

## Covington Lures Back FDA Drug Quality Leader

By **Jeff Overley**

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Covington & Burling LLP has lured back a former associate after an eight-year stint at the U.S. Food and Drug Administration, giving the firm insider perspective on the agency's fast-evolving approach to drug safety.

Tom Cosgrove, a Covington attorney from 2002 to 2009, is returning to the firm's Washington, D.C., office as partner after serving at the FDA since 2010 in a number of senior positions. Perhaps most notably, Cosgrove was acting director of the FDA's Office of Compliance, which conducts inspections globally to keep unapproved or dangerous drugs out of U.S. pharmacies and medicine chests.



Tom Cosgrove

Recent years have seen the FDA grapple extensively with fraudulent conduct — such as manipulation of manufacturing data — by newer drugmakers in China and India. But a wave of enforcement actions seems to be “causing changed behavior,” Cosgrove told Law360.

“On the issue of data integrity, I believe that companies want to understand what FDA expects and want to satisfy FDA's requirements, and I expect to play a role in helping them meet FDA's expectations,” Cosgrove said.

The globalization of pharmaceutical manufacturing has given rise to elaborate supply chains, and Cosgrove predicted that drugmakers will increasingly place stepped-up scrutiny on business partners, such as contract manufacturers.

“I think companies are looking hard at their supply chain risks and wondering how much they can trust other companies that make up the links in that chain,” he said. “These challenges, brought about by increased globalization, will only continue to grow.”

The FDA's oversight is changing in important ways, Cosgrove noted, singling out FDA recognition of inspections conducted by many European regulators and the FDA's standardization of inspections through its so-called New Inspection Protocol Project.

“Companies need to understand and keep abreast of these changes,” Cosgrove said.

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