

Kate Hardey Quoted in *Lexology Pro* on FDA's Proposed PreCheck Program

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In a recent *Lexology Pro* article discussing the US FDA's proposed PreCheck program, which aims to strengthen domestic pharmaceutical manufacturing in response to Executive Order 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines," Health Care Partner Kate Hardey was quoted on the challenges pharmaceutical companies face, including making long-term commitments and contracting decisions amid regulatory uncertainty.

"Pharmaceutical companies often enter multi-year contracts that can be difficult to modify or exit if necessary, making it challenging to make long-term commitments and contracting decisions while the program is being developed," Kate explained.

She also addressed the importance of understanding the program's timelines and scope, particularly for companies planning new construction or facility upgrades.

"For Phase 1 Facility Readiness, proposed timelines for submission and review for pre-operational feedback will be particularly important for timing new construction projects. For Phase 2 Application Submission, it will be important to define expected timelines for the FDA's proposed earlier assessment and inspection activities within the review cycle. Additional questions include whether the program will be applied beyond new greenfield builds to tech transfers or other manufacturing upgrades, such as facility expansions."

Companies looking to address challenges through onshoring efforts might also consider "developing a risk-based matrix for all key manufacturing and supply chain activities to identify key foreign dependencies and evaluate what could be moved or resourced from foreign to domestic sources," said Kate.

["FDA's PreCheck: pharma industry calls for clarity in 30 Sep public meeting,"](#) *Lexology Pro*, October 1, 2025

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