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Bradley Merrill Thompson Quoted in "Will a New FDA User Fee Discourage Medical Device Innovation?"

Bloomberg BNA Medical Devices Law & Industry Report

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Bradley Merrill Thompson ,a Member of the Firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office, was quoted in the *Bloomberg BNA Medical Devices Law & Industry Report,* in "Will a New FDA User Fee Discourage Medical Device Innovation?" by Bronwyn Mixter. *(Read the full version – subscription required.)*

Following is an excerpt:

"While in theory the de novo pathway serves a real need, the amount of the user fee could discourage innovation," Bradley Merrill Thompson, a Washington-based health-care attorney with Epstein Becker & Green PC told *Bloomberg BNA* in a June 1 email. Thompson also is a *Bloomberg BNA* advisory board member.

"There are actually quite a few new product innovations that are clearly low risk, but don't have a natural, existing predicate device so the 510(k) pathway isn't available," Thompson said. "Historically the problem has been that FDA has been a bit too demanding in terms of the evidence it requires, in some cases rising to the level of nearly a PMA."

Thompson said "another problem has been time, in that the de novo process has historically taken way too long."

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"Both of those 'problems' are within the control of FDA, and my sense is that FDA has been a bit more practical in terms of the evidence demanded, and a bit speedier," Thompson said. "But the ultimate problem with the de novo process is that unlike the PMA, anyone who pursues a de novo does so for the benefit of all of their competitors. Basically it creates an easy pathway for competitors to follow along at much less cost for them. That problem is inherent in the process, and is not going to go away. Nonetheless, if FDA is practical in terms of the evidence and speed in terms of the review, some companies will choose this pathway over the PMA."

But Thompson said his fear "is that the FDA is making the user fee so high that it will actually make the PMA process look more attractive for larger companies. Or worse, it will simply discourage new technology from small companies that don't have the resources to pay the fee" and the medical device industry "relies on small companies for many of the most groundbreaking innovations."

"The bottom line is I started to see some hope for the process, but the amount of the user fee I fear will discourage innovation," Thompson said.