Triaminic Vapor Patch products due to several reports of serious adverse health effects, including seizures.

Novartis said it is recalling the products because serious adverse health effects could result if the Vapor Patch is ingested by a child removing the patch and chewing on it. Novartis warned that consumers who have Triaminic Vapor Patches should stop using them immediately because the company has received multiple complaints of injuries, including seizures.

Reported adverse events associated with swallowing products containing camphor or eucalyptus oils, such as those confirmed with the Triaminic Vapor Patch, can vary from minor symptoms, such as burning sensation in the mouth, headache, nausea and vomiting, to more severe reactions, such as seizures, Novartis said.

The company said all lots are being recalled in both product lines of mentholated cherry scent and menthol scent. The recall is being conducted with the knowledge of the FDA, Novartis said.

Triaminic Vapor Patch is labeled as a cough suppressant for children two years of age and older, the manufacturer said, noting that the directions on the label indicate the patch is to be applied to the throat or chest to allow the vapors to reach the nose and mouth.

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