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Navigating Product Liability's Complex Regulatory Landscape

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Your product group is planning for the debut of the company's exciting new widget. Being responsible corporate citizens, they check in with the legal department to confirm the regulatory and risk landscape. The group starts by asking the seemingly simple questions: What are the applicable laws and regulations? What are the foreseeable risk scenarios and associated damage potential? But rather than providing answers, the legal department only asks more questions: What are the product's components/ingredients? Will the product or its components contain anything toxic, corrosive, irritating, sensitizing, flammable or combustible? What are the foreseeable dangers associated with the product? What kind of product claims can be envisioned? And so on

Thus begins the process of navigating the complexities and ambiguities of all the potentially applicable laws and regulations that touch even the most basic products in the United States and make mitigating product liability risk such a challenge. By better understanding how these regulations work, risk managers should be able to develop a plan to reduce the likelihood of a costly fine, lawsuit or product recall.

How Many Agencies Does it Take to Screw in a Lightbulb?

You have likely heard some version of the joke "how many [fill-in-the-blanks] does it take to screw in a lightbulb?" While the punchlines are intended to be humorous, the answer to "How many agencies does it take to screw in a lightbulb?" may be more likely to elicit groans than laughter from those in regulatory compliance roles: Up to six federal agencies regulate aspects of a single lightbulb.

First, the Department of Energy regulates lightbulbs because they "consume energy" and therefore must meet certain energy consumption standards promulgated under the Energy Conservation Program (ECP). The ECP was developed through the regulatory framework of the Energy Policy and Conservation Act, originally enacted in 1975 to "reduce the growing demand for energy in the United States, and to conserve nonrenewable energy resources produced in this nation and elsewhere, without inhibiting beneficial economic growth." Although the focus of the law originally was to conserve oil, the ECP has evolved to encompass many different forms of energy. As a result, the ECP specifically addresses—and the DOE has adopted regulations specifically applicable to—different types of light bulbs.

Second, the Federal Trade Commission is responsible for administering the labeling requirements of the ECP and has also specifically addressed the labeling of lightbulbs under the separate Fair Packaging and Labeling Act (FPLA). Under the FPLA, the FTC's authority spans labeling for products that are "used or consumed in a timely manner." The FPLA, as administered by the FTC, is the source for the requirement that labels for covered products include a declaration of identity, quantity and responsibility.

Third, the Consumer Product Safety Commission (CPSC) has jurisdiction over any hazards that a defective product might pose to consumers under the Consumer Product Safety Act (CPSA), and oversees compliance with industry manufacturing standards. Specifically, under the CPSA, it is unlawful to sell any consumer product "that is not in conformity with an applicable consumer product safety rule under this chapter, or any similar rule, regulation, standard or ban under any other Act enforced by [the CPSC]." Products not subject to specific regulations are still subject to reporting provisions if the product fails to conform to product standards, including any "voluntary standards" on which the CPSC relies, or if the product contains a defect that poses a "substantial product hazard" or otherwise creates an unreasonable risk of serious injury or death. In addition, if the lightbulb is inserted into a "children's product," further regulations come into play. There is ample room for debate over what is or is not a "consumer product," a "substantial product hazard," or a "children's product."

Fourth, the Environmental Protection Agency has jurisdiction over the proper storage and disposal of large quantities of mercury-containing products under the Universal Waste Rule (UWR). The UWR was adopted in 1995 to "ensure that the wastes subject to this system will go to appropriate treatment or recycling facilities pursuant to the full hazardous waste regulatory controls." Although the regulations apply only to the disposal of large quantities of lightbulbs, the EPA does require labeling that informs consumers, "Contains mercury. For more on clean up and safe disposal, visit epa.gov/cfl."

Fifth, the Food and Drug Administration (FDA) regulates and sets the performance standards for any products that emit "electronic product radiation" (think ultraviolet lights such as tanning or therapeutic lights). While it may seem unlikely that a lightbulb—neither food nor drug—could fall into the FDA's jurisdiction, it makes logical sense that the FDA obtained regulates radiation-emitting products such as those that may be used in medical or diagnostic equipment. The difficulty, then, is in knowing whether the product emits electronic product radiation.

Sixth, the Federal Communications Commission oversees the proper and responsible use of any products that emit radio frequency. Given the FCC's main focus, which is to regulate interstate and international communications by radio, television, wire, satellite and cable, the FCC may not jump to mind as a potential regulator relevant to a lightbulb. However, FCC materials suggest that "fluorescent lamp ballasts," which regulate voltage to the lightbulb, are categorized as incidental radiators.

The complexity of lightbulb regulation is not an anomaly. It illustrates the broad truth that jurisdiction of federal regulators is not necessarily confined to a specific product or specific industry and may overlap with the jurisdiction of other federal regulators. Focusing on the federal level alone, there are hundreds of regulators doing business as agencies, departments, commissions and bureaus. Despite the Constitution's supremacy clause, states are not necessarily sidelined from the regulatory action either.

Not all of the hundreds of potential regulators will touch your company's products, supply chain or product labels. And a simple search of "lightbulb" will not turn up every potentially applicable regulatory scheme. To get answers, you must know to ask questions like, "Does my product consume energy, contain mercury, emit product radiation or emit radio frequency?" Thus, the challenge lies in knowing what questions to ask to identify or exclude the volume of potential regulators.

Developing a Product Recall Contingency Plan

A company that wishes to do business must therefore plan in the face of complexity and uncertainty. That typically means budgeting for potential risk scenarios, planning for possible recalls and, in some cases, grappling with the ultimate question of whether to recall your product. Earlier, the product group asked for input on the product regulatory and risk landscape. How will you give it to them?

Which comes first: the chicken or the egg? Do you start with a product specification sheet in order to assess regulatory and litigation risk or does the product specification sheet grow out of a regulatory or litigation risk assessment? Developing the product specification sheet will likely be an evolving process as will the manufacturing, marketing and packaging plans. A draft will help identification and discussion of the likely regulatory and litigation risk scenarios, which could lead to adjustments in the product, the manufacturing plan, or the company's plan for how and where the product will be sold and what claims will be made about it.

Who should consider and advise on the regulatory and risk scenarios? As the lightbulb example illustrates, a broad range of expertise can be necessary with even the simplest of products. Unless and until your company has built a level of experience with retail products, your team of initial reviewers should cut across a broad array of practice areas. You should provide the initial product specifications and as much detail as you can about the manufacturing, marketing and packaging plans. Then, elicit advice as to the likelihood and the circumstances under which your product and the related manufacturing, packaging and marketing plans will trigger regulatory requirements or scrutiny. Ask for a checklist of issues, a decision tree, a questionnaire or a description of "triggers" for regulatory requirements from members of the reviewing team so that you can provide it to the product team to highlight the circumstances that could transition aspects of the product from unregulated to regulated.

After an initial look by a broad team, you should then be able to narrow the potential issues and, thus, the team. In addition, once your company builds its experience with retail products, you likely will have internalized the checklist of issues to spot, such as labeling or record-keeping requirements. Your company's range of products will also likely affect the base of knowledge from which it begins the process of spotting potential regulatory issues associated with more substantive aspects of the product.

Focusing more on the attributes of the product itself, your legal team can partner with the product team to research directly applicable regulatory requirements, such as the energy consumption standards that apply to the lightbulb. The product team should likewise research relevant industry standards—such as those promulgated by the National Fire Protection Association (NFPA), American National Standards Institute (ANSI), or American Society for Testing and Materials International (ASTM)—and testing or certification organizations. These types of organizations can not only help navigate regulatory complexity, but can also help focus on what is well accepted and therefore unlikely to draw regulatory attention or what is on the margins and thus could draw scrutiny.

After identifying the applicable regulatory requirements and planning around them, turn next to the litigation risk assessment, including projections for the financial planners and accountants. Details about the product and the marketing, sales, packaging and manufacturing plans will flesh out the risk scenarios and associated potential damage. Your legal team can research verdicts, judicial opinions, settlements, recall reports, agency enforcement actions and news articles to identify: likely claimants, such as customers, users or enforcement authorities; potential defendants and enforcement targets, such as the manufacturer (including component parts manufacturer), wholesaler or distributor, importer or retailer; potential personal injury or property damage scenarios; other potential products liability scenarios, such as product deficiency representation claims (based on representations about product, product pricing, or how or where product was made); potential trade practices claims; intellectual property-related claims; or class action scenarios.

For each category and source of risk, the legal and product teams as well as the customer service, risk, and claims teams can work together to identify the most likely injury or damage scenarios along with the projected worst-case scenarios, such as product recall, class action, or grave or widespread personal injury. Projected budgets and damages may take into account the volume in the market and the associated sales price. Accountants, underwriters or claims teams may have input on how to discount those scenarios based on their probability. The scope and amounts of your insurance coverage—or the lack of it—will also impact your cost projections and contingency planning.

Having a recall plan of action is also part of managing regulatory and litigation risks. For example, a recall under the Consumer Product Safety Act (CPSA) could require you to stop distribution of the product, notify anyone who transports, stores, or distributes it, notify appropriate officials, give public notice of the defect or danger, and then repair or replace affected products or refund the purchase price. In addition, the CPSC has the authority to: 1) ban a hazardous product that presents an unreasonable risk of injury and for which no safety standard would adequately protect the public from risk, 2) obtain injunctive relief to restrain violations of the CPSA, and 3) seek civil and criminal penalties for knowing and willful violations of the CPSA.

Once a company determines that it must report a product hazard to a governing agency, it can expect to undertake many if not all of these same measures either on a negotiated basis or on a "voluntary" basis even if the CPSC does not order a recall under the CPSA. But even with a good recall plan, sufficient insurance coverage and a high likelihood of a negotiated, if not ordered, recall, anticipated damage to the business and brand remains a powerful disincentive to report and recall in the face of uncertain requirements. The question may be less whether or not to recall and more about whether or not to report to a governing agency.

Remember, however, that a customer or competitor may be able to force the company onto the regulatory radar, and the failure to self-report is highly correlated with fines. So the regulatory scheme is stacked to incentivize reporting and recall.

Of course, given the complexity of the regulatory landscape, it is important to address these issues before an incident occurs. By having the right plan in place, your company will be better positioned to manage the risks that arise from these product liability challenges.

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