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PMA panel votes: More than meets the eye

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FDA advisory panel meetings to review pre-market applications (PMAs) are high-stakes events. While FDA is not bound by the vote of the advisory panel, it has been long-accepted that the agency typically follows the recommendation of the panel.

Which got us thinking: are conventional wisdom and the data on PMA advisory decisions consistent? We previously looked at advisory panel data to see whether some seemingly minor procedural changes in panel voting had affected voting patterns. The data suggested that these changes had had an effect, but not in the way most people would have predicted.[1]

Thus, we decided to take a closer look at the relationship between panel votes and the ultimate outcomes and time to resolution of PMAs. Once again, the results were not what might have been expected.

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For example, between the change in the panel voting system in 2010, and 2016, our study cut-off, 52 devices were reviewed by panels. All but four of them were approved, even though roughly 25% of the individual panel votes had been negative. (Panels vote on safety, effectiveness, and benefit-risk.)

Not all of the devices that eventually got approved sailed through the process; for example, a new study might have been required. Still, it is notable that all but four that got to the panel stage crossed the finish line. (And one of the four failures apparently went out of business after a unanimous, positive panel vote and before approval.)

What about the strength of the vote? Did that lead to shorter times to approval? Eking out a positive 7-6 win on effectiveness is presumably different than a 13-0 vote. In fact, the data show that time to approval post-meeting tended to be faster with stronger panel support ($p < 0.05$). Whether this is due to the influence of the final vote on FDA, or a narrow vote reflects more problematic data is unknowable. There are findings of interest as well, but we won't give them away.[2]

In case you were wondering, looking at more recent advisory panels wouldn't have much impact on the data. In the past 2 1/2 years, there have only been 7 PMA advisory panels: 2 in 2017, 5 in 2018, and not one so far in 2019. (There have, however, been 9 device panel meetings covering other topics in the same time period, including 2 on pending de novo requests.)

PMAs are complicated, and each PMA has its own narrative and story. Moreover, votes are not all that matter. FDA officials always caution that they consider the comments by panel members, and not just their votes. Nor should one gainsay the significance of panel votes on investors, clinicians, and others.

Furthermore, we looked at two factors — votes and approval, but other variables changed over time, e.g., FDA's user fee commitment. Even so, our research suggests that conventional wisdom sometimes needs a good dose of empirical scrutiny.

NOTES

[1] See our prior post at https://bit.ly/2N427mx and our prior article at https://bit.ly/2IXwq8G.

[2] The full article is linked at https://bit.ly/2MhNLj5.

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