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## QUOTED. Aparna Higgins.

by

A panel of experts discussed the fate of the Medicare Coverage for Innovative Technology (MCIT) rule during AdvaMed's annual Medtech Conference. Aparna Higgins, a senior policy fellow at the Duke-Margolis Center for Health Policy, stressed that FDA and CMS criteria are not the same.

"The evidence standards that are used to satisfy FDA safety and effectiveness criteria are not the same that Medicare uses in terms of determining what is reasonable and necessary," she said, "and there's also no way to ensure that there will be evidence upon approval that shows the benefits or risks for Medicare beneficiaries in clinical trials and there is no authority to limit or remove coverage." – Aparna Higgins, senior policy fellow, Duke-Margolis Center for Health Policy

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