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# The Intersection Of CPSIA And Wyeth

*Law360, New York (May 06, 2009)* -- Backlash against the recently enacted Consumer Product Safety Improvement Act ("Act"), which went into effect on Feb. 10, 2009, can already be seen in scathing editorials from individuals across interest groups.

Though the intent of the Act, which is to protect the most vulnerable members of the American public from potentially harmful materials, is certainly a worthwhile goal, in practice, the Act's sweeping language may do more harm than good.

In theory, the Act would force large-scale manufacturers to import quality products and ensure all children's goods it produces to be free of potentially harmful materials.

But in practice, the high costs imposed by the Act affect not only large corporations, but small business owners, some of whom may be put out of business because they are unable to follow the Act.

Further, as a result of the Supreme Court's recent opinion in Wyeth v. Levine,[1] even abiding by federal standards may not save manufacturers, large and small, from big-dollar lawsuits, and the threat of such actions may further push companies to get out of this business altogether.

While losses to businesses and consumer options may be worth the desired increase in safety, that economic impact is real and, especially in the current economic climate, must be weighed against what, if anything, is actually gained from stricter laws and regulation aimed at potentially toxic products.

These issues also raise the question of whether we want our government or juries deciding whether a product is safe.

## Background on the Consumer Product Safety Improvement Act

The Consumer Product Safety Improvement Act was signed into law on Aug. 14, 2008, as Public Law 110-314. It amended the Consumer Products Safety Act by banning lead and phthalates from children's products, increasing fines and other penalties for safety violations, and increasing the responsibilities and budget of the federal Consumer Product Safety Commission amongst other actions.

Enforcement of the Act is primarily the province of the Consumer Product Safety Commission ("Commission").[2]

The Act bans any children's product containing more than 300 parts per million (ppm) total lead content within one year of the enactment of the Act.[3]

Within three years, the Act bans any children's product that contains more than 100 ppm of lead content, unless the Commission determines this limit is not technologically feasible.[4]

Any item that contains more lead content than permitted according to the timeline in the Act "shall be treated as a banned hazardous substance under the Federal Hazardous Substances Act."[5]

The Act also prohibits the sale of any children's toy or child care article that contains concentrations of more than 0.1 percent of six different types of phthalates.[6]

The Act defines a “children's products” as "a consumer product designed or intended primarily for children 12 years of age or younger."[7]

The Commission takes into consideration several factors in determining a consumer product's primary intent, including the manufacturer's statement and representation of the product in packaging, display, promotion or advertising as appropriate for children 12 or younger.[8]

As a result of this broad definition, swept under the Act are a wide variety of products ranging from traditional children's toys, cribs and baby formula, to children's clothing, books and diapers.

Section 102 of the Act requires all manufacturers of children's products to submit its products to mandatory third-party testing. The third-party tester in turn issues a certificate of compliance to the manufacturer.[9]

On Jan. 30, 2009, the Consumer Products Safety Commission granted a one-year stay to the testing and certification requirements of Act.[10]

Even though the testing requirement only falls on manufacturers, retailers or resellers must abide by regulations in the Act and could be subject to hefty fines if a product fails to meet the guidelines.[11]

While the Act's intent may have been to force large manufacturers to ensure quality compliance, the result is that small retail owners, including thrift shops, second-hand stores and used book stores, are responsible for knowing the content of inventory of unknown origins.[12]

These retailers can be held liable under the Act for selling noncompliant products.[13]

## Preemption in the Act

Adding to the confusion of the broad regulations outlined above, several sections within the Act itself create the possibility that manufacturers and retailers will have to be mindful of not only federal regulations, but those of the individual states as well.

Section 231 of the Act explicitly prohibits the Commission from any attempt to expand preemption beyond the limit already specified in the Act:

The provisions of sections 25 and 26 of the Consumer Product Safety Act (15 U.S.C. 2074 and 2075 respectively) ... establishing the extent to which those Acts preempt, limit or otherwise affect any other federal, state or local law, any rule, procedure or regulation, or any cause of action under state or local law may not be expanded or contracted in scope, or limited, modified or extended in application ... In accordance with the provisions of those Acts, the Commission may not construe any such Act as preempting any cause of action under State or local common law or State statutory law regarding damages claims.[14]

However, Section 231(b) states that nothing in the Act shall preempt any warning requirement that is established pursuant to state law that was in effect on Aug. 31, 2003.[15] This means that state requirements, such as California's Proposition 6516 would still be valid and are not preempted by the Act.

Further, Section 106(h) provides that a state may apply to the Commission for exemption from the federal safety standards or regulations if it desires to have a standard that is even stricter than the federal one, so long as the effect of this heightened standard will not unduly burden interstate commerce.[17]

In order to make this determination, the Commission may take into account several factors, including technological and economic feasibility of complying with such a regulation.[18]

## The Wyeth Decision

While the Act makes companies responsible under both state and federal regulations, the recent Supreme Court decision in Wyeth v. Levine, may require corporations to satisfy a stricter and often unknown standard of care set by state juries.

On March 4, 2009, in Wyeth v. Levine[19], the Supreme Court issued a decision holding that federal approval of labels giving warnings about the effects of drugs does not preempt lawsuits bringing state law claims of inadequate warnings. Thus, even if a company satisfies federal requirements, this fact alone does not preclude a common law tort action in state court.

In this case, the plaintiff, Diana Levine, was administered the drug Phenergan by means of the "IV-push" method, whereby the drug is injected directly into the patient's vein. Phenergan entered Levine's artery, causing gangrene and resulting in amputation of her arm.

The labeling for this drug, which was approved by the U.S. Food and Drug Administration, included warnings as to the health risks from inadvertent intra-arterial injection, and in particular warned of risks from using the "IV-push" method for intravenous administration of the drug.

After being held liable in Vermont state court for failing to adequately warn of the risks from intra-arterial injection, Wyeth sought certiorari with the U.S. Supreme Court on the grounds that the claims were preempted based on the conflict between the failure-to-warn claims and the FDA's approval of the labeling for Phenergan.

The sole issue in Wyeth was whether the state-law claims impermissibly conflict with Wyeth's federal labeling duties, either because it would have been impossible to comply with both the state-law duty to amend the labeling and the FDA regulations, or because the state tort action would create "an unacceptable ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[20]

The majority opinion held that it was not impossible for Wyeth to comply with both the state-law duty to include strengthened warnings on the risks of intra-arterial injection and the FDA labeling requirements.[21]

The majority imposed upon Wyeth the obligation to produce "clear evidence" that it would have been impossible to include additional warnings on the label and also comply with the FDA labeling regulations.”[22]

Characterizing the impossibility pre-emption as a "demanding defense," the reasoning in Levine could require a defendant to show that there was no possible manner in which it could comply with both the state-law duties and the federal requirements.[23]

As was the case in Levine, if there is any potential avenue by which the defendant could comply with stricter state-law requirements and also stay in compliance with the federal requirements, a court may not find preemption under the theory of impossibility.

## Implications of Wyeth on the Consumer Product Safety Improvement Act

The Wyeth decision may open the already flooded court system to trial lawyers eager to capitalize on its holding.

The ambiguity of the requirements under the Act, coupled with the Commission's refusal to issue advisory opinions regarding compliance[24], already has many well-meaning companies, eager to comply with regulations, uncertain of their liability.

On top of this, the Wyeth holding adds another layer of uncertainty to manufacturers who will have to navigate the regulations of the Act in addition to state regulations and state tort law.

This decision raises two issues. First, in permitting state juries to determine liability against companies, even if they comply with federal regulations, the Wyeth decision questions the rationale of having federal agencies setting standards at all.

The purpose of the Consumer Products Safety Commission, according to their Web site, is to "[protect] the public from unreasonable risks of serious injury or death from thousands of types of consumer products under the agency's jurisdiction."[25]

The Commission, as an expert on consumer products, is presumably in the best position to determine what regulations ensure that only safe products enter the marketplace.

Further, while the Act explicitly permits states to impose more stringent safety requirements than those imposed by the federal authority, states must obtain approval from the Commission before doing so.

The Wyeth decision would permit state juries to supersede the authority of the Commission by finding that a failure to do more than is required by the Commission is nevertheless tortious conduct.

As noted by Justice Alito in his dissent to the Wyeth majority holding, "the real issue is whether a state tort jury can countermand the FDA's considered judgment" regarding the safety of a drug.[26]

The Wyeth majority found that because the FDA has limited resources to monitor 11,000 drugs on the market, state tort cases are crucial to "uncover[s] unknown drug

hazards and provide incentives for drug manufacturers to disclose safety risks promptly."[27] The court described this as an "additional, and important, layer of consumer protection that complements FDA regulation."[28]

But this rationale, in effect, puts state juries in the position of determining whether or not federal agencies have adequately done their job, and raises the question whether our government — with access to the brightest minds, research and funding — or lay juries are best-positioned to decide what action is required to ensure the public is protected from harmful products.

The second impact of Wyeth is that it will create an increased cost of business on all companies, large and small, that manufacturer or sell products that are or contain potentially toxic chemicals.

In Wyeth, a company that complied with federal regulations was still found liable for $6.7 million in damages as a result of a single injury.

The risk of such an outcome, with no way to know in advance when a product is safe or is accompanied by adequate warnings, may cause companies to simply refrain from developing or selling new products due to fear of liability.

This is not to suggest that companies should be introducing dangerous products into the marketplace. Rather, the concern is whether we want our federal agencies to determine, in advance, whether or not a product is safe.

The alternative is to rely on state tort law, which is asked to address these issues in the context of the "tragic facts" of one or more individuals, without regard for the many more individuals who may have been helped by a product.[29]

Thus, the question is not whether we want safe consumer products, but rather who do we want to charge with answering the question of when is a product safe.

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[1] Wyeth v. Levine, No. 06-1249, 555 U.S. _____ (March 4, 2009), available at, www.supremecourtus.gov/opinions/08pdf/06-1249.pdf.

[2] 15 U.S.C. § 2051 et seq.

[3] 15 U.S.C. § 1278a(a)(2)(B).

[4] Id. at § 1278a(a)(2)(C).

[5] Id. at § 1278a(a)(1).

[6] 15 U.S.C. § 2057c. The law prohibits the sale of children's products that contain more than 0.1 percent of the following phthalates (1) di-(2 ethylhexyl) phthalate (DEHP), (2) dibutyl phthalate (DBP), and (3) benzyl butyl phthalate (BBP). The law also temporarily prohibits the sale of children's products that contain more than 0.1 percent of three additional phthalates: (1) diisononyl phthalate (DINP), (2) diisodecyl phthalate (DIDP), and (3) di-n-octyl phthalate (DnOP). Whether the temporary prohibition becomes permanent will be decided at a later date after a scientific review by the Chronic Hazard Advisory Panel. Id.

[7] 15 U.S.C. § 2052(a).

[8] U.S. Consumer Product Safety Commission, Consumer Product Safety Improvement Act, FAQs, www.cpsc.gov/ABOUT/Cpsia/faq/children.html (last accessed April 27, 2009).

[9] 15 U.S.C. § 2063(a).

[10] Press Release, U.S. Consumer Product Safety Commission, CPSC Grants One Year Stay of Testing and Certification Requirements for Certain Products (Jan. 30, 2009), www.cpsc.gov/cpscpub/prerel/prhtml09/09115.html.

[11] For example, Section 217 of the Act provides that failure to conform with the product safety standards outlined in the Act is punishable by a civil fine of up to $100,000 for each violation. 15 U.S.C. § 2069(a). Although the civil penalties section limits penalties only to those who "knowingly" fail to conform to the standards, knowingly is defined as not only actual knowledge, but "the presumed having of knowledge deemed to be possessed by the reasonable man who acts in the circumstances including knowledge obtainable upon the exercise of due care to ascertain the truth of the representations." Id. at § 2069(d). A retailer cannot absolve itself of responsibility by simply stating that it was not provided with a testing certificate. That retailer would be responsible, under the Act, to conduct the testing on its own if it could not ascertain a certificate for its products or face civil liability.

[12] CNN.com, New Lead Rules May Be Toxic to Thrift Stores, www.cnn.com/2009/US/02/08/thrift.stores.lead/index.html (last visited April 30, 2009).

[13] Walter Olsen, Scrap the Consumer Product Safety Improvement Act, Forbes.com, (Jan. 16, 2009), www.forbes.com/2009/01/16/cpsia-safety-toys-oped-cx_wo_0116olson.html.

[14] Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 231, 122 Stat. 3016 (2008) (not part of the Consumer Product Safety Act).

[15] Id.

[16] California's Proposition 65 requires businesses to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a chemical listed by the same as being known to cause cancer or birth defects or other reproductive harm. California Office of Environmental Health Hazard Assessment, Proposition 65 in Plain Language!, oehha.ca.gov/Prop65/background/p65plain.html (last accessed April 30, 2009).

[17] Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, § 106, 122 Stat. 3016 (2008) (not part of the Consumer Product Safety Act).

[18] Id.

[19] Wyeth v. Levine, No. 06-1249, 555 U.S. _____ (March 4, 2009).

[20] Id. at Majority Op. (slip op.) at pp. 6-7 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[21] Id. at pp. 11-16.

[22] Id. at pp. 15-16.

[23] Id. at p. 16.

[24] U.S. Consumer Product Safety Commission, Consumer Product Safety Improvement Act, FAQs, www.cpsc.gov/about/cpsia/faq/102faq.html#102q8 (last accessed April 30, 2009).

[25] U.S. Consumer Product Safety Commission, About Us, Overview, www.cpsc.gov/about/about.html (last visited April 30, 2009).

[26] Wyeth at Dissent Op. (slip op.) at p. 2.

[27] Id. at Majority Op. (slip op.) at p. 23.

[28] Id.

[29] Wyeth at Dissent Op. (slip op.) at p. 1.