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New Consumer Product Safety Commission Database Sharply Raises Regulatory Risks and Product Liability Exposure for a Surprisingly Broad Range of Products and Substances

Many manufacturers and private label distributors who do not regularly monitor developments at the Consumer Product Safety Commission ("CPSC") may find themselves doing an abrupt about-face on March 11, 2011, when SaferProducts.gov, a publicly available, searchable database created by new regulations promulgated by the CPSC, begins operations.[1] The database will contain safety information about all products under CPSC's jurisdiction, including many products that companies may not be aware fall under CPSC's jurisdiction. For example, CPSC has jurisdiction to impose poison prevention packaging on foods (including dietary supplements), drugs and cosmetics under the Poison Prevention Packaging Act (and already does so for certain of these products).[2] Likewise, the CPSC has jurisdiction over consumer products and children's products under the Consumer Product Safety Act[3] and all kinds of fabrics and fabric products pursuant to the Flammable Fabrics Act.[4] Hazardous substances, defined as any substances or mixtures that are toxic, corrosive, irritants, strong sensitizers, flammable or combustible, or that generate pressure through decomposition, heat or other means, and that may cause substantial personal injury or illness, are regulated by CPSC under the Hazardous Substances Act.[5] Early indications are that CPSC intends to interpret its jurisdiction liberally in determining what products its database should capture. For example, in response to objections from a commenter during rulemaking about including reports for over-the-counter drugs and dietary supplements in the database, the CPSC responded, "We have no intention of including reports of harm solely involving products or substances not within our jurisdiction, but will include all products and substances that do fall within our jurisdiction, including complaints about drug product labeling."

Designed to provide an early warning system to consumers about product defects, the new database opens a Pandora's box of significant questions and potential problems for manufacturers and private labelers. These include:

- How can I investigate a safety report when I receive only brief details about it and no contact information from the submitter?
- What do I do about reports about products I don't make—or don't make any longer—so that my name doesn't wrongly appear in the database?
- How can I complete an investigation and submit a meaningful comment refuting the report within ten days when I get only a thumbnail sketch of the problem?
- How can I convince the CPSC not to publish a report or to correct information in it that is inaccurate if I don't get enough details about the safety problem to properly investigate it?
- How will the CPSC ensure that safety reports in the database are legitimate and not a campaign backed by one of my competitors to damage my reputation?
- How will CPSC ensure that the primary beneficiaries of the database are not the private plaintiffs' bar who may see it as a rich lode of information to mine for mass product liability and state unfair business competition actions?
- How do I comply with other non-CPSC reporting obligations and regulations without increasing my regulatory and product liability exposure?

We summarize the regulations and potential issues below, including the need for significant advance planning to control risk exposure.

The Regulations

On November 27, 2010, the CPSC finalized its regulations creating SaferProducts.gov.[6] Congress had directed CPSC to "establish and maintain a publicly available, searchable database on the safety of consumer products and other products or substances regulated by the CPSC" pursuant to section 212 of the Consumer Product Safety Improvement Act ("CPSIA").

Reports of Harm

Included in the database will be reports of harm, defined as "any injury, illness or death or any risk of injury, illness or death, as determined by the Commission, relating to the use of a consumer product."[7] CPSC has intentionally set the bar for defining "harm" low. For example, it refused to qualify "risk of injury, illness or

death" with "substantial," stating that it would rely upon its expertise to determine whether a reported risk supported a finding of harm. Reports may be submitted by a broad variety of users, including consumers, relatives, parents, healthcare professionals, police and fire officials and observers of the product being used.[8] They can also include users such as competitors and lawyers seeking clients, as CPSC believes that "The fact that a submitter may have a professional interest in the report does not negate the truth of the report."[9] Rejected as too restrictive were recommendations that submitters have first-hand knowledge of the event underlying the report. To ensure integrity of report information, CPSC relies upon a disclaimer on the website,[10] possible liability of the submitter under the False Statements Act and a requirement that the submitter disclose his or her name and full mailing address in submitting reports.[11] The possibility that these safeguards may not be sufficiently robust led one commenter to remark that this means the database will be reduced to a "blog consisting of hearsay reports from people without personal knowledge who have a vested interest in increasing the number and severity of negative reports."

Minimum Requirements for Report

Minimum requirements for publication of the report on SaferProducts.gov include: (1) a description of the product, sufficient to distinguish it as a product regulated by the CPSC; (2) Identity of the manufacturer or private labeler ("Manufacturer");[12] (3) Brief narrative description of harm;[13] (3) Incident date; (4) Contact information (first and last name of submitter plus full mailing address); and (5) Verification that the submitter has reviewed the report and that the information contained in it is true and accurate to the best of the submitter's knowledge, information and belief.

Transmission of Report to Manufacturer

To the extent practicable, CPSC will transmit a report of harm to the Manufacturer within five business days of submission of the completed report.[14] However, CPSC will only submit the name and contact details of the submitter to the Manufacturer if the submitter has expressly consented. Also not transmitted will be the identity of the victim, photographs which could be used to identify a person and medical records (unless proper consent is obtained). As in most cases, consent to transmit such information cannot be expected, and manufacturers will have almost nothing to begin investigating the report if they have not received duplicate reports of the incident from other sources such as the Food and Drug Administration ("FDA") or their own reporting system. If a serious incident is alleged, there may be no independent means to verify or refute it. In addition, based on the report, the Manufacturer may have to decide whether this automatically triggers other non-CPSC regulatory reporting requirements, even absent any means to verify the report's truth.[15] Although Manufacturers will be able to use the information transmitted for the purpose of verifying the report, they will not be able to use the information for other purposes, such as offering consumers a remedy. However, consumers will be permitted to request one based on the information.

Manufacturer Comment

Only the Manufacturer is permitted to comment on the report, and it will be published on the database along with the report. Such comment must: (1) relate to the information contained in the specific report which identifies the Manufacturer; (2) bear the unique identifier provided by the CPSC; and (3) be verified by the Manufacturer (the Manufacturer must verify that it has reviewed the report and comment and that the information in it is true and accurate to the best of the firm's knowledge, information and belief). Although the CPSC recognizes that Manufacturers may receive groups of complaints about the same problem, the database as organized will not permit responses to be grouped for the purpose of comments. Each report will need to be commented upon individually. The Manufacturer may request that all or portions of the report be designated as confidential information, with the Manufacturer bearing the burden of proof for establishing confidentiality.[16] Unless the manufacturer has received additional information from other sources reporting the same complaint, it is unclear what the Manufacturer will have to usefully comment upon.

Publication of Report

The CPSC must publish the report on SaferProducts.gov no later than the tenth business day after such report of harm has been transmitted to the Manufacturer. However, either before or after publication, any person (including the Manufacturer) may claim that all or portions of the report contain materially inaccurate information. This is defined as "information that is false and misleading, and which is so substantial and important as to affect a reasonable consumer's decision about the product, including: (i) the identification of a consumer product; (ii) identification of a Manufacturer; (iii) harm or risk of harm related to use of the consumer product; or (iv) the date, or approximate date on which the incident occurred." To the extent that such person wishes to have such information corrected or redacted on an expedited basis (such as before the report is published), the CPSC has established an expedited review process. Users are requested to limit their submissions to no more than five pages. Requests by Manufacturers must be conspicuously marked. However, even if a Manufacturer could prepare an adequate response of no more than five pages, no deadlines have been set for CPSC to make its expedited determination, so use of this review process will not prevent publication of the report if no determination is made by the tenth business day. However, if the CPSC's determination is made before the publication deadline, the agency can: (1) decline to add the materially inaccurate information (including the entire report) to the database; (2) correct it, and if the minimum requirements for publication are still met, publish the amended report; or (3) add information to correct the materially inadequate information. If such determination occurs after publication, the CPSC is

obliged, similarly, to delete, correct or add information to correct materially incorrect information no later than seven business days after making its determination. Portions of the report not altered will remain in the database indefinitely. In the event that the product is not the manufacturer's product or is no longer manufactured by the Manufacturer, the CPSC expects that the Manufacturer will immediately notify the CPSC so that the correct Manufacturer (if any) can be notified. However, in order to ensure that the CPSC does not publish the report under the wrong Manufacturer's name, a request for an expedited review would likely need to be made immediately after receipt.

Material Inaccuracies in Manufacturer Comment

Any person may claim that a manufacturer comment contains "materially inaccurate information." This is defined as information identical to (i)-(iv) described in the previous section, with the addition of information relating to (1) the status of a Commission, or Manufacturer investigation; (2) whether the Manufacturer is engaged in a corrective action and whether such action has been approved by the Commission; or (3) whether the Manufacturer has taken, or promised to take, any other action with regard to the product. One commenter noted that, by allowing any person, including class action attorneys, competitors and others who might have inappropriate motives to challenge the comments, the CPSC will "be creating a 'free for all' atmosphere by encouraging such people to collaterally battle about issues using the CPSC's database," with CPSC acting as a referee.

Manner of Submission

Reports of harm are to be submitted to CPSC's internet website on a specially developed electronic incident form. Submissions can also be made telephonically, by email and in writing. Manufacturers who register with the Commission may submit comments through a manufacturer portal which will be maintained on CPSC's website, by email, or in writing. Reports of harm will be transmitted to Manufacturers through the business portal or in writing addressed to the Manufacturer's principal place of business.

Other Information

In addition to materials relating to the reports, the CPSC will also include all voluntary or mandatory recall notices that have been made available to the public on SaferProducts.gov in a searchable form.[17] Additional information may be included by CPSC if it is in the public interest and otherwise consistent with the requirements of 6(a) and (b) of the Consumer Product Safety Act (confidentiality requirements).

Conclusions

Manufacturers should determine which of their products and substances are subject to CPSC jurisdiction and thus potentially the subject of reports of harm. Those doing the inventory should interpret CPSC's jurisdiction broadly, particularly as CPSC is required to make an annual report to Congress about the database, with an additional report to be prepared by the General Accounting Office within two years of the beginning of operations. Under these circumstances, CPSC will likely be motivated to amass a large database to satisfy Congress that it is doing its job of protecting consumers from defects. These reporting requirements also mean that CPSC is likely to be aggressive in publicizing the website and encouraging consumers to use it frequently, so that the volume of reports submitted is likely to be large. Manufacturers should register with the Commission to be in a position to monitor and respond to any reports transmitted as soon as the database commences operations. Manufacturers should also consult with counsel responsible for other non-CPSC reporting obligations, CPSC counsel and product liability counsel before the database becomes operational. Proper steps need to be taken in advance, such as drafting of standard operating procedures, analyzing CPSC jurisdiction (or lack thereof) over products, and appointment of individuals responsible for monitoring and interfacing with the website in order to ensure compliance with CPSC and non-CPSC regulatory requirements, as well as to minimize product liability exposure.

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1. 21 C.F.R. § 1102

2. 15 U.S.C. §§ 1471-1477; 16 C.F.R. Part 1700. For example, CPSC has already mandated child resistant packaging for prescription drugs, over-the-counter (“OTC”) drugs which have been switched from prescription to non-prescription status, dietary supplements and OTC drugs containing a certain amount of iron, mouthwash containing a certain amount of alcohol, cosmetics containing a certain amount of low-viscosity hydrocarbons (*e.g.*, baby oil), and OTC drugs containing methyl salicylate, to name a few. 16 C.F.R. § 1700.14. CPSC's jurisdiction over medical devices is unclear. While medical devices are not included in the list of FDA-regulated products subject to CPSC jurisdiction under the Poison Prevention Packaging Act, it is possible that CPSC could exert jurisdiction over them under the Federal Hazardous Substances Act. Public statements made by CPSC Commissioners and on its web site do not make it clear whether and what kind of medical devices CPSC might exert jurisdiction over. *See* http://www.cpsc.gov/PR/moore_prism.pdf at 23;. http://www.cpsc.gov/LIBRARY/CPSCNanoStatement.pdf; http://www.cpsc.gov/BUSINFO/notcpsc.html. Similarly, it may not be clear to CPSC staff whether complaints about certain products relate to a medical device or a consumer product. For example, contact lens solution and vaginal moisturizers are both considered to be medical devices by the Food and Drug Administration.

3. 15 U.S.C. §§ 2051, et seq.

4. 15 U.S.C. §§ 1194 et seq.

5. 15 U.S.C. §§ 1261-1278.

6. Publicly Available Product Safety Information Database, 16 C.F.R. Part 1102.

7. Consumer product means any product or substance regulated by the CPSC.

8. The CPSC will not accept reports from persons who cannot verify that they are over 18 years of age.

9. CPSC will not permit submitters to withdraw their reports unless they tell CPSC that they have submitted materially inaccurate information. This is supposedly to prevent manufacturers and private labelers from imposing withdrawal as a condition under a settlement agreement involving the report. If, by notifying the CPSC of materially inaccurate information, consumers expose themselves to prosecution under the False Statements Act, this is likely to act as a powerful deterrent to withdrawals of inaccurate and false reports.

10. "The Commission does not guarantee the accuracy, completeness or adequacy of the contents of the CPSC Database, particularly with respect to the accuracy, completeness or adequacy of the information submitted by persons outside of the CPSC."

11. The CPSC did not explain how it would investigate the legitimacy of complaints when only a mailing address is supplied, particularly a post office address.

12. “Manufacturer” is defined as any person who manufactures or imports a consumer product. A private labeler is defined as anyone who is the owner of a brand or trademark on the label of a product which bears a private label. The term manufacturer does not include licensors. The CPSC reasons that private parties (like licensors) can allocate responsibilities under its regulations by contract.

13. Reports that focus solely on quality or cost of products with no discernible risk of harm will not meet this requirement.

14. Examples of impracticability include (1) Manufacturer is out of business with no identifiable successor; (2) Submitter has misidentified a Manufacturer; (3) Report contained inaccurate or insufficient contact information for Manufacturer; (4) Commission cannot locate valid contact information for Manufacturer.

15. Query whether the minimum requirements set by CPSC for a safety report meet those of other agency's requiring safety reports such as FDA.

16. "Confidential Information is considered to be information that "contains or relates to a trade secret or other matter referred to in 18 U.S.C. Sec. 2905 or that is subject to 5 U.S.C. Sec. 552(b)(4). It is unclear why portions of a report would contain confidential information, and the CPSC recognizes this, so the burden of proof is likely to be high.

17. Presumably this would include notices issued by other agencies that have been made public, such as FDA's.