



Issue 3, 2018

● Welcome

Welcome to the third issue of *Product Lines* – our quarterly e-newsletter that focuses on toxic torts and products liability issues.

For this edition, we are reporting on several important and timely legal issues. As you will see, we strive to make these e-blasts both informative and valuable by having our attorneys comment on WHY these issues are important and how they could affect your business.

As always, if you have a particular topic you would like to hear more about, please let us know. Thank you for reading.

The [Toxic Tort Litigation](#) and [Product Liability Litigation](#) Practice Groups

● The Rise of Use of Medical Devices Force FDA to Change the Rules

"In an ever-changing healthcare landscape, FDA seeks a new procedure that will let the market continue to develop but also offer a safe environment for the users."

Why this is important: Through the De Novo Classification Proposed Rule, the FDA aims to modernize the pathway for the review of new, low- to moderate-risk medical devices for which there are no legally marketed predicate devices. If finalized, the proposed rule would establish certain procedures and criteria used in the De Novo classification process, providing market applicants with a better understanding of how to navigate the certification process. Additionally, the proposed rule would establish a 120-day review period. By providing needed structure and clarity to the De Novo classification process, the proposed rule would provide a more efficient means for startup and established applicants to see a new medical device to market. The FDA is accepting comments on the proposed rule until March 7, 2019. Interested parties can submit comments on the proposed rule [here](#). --- [Joseph A. Ford](#)

● Clean Water Act Liability for Groundwater Contamination

"In just the past year, litigation related to the groundwater conduit theory has generated diverging opinions from numerous federal courts, leaving businesses uncertain regarding their potential liability."

Why this is important: The Clean Water Act ("CWA") regulates navigable waters, but generally does not apply to groundwater (water found underground in the spaces in soil, sand and rock). The groundwater conduit theory proposed by CWA citizen suit plaintiffs would hold businesses liable for discharges to groundwater that can be connected to a navigable water source. The Fourth Circuit adopted this theory in April, and the Sixth Circuit rejected it in September, creating a circuit split that many experts believe is ripe for Supreme Court review. If the Supreme Court agrees to hear a groundwater conduit case and validates the theory, liability could be drastically expanded as any spill or accidental discharge could fall under the purview of the CWA--if evidence arises that the affected groundwater is hydrologically connected to a navigable waterway. --- [James E. Simon](#)

● **5 Lawsuits that Could Change the Food Industry**

"From unknown ingredients and debatable labels to the spreading of salmonella and E. coli, this year has not been short of litigation that can make a big impact."

Why this is important: FDA recalls of various foods have increased dramatically in recent years, and one reason is improved technology. According to FDA Commissioner Scott Gottlieb, the FDA now has the ability to test samples from infected patients and use genetic testing to link the pathogens to specific food sources. From beef potentially contaminated with salmonella, Cheerios with alleged trace amounts of an herbicide, to an E. coli outbreak linked to romaine lettuce, this past year alone has seen many common foods face recalls or litigation. In addition to contamination, labeling also has become a source of litigation. For example, labeling a consumer food or drink as "natural" is risky for manufacturers, as there is no legal definition of that word. All of this is important because everyone cares about what they consume and how much they must pay for it. Class actions, recalls and other litigation may be good for public health, but may be bad for your pocketbook. Watch what you eat. --- [Heather Heiskell Jones](#)

● **FDA Updates to Medical Device Safety Action Plan to Enhance Post-Market Safety**

"We're setting an important and ambitious new goal when it comes to device safety: Ensuring that the FDA is consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices."

Why this is important: This announcement follows the FDA's release of its Medical Device Safety Action Plan in which it outlined various actions to improve the safety and efficiency of medical devices. The announcement focuses on the FDA's continuing efforts to overhaul the post-market surveillance system from the current passive system, which relies on reports from device users, to a more active system, which will rely on "real-world evidence and timely receipt of robust safety information." The active surveillance system will result in more real-world data that can be promptly analyzed by the FDA and the medical technology industry to improve the effectiveness and safety of medical devices. A major hurdle the FDA faces in this effort, however, is funding. Currently, the FDA has initiated only pilot programs of the active surveillance system, most recently focusing on devices for women's health. As more funding is secured and the program continues to grow, more participants in the industry will have access to real-world evidence to help identify potential issues related to medical devices and develop effective innovations to improve patient safety. --- [Joseph A. Ford](#)

● **A Coal Ash Spill Made These Workers Sick. Now, They're Fighting for Compensation.**

"The outcome is likely to be closely watched by others around the country who live near coal ash sites, and by companies that produce and dispose of coal ash waste."

Why this is important: Even as coal usage at power plants declines, coal ash and other byproducts make up a significant component of the industrial wastestream. Management of coal ash continues to be debated, as does the science behind the risks of exposure to coal ash. Toxic exposure claims by cleanup workers and potentially neighbors to storage or treatment facilities are a real possibility following the massive Kingston coal ash spill.

--- [Clifford F. Kinney, Jr.](#)

● **Federal Judge Asks California Attorney General if PG&E Committed State Crime**

"U.S. District Judge William Alsup asked the office of Attorney General Xavier Becerra to answer the extent to which any 'reckless operation or maintenance of PG&E power lines would constitute a crime under California law.'"

Why this is important: A federal district court asking a state's top law enforcement official whether a corporation has committed a crime presents an interesting twist on what seems to be a growing trend of state and federal prosecutions against corporations. While the district court is tasked with overseeing the defendant's compliance with the terms of its probation, including that defendant not commit any state, federal or local crimes, the judicial inquiry to a non-party law enforcement agency potentially could lead to a separate state-level investigation or charging decision. Further, the context of the devastating Camp Fire provides another level of complexity, as corporate prosecutions frequently involve complicated questions of criminal intent and prosecutorial discretion. --

- [Gerald M. Titus III](#)

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