THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008 ("CPSIA") UPENDED THE ONCE LARGELY SETTLED AND SLEEPY AREAS OF LAW OVERSEEN BY THE CONSUMER PRODUCT SAFETY COMMISSION, RELEASED A CASCADE OF REGULATORY AND COMPLIANCE ACTIVITY, AND GENERATED WAVES OF UNCERTAINTY AND APPREHENSION.

by Peter J. Biersteker, C. Kevin Marshall, and Danielle M. Hohos

A virtually unnoticed and uncodified provision of the CPSIA requires the Commission to establish and maintain a publicly available, searchable, and internet-accessible database on the safety of all consumer products as well as all products or substances the Commission regulates under other laws.[1] The proposed new database, SaferProducts.gov, would supplement rather than supplant the Commission's two existing publicly available, searchable databases: the National Electronic Injury Surveillance System ("NEISS") database, which tracks emergency-room visits associated with consumer products, and the Commission's database of recalls and other notices.

The Commission has proposed an implementing regulation for SaferProducts.gov. It passed by a bare 3-2 party-line vote; more than 20 different amendments were considered, with most of them rejected. All five commissioners issued written statements explaining their votes. While some commissioners praised the proposed regulation as the epitome of "open government" and as necessary to eliminate "blind spots," others denounced it as "not ready for prime time" and as establishing a system of "garbage in/garbage out."[2]

The Commission published the proposed rule on May 24, 2010, with a deadline for comments of July 23, 2010.[3] The database is scheduled to go live no later than March 11, 2011.

Having an additional central, publicly available repository may further facilitate investigations, reveal issues and trends, and educate purchasers. But the reality may not live up to that billing. SaferProducts.gov, as proposed, threatens to confuse and mislead consumers while drawing a bull's-eye around manufacturers. Manufacturers, trade associations, and other stakeholders should follow developments related to the proposed rule as they prepare appropriately for implementation.

WHAT CONGRESS REQUIRED AND THE COMMISSION HAS PROPOSED

Although there are numerous issues, three aspects of the proposed SaferProducts.gov database are especially controversial from both a legal and a policy perspective.

SaferProducts.gov DATABASE MAKE CONSUMERS SAFER—BE THE BANE OF CONSUMER PRODUCT MANUFACTURERS?

Who May Report. Congress in Section 6A specified that the database include "reports of harm" from five individuals or groups: consumers, governmental agencies, healthcare professionals, child service providers, and public safety entities. In the teeth of this finite enumeration, the Commission's proposed regulation expands the scope of submitters in two ways.

First, the proposal defines "consumer" as "including, but not limited to, users of consumer products, family members, relatives, parents, guardians, friends, and observers of the consumer products being used."[4]

Second, the proposed rule adds to Congress's five categories of submitters a sixth: "others." This category includes—but is not limited to—"attorneys, professional engineers, investigators, nongovernmental organizations, consumer advocates, consumer advocacy organizations, and trade associations."[5]

Each of these two expansions raises a legal question: Is the definition of "consumer" so broad as to make the other statutorily specified categories largely superfluous (contrary to ordinary rules of statutory interpretation) and also impermissibly broader than the ordinary understanding of "consumer"? The Consumer Product Safety Act, for example, in defining "consumer product," seems to use "consumer" to refer to someone who buys or uses a product for personal purposes in or around a residence or school or in recreation.[6]

Even more questionable, nowhere does the proposed regulation identify the Commission's authority for adding the category of "others," which is at odds with Congress's seemingly exhaustive list of submitters. Commissioners Nancy Nord and Thomas Moore both solicited comments on this question, and Commissioner Anne Northup denounced the addition as having "zero basis" in the statute.

These expansions also raise practical problems. Both authorize persons to submit a report even though they lack either firsthand knowledge of an incident or a professional or legal duty to respond to an incident. "Consumers" (as defined by the Commission) and "others" are more likely to submit inaccurate reports. The breadth of the proposed definition of "harm" exacerbates this problem, by including not just injuries, illnesses, and death, but also any "risk" of these results.

However, it is malice rather than ignorance that poses the greatest risk to manufacturers; anonymous submitters can include competitors, advocacy groups, and even attorneys who may have sued on behalf of consumers. The database accordingly may become salted with both inaccurate and duplicate reports that will linger unless and until the falsely accused manufacturer can persuade the Commission to investigate and then remove or otherwise correct the error. Apart from the increased burden on businesses, the ability of even a diligent manufacturer or retailer to police effectively the accuracy of the database is far from certain, as discussed herein.

What Information Must Be Included in a Report? Congress required, "at a minimum," that a "report of harm" include six pieces of information: (1) a description of the product; (2) identification of the product's manufacturer (or private labeler); (3) a description of the harm; (4) the submitter's contact information; (5) the submitter's verification that the information "is true and accurate to the best of the person's knowledge"; and (6) a consent to posting the submitted information to the database.

Whereas Section 6A's list of who may submit reports appears fixed, its list of required items in a report is explicitly not. The Commission's proposed rule nevertheless adds nothing to Congress's "minimum." Although submitters *may* submit more than the minimum information, the Commission neither required any additional information for a report to be published nor identified any further particular optional information that might be helpful. For example, it would be helpful to include in reports the date and location of the incident, as well as the date and location of the manufacture of the product involved. Indeed, this kind of information is among the required fields for the database of the National Highway Traffic Safety Administration, which was established under an enabling statute upon which Section 6A is partially based.

The Commission also marginalized some of the statutory minimum requirements. For example, the requisite "verification" would be satisfied under the proposed regulation by a submitter's simply checking a box saying that the information "is true and accurate to the best of the person's knowledge."[7]

Skimping on the content of the "reports of harm" diminishes the usefulness of the database and exacerbates concerns

that the database will contain duplicate and inaccurate information. Commissioners Moore, Nord, and Northup all worried that the skeletal information requirements for "reports of harm" could hinder efforts to weed out duplicate reports. It is unlikely that the means the Notice of Proposed Rulemaking identified will succeed in weeding out duplicate or inaccurate reports; such means include sorting data (but not by date or location of either the incident or the product's manufacture) and using challenge-response tests, analogous to those used by ticket-purchasing web sites, to ensure that computers are not submitting the reports.

The failure to require enough information to automatically screen the submitted data is especially problematic, given that the Commission lacks the resources to examine submissions individually. Historically, the Commission has relied on subject-matter experts manually analyzing trends to detect hazardous products, link incidents, and predict the probability of repeated occurrences. This is a difficult task, given that the Commission receives 18,000 reports of incidents concerning 15,000 categories of products each year even without the planned database. With the database, the number of incidents will only increase.

With respect to verification, the Commission in the proposed rule rejected recommendations that the verification page contain a federal criminal-penalty warning about supplying false information. It also rejected a proposal to note in the database whether the submitter responsible for a report of harm insisted on anonymity or consented to the release of his or her contact information to the manufacturer, as well as a proposal to identify which reports were under investigation for possible inaccuracy. Exasperated, Commissioner Northup characterized the proposed verification check box as "essentially useless."

The database will include the statutorily mandated disclaimer that the Commission does not guarantee the accuracy, completeness, or adequacy of the database's contents. But the database will still be an official record of the Commission;[8] the disclaimer will provide little guidance on what, if any, use to make of a particular report; and the disclaimer is a thin substitute for actually improving the quality of the database.

Opportunity for Corrections. Before a report of harm may be included in the database, Congress required that the identified manufacturer or private labeler (1) be provided the report of harm within five business days "to the extent practicable"; (2) have the opportunity to comment on the information in the report; (3) have the opportunity to request that its comment appear in the public database (a request the Commission must grant absent a finding of inaccuracy); and (4) have the opportunity to protect any confidential information in the report.

But Section 6A gives the manufacturer or private labeler *no* right to receive the submitter's contact information unless the submitter gives "express written consent." And the Commission ordinarily will publish the report of harm on the internet "not later than" *10 business days* after sending it to the manufacturer—regardless of whether the manufacturer has responded.

Following publication of a report or comment, the Commission has a duty to remove or correct information it concludes is materially inaccurate. Congress required the Commission to make the correction within seven business days of determining, after investigation, that a material inaccuracy exists, but neither the statute nor the proposed implementing regulation specifies how long the Commission may investigate.

POTENTIAL PROBLEMS

Consumers. These issues with the proposed database create several potential problems for consumers, particularly when they are seeking to use it for purchasing decisions. First, the Commission seemingly has sacrificed its goal of educating and guiding consumers on the altar of "open government." The likelihood of inaccurate information in a given report leaves consumers without credible guidance as to any report. Whether they respond by believing or disbelieving everything, the usefulness of the database is undermined.

Second, a mere collection of incidents about a product, even if each report of harm were accurate, may provide a false picture of its safety. The database as proposed takes no account of the number of each product in circulation. If a product has 10 reports of deaths in the database, it would help to know whether 10 or 10 million products have been sold. Niche products will deceptively appear to be relatively safer than mass-marketed products.

Third, the database may create privacy concerns for injured consumers. The proposed rule does have some safeguards, such as prohibiting nonconsensual disclosure of an injured consumer's name and protecting against posting of medical records and photographs with personally identifying information. But it is open to question how much these will matter if a third party submits a report and includes detailed information, including data about incidents involving minors. Under the proposed rule, an injured consumer objecting to a report would be in the same position as the manufacturer—lacking the submitter's contact information, yet hoping to persuade the Commission to investigate, agree with his or her objections, and eventually remove or otherwise correct the report.

Businesses. The database and implementing regulations pose even greater problems for manufacturers, private labelers, and retailers—reputational costs, response costs, and litigation costs.

First, perhaps the biggest issue for businesses is the possibility of misuse of the database for publicity purposes. Such misuse may be intentional, such as an effort by an advocacy group or competitor to "spam" the database to target a company or pressure the Commission. It also may be accidental, such as the prosaic risk that duplicate reports will exponentially magnify the apparent risk of a product, which in turn might draw the unwarranted attention of advocacy groups or the Commission. As Commissioner Robert Adler noted, the incident reports in the database can be mined and used as "an early warning system" by the Commission to identify harmful products.

The Commission has no deadline for completing an investigation of alleged inaccuracies in a report, which triggers the obligation to correct inaccuracies within seven days, so efforts at correction may languish. And it remains unclear how the Commission's duty under Section 6 of the Consumer Product Safety Act to correct publicly disclosed inaccurate or misleading information about a manufacturer's safety record "in a manner equivalent to that in which such disclosure was made"[9] will bear on errors in the database.

Second, and related, the database will cause businesses to expend money and resources to address reports of harm, investigating and then responding both to the Commission and, likely, to the public. That task is difficult and may even be impossible, given both the probable anonymity of the submitter and injured consumer and the paucity of information required, such as the Commission's failure to require the submitter to identify the date and location of the incident that is the subject of the "report of harm." Additionally, if the manufacturer would like its comments published simultaneously with the report of harm, it must provide them within 10 days of the Commission's transmission of the report. Otherwise, the report will be published without comment from the manufacturer until such time as the manufacturer submits comments. If comments are received more than one year after the transmission of the report, the Commission can choose not to publish them. Even where an investigation of the report is feasible, the Commission, in preparing the proposed regulation, estimated optimistically that a manufacturer would need four and a half hours to respond to each report it received.[10]

Third, one can expect attorneys to mine the searchable database (perhaps "finding" information they submitted as "others" or "friends and observers") to prepare lawsuits, exert pressure for settlements, and even generate evidence, particularly on entitlement to punitive damages. Although it is arguable whether the database will be admissible evidence under the public records and reports exception to the hearsay rule,[11] the information in the database will certainly be relied upon by attorneys and experts in the course of litigation.

Experience with the Commission's NEISS database suggests what may come. NEISS collects data about product-related incidents from hospitals and enters it into a searchable database, which the Commission staff analyzes for enforcement purposes. Plaintiffs have used its contents in court. For example, in 1993, an expert extrapolated from NEISS data to testify that there were 938 injuries associated with Q-tips swabs—more than 23 times the 40 reports that the manufacturer had received. The jury awarded $1.5 million in compensatory damages and $20 million in punitive damages.[12] The verdict was reversed on appeal on the ground that the manufacturer lacked constructive knowledge of information contained in the NEISS database.[13] As to the database created pursuant to Section 6A, however, any such defense will be a hard sell, given that the Commission will notify the manufacturer of each report and, as Commissioner Adler noted, "companies will no longer be able to claim they have never heard of a complaint regarding their products."

Notice through the database conceivably could also be used to assess civil penalties for late reporting under Section 15 of the Consumer Product Safety Act.[14] This too is an issue that the Commission did not address in the proposed rulemaking, but the Commission's recent rule elaborating the factors it will consider in assessing the civil penalties leaves room for it to pursue this course.[15]

WHAT CAN BUSINESSES DO?

A little effort now to stay informed and be prepared will serve businesses well as the Commission develops the database.

Although Congress has mandated the database, and pending bills to "fix" the CPSIA would not alter that mandate, the proposed rule is not yet final. Businesses whose products are subject to regulation by the Commission and trade associations should follow developments via the Commission's web site (which has a section devoted to the CPSIA, organized by topic) to enable themselves to prepare for the final rule.

The Commission has ample authority to improve the SaferProducts.gov database, but it is not clear how open the majority of the Commission will be to making changes in response to the comments it has received. Unless the Commission solicits further comment on the proposed rule, there is little that interested businesses can do externally but wait to see whether the final rule addresses any of the problems noted herein. Particularly worth watching are the final determinations of whether to include the "others" category of those who may submit reports and the expansive definition of "consumer." If not changed in the final rule, both provisions may be open for litigation, a rarity in this area of law. Also worth watching is whether the comments prompt the Commission to reconsider any of the amendments that the minority commissioners unsuccessfully submitted. Commissioner Northup summarized these on pages 4, 5, and 7 of her statement of April 22, 2010.

Internally, an ounce of prevention will save a pound of anguish later. To prepare for the launch of the database in 2011, businesses whose products (or substances) are subject to regulation by the Commission should register with the Commission to use the portal on the database, in order to receive reports from the Commission promptly. Correspondingly, they should develop processes for receiving and swiftly distributing, investigating, and responding to any report. The receipt of a skeletal report of harm—which starts the 10-day clock running—is not the time to determine on the fly who within the company needs to see the report and who should oversee, decide on, and submit any comment. Apart from commenting to the Commission on reports it receives, a business must respond appropriately to valid or perceived product-safety issues that may emerge from its internal investigations and reports, by notifying the Commission, where appropriate, and responding to consumer complaints about its products

The world has changed, and companies need to be ready for it. ■

Peter J. Biersteker
Washington
+1.202.879.3755
pbiersteker@jonesday.com

C. Kevin Marshall
Washington
+1.202.879.3851
ckmarshall@jonesday.com

Danielle M. Hohos
Washington
+1.202.879.7644
dmhohos@jonesday.com

[1] *See* CPSIA § 212, new § 6A of the Consumer Product Safety Act, 15 U.S.C. §§ 2051 *et seq.*
[2] *See* http://www.cpsc.gov/pr/statements.html (web sites herein last visited Oct. 20, 2010).
[3] 75 Fed. Reg. 29156 (to be codified at 16 C.F.R. pt. 1102); *see* http://www.cpsc.gov/about/cpsia/sect212.html.
[4] 16 C.F.R. § 1102.10(a)(1) (proposed).
[5] *Id.* § 1102.10(a)(6) (proposed).
[6] 15 U.S.C. § 2052(a)(5).
[7] *See* § 1102.10(d)(5) (proposed); 75 Fed. Reg. at 29158. The submitter also must generically identify its type ("consumer," "other," etc.). *See* § 1102.10(d)(5) (proposed).
[8] 16 C.F.R. § 1102.10(i) (proposed).
[9] 15 U.S.C. § 2055(b)(7).
[10] 75 Fed. Reg. at 29175.
[11] Fed. R. Evid. 803(8).
[12] *Strothkamp v. Chesebrough-Pond's, Inc.*, No. 60645, 1993 WL 79239 (Mo. Ct. App., Mar. 23, 1993).
[13] *Id.*
[14] 15 U.S.C. § 2064.
[15] *See* 16 C.F.R. § 1119.