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The Park Doctrine and Clinical Trials

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The Park Doctrine, based on a 1975 U.S. Supreme Court decision, is also known as the "Responsible Corporate Office Doctrine." The Park Doctrine states that a person in charge of the operation of a business or part of a business, such as a manager, may be held responsible for the actions of people who report to him or her, even if the manager did not personally participate in the actions.[1] The Doctrine potentially holds a manager responsible for a misdemeanor violation whether or not the person "acted with intent or even negligence."[2]

Under the Doctrine, a manager's failure to appropriately supervise, prevent or remedy deficiencies may result in criminal, civil and administrative penalties. Once a person has been convicted of a misdemeanor, per the Doctrine, under the Food, Drug and Cosmetics Act (the Act), any subsequent violation of the Act is a felony. This is true even if there is no proof that the manager acted without the intent to defraud or mislead. As a result, such misdemeanors and/or felonies may serve as the basis of debarment by the FDA.[3]

Use of the Doctrine fell out of favor in the 1980s. However, it has recently received significant attention because of the FDA's renewed willingness to work with the Office of Inspector General (OIG) and the Department of Justice (DOJ) to use the Doctrine to prosecute individuals in supervisory positions.

Recent Applications

There has been a recent uptick in the application of the Park Doctrine by the DOJ. Most significantly, the DOJ applied the Park Doctrine in the Purdue Fredrick case in 2007 and the Synthes case in 2011.

Purdue Fredrick

In the Purdue Fredrick case, the company allegedly promoted, and/or allowed to be promoted, Oxycontin (the extended release version of oxycodone) as less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications.[4]

After negotiations with the U.S. Attorney/DOJ's offices, Purdue Fredrick agreed to pay $600 million in criminal and civil penalties and agreed to subject itself to independent monitoring. In addition, due to the Park Doctrine, the president, former chief medical officer, and top lawyer of Purdue Pharma (a subsidiary of Purdue Fredrick) personally pled guilty to misleading regulators, doctors and patients about the drug's risk of addiction and its potential for abuse.[5] These executives agreed to pay $34.5 million in fines.[6]

Synthes

In the Synthes case, the U.S. Attorney/DOJ's offices and the FDA worked together to prosecute corporate officials for the unapproved testing of bone cement that resulted in the death of three patients.[7]

As a result of this prosecution, executives of the medical device company were sent to jail, and both Synthes and its subsidiary Norian Corp. pled guilty to corporate healthcare fraud

charges and agreed to pay $23 million in fines. Additionally, under the terms of the settlement agreement, Synthes agreed to sell Norian (which it did, to Johnson & Johnson).[8]

The Decision to Prosecute

The FDA asserts that knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution under the Doctrine, but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation. The FDA has outlined a list of 10 factors it considers when applying the Doctrine:[9]

- The individual's position in the company
- The individual's relationship to the violation
- Whether the individual had the authority to correct or prevent the violation
- Whether the violation involved actual or potential harm to the public
- Whether the violation was obvious
- Whether the violation reflected a pattern of illegal behavior and/or failure to heed prior warnings
- Whether the violation was widespread
- Whether the violation was serious
- The quality of the legal and factual support for the proposed prosecution
- Whether the proposed prosecution is a prudent use of agency resources

The FDA points out that these factors are illustrative but neither binding on the FDA nor comprehensive.

Exposure in Clinical Trials

The FDA and DOJ, to date, have applied the Doctrine infrequently. They have, however, applied it to clinical trials when one of the issues was the absence of IND or IDE approval. Additionally, they have made it clear that they will apply the Doctrine when they deem it necessary and appropriate. Given the FDA's recent, more aggressive enforcement actions, potential enforcement under the Doctrine is not an idle threat.

Exposure to the Park Doctrine often occurs under the auspices of the Food, Drug & Cosmetics Act (FDCA). Its application is not limited to clinical research activities by study sponsors, but may also be applied to the actions of contract research organizations (CROs), research sites, and their providers. In other words, under the Doctrine, the FDA can hold the chief compliance officer, chief legal officer, chief medical officer, chief executive officer, and appropriate middle managers of multi-billion-dollar pharmaceutical companies or healthcare systems responsible for the actions of a principal investigator or even a study coordinator.

Defenses and Prevention

Defenses

Critics of the Park Doctrine assert that the policy extends far beyond what was originally contemplated in the Supreme Court decision. The DOJ stated in its own brief to the Supreme Court, in the Park case, that it is the government's policy "to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations, but fail to do so." As a result, although the Park Doctrine is currently interpreted as a no intention/strict liability offense, there may be a potential defense in asserting that

some level of negligence is required. Other potential defenses include demonstrating that the imposed requirements are "objectively impossible" or proving that the "responsible corporate agent" being prosecuted was "powerless" to prevent or correct the violation."[10]

Prevention

Exposure under the Doctrine can result from deficiencies in training or supervising employees or contractors in their legally required responsibilities. The FDA and DOJ are most likely to apply the Doctrine to deficiencies that rise to an egregious level, based on the factors listed above.

One way to help prove that the responsible corporate agent being prosecuted was not negligent and was "powerless" to prevent or correct the violation(s) is to demonstrate that he or she planned, created, managed, and/or participated in a comprehensive and legitimate compliance program that, despite good intentions, did not prevent noncompliance.

The OIG for the Department of Health and Human Services (HHS) has set forth initial recommendations on developing a compliance program. The components of such a program include the following:

- Implementing written policies and procedures
- Designating a compliance officer and compliance committee
- Conducting effective training and education
- Developing effective lines of communication
- Conducting internal monitoring and auditing
- Enforcing standards through well-publicized disciplinary guidelines
- Responding promptly to detected problems and undertaking corrective action[11]

Organizations with significant involvement in clinical research typically have a quality assurance/regulatory affairs program that covers Good Clinical Practice and human subjects protection requirements. However, exposure under the Park Doctrine is not merely limited to these areas, but also to violations of other laws and regulations, including the False Claims Act and the Anti-Kickback Laws. It is thus important that organizations create a formal compliance program appropriate to the extent of its activities. Such a compliance program protects not only the organization and its management but also the study subjects. The threat of an enforcement action under the Park Doctrine should not be required to motivate compliance, but it is an exceptionally big stick for the FDA and DOJ to wield when they deem it necessary.

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