PRODUCT LIABILITY

UP NEXT: THE PERSONAL CARE AND COSMETICS INDUSTRY

The use of "no injury" theories and the misuse of class action procedures continue to dominate the product liability landscape. But companies need to keep an eye on other trends as well—particularly those in a handful of industries where new product liability litigation appears to be lurking just around the corner.

"Going into 2017, we think we'll see a growing stream of product liability actions targeting certain industries," says April Ross, a partner at Crowell & Moring. For example, the medical device industry will not only continue to face its usual slate of personal injury litigation, it should expect more suits that focus on the "hackability" of Internet-connected medical devices and resulting product liability claims. Such cybersecurity and product liability issues are expected to arise in other industries where interconnectivity is at play, from autonomous vehicles to drones to 3-D printing and beyond.

Of special note, Ross continues, is the potential for a wave of product liability litigation in the personal care and cosmetics industry—a wave that is "right on the cusp of hitting." The industry is regulated by the 1938 Food, Drug, and Cosmetic Act, and under the act "cosmetics traditionally get far less scrutiny than food and drugs," she explains. Cosmetics manufacturers do not need approval for products or regularly share safety information with the Food and Drug Administration, and the FDA does not independently test the safety of ingredients or order recalls. "In general it's a passive regulatory regime, leaving much of the area largely unregulated," Ross says.

Converging events are now putting cosmetic industry product ingredients in the spotlight. A number of chemicals used in cosmetics are more heavily regulated in Europe. And some chemicals commonly used in the industry are coming under fire from consumers and environmental groups in other contexts—witness the recent lawsuits over the use of formaldehyde in lumber products. "All of this has led to an increasing media focus on the chemicals used in cosmetics and personal care products and alleged links to health concerns," says Ross. Presumably, the plaintiffs' bar is paying attention as well. The result, she says, "may be a growing litigation focus on cosmetics, including class actions from workers with prolonged exposure to such products, such as cosmetologists and salon operators."

QUESTIONING THE RELEVANT SCIENCE

For the industry, the key to the best defense lies in understanding and questioning the relevant science—or lack thereof. "There's often no strong epidemiological evidence supporting these health-related claims," says Ross. "So we can expect to see courts grappling with the scientific evidence, and specifically their gatekeeping function under *Daubert* or its state equivalents."

The issue is already starting to play out in courtrooms. In two high-profile cases in Missouri in 2016, juries awarded a total of $127 million to plaintiffs who claimed that the use of talcum powder had caused their ovarian cancer. A few months later, a New Jersey court threw out two similar cases, citing the "narrowness and shallowness" of the scientific evidence.

"There was actually overlap between the experts in these cases, and the evidence was not markedly different," say Ross. "The judges reached different decisions about what they would deem admissible in court. We'll continue to see cases develop around these gatekeeping questions. How these play out will determine, in part, whether this litigation

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trend has a long lifespan or whether it has a short one."

Changes on the legislative front are also expected to determine that future. In the seven decades since the Food, Drug, and Cosmetic Act was passed, much of the law has been updated, but the provisions related to cosmetics have remained unchanged. There now appears to be a building consensus that change is in order. "There is a lot of alignment in principle from stakeholders on all sides of the issue," says Ross. "The manufacturers, trade groups, environmental groups, consumer groups all appear to be in agreement that legislative action is needed."

That consensus has led to the introduction of two competing bills in Congress. A Senate bill would give the FDA authority to review and test ingredients, issue recalls, and require reporting of adverse events—much like the act's food- and drug-related provisions. Meanwhile, a House bill would establish procedures regulating manufacturing and distribution plants and require ingredient disclosures. It would also require the FDA to establish a safety oversight program, but would not give it the authority to issue recalls.

"The new session of Congress in 2017 may produce a compromise bill that will get more traction than these two competing bills have been getting and lead to a legislative overhaul with respect to cosmetics," says Ross. "That will then trickle down to new regulations, which will bring the kind of pressure that often drives litigation."

KEY POINTS

A new industry focus

Plaintiffs are looking at chemicals in cosmetics.

An opening for defendants

The science behind claims is still weak.

Legislative movement

Congress may soon update the Food, Drug, and Cosmetic Act.

THE EPA TAKES A NEW LOOK AT CHEMICALS

In June 2016, Congress amended the 1976 Toxic Substances Control Act (TSCA) in a bipartisan effort that updated the regulation of chemicals for the first time in 40 years.

The legislation—known as The Frank R. Lautenberg Chemical Safety for the 21st Century Act—recasts the way that the Environmental Protection Agency oversees chemical safety.

The law requires the EPA to conduct safety assessments of chemicals commonly used in commerce and prioritize them in terms of risk; expands the EPA's ability to require testing of chemicals; allows industry to request risk assessments for specific chemicals; and gives the EPA the power to manage risk though labeling requirements, usage restrictions, and phasing out or outright bans on chemicals, among other actions.

While the EPA is working to implement the law and has plans to publish regulations governing the prioritization of chemicals in commerce and the evaluation of their safety by mid-2017, some observers believe that the plan is too ambitious, especially given the change in administration.

Congress essentially left it to the EPA to work through a number of questions, such as which chemicals to review and in what order to review them. However, despite the deadlines Congress imposed, observers point out that it might be some time before the final regulations come out.

Eventually, however, the risk assessments themselves will no doubt provide additional ammunition for the plaintiffs' bar. "Those assessments tend to live for a very long time," says Crowell & Moring partner April Ross. "They will be cited by experts as evidence that a given chemical can create health problems and trigger more product liability litigation."