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Benson quoted in Law360's article Product Liability Legislation And Regulation To Watch In 2019

Law 360
Michael Best Partner Paul Benson was quoted in the *Law360* article "Product Liability Legislation And Regulation To Watch." See section under USDA GMO Labeling Rule.

How the U.S. Food and Drug Administration modernizes the process for clearing medical devices to enter the marketplace and debates over how plant-based alternatives to milk and meat should be labeled will be among the key regulatory developments product liability attorneys will be watching in the new year.

FDA Update to Medical Device Clearance Pathway

The FDA has proposed updating its process for how it clears most medical devices to be marketed in the United States. The agency in November said it wants manufacturers to be less reliant on older medical devices to show theirs are safe and effective.

Manufacturers going through the 510(k) pathway usually rely on comparisons to older devices already on the market, known as predicate devices, to show a new device is as safe and effective as the older product.

The FDA said it wants companies to focus on using predicate devices that aren't more than 10 years old; currently, almost 20 percent of medical devices are cleared based on a predicate that's older than that. It also said it is considering publicizing medical devices currently on the market that relied on older predicates during the clearance process.

To read the full article, click here.

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