

# Product Liability



**Fish & Richardson has unparalleled expertise trying cases where technology and legal complexity intersect.**

Given our rich history of making the complex understandable in our intellectual property trial practice, we are uniquely positioned to litigate product liability matters that combine advanced technology with the intricate legal and regulatory landscape. Fish attorneys have an exceedingly thorough understanding of our clients' technologies and industries. Our experienced litigation teams are adept at managing large, sophisticated cases that include daunting amounts of discovery and proceedings in multiple venues, including district courts, state courts, and before regulatory agencies. Fish's seasoned trial attorneys are skilled at distilling complicated scientific and technical topics into compelling stories that persuade judges and juries.

**What is product liability litigation?** Product liability litigation involves high-stakes, elaborate civil claims—often brought by large groups of plaintiffs—alleging injury caused by a defective drug, device, or product. Product liability matters present multi-front challenges and often implicate controversial scientific, technical, medical, environmental, or regulatory issues, all relating to the safety and effectiveness of products.

One common challenge is strategically managing the large number of cases filed in multiple jurisdictions across the country, which may or may not be brought as class actions. Some matters may be consolidated into multidistrict litigation (MDL) proceedings, which allow federal district courts to temporarily transfer pending cases in multiple districts to a single district for coordinated and/or consolidated pretrial proceedings. Out of the consolidated MDL cases, a representative pool of bellwether cases may then be tried to assess the strengths of both sides' arguments, which in turn may be used to guide settlement discussions. Parallel cases in state courts are also common.

Another challenge is to manage defenses on multiple fronts beyond the court system, as product liability litigation often triggers concurrent proceedings and scrutiny from federal and state investigative and regulatory authorities, as well as congressional inquiries. These types of proceedings and inquiries need prompt attention from savvy counsel who know how to carefully and properly navigate risk and protect enterprise interests. Qui Tam or False Claims Act risks may also arise from whistleblower involvement, and companies and boards may have to simultaneously field and manage disclosure, public relations, and internal investigation responses at a rapid pace.

A successful product liability case requires the ability to present reliable, credible, and favorable expert testimony and to undermine—and ideally exclude—unreliable expert testimony presented by the other side. At the center of every product liability case is the plaintiffs' burden to prove that the allegedly defective product is both capable of causing the alleged injury and did in fact cause the specific plaintiff's injury. These inquiries often involve in-depth analysis and presentation of medical, scientific, and/or technical evidence. Experts such as physicians, epidemiologists, biostatisticians, chemists, and engineers play a critical role in presenting this evidence. Product liability cases also may involve regulatory specialists to address issues such as compliance with FDA regulations.

**Fish's experience in product liability litigation.** Fish offers a deep bench of veteran trial attorneys who have experience litigating in a broad array of fields, including pharmaceuticals, medical devices, automotive, aircraft, motorcycle, industrial equipment, and mining products. Fish attorneys have played critical roles in high-profile products and environmental liability cases, including serving as lead defense counsel in the national Fen-Phen litigation and achieving an acquittal for a high-level executive in the asbestos-related environmental criminal prosecution in *United States v. W.R. Grace*, one of the most significant environmental trials in the history of the country.

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“Fish & Richardson has a reputation among general counsel for being comfortable taking on complex, high-end work with tremendous risk exposure.”

– BTI Consulting

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Fish was named among the Top 15 Most Feared Firms in Litigation by corporate counsel in the *BTI Litigation Outlook 2017* report, and earned high praise for our work in these areas:

- Class actions
  - Complex commercial litigation
  - Complex employment litigation
  - Intellectual property litigation
  - Product liability litigation
  - Securities and finance litigation
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## Recent product liability victories

### • *In re Fresenius GranuFlo/NaturaLyte Dialysate product liability litigation.*

In November 2011, Fresenius' Chief Medical Officer wrote a memorandum which he distributed to medical directors at Fresenius clinics. In the memorandum, he alleged that a study he had commissioned demonstrated that Fresenius' acid-concentrate products GranuFlo® and NaturaLyte®, which are used during dialysis, were causing patients' serum bicarbonate levels to rise, which in turn was causing electrolyte imbalances leading to sudden cardiac arrest and death. Based on the memo, the FDA issued a Class I recall of the products, based on its belief that the products could result in serious injury or death. As a result of the recall, over twelve thousand plaintiffs sued Fresenius alleging that GranuFlo® and NaturaLyte® dialysate products caused cardiac death in hemodialysis patients. The plaintiffs' cases proceeded in multiple jurisdictions, including consolidated MDL and Massachusetts state court proceedings and various independent state court cases, which required a sophisticated strategy for managing simultaneous defenses across multiple fronts.

On the regulatory front, within a few months, the Fish team demonstrated to the FDA that the underlying science and conclusions of the memo were flawed and convinced the FDA to recall the recall. Fish's trial team scored a strategic victory for Fresenius by bringing a successful, outside-the-box motion in limine and related Daubert motion to exclude, as unreliable science, the faulty internal study linking Fresenius' products to increased risk of cardiopulmonary arrest that precipitated the entire case. Building on that success, with the assistance of a nationwide team of top experts, gathered together by Fish, our team broke down the science for the judge and jury and walked them step-by-step through the plaintiffs' faulty chain of causation, resulting in a defense verdict of no causation at the first and only bellwether trial. On the heels of the bellwether trial, Fresenius was able to obtain a favorable global settlement agreement.

### • *Rodriguez v. Gilead Sciences Inc. et al.*

The defendants were sued by an individual plaintiff in a Texas state court alleging that their blockbuster hepatitis-C drug Harvoni had caused him to have heart damage. Fish's team removed the case to federal court and obtained dismissal of their co-defendants (the principal investigator for the clinical trial in which the plaintiff participated and his clinic) at the pleadings stage. The court later granted summary judgment on the plaintiff's remaining claims.

Fish's product liability experience is complemented by our subject matter expertise, which has been honed over decades of excellence in intellectual property law. As the premier patent and high-profile, complex litigation practice in the nation, Fish has unparalleled depth and breadth of technical expertise, proven trial skills, and strong industry knowledge. Fish has more than 300 attorneys with degrees in science or technology, 80 of those with PhDs in their respective fields. Our life sciences, pharmaceutical, medical device, biotechnology, and consumer products practices are particularly well-suited to tackle the complex medical and technical issues presented by product liability litigation.

The seamless integration of Fish's various offices and practice groups allows us to build trial teams to handle the volume of parallel legal proceedings associated with product liability litigation. Our Commercial Litigation group excels at trying intricate, high-profile, and high-stakes business disputes. Our Regulatory group provides valuable insight on regulatory compliance and successfully represents clients before administrative and regulatory agencies, including the FDA. Our False Claims/Qui Tam group guides clients through internal investigations, pre-litigation work aimed at influencing the government's decision to not intervene, and litigating aggressively against whistleblowers, if necessary. Fish's White Collar Defense and Government Investigations group includes practitioners with sterling reputations and deep substantive experience from years in government service as federal prosecutors and enforcers, ready to defend our clients' rights and reach favorable resolutions that make the most sense for the company.

Combining the strength we bring from each of these practice areas with our depth of technical knowledge and our unique ability to make the complex understandable, Fish is changing the playbook on how product liability cases can be managed, conducted, and won.

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Atlanta Austin Boston Dallas Delaware Houston Munich New York Silicon Valley Southern California Twin Cities Washington, DC

Fish & Richardson is a global patent, intellectual property (IP) litigation, and commercial litigation law firm with more than 400 attorneys and technology specialists across the U.S. and Europe. Fish has been named the #1 patent litigation firm in the U.S. for 13 consecutive years and is one of the busiest post-grant firms, representing more petitioners at the PTAB than any other firm. Fish has been winning cases worth billions in controversy – often by making new law – for the most innovative clients and influential industry leaders since 1878. For more information, visit [www.fr.com](http://www.fr.com).