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Pink Sheet Podcast: US FDA Biosimilar Strategy, Gene Therapy Accelerated Approvals, FDA v. Partisan Politics

by **Pink Sheet Team**

Pink Sheet reporter and editors discuss the impact of FDA biosimilar promotion guidance on the future of the interchangeability designation, upcoming guidance on accelerated approval for gene therapies, and partisan attacks on the agency from Capitol Hill.

Pink Sheet Executive Editor Derrick Gingery, senior writer Sarah Karlin-Smith, Senior Editor Sue Sutter and Editor in Chief Nielsen Hobbs consider whether new biosimilar promotion guidance could be a step toward administratively eliminating the interchangeability designation (:34), the impact of upcoming accelerated approval guidance on gene therapy development (14:15), and whether a recent spate of partisan attacks that US Food and Drug Administration Commissioner Robert Califf had to endure represents a shift in attitude toward the agency (27:13).

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