

White Collar Defense & Government Investigations

The U.S. Food and Drug Administration (FDA) and the U.S. Department of Justice (DOJ) have recently increased their emphasis on bringing strict-liability criminal prosecutions under the *Park* Doctrine against companies and individual corporate officers for FDA-related violations. Our experience in FDA-related criminal defense work long pre-dates this recent trend, and allows us to effectively represent companies and individuals in FDA criminal enforcement actions. We have represented parties in criminal investigations involving such allegations as falsification of data; failure to properly file adverse reaction reports; improper promotion or advertising of off-label uses; product adulteration, including failure to follow Good Manufacturing Practices (GMPs); and providing illegal gratuities to FDA officials.

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