D.C. Circuit Holds That Former Purdue Pharma Executives Who Pleaded Guilty to Misdemeanor Misbranding May Be Excluded From Participation in Federal Health Care Programs

On July 27, 2012, in *Friedman et al. v. Sebelius*, the United States Court of Appeals for the D.C. Circuit held that the Department of Health & Human Services may exclude from participation in federal health care programs three former Purdue Pharma executives who pleaded guilty to misdemeanor misbranding of Oxycontin. *Friedman* is the first appellate decision to address whether a misdemeanor conviction under the Food, Drug, and Cosmetic Act can expose a defendant to permissive exclusion under 42 U.S.C. § 1320a-7(b). *Friedman* holds that an individual will be subject to permissive exclusion "if the conduct underlying the conviction is factually related to fraud." The *Friedman* decision — a full copy of which can be found here — underscores the value of obtaining, if possible, some type of assurance from the government that HHS will not seek exclusion if a corporate or individual client agrees to plead guilty to a misdemeanor FDCA offense.

On May 10, 2007, Purdue Pharma pleaded guilty to felony misbranding, admitting to allegations that it falsely marketed Oxycontin as posing a lower risk of abuse and addiction than non-time released painkillers. On that same day, three of the company's top executives — Michael Friedman (president), Howard Udell (general counsel), and Dr. Paul Goldenheim (medical director) — pleaded guilty, under the so-called "Responsible Corporate Officer doctrine," to "misdemeanor misbranding . . . for their admitted failure to prevent Purdue's fraudulent marketing of Oxycontin." In their plea agreements, the executives disclaimed any knowledge of the fraudulent marketing of Oxycontin; they admitted only that they failed to discharge their "'responsibility and authority to prevent in the first instance or to promptly correct' the misrepresentations certain unnamed Purdue employees made regarding Oxycontin."

Several months after the executives' pleas were entered, the Office of the Inspector General determined that they "should be excluded from participation in Federal health care programs for 20 years, pursuant to 42 U.S.C. § 1320a-7(b)(1)," which permits HHS to exclude an individual convicted of "a misdemeanor related to fraud." HHS's Departmental Appeals Board ("DAB") later reduced the exclusion period to 12 years, but it rejected the executives' argument that their convictions for "misdemeanor misbranding" did not constitute "'misdemeanor[s] relating to fraud.'"

The executives sought judicial review of the DAB's order. The district court agreed with the DAB that, "by its plain terms," § 1320a-7(b)(1) "appears to permit the exclusion of anyone convicted of an offense 'having a connection with or reference to' fraud . . . in the delivery of a health care item or service." The district court further held that the executives' misdemeanor convictions met that criterion because they arose out of the misleading marketing practices underlying Purdue Pharma's felony misbranding plea.

The D.C. Circuit affirmed the district court's decision, holding that § 1320a-7(b)(1) "unambiguously" permitted HHS to exclude the executives. The D.C. Circuit was not troubled by the fact that, under its interpretation of the statute, "one 'who pleads guilty [to] a strict liability misdemeanor offense that requires no proof of conscious wrongdoing, fraud, or falsehoods'" is subject to a "career-ending disabilit[y] . . . based on misconduct by others that he had no knowledge of." "Surely," the court wrote, "the Government constitutionally may refuse to deal further with senior corporate officers who could have but failed to prevent a fraud against the Government on their watch."

The D.C. Circuit's opinion does contain a silver lining for the executives. The court held that "the decision of the DAB was arbitrary and capricious with respect to the length [12 years] of the exclusion." The court did "not suggest the [executives'] exclusion for 12 years based upon a conviction for misdemeanor misbranding might not be justifiable." The court was concerned, however, "that the DAB did not justify" the length of the exclusion. Although the DAB will have a chance to provide an adequate justification on remand, the court's opinion suggests that it will not be easy for the DAB to come up with a "reasoned explanation" for such a lengthy exclusion period.

If you would like further information, please contact the Ropes & Gray attorney who usually advises you.