

PRODUCTS LIABILITY

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Expert Analysis

New CPSC Database Raises Regulatory Risks and Product Liability Exposure

*By Jill B. Deal, Esq., William R. Nordwind, Esq., and Bruce R. Parker, Esq.
Venable LLP*

Manufacturers and private-label distributors that do not regularly monitor developments at the Consumer Product Safety Commission may find themselves doing an abrupt about-face since SaferProducts.gov, a publicly available, searchable database created by new regulations promulgated by the CPSC, began operation in March.

The database will contain safety information about all products under the CPSC's jurisdiction, including many products that companies may not think fall into that category.

For example, the 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 some of these products).

Likewise, the agency has jurisdiction over consumer products and children's products under the Consumer Product Safety Act and all kinds of fabrics and fabric products pursuant to the Flammable Fabrics Act.

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 the CPSC under the Hazardous Substances Act.

Early indications are that the 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 packaging."

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 10 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 the 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 Nov. 27, 2010, the CPSC finalized its regulations creating SaferProducts.gov. Congress had directed it 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 the Consumer Product Safety Improvement Act's Section 212.

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."

The 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 can be submitted by a broad variety of users, including consumers, relatives, parents, health care professionals, police and fire officials, and observers of the product being used.

They can also include users such as competitors and lawyers seeking clients, as the CPSC believes that "the fact that a submitter may have a professional interest in the report does not negate the truth of the report." Rejected as too restrictive were recommendations that submitters have firsthand knowledge of the event underlying the report.

Included in the database will be reports of "any injury, illness or death or any risk of injury, illness or death, as determined by the CPSC, relating to the use of a consumer product."

To ensure the integrity of reported information, the CPSC relies upon a disclaimer on the website, 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.

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.”

TRANSMISSION OF REPORT TO MANUFACTURER

To the extent practicable, the CPSC will transmit a report of harm to the manufacturer within five business days of submission of the completed report. However, the agency 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 that 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 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.

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

Minimum requirements

The minimum requirements for publication of the report on SaferProducts.gov include:

- A description of the product, sufficient to distinguish it as a product regulated by the CPSC.
- Identity of the manufacturer or private labeler.
- Brief narrative description of harm.
- Incident date.
- Contact information (first and last name of submitter plus full mailing address).
- 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.

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 comments must:

- Relate to the information contained in the specific report that identifies the manufacturer.
- Bear the unique identifier provided by the CPSC.
- 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 can request that all or portions of the report be designated as confidential information, with the manufacturer bearing the burden of proof for establishing confidentiality. 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 10th 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 the 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 10th business day.

However, if the CPSC's determination is made before the publication deadline, the agency can:

- Decline to add the materially inaccurate information (including the entire report) to the database.

- Correct it and, if the minimum requirements for publication are still met, publish the amended report.
- 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 company, the CPSC expects that the manufacturer will immediately notify the CPSC so that the correct manufacturer (if any) can be notified. However, 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 MANUFACTURERS' COMMENTS

Any person may claim that a manufacturer's comment contains "materially inaccurate information." This is defined as information identical to that described in the previous section, with the addition of information relating to

- The status of a CPSC or manufacturer investigation.
- Whether the manufacturer is engaged in a corrective action and whether such action has been approved by the CPSC.
- 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 the agency acting as a referee.

MANNER OF SUBMISSION

Reports of harm are to be submitted to the CPSC's website on a specially developed electronic incident form. Submissions can also be made telephonically, by email and in writing.

Manufacturers that register with the agency can submit comments through a manufacturer portal that will be maintained on the 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 include all voluntary or mandatory recall notices that have been made available to the public on SaferProducts.gov in a searchable form. Additional information may be included by the CPSC if it is in the public interest and otherwise consistent with the confidentiality requirements of the Consumer Product Safety Act.

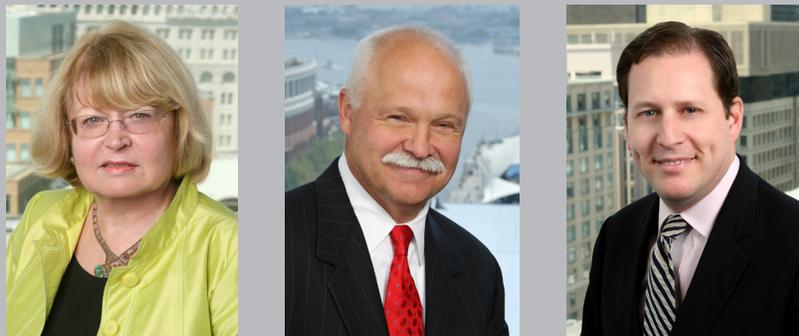
CONCLUSIONS

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 the CPSC's jurisdiction broadly, particularly as the agency is required to make an annual report to Congress about the database, with an additional report to be prepared by the Government Accountability Office within two years after the beginning of operations.

Under these circumstances, the 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 the 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 CPSC 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.



Jill Deal (left) is a food and drug partner at **Venable LLP** in Washington. Her practice focuses on laws governing consumer goods, including therapeutic products regulated by the FDA and consumer products regulated by the CPSC. **Bruce Parker** (center) is a litigation partner at the firm, focusing on product liability and toxic-tort litigation, in particular, that involving drugs and medical devices. **Will Nordwind** (right) is a government relations and regulatory and legislative affairs partner at Venable's Baltimore office, concentrating on telecommunications policy matters.

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