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NEWSLETTER

FDA and CPSC Turn Attention to Lithium Batteries

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As 2017 begins, the two key federal agencies with product safety mandates—the Consumer Products Safety Commission (CPSC) and the U.S. Food and Drug Administration (FDA)—have focused their attention on lithium battery-related concerns. While the CPSC has the potential to regulate a larger range of products, both of these agencies have the authority to impose safety requirements on the manufacturers and distributors of the products within their jurisdiction.

CPSC Launches Broad-Based Investigation

In October 2016, the CPSC Commissioners unanimously directed the agency to undertake an investigation of what Chairman Kaye called the "emerging and ongoing hazards associated with high energy density batteries," including lithium ion. This investigation has significant implications for manufacturers, distributors, and retailers of both lithium ion batteries and the products powered by those batteries.

This action was spurred in no small part by the ongoing publicity surrounding the recall of Samsung's Galaxy Note 7 mobile phone. But the agency has a long history of dealing with defective lithium ion batteries. Among other things, CPSC led the intra-government investigation and recall of hoverboard self-balancing scooters in the 2015 holiday season.

In situations like this, CPSC staff typically conducts some form of review and drafts a report that summarizes the issues, outlines potential CPSC responses, and recommends some of them. And CPSC's active involvement in lithium ion battery and related product recalls in recent years has created at the agency a relatively deep

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pool of in-house expertise on failure modes and related issues. But CPSC staff likely will still seek support and input from the public. There is also little doubt that third party certification organizations will actively promote CPSC endorsement of their standards as a solution.

The next steps recommended by the staff could lead to the imposition of labeling and other regulatory requirements (e.g., testing) on some or all battery-powered consumer products and/or their packaging—including products that do not currently bear mandatory warning labeling, such as mobile phones.

If CPSC concludes that additional regulation is warranted, the agency is likely to choose one or more of three means of imposing new regulatory requirements: (i) formal adoption as rules of enforceable regulatory standards; (ii) formal identification in rules of product characteristics that it deems create substantial product hazards; or (iii) informal issuance of guidance stating the agency's position on the appropriateness of certain voluntary standards (including recommended changes to those standards).

First, the agency could establish a "consumer product safety rule" adopting a formal standard for lithium ion products under Section 7(a) of the Consumer Product Safety Act (CPSA).[1] This type of rule sets forth minimum requirements that a product must meet in order to be deemed not to pose a "substantial product hazard." As part of those requirements, CPSC has frequently mandated compliance with a specific industry standard or standards (e.g., UL, ANSI, IEC), but it also can create wholly new regulatory elements.

Under Section 14(a) of the CPSA,[2] any product for which an applicable consumer product safety rule exists must be certified and tested to meet that rule's requirements. If the rule incorporates by reference an otherwise "voluntary" industry standard, compliance with that standard is no longer voluntary.

Second, the agency might make a determination by rulemaking under Section 15(j)[3] that certain product characteristics, or the lack thereof (such as compliance with a voluntary standard or failure to include some safety components) pose a "substantial product hazard." If CPSC does so, a noncompliant product would almost certainly be found by a court to be unsafe for consumers, and therefore illegal to distribute or sell.

In theory, a Section 15(j) rule differs from a consumer product safety rule in that, among other things, a Section 15(j) rule does not expressly require testing and certification against the voluntary standard referenced. In practice, however, for prudent companies there is little practical difference between the two types of rules. A Section 15(j) rule is, like a consumer product safety rule, enforceable by CPSC even without a product failure. And it sets a standard likely to be relied upon by courts hearing personal injury or product liability claims tort cases.

From CPSC's perspective, the primary real-world difference between a Section 7 and a Section 15(j) rule is that CPSC has proven able to promulgate Section 15(j) rules far more quickly than a Section 7 rule.

But there is a third approach that enables CPSC to move even more quickly: the agency can simply use its "bully pulpit" authority to promote compliance with a voluntary standard. In the past, CPSC has issued statements explaining that it believes a particular "voluntary" standard represents the minimum needed to *not* pose a substantial product hazard. While this sort of "guidance" is not directly enforceable by CPSC, they are

taken seriously by prudent companies. In a pertinent example, CPSC recently used this method to urge the adoption of a new UL standard for hoverboard scooters containing lithium ion batteries. In that case, CPSC sent an open letter to retailers stating that CPSC believed that no hoverboard was safe unless it complied with the UL standard. This letter effectively resulted in a ban on the products, without any rulemaking proceeding.

As part of its reliance on voluntary industry standards, CPSC can also promote changes to those standards. CPSC already is a participant in several organizations that draft product safety standards. It can and does promote changes the agency believes should be included in the standard. While the CSPC technically has no more control over those bodies than any other participant, their regulatory authority provides them with a leadership role when they bring proposed changes to the table. Recent public statements by CPSC leadership and staff suggest that the agency may already have some changes in mind, and may redouble its attention to promoting changes within the voluntary standards.

FDA Focuses on Medical Carts and E-Cigarettes

Like the CPSC, the FDA has recently voiced concerns over the use of lithium batteries in both high-powered medical carts and e-cigarettes. However, FDA has not yet indicated whether it is going to prioritize the issue in the same manner as CPSC.

On December 27, 2016, the FDA issued a letter to "Health Care Facility Administrators and Professionals" advising them of reported incidents involving mobile medical carts powered by both lithium ion and lead batteries. Mobile medical carts powered by these batteries include, but are not limited to, crash carts, mobile workstations, and medication dispensing carts.

According to the FDA, it received 12 incident reports between January 2013 and July 2016. These reports included overheating, smoke, explosion, and fire. While there were no reported injuries, one event did require the evacuation of patients and staff.

The FDA letter included recommendations on how to mitigate potential risks with an emphasis on preventative maintenance, what to do in the case of a fire and, generally, inspection, storage and charging procedures for such carts.

Shortly thereafter, on January 4, 2017, the FDA's Center for Tobacco Products (CTP) announced that it will host a public workshop focused on the lithium battery hazards presented by e-cigarettes, part of a broader category of products that the FDA terms Electronic Nicotine Delivery Systems (ENDSs). FDA's announcement states that the workshop is a response to recent reports of battery-related incidents such as exploding batteries. The workshop will give CTP an opportunity to hear from stakeholders and the public about ENDS battery safety. Other issues will include how safety hazards are and will be communicated to consumers and the general public. The FDA also will be opening a public docket to solicit comments from the public.

While FDA currently does not appear to be as far along as CSPC in its evaluation of potential regulatory responses, the FDA potentially wields greater power due to the pre-market approval required for many FDA-regulated products including ENDSs. That pre-market approval may provide the FDA with a rapid opportunity to force design changes on manufacturers seeking to bring new products to market without the need to wait for the development of new voluntary standards or the promulgation of new regulations. Manufacturers of batteries intended for use in FDA-regulated products may well face mandatory changes far sooner than manufacturers of CPSC-regulated products.

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[1] 15 U.S.C. § 2056(a).
[2] 15 U.S.C. § 2063(a).
[3] 15 U.S.C. § 2064(j).