

DOJ Intensifies Pressure against Corporate Executives in Off-Label Marketing Arena

With the May 10 announcement that three senior Purdue executives had pled guilty to misdemeanor violations of the Food Drug and Cosmetic Act under a doctrine of *vicarious* liability, DOJ revived a rarely used, 30-year-old theory of criminal liability to convict individuals who had done nothing wrong. This marks a significant escalation of DOJ's tactics in the off-label marketing and misbranding arena.

The doctrine used to convict the Purdue executives was created by a pair of U.S. Supreme Court cases: *U.S. v. Dotterweich* and *U.S. v. Park*. Under the *Park* or "responsible corporate officer" doctrine, a corporate officer or manager can be convicted of a misdemeanor under the FDCA without proof of personal wrongdoing if, by virtue of his position in the company, he had the responsibility and authority either to prevent or promptly to correct the violation at issue.

While the doctrine is stated broadly in *Park* and *Dotterweich*, as a matter of policy and practice, FDA has limited its use to cases where the executive or corporate manager had warning from FDA or otherwise knew about the underlying violations and yet failed to take action. Despite this longstanding FDA policy, DOJ chose to prosecute the Purdue executives without evidence that the executives failed to act in the face of knowledge or warnings of FDCA violations. While this may technically fall within the scope of the principle announced in *Park* and *Dotterweich*, it goes well beyond the circumstances in which the doctrine had previously been applied.

DOJ's revival and expansion of the responsible corporate officer doctrine has potentially serious consequences for the pharmaceutical and medical device industries.

- The doctrine is not limited to officers and senior executives. Any corporate manager may face strict vicarious criminal liability under the FDCA if her position is one that gives her the responsibility and authority to prevent or correct violations of the statute.
- An executive or manager facing prosecution under this doctrine may face not only criminal fines of up to \$100,000 per violation, but also imprisonment for up to one year. While the Purdue executives will not be imprisoned under the terms of their plea agreements, they will pay over \$34 million in disgorgement and criminal fines.
- Finally, the responsible corporate officer doctrine is not limited to off-label marketing or misbranding violations. While *Park* and *Dotterweich* involved the FDCA's adulterated food and misbranded drug provisions, the principle of strict vicarious liability that they announced was not limited to those provisions.

While it is difficult to protect adequately against this type of liability, pharmaceutical and medical device manufacturers may want to take a careful look at current compliance policies and practices in this area and address any issues that may exist in their structure or implementation.

Contact Information

If you have any questions about DOJ's revival of the responsible corporate officer doctrine and its potential effect on your business activities, please do not hesitate to contact one of our attorneys below or your regular Ropes & Gray contact.

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