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Federal Government Urges Appellate Court to Uphold Executives' Exclusions from Federal Health Care Programs

By Christopher R. Hall and Gregory G. Schwab

We have previously written (in prior *White Collar Watch* articles and *The Champion*) about the federal government's attempt to exclude from federal healthcare programs three former Purdue Frederick Co. ("Purdue") executives. The government recently filed a brief in the Court of Appeals for the District of Columbia to affirm a district court ruling that sustained an order debaring the executives for a period of 12 years. The lower court's order effectively ended the managers' careers because no company that receives funds directly or indirectly from federal healthcare programs may employ them during the exclusion period. The government's most recent brief seeks to cement the ability of the Secretary of HHS to end the careers of executives convicted under the "responsible corporate officer" ("RCO") doctrine.

We begin with a brief overview. In 2009, HHS excluded the three Purdue executives for 20 years after they pleaded guilty to a misdemeanor provision of the Food Drug and Cosmetic Act. Section 301 of the FDCA holds persons who introduce misbranded or adulterated food or drugs into interstate commerce strictly liable and subjects them to a term of imprisonment of not more than one year. Typically, criminal laws require knowledge or intent before criminal liability attaches, but Congress—in enacting this provision of the FDCA—and the Supreme Court—in upholding the provision—have established the so-called responsible corporate officer doctrine. By operation of this exception to the criminal intent requirement, people who have a "responsible relation" to the illegal sale of adulterated or misbranded food or drugs are guilty of a misdemeanor offense on a showing that they failed either (1) to prevent the offense, or (2) to remedy the wrong immediately upon learning of it. The Purdue executives agreed in a criminal proceeding that they had a "responsible relationship" to the illegal distribution by their company of an addictive pain killer called OxyContin, but have opposed an attempt by the Secretary of HHS to administratively exclude them from the healthcare industry for 20 years. They have opposed the Secretary's effort on the ground that the exclusion statute and administrative regulations require a showing of fraud, unlike the criminal statute. An HHS Departmental Appeals Board upheld the exclusion but reduced the period from 20 to 12 years. The executives appealed from this ruling first to a federal district court and now to the D.C. Court of Appeals.

The Purdue executives appealed on the grounds that: (1) their misdemeanor convictions are not an excludable offense under debarment provisions of the Social Security Act, and (2) HHS abused its discretion and acted in an arbitrary and capricious fashion when it meted out the 12-year exclusion period. The executives cite as support the fact that their convictions were based merely on their status as “responsible corporate officers” and not on a showing of intent or actual knowledge of wrongdoing by them.

The government filed its appellate brief on October 5, 2011. It makes an argument in two steps. First, the government notes that the Social Security Act authorizes the Secretary to exclude persons found guilty of a crime “relating to” fraud or the unlawful distribution of a controlled substance. 42 U.S.C. § 1320a-7(b)(1), (3). The government then notes that the failure of Purdue Executives to prevent and detect misbranding of OxyContin by their company “related to” fraud in the ordinary sense of that term regardless of whether they lacked personal knowledge of their employees’ fraudulent scheme or embraced their employees’ bad intent.

The government also asserts that the appeal represents a collateral attack on the RCO convictions, and urges the Court of Appeals not to provide the executives with a “forum for questioning the fairness or reasonableness of federal prosecutors’ decision to prosecute the Purdue Executives as responsible corporate officers.”

Oral argument in the U.S. Circuit Court of Appeals for the D.C. Circuit is set for December 6, 2011. The Purdue executives will likely submit a reply brief in the coming weeks.

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