DORSEY™
DORSEY & WHITNEY LLP

PRODUCTS LIABILITY UPDATE

VOLUME 1 **ISSUE 1**

SPRING 2009

Consumer Product Safety: A New Wave of Regulation May Lead to Increased Product Liability

By Mark R. Kaster and Nena F. Street, Dorsey & Whitney LLP

Mark Kaster
Partner
(612) 340-7815
kaster.mark@dorsey.com

Partner, Regulatory Affairs Group. Counsels of clients in regulated industries. Concentration on administrative and regulatory matters, with emphasis on both public and private risk assessment and regulatory processes. Represents of clients before both federal and state agencies and local units of government.

Nena Street
Associate
(612) 492-6876
street.nena@dorsey.com

Nena Street is an Associate in Dorsey's Regulatory Affairs Group practicing in the areas of Environmental Law, Public Private Partnerships, and Consumer Product Safety.

The Consumer Product Safety Improvement Act ("CPSIA") was enacted in August 2008, following thousands of toy recalls during and after the 2007 holiday season. CPSIA is an ambitious undertaking, seeking to fundamentally reform consumer product safety in the United States. The law, however, has created a legal minefield for manufacturers, importers, warehousers, retailers, lenders and other participants in the consumer products industry.

This article provides a brief introduction to CPSIA, including a summary of some of the key provisions and an update on agency rulemaking. Throughout the article, we provide important tips for navigating the law. For additional insight, please visit our consumer products safety blog at www.ConsumerProductsLaw.com.

Duty to Test and Certify Consumer Products

Although CPSIA has received great attention for its impact on children's products, the law includes a provision which significantly expands product testing requirements for many products. CPSIA requires every manufacturer and importer of a product that is subject to a consumer product safety rule, ban, standard, or regulation under any Act enforced by the Consumer Product Safety Commission ("CPSC") to adopt a reasonable product testing program and then certify compliance.

A product requires certification if it is regulated in any way by the CPSC. Determining whether a product is regulated can be difficult, and requires analysis of a large range of laws and regulations, and even requires interpretive guidance. The CPSC enforces not only the Consumer Product Safety Act but also consumer products regulated under the Federal Hazardous Substances Act, the Flammable Fabrics Act, the Poison Prevention Act, the Children's Gasoline Burn Prevention Act, the Refrigerator Safety Act and the Virginia Graeme Baker Pool and Spa Safety Act.

The CPSC stayed enforcement of most CPSIA testing and certification requirements until February 10, 2010, but the stay does not provide much relief. First, the stay does not delay implementation of lead or phthalate content limits, it merely delays the requirement that manufacturers or importers of regulated products "prove" compliance through testing and certification. Second, the stay does not bind state attorneys general (AG's) and thus the state AG's may opt to enforce the testing and certification provisions. Moreover, third-party lawsuits may also challenge the stay.

Consumer Product Safety: A New Wave of Regulation May Lead to Increased Product Liability

(Continued)

It is thus important for manufacturers and importers to commence a program of testing to assure that products regulated by the CPSC comply with applicable rules, standards and guidance. In fact, states like California, Minnesota, and others have already begun to fashion their own product safety statutory frameworks.

New Requirements for Children's Products

CPSIA requires an additional level of testing and several other requirements for "children's products." The scope of this new term of art has been subject to much debate in recent months.

A "children's product" is defined under CPSIA as "a consumer product designed or intended primarily for children 12 years of age or younger." In determining whether a consumer product is "primarily intended for children 12 years of age or younger," several specific factors must be considered, including the manufacturer's statement about the intended use of the product and whether children under 12 commonly recognize the product as intended for their use.

Given the dearth of authoritative guidance, applying the term to specific products is complex and precarious, particularly in light of the enhanced enforcement arsenal at the CPSC. We encourage companies to exercise caution when making this determination and to seek legal counsel to help address uncertainties and manage risks.

Lead Content Limit

CPSIA adopted a retroactive lead content limit for children's products which is already in effect. As of February 10, 2009, children's products moving through the stream of commerce may not have more than 600 parts per million (ppm) lead content by weight for any part of the product. The lead content limit will get progressively lower over the next three years, decreasing to 300 ppm on August 14, 2009, and then to 100 ppm on August 14, 2011, if technically feasible. This aggressive reduction of lead content in children's products is proving traumatic to the industry.

Recently, the CPSC issued an enforcement policy indicating that it will not impose penalties against anyone for making, importing, distributing, or selling:

- children's products made of certain natural materials, such as wood, cotton, wool, or certain metals and alloys that the CPSC has recognized rarely, if ever, contain lead;
- ordinary children's books printed after 1985; or
- dyed or undyed textiles (not including leather, vinyl or PVC) and non-metallic thread and trim used in children's apparel and other fabric products.

Companies may also find refuge in one of the three exemptions to the lead content limit once the CPSC completes its rulemaking. So far, the CPSC has not issued any rules with respect to the first two exemptions, which allow the CPSC to exempt a product if there is no risk of lead absorption or to exempt parts of a product that are inaccessible to a child.

The CPSC has issued rules relating to the third exemption, which allows the CPSC to establish alternative lead limits for electronic devices that cannot feasibly meet the 600 ppm lead content limit. On February 12, 2009, the CPSC published its Interim Final Rule on this exemption. The Rule exempts certain lead-containing component parts in children's electronic devices that are unable to meet CPSIA lead limits due to technological infeasibility and in which the use of lead is necessary for the proper functioning of the component part. It also establishes new lead limits for specific products. Lastly, the Rule exempts components of electronic devices that are removable and replaceable, like batteries or light bulbs, and that are inaccessible when the product is assembled and in functional form.

Phthalate Ban: Children's Toys and Child Care Articles

As of February 10, 2009, children's toys and child care articles may not contain more than 0.1% of certain phthalates, which are chemicals used to soften plastic. Like the lead content standard, this standard has been held to apply retroactively to all products in inventory.

The scope of products which must comport with the phthalates ban is unclear. Under CPSIA, "children's toy" means a children's product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays and the term "child care article" means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething. The CPSC is evaluating many product categories to determine the scope of the regulation.

CPSC and State Enforcement

CPSIA magnified the CPSC's recall authority, as well as civil and criminal penalties for noncompliance. The maximum civil penalty for violations of the consumer product safety laws is now $100,000 (previously $5,000) for each violation, up to

Consumer Product Safety: A New Wave of Regulation May Lead to Increased Product Liability

(Continued)

$15,000,000 (previously $1,250,000) for a series of related violations. Willful and knowing violations of consumer product safety laws could lead to five years (previously one year) imprisonment. Directors, officers and agents of the manufacturer no longer must have actual notice of a violation to be criminally liable. In addition, the law includes a whistleblower provision to protect employees who report violations. State AG's are also empowered to enforce CPSIA and may seek injunctive relief to stop the sale of products that do not meet federal requirements.

Compliance with the CPSIA may not be enough – Impact of State Laws

The preemptive reach of the Consumer Product Safety Act as amended by the CPSIA is unclear. For instance, CPSIA explicitly allows states to regulate consumer products if the state requirements are identical to the federal requirements. It also specifies that the CPSC may not expand the preemptive effect of the statutes it enforces through rulemaking. In addition, CPSIA provides that it does not preempt or affect certain state warning requirements (e.g., California's Prop 65).

We continue to track the evolution and application of several state consumer product safety laws with care and will provide regular updates. If you are a business subject to CPSC regulation, it is very important to remain up-to-date on state consumer product regulations. States across the country are at various stages of adopting laws which require warning labels or other chemical content limits in children's products.

Conclusion

Navigating the minefield of consumer product safety laws requires vigilance and careful risk management. If you manufacture, import, market, distribute, license, sell or resell a product that is subject to CPSC oversight or state consumer product regulations, you must be proactive. Develop a program for testing and certification of regulated products and confirm that your products are safe. Failure to implement a consumer products safety program for your company may have dire consequences, including product recalls, product confiscation or disposal, increased regulatory costs, enhanced enforcement penalties, damage to reputation, liability to customers, liability to license partners and increased risk of product liability.

NEWS ALERTS

Supreme Court Holds that State-Law Products Liability Claim against Wyeth is not Preempted by FDA Approval.

The U.S. Supreme Court recently held, in *Wyeth v. Levine*, that a state-law products liability claim was not preempted by FDA approval for the marketing of a drug and its label. The drug in question, Phenergan, is used to treat nausea and is administered intravenously. If Phenergan inadvertently enters a patient's artery, rather than a vein, it causes irreversible gangrene. After suffering such gangrene and subsequent amputation of her hand resulting from such an injection, Diane Levine sued Wyeth relying on common law negligence and strict liability theories, alleging that the labeling of the drug was defective because, although it warned of the danger of gangrene, it failed to instruct clinicians not to use the IV-push method of administration. Wyeth argued that Levine's claims were preempted by federal law because the drug's label had been approved by the FDA.

Justice Stevens, writing for a 6-3 majority, found no direct conflict between state and federal law that would make it impossible to both comply with FDA labeling requirements and strengthen the Phenergan warnings. The mere fact that the FDA had approved Phenergan's label did not establish that it would have prohibited a change strengthening the warnings. Because the FDA had not considered and rejected stronger warnings regarding the dangers of IV-push administration, Wyeth could have unilaterally strengthened those warnings. Neither would complying with state law obstruct the purpose of federal drug-labeling regulation. The failure of Congress to provide a federal remedy for consumers harmed by unsafe drugs indicated that it determined that state-law actions provided appropriate relief. The court also noted that manufacturers have access to information superior to that of the FDA regarding the risks of their drugs. State tort suits uncover unknown hazards and provide incentives for manufacturers to disclose safety risks promptly.

Senate Bill Would Limit Protective Orders

Senators Herb Kohl, D.-Wis., and Lindsey Graham, R.-S.C., recently introduced the "Sunshine in Litigation Act of 2009." The proposed bill, S. 537, would require courts to weigh the "public interest in the disclosure of potential health or safely hazards" against the privacy interests of the parties to litigation. A protective order could be issued only if a court makes findings of fact that a protective order would not restrict the disclosure of information relevant to the protection of public health and safety, or that the public interest in such disclosure is outweighed by a "specific and substantial interest" in maintaining confidentiality. In addition, the court would have to find that the requested protective order is no broader than necessary to protect the privacy interest asserted.

As quoted in the Congressional Record, Mr. Kohl asserts that the bill is necessary to "curb the ongoing abuse of secrecy orders in the Federal courts," particularly with respect to product liability litigation. He cites confidentiality agreements included in the settlement of multiple lawsuits regarding the alleged tread separation of Bridgestone and Firestone tires as an example of such "abuse," and argues that such agreements led to numerous additional deaths and injuries that could have been prevented had protective orders not been issued. According to Mr. Kohl, the proposed legislation would not prohibit secrecy agreements or place an undue burden on judges, but simply require that "where the public interest in disclosure outweighs legitimate interests in secrecy, courts should not shield important health and safety information from the public."

NEWS ALERTS

Limits on Punitive Damages?

In 2007, the U.S. Supreme Court held in *Philip Morris v. Williams*, 127 S. Ct. 1057, 1065 (2007) that the Constitution's Due Process Clause bars punitive damages for injuries inflicted by a defendant on non-parties, reversing a judgment for punitive damages awarded by an Oregon state court. On remand, the Oregon Supreme Court unexpectedly reinstated the $79.5 million punitive damages award against the cigarette maker. The U.S. Supreme Court again granted certiorari (for the third time in the case) and heard oral argument, but then dismissed the case on the grounds that certiorari had been "improvidently granted." Thus, after 10 years of litigation, the Supreme Court left the punitive damages award (now $150 million with interest) intact.

Does the U.S. Supreme Court's about face indicate that the Court has modified its stance on punitive damages? The answer likely is no. The unusual result in *Philip Morris* turns almost entirely on a peculiar aspect of Oregon state law. In its 2007 opinion, the U.S. Supreme Court held that the Oregon Supreme Court had applied the wrong constitutional standard in rejecting Philip Morris' appeal from the trial court's denial of its proposed instruction on punitive damages. On remand, the Oregon Supreme Court determined that it did not need to revisit the constitutional issue, because an independent state law basis existed for upholding the verdict. Specifically, the Oregon Supreme Court found that Philip Morris's three-and-a-half page long proposed instruction contained numerous misstatements of Oregon law, and that under Oregon's "clear and correct in all respects" rule, a trial court's refusal to give a proposed instruction could not be reversed unless the proposed instruction was "altogether free from error."

The U.S. Supreme Court's dismissal of the appeal leaves intact the limitations on punitive damages established in *Philip Morris, State Farm*, and *Gore v. BMW*. It does, however, suggest that in proposing instructions, defendants must carefully consider state law requirements in addition to constitutional considerations.

Dorsey in the News

Federal Court Decision Could Limit Class Action Exposure for Product Liability Defendants

Dorsey & Whitney LLP was recently involved in obtaining a federal court decision that could limit class action exposure for product liability defendants. Dorsey is local liaison counsel for the German and US Bayer defendants in the Baycol Products Liability Litigation (MDL 1431), a multi-district action venued in Minnesota federal district court before Chief Judge Michael Davis. Judge Davis was recently asked to enjoin members of a putative class that he had refused to certify from relitigating the matter in state court. The Court had previously denied federal certification of a West Virginia economic loss class and entered summary judgment against the named plaintiff, George McCollins. Keith Smith and Shirley Sperlazza, members of the putative McCollins federal court class, then sought certification of the same class in West Virginia state court. Judge Davis granted Bayer Corporation's motion to enjoin Mr. Smith and Ms. Sperlazza from relitigating class certification. The Court held that as adequately represented members of the putative McCollins class, plaintiffs were held to be subject to the jurisdiction of the District Court and bound by its final judgment denying class certification. Judge Davis therefore held that it had the authority under the All Writs Act and the relitigation exception to the Anti-Injunction Act to enjoin Mr. Smith and Ms. Sperlazza from seeking state court class certification. Mr. Smith's and Ms. Sperlazza's appeal to the United States Court of Appeals for the Eighth Circuit is currently pending.

Attorney Profile: Mark Kaster

Mark Kaster is a partner in Dorsey & Whitney's Regulatory Affairs Group. Mr. Kaster's practice emphasizes safety and health matters in complex cases involving consumer products, workplace safety, toxic torts, and environmental liabilities. Mr. Kaster started at Dorsey in 1984, and has national expertise in handling products safety matters, environmental risk management, occupational health and safety issues, asbestos liability, indoor air concerns, mold and toxic materials law, California Proposition 65, state products safety laws, ISO compliance, green marketing, EU Reach programs, due diligence reviews and safety/environmental auditing. He was part of the defense team in one of the first national Superfund cases in U.S. v. Reilly Tar and Chemical Co.

His practice includes representation before federal and state agencies, including the Consumer Product Safety Commission, the Occupational Safety and Health Administration and the Environmental Protection Agency. Mr. Kaster has also appeared before numerous arbitration panels, government boards and state tribunals. His clients include Fortune 500 companies for whom he regularly advises on risk management, product recalls, and environmental, health and safety matters. He is a member of the firms mergers and acquisitions group and counsels clients in their business transactions.

Mr. Kaster graduated from William Mitchell College of Law with coursework at the University of Exeter, England. He has a Masters Degree from the University of Minnesota School of Public Health. Mr. Kaster has been an adjunct professor at Hamline University and is a regular speaker at health and safety programs. Mr. Kaster recently started the Dorsey blog site www.ConsumerProductsLaw.com, which provides current information on product safety and products liability. You can contact him at kaster.mark@dorsey.com.

Products Liability Group

DENVER

Stephen Bell
bell.steve@dorsey.com

Jennifer Good
good.jennifer@dorsey.com

Stephen Hall
hall.stephen@dorsey.com

Gregory Tamkin
tamkin.greg@dorsey.com

DES MOINES

Dennis Johnson
johnson.dennis@dorsey.com

FARGO

Kristy Albrecht
albrecht.kristy@dorsey.com

Sarah Andrews Herman
herman.sarah@dorsey.com

Matthew Kipp
kipp.matthew@dorsey.com

LONDON

Ron Moscona
moscona.ron@dorsey.com

MINNEAPOLIS

Theresa Bevilacqua
bevilacqua.theresa@dorsey.com

Timothy Branson
branson.tim@dorsey.com

Robert Cattanach
cattanach.robert@dorsey.com

Megan Dempsey
dempsey.megan@dorsey.com

Paul Dieseth
dieseth.paul@dorsey.com

Skip Durocher
durocher.skip@dorsey.com

George Eck
eck.george@dorsey.com

Roy Ginsburg
ginsburg.roy@dorsey.com

Alene R. Grossman
grossman.alene@dorsey.com

Patricia Houser
houser.patricia@dorsey.com

Mark Kaster
kaster.mark@dorsey.com

Corwin Kruse
kruse.corwin@dorsey.com

Michael Lindsay
lindsay.michael@dorsey.com

Stephen Lucke
lucke.steve@dorsey.com

Eric Ruzicka
ruzicka.eric@dorsey.com

Christopher Ryan
ryan.chris@dorsey.com

Peter Sipkins
sipkins.peter@dorsey.com

William Stoeri
stoeri.bill@dorsey.com

Nena Street
street.nena@dorsey.com

Brian Vander Pol
vanderpol.brian@dorsey.com

Rebecca Weisenberger
weisenberger.rebecca@dorsey.com

Gregory Weyandt
weyandt.greg@dorsey.com

Emily Willits
willits.emily@dorsey.com

Jonathan Wilson
wilson.jonathan@dorsey.com

Elizabeth Wright
wright.elizabeth@dorsey.com

NEW YORK

Patrick Feeley
feeley.patrick@dorsey.com

Robert Martin
martin.robert@dorsey.com

Joseph Perkovich
perkovich.joseph@dorsey.com

Brooke Pietrzak
pietrzak.brooke@dorsey.com

David Singer
singer.david@dorsey.com

PALO ALTO

Jennifer Prieb
prieb.jennifer@dorsey.com

SEATTLE

Nathan Alexander
alexander.nathan@dorsey.com

Robert Crowley
crowley.robert@dorsey.com

Peter Ehrlichman
ehrlichman.peter@dorsey.com

James Hermsen
hermsen.james@dorsey.com

James Howard
howard.james@dorsey.com

Lisa Marchese
marchese.lisa@dorsey.com

John Schochet
schochet.john@dorsey.com

SHANGHAI

Xia Chao
chao.xia@dorsey.com

SOUTHERN CALIFORNIA

Steven Allison
allison.steve@dorsey.com

John Baker
baker.john@dorsey.com

Juan Basombrio
basombrio.juan@dorsey.com

Eve Brackmann
brackmann.eve@dorsey.com

Zach Bulthuis
bulthuis.zach@dorsey.com

Karen Morao
morao.karen@dorsey.com

Kent Schmidt
schmidt.kent@dorsey.com

Faisal Zubairi
zubairi.faisal@dorsey.com

WASHINGTON, D.C.

Timothy Koeppl
koeppl.timothy@dorsey.com

Creighton Magid
magid.chip@dorsey.com