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Product Liability Defense In The Last Decade — And The Next

By **Lori Cohen and Sara Thompson** (February 3, 2020, 4:54 PM EST)

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The start of a new decade has us nostalgic for the many major changes we saw between 2010 and 2019 — and thinking about what new changes may be on the horizon. For product liability litigators, the last decade saw a true sea change in the litigation landscape that many did not fully anticipate, with both pro-plaintiff developments and more defense-friendly course corrections.

Here are just some of the most significant changes we have seen over the last 10 years, and our best attempts to predict how product liability litigation may change in the next 10 years.

5 Ways Product Liability Defense Has Changed During the Past Decade

Development of Generic Drug Preemption

At the start of the past decade, the U.S. Supreme Court had recognized the defense of federal preemption only for medical device manufacturers whose devices were subject to premarket approval, pursuant to its decision in Riegel v. Medtronic Inc.[1]

The court had just rejected a preemption defense for brand-name drugs in Wyeth Pharmaceuticals v. Levine in 2009.[2] But in 2011, the court issued its landmark ruling in PLIVA Inc. v. Mensing, which established that state law failure-to-warn claims against generic drug manufacturers are implicitly preempted by federal law.[3]

The court acknowledged that generic drug manufacturers are required by federal law to conform their labeling, including all warnings in both package inserts and medication guides, to the labeling approved by the U.S. Food and Drug Administration for the reference listed drug — and are therefore prohibited by federal law from varying the generic drug's labeling from the reference listed drug labeling, even to strengthen it.[4]

The high court noted that if it were to allow state law claims imposing a duty on generic drug manufacturers to alter their FDA-approved labeling, it would be "impossible for the [m]anufacturer to comply with both their state law duty to change the label and their federal law duty to keep the label the same."[5]

In 2013, the Mutual Pharmaceutical Co. v. Bartlett decision expanded the scope of preemption defenses to also include state law design defect claims against generic drug manufacturers.[6] Subsequent decisions have applied Bartlett's reasoning to design defect claims against brand-name drugs as well, to the extent they assert a duty to change a drug's design or formulation, or to withdraw it from the market when the manufacturer could not do so without prior FDA approval.[7]

Increase in Multidistrict Litigation and Relationship to Increased Advertising

The past decade saw a dramatic increase in the number and size of multidistrict litigations in the federal court system, the majority of which continue to be product liability litigation. According to a recent report, at the end of 2018, the 248 pending MDL dockets accounted for 52% of all pending federal civil cases.[8]

Of the total number of actions pending as of April 2019, approximately 92% to 95% of all actions filed in MDLs are product liability.[9] The past decade also saw the largest (non-asbestos) MDLs ever; the In re Ethicon Inc. Pelvic Repair System Products Liability Litigation MDL in the Southern District of West Virginia holds the current record, with over 40,000 historical cases.[10]

The dramatic rise in number of filings in product liability MDLs has largely been prompted by plaintiffs attorney advertising and social media, which have skyrocketed over the last decade — particularly with respect to drug and device product liability cases, advertised by plaintiffs firms that aggregate hundreds or even thousands of cases.

It's clear from the statistics that MDL filings in the product liability sphere are becoming increasingly popular among the plaintiffs bar, and present unique challenges to defendants facing the snowball effect of a barrage of filings flowing from nationwide advertising efforts. The statistics and data on how much is spent on mass tort advertising is baffling; this will be the subject of continued debate and efforts in litigation, state bars and other reform arenas.

Third-Party Litigation Funding

One of the most significant developments of the past decade is the rise in popularity of third-party litigation funding. According to some reports, there has been a drastic increase in the amount of outside funding available to finance litigation. This has allowed the plaintiffs bar to become more organized and engage in more mass advertising — which has in turn fueled the rise in MDL filings and mass tort litigation overall.

Some reports suggest that from 2013 to 2017, litigation funding grew more than 400%.[11] Another report estimated the litigation funding market as a $3 billion industry, with the number of lawyers reporting their firms utilized litigation funding increasing from 7% in 2013 to 28% in 2015.[12]

Litigation funding has not been without controversy, as there have been numerous disputes in the courts regarding its discoverability, issues surrounding control of settlement authority, and associated taxation complications. Litigation funding will continue to provoke battles over the need for more transparency and the admissibility of funding information in litigation.

Major Personal Jurisdiction Successes Limit Forum Shopping and Litigation Tourism

At the start of the decade, the Supreme Court issued landmark personal jurisdiction rulings in Goodyear Dunlop Tires Operations SA v. Brown and Daimler AG v. Bauman.[13]

Taken together, these decisions make clear that the critical question in assessing general personal jurisdiction is whether a defendant's "affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum State."[14] As Daimler clarified, absent exceptional circumstances, a corporation is "at home" only (1) where it is incorporated; and (2) where it has its principal place of business.[15]

In another landmark decision, Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County, the Supreme Court rejected "litigation tourism" and reaffirmed that for specific personal jurisdiction to exist, there must be "an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation."[16]

Since Bristol Myers-Squibb was decided in 2017, the product liability litigation landscape has shifted considerably, as plaintiffs have struggled to find some connection between the previously-chosen forum and either the defendant or the product at issue. Collectively, these cases have allowed corporate defendants to fight forum shopping and litigation tourism, in which plaintiffs file their lawsuits in the most plaintiff-friendly venues, even if neither they nor the defendant have any connection to the venue.

Discovery Proportionality Rule

On Dec. 1, 2015, a set of changes to the Federal Rules of Civil Procedure went into effect that was widely regarded as one of the most significant revisions to the rules since they were enacted. The most important amendment was to Rule 26(b)(1) and the new proportionality rule.

The amendment eliminated the familiar "reasonably calculated" language that seemed to allow nearly any topic to be fair game for discovery, and now allows parties to obtain discovery regarding nonprivileged matters relevant to any party's claim or defense "and proportional to the needs of the case."

The rule goes on to list several factors to consider when evaluating the proportionality of the case, including the importance of the issues at stake, the amount in controversy, the parties' relative access to relevant information and resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

The new rule has required the parties to cooperate at the onset of litigation and work together to streamline the discovery process, as well as avoid costly discovery disputes. Where a party pushes for particularly burdensome discovery, the rule gives the court flexibility to employ cost-sharing and cost-shifting options if appropriate.

5 Changes We May See in the New Decade for Product Liability Defense

Expansion and Development of Preemption Law

The end of the last decade saw the Supreme Court reject the U.S. Court of Appeals for the Third Circuit's

attempt to leave the applicability of preemption for juries to decide, in Merck Sharp & Dohme Corp. v. Albrecht. But the court's guidance to trial court judges about how to decide preemption issues is far less clear than it could have been.

This decade will see considerable fleshing out of when there is clear evidence that the FDA would have rejected a warning such that preemption may apply, even for brand name drugs, and a continuing push by plaintiffs to try to find loopholes and escape clauses within the Supreme Court's ambiguous guidance. The same has continued for the last decade following the "parallel claims" exception recognized in Riegel for medical device preemption, and for generic preemption post-Mensing and Bartlett.

Additionally, the development of preemption case law at both the Supreme Court level and in the lower courts will be considerably influenced this decade by the newly-confirmed more conservative judges that have reshaped the balance of power in the federal court system since 2017, and will likely reflect less hostility to, and more acceptance of, preemption.

The Changing Face and Location of Corporate Headquarters

Following the favorable personal jurisdiction rulings of the last decade, many manufacturers and distributors of products may be considering moving their corporate headquarters to less plaintiff-friendly environs, or even moving them internationally. Several Fortune 100 companies have changed their state of incorporation and/or their corporate headquarters recently, including McKesson Corp. moving its principal place of business from plaintiff-friendly San Francisco, California, to more defense-friendly Irving, Texas.

In the pharmaceutical and medical device space, manufacturers and distributors that are tired of facing a barrage of lawsuits in tough venues such as the Court of Common Pleas of Philadelphia may opt to move to greener pastures, both literally and figuratively. Companies with significant patent litigation portfolios in particular may choose to change their state of incorporation and/or principal place of business to avoid a litigation disadvantage that may also impact their product liability litigation interests.

Controlling the Burdens and Costs of the MDL System

If the last decade saw the rise of MDLs to encompass more than half of pending federal litigation, and saw the adoption by federal courts of a proportionality rule for discovery, it stands to reason that MDL courts and the Judicial Panel on Multidistrict Litigation will feel pressure in the new decade to tame the beasts that MDLs have often become.

With many of the most recently formed MDLs in the drug and device industries numbering in the tens of thousands, and the federal court backlogs worsening year over year, the JPML and the federal court system as a whole are incentivized to adopt reforms to fix this growing problem. Revisions to the statutes authorizing the multidistrict litigation system and to the rules of the JPML would provide an avenue to rein in federal mass tort litigation.

Interplay Between Congressional Oversight and Litigation — Especially on Opioids

Over the last decade, government enforcement activities have continued to increase and expand, particularly in the drug and device space. This increase in government oversight in turn has fueled product liability activities.

But Congress' sudden willingness to wade into the fray has the potential to be a game changer. We have seen legislation introduced and congressional hearings called immediately after a recall of a cosmetic product was announced and liability litigation exhibits became public and received media attention.

The opioid crisis, and the resulting congressional scrutiny and government enforcement and policymaking focused on opioids, has presented an existential threat to the pharmaceutical industry that is likely to dominate the next decade. With gridlock in Washington, D.C., and significant disagreement among municipalities and policymakers over how to resolve the crisis, the courts and litigants will be tasked with grappling with this Gordian knot.

Renewed Focus on Health, Safety and Sustainability

The last decade saw a renewed focus on artificial versus natural ingredients, and the health and safety impacts of products, with litigation flowing from growing public concern that companies may deliberately hide the ingredients in their products and the risks they pose, and may mislead consumers on the safety of what they buy and consume.

The public interest spotlight on both personal wellness and environmental sustainability also brings increasing scrutiny on the safety and environmental impact of common chemicals in household products, pesticides used at home or on commercial food crops, and chemicals used in manufacturing and construction.

With each new discovery of chemical ingredients and exposures that are potentially harmful, and the search for responsibility for any such harm, manufacturers will face increased scrutiny of their ingredients and processes, as well as their suppliers and contracting partners, and potentially may also see new product liability battles in the ever-evolving litigation landscape.

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[1] Riegel v. Medtronic Inc., 552 U.S. 312 (2008).

[2] Wyeth Pharmaceuticals v. Levine, 555 U.S. 555 (2009).

[3] PLIVA Inc. v. Mensing,564 U.S. 604 (2011).

[4] Id. at 604, 617-25.

[5] Id. at 618.

[6] Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013).

[7] See e.g., Drager v. PLIVA USA Inc., 741 F.3d 470 (4th Cir. 2014); Yates v. Ortho-McNeil-Janssen Pharms. Inc., 808 F.3d 281 (6th Cir. 2015); Houston v. United States, 638 F. Appx. 508 (7th Cir. 2016).

[8] Alex Fuchsberg and Alex Dang, MDLs Are Redefining The US Legal Landscape (Oct. 30, 2019), https://www.law360.com/articles/1214276/mdls-are-redefining-the-us-legal-landscape.

[9] Elizabeth Chamblee Burch, Basis MDL Statistics, https://www.elizabethchambleeburch.com/mdl-data.

[10] United States Judicial Panel on Multidistrict Litigation, MDL Statistics Report - Distribution of Pending MDL Dockets by Actions Pending, (Dec. 16, 2019), https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDLs_by_Actions_Pending-December-16-2019.pdf.

[11] Diane Injic, The growth of litigation funding and its potential effects on commercial auto insurance: Part one, (June 10, 2019), https://www.verisk.com/insurance/visualize/the-growth-of-litigation-funding-and-its-potential-effects-on-commercial-auto-insurance-part-one/.

[12] Legalist, Statistics on litigation funding, https://www.legalist.com/wiki/statistics-on-litigation-funding.

[13] Goodyear Dunlop Tires Operations SA v. Brown, 564 U.S. 915, 919 (2011); Daimler AG v. Bauman, 571 U.S. 117 (2014).

[14] Daimler at 127 (quoting Goodyear Dunlop Tires Operations SA v. Brown, 564 U.S. 915, 919 (2011)).

[15] Daimler, at 137.

[16] Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County, 137 S. Ct. 1773, 1780 (2017) (internal citation omitted).