



WHITE COLLAR COMPLIANCE & DEFENSE

ALERT

EVEN WITHOUT KNOWLEDGE OR PARTICIPATION, CORPORATE OFFICERS CAN BE CRIMINALLY LIABLE FOR SUBORDINATES' MISDEEDS

By Eric E. Reed

The Food and Drug Administration and the U.S. Court of Appeals for the D.C. Circuit's treatment of former Purdue Pharma executives is a reminder to executives and in-house counsel, particularly those in regulated industries, that they can face criminal liability and career-ending debarment for their company's conduct, even if the executives did not personally participate in the conduct or even know about it. A copy of the D.C. Circuit's opinion [can be found here](#).

The case arose from Purdue Pharma's conviction of felony misbranding under the Food, Drug and Cosmetic Act. Specifically, the company pleaded guilty to marketing OxyContin (which is also a scheduled controlled substance) as "less addictive." The government also criminally charged some of Purdue Pharma's executives, including its former general counsel, under the responsible corporate officer (RCO) doctrine. That is, the former executives did not participate in the misbranding and had no actual knowledge of the conduct. The former executives pleaded guilty to misdemeanor misbranding.

As is often the case in regulated industries, resolving the criminal exposure did not conclude the matter, as the Department of Health and Human Services' Office of the Inspector General followed up with a 20-year exclusion of the executives from participation in

federal health care programs. This was a career-ending exclusion, as no pharmaceutical company participating in Medicare, Medicaid or other federal health programs could employ the excluded individuals. The exclusion's length was unprecedented, and exceeded both the statutory default of three years and the longest prior exclusion of 10 years.

The Departmental Appeals Board reduced the exclusion to 12 years based on the executives' cooperation, but the damage was done. The D.C. Circuit upheld the exclusion, but remanded the case to the district court with instruction to remand to the agency for purposes of explaining the departure from prior exclusion precedents. Regardless of whether the 12-year exclusion is ultimately reduced on remand, the excluded individuals' records are permanently blemished.

The RCO doctrine is generally limited to the health care and environmental industries, but similar concepts exist in other industries, such as "control person" civil liability for securities violations. For actors in all industries, the Purdue case stands as a reminder of the following:

1. Ignorance of misconduct by subordinates is not always a defense for corporate officers. In-house counsel are not exempt from this practice, as the government continues to co-opt them to a watchdog role.

2. Robust compliance programs, with visible-top level support and regular testing, can prevent violations or at least detect them early enough to mitigate risk and allow the entity to consider self-reporting in an effort to avoid or minimize criminal or regulatory exposure.

3. When violations occur, resolving regulatory or criminal charges may not conclude all liabilities for a particular occurrence. As in the Purdue case, criminal convictions can form the basis for parallel regulatory action, such as debilitating exclusions.

4. In such parallel proceedings, facts admitted or proved in an initial proceeding may bind in the later matters.

5. When navigating such exposure, the guidance of experienced counsel is a must.

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