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PRODUCT SAFETY DATABASE

CONSUMER PRODUCT SAFETY COMMISSION

Many drug companies are unaware their products fall within the reach of the Consumer Product Safety Commission's new product safety database, set to go live in March, say attorneys Jill B. Deal, Bruce R. Parker, and Julie Galbo-Moyes in this BNA Insight.

Contending that the CPSC intends to interpret its jurisdiction liberally in determining what products its database should capture, the authors offer helpful tips for manufacturers and private labelers in a practical question-and-answer format. Given the uncertainty that still exists surrounding the database, the authors also counsel manufacturers and private labelers to develop a risk management strategy, and to put into place a system for handling consumer safety reports, before the database becomes operational.

New Risks for Drug Companies to Manage: CPSC'S New Product Safety Database

BY JILL B. DEAL, BRUCE R. PARKER, AND JULIE GALBO-MOYES

In March 2011, the Consumer Product Safety Commission's new product safety database, SaferProducts.gov, will begin accepting reports about any products subject to CPSC's jurisdiction.[1] Many companies may not be aware that their products fall within the CPSC's jurisdiction. For example, the agency has jurisdiction to impose poison prevention packaging on foods, drugs and cosmetics under the Poison Prevention Packaging Act ("PPPA").[2] The PPPA authorizes

[1] 21 CFR Sec. 1102.

[2] 15 U.S.C. Sections 1471-1477; 16 C.F.R. Part 1700. Similarly, CPSC has jurisdiction over consumer products and children's products under the Consumer Product Safety Act, and all kinds of fabrics and fabric products under the Flammable Fabrics Act. 15 U.S.C. Secs. 2051 et seq.; 15 U.S.C. Secs. 1194

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the CPSC to regulate special packaging standards for any household substance, including drugs as defined in the Food, Drug and Cosmetic Act.[3] Therefore, drug products subject to FDA jurisdiction will also fall within the jurisdiction of the CPSC, if customarily sold to consumers or stored in the home.[4]

To date, the CPSC has only regulated certain of these products. For example, the CPSC has already mandated child resistant packaging for orally-administered prescription drugs and over the counter (''OTC'') drugs that have been switched from prescription to nonprescription status.[5] Manufacturers of drug products that do not fall within the categories currently regulated by the CPSC, (such as prescription drugs that are injected, rather than orally-administered), may find themselves doing an abrupt about-face on March 11, 2011, when the database begins operations.[6]

Early indications are that the CPSC intends to interpret its jurisdiction liberally in determining what products its database should capture. For example, during rulemaking one commenter objected to including reports for over-the-counter drugs and dietary supplements in the database, fearing it would prompt consumers to inadvertently submit drug safety complaints that do not involve packaging issues to the CPSC, rather than the FDA. In response, the CPSC stated, ''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.'' Because the CPSC's jurisdiction exceeds the range of products it has regulated to date, even companies not currently subject to CPSC regulation should assess which of their products and substances could potentially be the subject of safety reports to the CPSC.

Significant Concerns for Manufacturers and Private Labelers

CPSC has also set the bar for acceptance of safety reports (called ''reports of harm'') intentionally low. The agency will accept reports relating to ''any injury, illness or death or any risk of injury, illness or death, as determined by the [CPSC].'' In creating a public, searchable database to receive such reports, CPSC has established a system that will likely generate high volumes of safety reports (which may or may not be accurate or legitimate) at the expense of complaint investigation and resolution. In doing so, CPSC has turned a law designed to provide an early warning system to consumers about product defects into a Pandora's box of significant and potential issues for manufacturers and private labelers that may significantly affect regulatory and product liability risks. These include:

1. **Question**: How can I investigate a safety report when I receive only brief details and no contact information about the submitter?

Answer: You likely will not be able to. If the report meets the minimum requirements, that is, (1) product description; (2) identity of manufacturer or labeler; (3) brief narrative description of harm (or risk of harm); (4) contact information (first and last name of submitter and full mailing address); (5) verification from the submitter that the information is true and accurate and the submitter does not expressly consent to his/her contact details being provided to you, all the CPSC will forward to you within five days of receipt is the safety report. Commenters during the rulemaking process urged CPSC to require additional details, such as make and model numbers, to enable better investigation and resolution of complaints. Although CPSC agreed to add some on-line prompts for certain information in the complaint form, the agency refused to require submission of the requested information due to the deterrent effect such requirements might have on consumers. Those who work with clients handling complaints know that, in most cases, reporters won't consent to having their contact information submitted to manufacturers or private labelers. CPSC is under the impression that, in these situations, you will likely get a report of the incident contemporaneously from some other source that will enable you to sufficiently identify the product so as to properly investigate the complaint. Those who have worked with industry on complaint handling know that, in most cases, this won't occur. In such cases, your investigation will unfortunately be limited by the information contained in the report.

2. **Question**: What do I do about reports about products I don't make—or don't make any longer—so that my company does not wrongly appear in the database?

Answer: If you are a manufacturer or private labeler who is likely to be the subject of reports, you will need to register your company with CPSC. Registration with SaferProducts.gov for use of CPSC's secure business

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et seq. Hazardous substances – defined as substances or mixtures that are toxic, corrosive, irritants, strong sensitizers, flammable or combustible, or substances that generate pressure through decomposition, heat or other means and may cause substantial personal injury or illness – are regulated by the CPSC under the Hazardous Substances Act. 15 U.S.C. Secs. 1261-1278.

[3] 15 U.S.C. Sec. 1471 (2)(B); 15 U.S.C. Sec. 321(g)(1).

[4] 15 U.S.C. Sec. 1471 (2)(B).

[5] CPSC has also mandated child resistant packaging for 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. Sec. 1700.14. CPSC's jurisdiction over medical devices is unclear. While they are not enumerated as being under CPSC's jurisdiction under the Poison Prevention Act, public statements made by CPSC Commissioners and the CPSC's website do not clarify whether and over what kind of medical devices CPSC would exert its jurisdiction. In certain cases, it may not be clear to CPSC staff receiving reports whether CPSC or another agency has jurisdiction. For example, FDA regulates contact lens solutions and vaginal moisturizers as medical devices.

[6] In addition, all biologics that have been approved by the FDA as drugs under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act (''FFDCA'') will be subject to the CPSC's jurisdiction over drug product packaging under the PPPA until March 23, 2010. A number of biologics are currently approved as drugs under section 505(b)(1) of the FFDCA. On March 23, 2020 – 10 years after the enactment of the Patient Protection and Affordable Care Act (''PPACA'') – all biological products approved as drugs by the FDA will be considered licensed biologics under section 351 of the Public Health Service Act. Section 7002(e) of the PPACA provides that companies may continue to submit applications for approval of biologics under section 505(b)(1) if (1) the biological is in a product class that has already been approved as a drug and (2) the application was submitted to FDA before enactment of the PPACA or not later than March 23, 2020.

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portal began January 18, 2011. This portal permits transmission of reports to a registered account user at your company who will be the only person permitted to respond to the report, although you will be able to designate several persons at your company to receive emails about the reports. With respect to reports about products you don't make, you need to report the mistake immediately to CPSC so that it does not post the report on the website 10 days after transmitting it to you. In addition, with respect to products you don't make and those you don't make any longer, you need to immediately use the portal to petition the CPSC not to publish the report because it contains ''materially inaccurate information.'' Although the CPSC has set up an expedited procedure for handling petitions that are kept brief (no more than five pages), there are no guarantees that the CPSC will act on your petition before the 10 days have expired. In order to prepare for the inevitable mistaken identity reporting of manufacturers/private labelers, companies need to immediately draw up a list of discontinued products (along with the date) and to keep that list updated in order to facilitate a prompt response that may keep such reports off the database.

3. **Question**: How can I complete an investigation and submit a meaningful comment refuting the report, or claim that it contains confidential information or materially inaccurate information within 10 days if I only get a thumbnail sketch of the problem?

Answer: In most cases, you likely won't be able to do so. If you don't get an independent report at the same time you get the CPSC report, you don't have reports of similar problems in your files, and you don't get any contact details, you likely will not be able to conduct and complete a meaningful investigation within 10 days before the CPSC publishes the report in the database.

4. **Question**: How can I convince the CPSC not to publish a report or to correct information in a report that is inaccurate if I don't get enough details about the safety problem to properly investigate it?

Answer: In easy cases (i.e., I don't make that product), you may be able to prevent publication by notifying the CPSC about the mistake immediately and petitioning for removal on the basis that the report contains materially inaccurate information (see response to Question 1). In less clear-cut cases, you likely won't be able to do so in time to prevent the report from being published on the database. You will be able to submit a comment on the report and have it published along with the report on the database, although your comment may not be particularly meaningful if you did not receive contact details. This initial comment must be made within 10 days after you have received the report from the CPSC. The Commission has also recently clarified that you will be able to submit additional comments, for example, as the investigation and resolution process at your company progresses. Even if you do succeed in investigating and resolving reports, it is not clear that the CPSC will recognize this by removing reports subject to such resolution from the database, particularly in light of the CPSC's stated intention to maintain reports in the database indefinitely. In addition, depending on how many reports you receive, the updating process may be time-consuming and burdensome.

5. **Question**: 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?

Answer: CPSC believes that everyone who reports information to the database is under a legal duty to provide accurate information and has required each submitter to verify before submission that they have done so. The agency also points out that submissions will be subject to the False Statements Act, 18 U.S.C. Sec. 1001. CPSC also believes that ''The fact that a submitter may have a professional interest in the report does not negate the truth of the report.'' In response to fears expressed during rulemaking about abuse, CPSC also represented that if it determined that ''false incident reports are being filed, we will consider what legal actions to take to address the problem and proceed accordingly.'' Notwithstanding CPSC's sunny view of human nature, the only information provided by a submitter about a possibly bogus complaint will be his/her name and full address (which could be a Post Office box). It is unclear at this time how CPSC, with only this information, will be able to investigate misuse in order to prevent competitor manipulation of the database. This is particularly troublesome as CPSC intends to encourage a very high volume of reports. To reduce their product liability and regulatory risk, companies must implement their own ''early warning systems'' before the database is operable, to signal possible manipulation of the database with respect to one or more of their products. Such signs may include a string of identical complaints about the same defect, a lack of contact details provided as well as no other information independently received about the complaint from third parties. Documenting these cases will form a basis for petitioning the CPSC to remove the reports unless CPSC can determine (and provide assurance to the company) that the database is not being manipulated. To the extent the manipulation can be shown to be blatant, the company may want to consider publicizing the manipulation to avoid investigation and litigation by third parties, such as the FTC and state attorneys general.

6.**Question**: 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 products liability and state unfair business competition actions?

Answer: They can't (see response to Question 5). It was pointed out during rulemaking that another voluntary passive reporting system, the Vaccine Adverse Event Reporting System (''VAERS''), has been manipulated by the private plaintiff's bar in connection with litigation attempting to link thimerosal in vaccines with autism. The commenter cited to a 2006 peer-reviewed article in *Pediatrics*, which concluded that ''[t]his review shows a previously undisclosed rise in the number of reports to the VAERS related to pending litigation for vaccine injury.''[7] Manipulation was significant. Authors reported that ''nearly one third of the reports in 2002 were related to litigation, and for mental retardation, it was nearly one half of reports.'' The commenter also noted that manipulation of the VAERS by private plaintiffs' attorneys in the 2009 *Wyeth v. Blackwell* decision, also involving allegations associating autism with thimerosal in vaccines, was viewed as so blatant by the Maryland Court of Appeals that it found the VAERS

[7] Goodman, Michael J. PhD and Nordin, James, MD, MPH, 117 Pediatrics 387 (2006).

was not reliable for use in medical studies. The CPSC did not respond to the VAERS evidence. The same early warning system recommended to companies to signal possible manipulation by competitors should also help alert companies to potential manipulation by private plaintiffs' attorneys and impending litigation.

7. **Question**: How do I comply with other non-CPSC reporting obligations and regulations without increasing my regulatory and products liability exposure?

Answer: If you make or market products that are arguably within CPSC's jurisdiction, the new database will greatly complicate your risk profile. The reports will be kept in the database indefinitely. The CPSC relies heavily on the disclaimer that it will post prominently on the database to ensure that users understand the database's shortcomings: ''The Commission does not guarantee the accuracy, completeness or adequacy of the contents of the Consumer Product Safety Information Database, particularly with respect to the accuracy, completeness or adequacy of information submitted by persons outside the CPSC.'' Notwithstanding this disclaimer, the CPSC intends to aggressively use the database to identify possible enforcement actions. Given the accessibility of the database, federal agencies like the FTC, state attorneys general, private plaintiffs and competitors are likely to use it, with the risk that the disclaimer may become lost in the shuffle. (The FDA, however, is unlikely to put much emphasis on the database because its own regulations covering safety reporting require information from submitters, which facilitate manufacturer investigations and the resolution of serious complaints.)

Risks Abound

Given the possibility that the CPSC and other parties may aggressively use the database to serve their own interests, it is too risky for manufacturers and private labelers with products arguably within CPSC's jurisdiction to ignore the database and allow reports to pile up. It is not clear at this point that the limitations of the database will easily be recognized by a court or an agency in the event that these reports result in investigations or litigation. Instead, manufacturers and private labelers need to develop a risk management strategy and a system to put in place before the database becomes operational. In the case of manufacturers and private labelers who already have reporting obligations, such as to the FDA, reporting and monitoring responsibilities will need to be integrated into the system already in place. If no system for handling consumer safety reports exists, a new one will need to be created, complete with standard operating procedures. Such a system should be designed to facilitate rapid responses to safety reports, due to the 10-day deadline before publication.

In addition to registration at SaferProducts.org, companies need a system for actively monitoring the database and responding to reports in a way that will not come back to haunt them in the future. This raises a host of additional questions that companies need to address, including:

- What do I do about reports that I don't believe fall within CPSC's jurisdiction?
- Do I simply process them under the procedures I use for the agency that I believe has jurisdiction?
- Would CPSC be barred from coming after me if I take that position?
- Do I process reports using both agencies' procedures?
- How do I comment on reports when I don't have any contact details and I don't have any independent data to verify the accuracy or existence of the complaint?
- Do I have to try to update these reports periodically at CPSC, even if my inquiries strongly suggest that they are bogus or de minimis?
- Does this increase my risk if a defect is identified years after the reports were originally filed?
- What do I say about products where the reported defect is a common side effect of use of the product, e,g., knives that cut fingers, or over-the-counter drugs that have warning labels stating that they cause irritation?
- In cases where I have resolved the problem, will I be able to update materials in the database to reflect this resolution or will I be able to get the reports forming the basis of the complaints removed?
- In cases where I already have reporting responsibilities to other agencies, given the accuracy and legitimacy problems of the CPSC database, do I analyze data received from the CPSC in conjunction with data from my existing reporting system, or separately in order to avoid creating the appearance of safety problems where none exist?

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