The Trial Bar's Most Wanted: Breaking Down Litigation Trends and Themes Affecting Key Industries

Introduction

A recent decision by the U.S. Supreme Court expanding general jurisdiction over out-of-state companies. Class action lawsuits regarding autonomous driving technology. Billions of dollars in settlements over companies' use of so-called "forever chemicals." Multidistrict litigation concerning toxic infant formula. These are just a few of the cases in 2023 that are keeping general counsel awake at night, as the plaintiffs' trial bar continues to pursue ever-larger and more complex claims against a variety of industries. In this report, we identify the top industry targets for litigation, and analyze the similar approaches the trial bar takes in their litigation tactics, regardless of the industry implicated.

I. Pharmaceuticals

According to Lex Machina's annual *Product Liability Litigation Report*, pharmaceutical claims continue to be a key driver of products liability litigation for 2023. Among the key trends observed are significantly larger multi-district litigations (MDLs), comprising thousands of claimants, driven by numerous factors.

"Mega MDLS"

The year 2023 witnessed the filing and/or consolidation of significantly larger MDLs than in prior years. These so-called "mega MDLs" are driven by several factors. First, plaintiff counsel seem to be targeting claims against widely used over-the-counter drugs, which significantly increases the potential plaintiff population. These large MDL's also demonstrate increased coordination among the trial bar with some of the most notorious plaintiffs' firms joining forces, and a commensurate increase in advertising spending. The recent *In re Acetaminophen – ASD/ADHD Prods. Liab. Litig.*, MDL is an example implicating all of these factors. Claimants in that litigation allege that acetaminophen use during pregnancy caused autism spectrum disorder and/or attention-deficit/hyperactivity disorders in children exposed in utero. That litigation now includes over two hundred cases in all fifty states, with counsel reporting potentially hundreds of thousands of claimants soon to file. Similarly, the *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL, which involves claims that thousands of consumers developed cancer after consuming the popular heartburn medication, features over 160,000 claimants. Assuming the factors contributing to the rise of "mega MDLs" do not change, we can expect "mega MDLs" to increase in the future.

Weight-Loss Drugs

Semaglutide prescription drugs have boomed in popularity, in part due to their effectiveness in diminishing appetite and promoting weight loss. But these lucrative drugs have come under increasing plaintiffs' scrutiny as a growing number of consumers have alleged that manufacturers downplayed, or failed to warn patients about, side effects such as gastrointestinal problems, malnutrition, and an increased risk of cancer. While manufacturers have countered that these symptoms were "extensively discussed" on FDA's approved label for the drug, at least two lawsuits are pending in Louisiana and Pennsylvania federal courts, with more class action litigation expected in the coming years.

Third Party Testing

As evidenced by the *Zantac* MDL, plaintiffs are increasingly basing their claims on testing from third-party testing laboratories like Emery Pharma, which allegedly detected high levels of cancer-causing nitrosamines in the heartburn medication, or Valisure, which claimed to have found carcinogens in the blood pressure drug valsartan. In addition, citizen petitions by Emery and Valisure to FDA, urging recalls, helped instigate litigation against the manufacturers, and raised questions about coordination between the trial bar and the laboratories that generate the studies and science at issue. Both Emery and Valisure came under later criticism for flawed and unreliable testing methodology: in a December 2022 letter, FDA identified certain "methodological deficiencies" and "analytical discrepancies" in Valisure's benzene testing, while *Zantac* MDL Judge Robin Rosenberg excluded plaintiffs' general causation expert witnesses under Federal Rule of Evidence 702, and granted summary judgment in favor of the defendants, finding the methodology used by Emery Pharma and other experts to be flawed and unreliable. As the Advisory Committee on the Federal Rules of Evidence continues to explore amendments to Rule 702, which addresses the "gatekeeping function" of federal courts with respect to the admission of expert evidence, issues regarding the reliability of expert opinions are sure to continue.

II. Medical Devices

Together with pharmaceuticals, medical device claims continue to drive costly products liability litigation, with plaintiffs claiming that the devices are either defectively-designed or that the manufacturer failed to warn patients about potential risks. But as medical technology grows ever more sophisticated, with diagnostic and data analysis capabilities equal to, or in some cases, surpassing those of human beings, the trial bar is increasingly turning its focus to "smart" devices, exploiting the gap between regulations and technology.

Product Recalls

Recent recalls of FDA-approved medical devices, including hernia and transvaginal mesh, surgical warming blankets, heart valves, intrauterine birth control devices, sleep apnea breathing devices, and knee implants, have led to hundreds of subsequent products liability claims from recipients who alleged that they were harmed as a result of the recalled devices. The trial bar's tracking of recalls remains the number one factor driving litigation. Similar to pharmaceutical claims, these cases have expanded in size due to increased advertising among key demographics for potential plaintiffs. These matters also demonstrate the trial bar's affinity to target industries and products with which they have familiarity. For example, with metal-on-metal hip litigation largely concluded, the trial bar turned its attention to polyethylene, initiating the Exactech hip, ankle and knee replacement MDL, where approximately 842 lawsuits remain pending as of November 2023 in U.S. District Court for the Eastern District of New York. In this MDL, claimants have alleged that they were injured by defective polyethylene inserts and liners in knee, ankle, and hip replacements, which could cause inserts to degrade prematurely, and were recalled by Exactech in August 2021 and 2022. Defendants also face increased costs from claims not just for physical injuries, but for alleged economic damages, including replacement devices, extended warranties, and repayment of associated costs—all of which have increased as a result of rising medical costs and inflation in the U.S.

Ethylene Oxiode (EtO) Sterilization

Ethylene oxide (EtO) is a common commercial sterilizer of medical equipment, and used to sterilize approximately 20 billion medical devices in the United States each year. Although EtO is the only effective sterilization method for many categories of medical devices, in 2018, the U.S. Environmental Protection Agency (EPA) classified EtO emissions as a probable human carcinogen--concerns that also were echoed by the federal Agency for Toxic Substances and Disease Registry (ATSDR). Since 2018, hundreds of private lawsuits have been filed against alleged EtO manufacturers and emitters, claiming that EtO emissions caused various forms of cancer and serious reproductive health effects. In addition, many municipalities located near EtO emitting facilities have brought toxic tort claims based on alleged environmental or occupational exposure, with one of the largest lawsuits being filed by workers and community members in Allentown, Pennsylvania. Given the proliferation of EtO claims across various plaintiff demographics, as well as the EPA's announcement in April 2023 that it was proposing tougher standards regarding EtO emissions, large-scale litigation against EtO manufacturers and emitters is likely to increase into 2024.

Artificial Intelligence

The use of artificial intelligence (AI) in the medical device space continues to grow rapidly, with computer-aided diagnosis (CAD) software being used to analyze and interpret mammograms, while surgical robots assist in performing fine motor operations and positioning of implants. In 2022, FDA approved or cleared almost one hundred AI-enabled medical devices, with more expected this year. However, as technology advances, questions emerge over causation and allocating liability, particularly where devices contain third-party software and/or components, and are used in collaboration with human decision-making. Nor is it settled across all jurisdictions whether diagnostic software programs constitute "products" for purposes of products liability claims, or whether "machine learning" AI should be subject to products liability standards, or capable of replacing physician decision-making, and subject to medical malpractice considerations. As the use of AI-enabled medical devices expands, and the judiciary's treatment of such devices continues to develop in line with FDA regulation, the trial bar is likely to exploit widening gaps between the evolving technology and the applicable legal framework.

III. The Personal Care Products Industry

Personal care manufacturers, distributors, and retailers have come under increasing fire from the trial bar over allegations that beauty products contain dangerous or unintentional ingredients that cause a variety of human health ailments. Fueled in part by the rise of TikTok and other social platforms, and complicated by shifting legislation, products liability claims involving personal care products increased in 2023 and may continue to rise over the next few years.

MOCRA

In December 2022, Congress enacted the first major statutory change to FDA's ability to regulate cosmetics since the Federal Food, Drug, and Cosmetic Act of 1938. The Modernization of Cosmetics Regulation Act (MoCRA) significantly expands FDA's authority over cosmetics and

creates substantial new compliance obligations. However, MoCRA does not provide federal preemption protection for state consumer protection or liability claims; nor does MoCRA provide any guidance on the kinds of claims brands can make about the safety of their products. Rather, MoCRA's recordkeeping requirements as to safety substantiation and adverse event reporting—which are not exempted from FOIA disclosure—as well as MoCRA's requirement that FDA enact regulations mandating Good Manufacturing Practices (GMP) and issue a report on the use of per- and polyfluoroalkyl substances (PFAS) in cosmetics, will all provide fodder for plaintiffs to scrutinize the sufficiency of companies' safety substantiation, testing, and manufacturing procedures.

"Clean" Beauty

Increasingly, the trial bar has scrutinized claims that companies' products are "clean," "natural," or "nontoxic," alleging, instead, that they contain synthetic ingredients, or ingredients allegedly linked to human health concerns like hair loss, reproductive issues, or in certain cases, cancer. This year alone, several plaintiffs have claimed they have sustained personal injuries to their hair and scalp arising from their use of hair products that contain the fragrance ingredient lilial, which has been linked by the European Commission to adverse health issues. More recently, the Judicial Panel on Multi-District Litigation consolidated claims by hundreds of thousands of plaintiffs who allege injuries from use of hair relaxer products sold by dozens of companies over the course of several decades. Class actions involving allegedly dangerous ingredients such as benzene, respirable titanium dioxide, and PFAS are also expected to increase.

"Junk" Science

Allegations of insufficiently vetted science continue to play a key role in shaping the outcome of personal care products litigation. Last year, FDA raised concerns over "methodological deficiencies" and "analytical discrepancies" in testing by Valisure, a purportedly independent testing laboratory, which revealed purportedly high levels of benzene in dry shampoo products that were subsequently recalled, and which became the subject of class action litigation. Similarly, in October 2023, a three-judge panel of a New Jersey appeals court overturned a $223 million jury award and ordered a new trial after concluding that the lower court improperly permitted jurors to hear evidence that plaintiff's use of allegedly contaminated talc-based products exposed him to asbestos and caused him to suffer mesothelioma. Instead, the panel concluded that the lower court failed to fulfil its "gatekeeping role" of assessing whether the plaintiffs' experts based their testimony on sound science.

IV. Automotive Technology

Advancements in automotive technology, particularly with respect to autonomous capabilities and so-called "smart" vehicles, have increasingly changed not only the way Americans drive, but the way automakers and their suppliers manufacture and market vehicles. These advancements, as well as increased regulatory scrutiny, have raised new challenges for the automotive industry, particularly with respect to products liability.

Personal Jurisdiction Challenges

In *Mallory v. Norfolk Southern Railway Co.*, 143 S.Ct. 2028, 216 L.Ed.2d 815 (2023), the U.S. Supreme Court concluded, in a 5-4 decision, that out-of-state corporations may be subjected to a state's long arm statute, granting general jurisdiction over any corporation registered in that state—regardless of how much business the company actually conducts in that state. Following *Mallory*, there has been an increase in "forum shopping" with plaintiffs filing claims in "judicial hellholes," exploiting uncertainty as to whether out-of-state corporations consent to general personal jurisdiction if they are registered to do business in that state—regardless of whether or not those claims arise from the corporation's contacts with the state.

Autonomous Capabilities

As driver-assisted technology proliferates, various class action plaintiffs have sought to hold automakers liable for accidents arising from the use of autonomous systems, as well as alleged misrepresentations about the efficacy of self-driving systems and software, and/or the sufficiency of vehicle warnings. Questions over who bears fault for an accident—the driver or the manufacturer—will increase the need for expert testimony and vehicle inspections. Additionally, questions about apportioning liability for malfunctioning autonomous systems will raise complicated issues in connection with managing risk, seeking contribution or indemnification from tortfeasors, and allocating damages.

Electric Vehicles

According to recent estimates, 1% of the approximately 250 million vehicles used in the United States are electric vehicles (EVs), with that number expected to swell by 2030. Concerns over EV batteries, and an alleged risk of combustion, have led to lawsuits against EV manufacturers, as well as the manufacturers of charging products. Questions about who bears liability for charging malfunctions or vehicle combustion, as well as allegations of insufficient testing or hasty design, are likely to pose significant legal challenges in the coming decade.

Global Supply Chain Disruption

Recent supply chain disruptions have led to litigation, arising, in part, from how manufacturers adapt to shortages of critical components. In addition to contract disputes between manufacturers, suppliers, transporters, and retail outlets, companies may find themselves under scrutiny from the class action trial bar over substitute components or improperly vetted suppliers, which plaintiffs allege contributed to defective products, or a failure to comply with product safety standards.

V. Consumer Goods

Finally, concerns over perceived threats to public safety—whether they arise from allegedly toxic or environmentally unfriendly products—are driving an increase in products liability claims involving consumer goods.

Infant Formula

Following the February 2022 recall of infant formula manufactured by Abbott Nutrition, as well as an additional report of an infant death related to possible bacterial contamination received by FDA, consumers and plaintiff attorneys have scrutinized formula manufacturers for allegedly

failing to warn consumers about the risks associated with infant formula consumption, and for marketing these products as safe. Among the chief claims advanced by plaintiffs are that premature babies who are fed certain brand formulas may be at risk of developing necrotizing enterocolitis (NEC), a rare intestinal disorder that can be fatal in many cases. As of November 2023, there were almost three hundred NEC baby formula lawsuits pending in multidistrict litigation, with the majority consolidated in the U.S. District Court for the Northern District of Illinois. Given the intense publicity surrounding the formula recalls, and heightened consumer fears over possible infant health risks, these cases are certain to be closely watched in 2024.

PFAS Litigation

Litigation involving the presence of per- and polyfluoroalkyl substances (PFAS), or so-called "forever chemicals" has boomed over the past several years. Traditionally used in a broad range of consumer goods for their water-resistant properties, PFAS can be found in products as varied as nonstick cookware to drinking water to cosmetics. However, in recent years, these substances have been linked to adverse human health concerns, including cancer. In June 2023, 3M announced the largest settlement over PFAS contamination of drinking water in U.S. history, at approximately $12.5 billion. 3M's announcement followed another recent settlement in MDL litigation between water companies across the country and DuPont, Chemours, and Corteva worth more than $1.1 billion.

Environmental Sustainability Claims

As consumers increasingly emphasize environmental sustainability in their everyday purchasing decisions, increasingly companies have come under fire from plaintiff attorneys for claims that they engage in "greenwashing," i.e., making false or misleading claims to consumers about how environmentally friendly a product actually is. For example, in November 2023, New York State filed a lawsuit against PepsiCo, accusing the food and beverage giant of allegedly contributing to high levels of single-use plastic pollution, failing to warn consumers about the possible health and environmental risks of its single-use plastics, and misleading the public about the company's efforts to fight plastic contamination. Other cases have questioned specific claims by defendants like "100% recyclable," "biodegradable," or "ethical," all the while arguing that defendants engage in (and what plaintiffs describe as) environmentally harmful practices.

Conclusion

Although the individual claims may differ, a review of recent products liability claims levied against industries targeted by the plaintiffs trial bar reveals common threads. For example, the drivers of litigation are the same regardless of the industry, such as, government action (FDA recalls or the enactment of MOCRA), studies (whether legitimate or not) implicating products (talc, PFAS and third-party testing labs) and areas of advanced innovation with new regulatory safeguards (AI and autonomous vehicles). The industries being targeted are industries in flux, driven by changing consumer demands, and unsettled by technological growth and shifting regulatory landscapes. In the absence of clear legal guidance, whether by the courts or regulation keeping pace with technological change, plaintiff attorneys will continue to exploit industry upheaval and change.

Once a product or area is targeted, the playbook is largely the same, with plaintiffs challenging labeling or marketing of the product (Tylenol, hair relaxers, and Exactech) or implicating environmental concerns (ETO, PFAS and the recent pollution action initiated by the New York attorney general). The trial bar then organizes and coordinates on funding, advertising, and executing a strategic filing plan to try to place the heart of the litigation in the most favorable jurisdictions. Plaintiff counsel often seek, through advertising and referral services, to aggregate as many plaintiff claims as possible, both for strategic efficiency and to pressure defendants with the prospect of lengthy and costly litigation.

To counter these plans, it is critical that manufacturers' also coordinate efforts, typically through reliance on trade associations and industry organizations, to shed light on plaintiff tactics like litigation funding, advertising and the advancement of junk science.