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How 2020 Changed Product Liability — And What's Next

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Like many other legal sectors, product liability regulation and litigation felt the sharp impact of the COVID-19 pandemic in 2020, which forced lawmakers and courtrooms to work remotely.

As we look to leave 2020 behind us and welcome 2021 with open arms, we reflect on recent developments, and consider upcoming trends — such as the applicability of Public Readiness and Emergency Preparedness Act immunity to product liability claims for COVID-19 products.

Regulatory Activity

Consumer Product Safety Regulation

In a year dominated by the pandemic and political gridlock in Washington, D.C., it comes as no surprise that we saw no major product safety laws or regulations in 2020.

In fact, the U.S. Consumer Product Safety Commission did not issue a single civil penalty last year, although it did recently refer a case to the U.S. Department of Justice. We expect an uptick in regulatory activity this year, as consumer product safety advocates urge the incoming Biden administration to take a more aggressive approach to product safety.

2020 did have some consumer product safety activity. The CPSC conducted a regulatory review of mandatory safety standards covering baby cribs and issued a notice of proposed rulemaking for crib bumpers and liners; numerous states passed new bans on flame retardants used in children's products; and consumer advocacy groups renewed calls to roll back Section 6(b) protections for consumer product companies under the Consumer Product Safety Act.

Recalls

Recalls across five industries — automotive, consumer products, pharmaceuticals, food and beverage, and medical devices — carried on at a relatively normal pace in 2020, despite the COVID-19 pandemic.

For automotive companies, safety issues with vehicle equipment like service brakes accounted for a majority of recalls last year. Lithium-ion batteries, infant and toddler products, and tip-over furniture recalls remain the top concerns for consumer product companies.

The U.S. Food and Drug Administration, while focused on the COVID-19 pandemic, continued to pursue its other top priorities — tackling the opioid crisis, issuing warning letters to companies throughout the supply chain, and targeting deviations in good manufacturing practices and quality concerns in the drug manufacturing practice.

In the food and beverage space, the top recall concerns continued to be undeclared allergens and bacterial contamination. Finally, medical device recalls decreased, as the FDA shifted its focus toward addressing shortages in personal protective equipment for health care providers.

The CPSC in 2021 and Beyond

Looking ahead, the Biden administration may have the opportunity to cement a Democratic majority for the five-person CPSC, with three commissioner seats to fill in the new term. Businesses can expect increased enforcement efforts, the introduction of new mandatory safety standards, and a preference for mandatory standards over the current deference toward voluntary standards.

But a Democratic-controlled commission is by no means guaranteed. The president nominates commissioners, and the Senate confirms them for staggered seven-year terms. The commission has not had a confirmed chairman since Elliot Kaye resigned after President Donald Trump's inauguration in 2017. Acting Chairman Robert Adler, a Democrat, has stated he will not seek renomination when his term ends in October 2021. Kaye's term expires at that time as well.

In March 2020, Trump nominated Nancy Beck to chair the CPSC, but her nomination stalled in the Senate. If the Senate confirms Beck before President-elect Joe Biden takes office, the commission will remain Republican-controlled until 2024, absent any resignations. But if Beck is not confirmed, then Biden has the chance to switch the power balance.

The uncertainty around the CPSC's makeup and leadership begets uncertainty in regulatory changes and enforcement priorities. Even so, there are a few key areas of interest to keep an eye on in 2021.

Businesses producing innovative internet-connected consumer products will be interested to follow the CPSC's Artificial Intelligence Forum in March. The commission is seeking input from the industry on voluntary standards and certifications for devices that integrate AI and related technologies.

And automobile manufacturers should closely watch the National Highway Traffic Safety Administration's stance toward software used in vehicles — and be prepared for stricter fuel conservation and vehicle emissions regulations as part of the Biden administration's climate change strategy.

Legal Developments for Smart Auto Technology

While KITT from "Knight Rider" only existed on the television screen, his smart-car progeny are now hitting the open road. Smart auto features have become increasingly common — many vehicles now offer interactive infotainment systems, and some even provide driving assistance through automated driving systems, or ADS.

Although fully autonomous vehicles are still in their infancy, the industry is poised for rapid growth. And the growth in smart auto technology has been accompanied by litigation.

Continuing 2019's trend, in 2020 plaintiffs filed more putative class action complaints against vehicle manufacturers related to infotainment systems in vehicles. In these complaints, plaintiffs typically alleged that software errors in the systems could cause safety problems, or that the software did not operate as represented.

These plaintiffs tended to assert claims for breach of warranty, violation of state-specific consumer protection laws, and misrepresentation or concealment. We expect these cases to become more active in the coming year.

In addition, 2020 brought one of the first product liability cases against a vehicle manufacturer based on a pedestrian fatality allegedly involving an ADS. Little was learned, however, because the court dismissed the case based on forum non conveniens.

Plaintiffs aren't the only ones responding to the growth in smart auto technology. The new year promises a new framework for vehicles with ADS. NHTSA recently submitted advance notice of proposed rulemaking, and is accepting written comments through Feb. 1.

Under the proposed framework, NHTSA is looking beyond the existing Federal Motor Vehicle Safety Standards, and is "considering the creation of a governmental safety framework specifically tailored to ADS." Mindful that overregulation may stifle innovation in ADS, NHTSA at this time does not plan to require specific design characteristics.

Instead, the agency proposes performance-oriented approaches and metrics, focusing on four core elements of ADS safety performance: sensing, perception, planning and control. Compliance with the forthcoming standards set out in NHTSA's voluntary programs and formal regulations could give vehicle manufacturers another defense to potential product liability claims stemming from ADS.

Developments in Multidistrict Litigation

Multidistrict litigations are a major component of the federal civil docket — the Judicial Panel on Multidistrict Litigation reports 180 pending MDLs. Between Oct. 1, 2019, and Sept. 30, 2020, the panel granted 21 motions to centralize, and 231,495 civil actions were transferred to or directly filed in MDLs.

Product liability claims account for 24% of pending MDLs, and 97% of all pending cases. Because of their size and complexity, MDLs provide ample opportunities for courts and counsel to enact change and adapt to developments in the legal profession.

Over the last year, certain trends in MDLs have begun to emerge that we expect to carry over in 2021.

Focus on Diversity and Inclusion

Courts handling MDLs are increasingly interested in promoting diversity and inclusion in MDL leadership. While women have made significant progress in securing those sought-after positions — studies have shown that courts awarded approximately 30% of MDL plaintiff leadership positions to women in 2018 — a significant gender gap remains. We expect courts to push for change in this area, and focus on providing women and attorneys of color more MDL leadership opportunities.

Increased Use of Census Data

Initial case censuses will likely become more commonplace in MDLs in the coming year. The process, currently employed in the Juul Labs Inc. and Zantac MDLs, provides key information regarding the plaintiffs' alleged exposure and harm.

MDLs benefit from censuses in several ways. First, they facilitate early vetting of claims to filter out meritless lawsuits, as they occur before plaintiff fact sheets are submitted. Second, they can shed light on the number and type of cases and identify candidates for leadership appointments.

Finally, the information they contain about the types of claims and damages involved can help guide initial case procedures. Given the growing concerns over the number of meritless claims in MDLs, we expect courts to welcome this process in the coming year.

Virtual Practice

In 2020, COVID-19 shutdowns and the shift to virtual practice significantly changed the legal practice. MDLs fared no differently.

Although virtual depositions and hearings were initially met with reluctance, continued shutdowns forced the courts and parties to accept the virtual world. Many MDLs have held several days of remote hearings, including hearings on Daubert motions, motions for summary judgment and motions in limine.

We expect virtual hearings to become common practice in MDLs, with attorneys having the option to appear either in person or by video. Whether they take the next leap and hold virtual trials remains unknown.

PREP Act

The COVID-19 pandemic set a dramatic stage for potential medical device and drug litigation in 2021. In a fitting metaphor, the Public Readiness and Emergency Preparedness Act severely limited the show's attendance.

The PREP Act provides tort liability protection for manufacturers, distributors and some service providers from claims arising from the manufacturing, development, distribution, administration or use of COVID-19 countermeasures. Covered countermeasures are essentially any COVID-19 product approved or authorized by the FDA or the Occupational Safety and Health Administration.

Where applicable, defendants are immune from suit and liability under both state and federal law. Claimants must seek remuneration from the Countermeasures Injury Compensation Program, which is run by the U.S. Health Resources and Services Administration.

These protections are widely felt: Manufacturers from clothiers to liquor distillers to world-class pharmaceutical companies have entered the COVID-19 market at some level, producing an array of diagnostics, treatments and vaccines that are or will be used by virtually every American consumer.

We have already seen litigation addressing PREP Act immunity. Several federal courts addressed a series of COVID-19 lawsuits against long-term care facilities claiming negligent failure to provide

countermeasures to protect residents from COVID-19. Those opinions show that PREP Act protections do not apply where not administering a product causes harm.

Perhaps responding to these decisions, the U.S. Department of Health and Human Services issued an advisory opinion and an amendment to the act, indicating that health care providers can indeed enjoy protection for prioritizing distribution of countermeasures, especially if done in accordance with public health guidelines. For example, refusing to vaccinate an otherwise healthy 25-year-old in favor of an elderly patient with underlying conditions can trigger protection against claims the 25-year-old may bring.

So far, we have not seen any direct product liability-type claims, which appear to fall squarely in protected territory. This may indicate a dampening effect on these claims, although the majority of current product offerings like face masks and test kits carry a relatively low risk of injury. As more advanced therapies and vaccines are developed and widely deployed, courts may see an influx of these claims.

The PREP Act does not apply to situations where the harm is not causally related to a countermeasure. It also does not apply to cases of willful misconduct, nor to fact patterns that do not fit the act's specific definitions for covered countermeasures, persons and activities.

Based on the current guidance and litigation landscape, the PREP Act blocks claims that are:

- Standard product liability claims against manufacturers and distributors;
- Claims against health care providers and program planners for administering a countermeasure; and
- Negligence claims against health care providers for not administering a countermeasure, as long as there is a well-reasoned rationing of limited countermeasures.

The following claims will likely proceed:

- Negligence claims against health care providers for not administering a countermeasure with no purposeful rationing of limited countermeasures;
- Claims that don't deal with covered countermeasures, but rather with products that are illegally marketed without FDA authorization or a defendant's personnel policies on COVID-19 mitigation;
- Claims that involve countermeasures which bear no causal connection to the claimed harm; and
- Claims alleging acts of willful misconduct.

We hope 2021 brings as much change as 2020, with vaccines taking us back to a new normal — and returning product liability litigation to the courtroom where it belongs.

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