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Articles

# FDA Offers Up New Pathway for Drugs That Can't Clear Normal Approval Hurdles

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Law.com spoke with Sheppard Mullin Life Sciences Partner, Dom DiSabatino for an article discussing the FDA's newly announced pathway for approving bespoke treatments aimed at rare diseases that cannot be evaluated through conventional clinical trials. This regulatory innovation opens substantial opportunities for biotech companies, particularly those developing therapies for ultra-rare conditions, by allowing drugs with a plausible mechanism of action to gain approval based on alternative criteria.

DiSabatino offered his insights on the significance and potential impact of the new scheme: "It's incredibly exciting, if it's rolled out in a way that's manageable to navigate," he noted. He further commented on broader implications, stating that the pathway "could also be used to approve broader platforms for developing gene therapies on demand to target harmful mutations." His perspective underscores the FDA's willingness to adopt a practical and flexible approach, heralding possible transformative advances for both patients and biotech developers.

Read the full article here. (A subscription is required)

## Attorneys

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