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Alison Frankel's **ON THE CASE**

Analysis: U.S. court tests liability of healthcare execs

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NEW YORK, Dec 6 (Reuters) - After decades in relative obscurity, a legal doctrine that holds corporate officers strictly liable for company wrongdoing is finding its way back into high-profile health-care prosecutions.

The "responsible corporate officer" doctrine, which establishes a misdemeanor charge for violations of the Federal Food, Drug and Cosmetic Act, provides for a prison sentence of up to one year, but defendants often receive only probation.

Recently the government has been seeking to reinvigorate the doctrine, and executives are finding themselves facing stiffer penalties than they had ever imagined.

On Tuesday, the Department of Health and Human Services will seek to convince a federal appeals court to uphold a 12-year ban of three former Purdue Pharma executives from any involvement in government-financed health-care programs. The executives had pleaded guilty in 2007 to misbranding of OxyContin.

And on Nov. 21, three former executives at the medical-device company Synthes Inc received prison sentences of between five and nine months each for their role in an illegal test of a bone-cement product. The government claimed that Synthes, which agreed to be bought by Johnson & Johnson in April, tried to cover up its conduct after three patients treated with the product died during surgery.

In pleading guilty under the doctrine, the Synthes executives did not admit knowledge of the test, but that was no help to them. The doctrine creates a strict-liability offense, meaning that prosecutors don't have to prove that an executive was even aware of an alleged violation, such as promoting drugs or medical devices for unapproved uses. They must only establish that the executive was in a position of responsibility to prevent the offense.

IMPORTANT TEST CASE

The principle behind the doctrine was validated by *United States v. Park*, a 1975 U.S. Supreme Court case affirming the misdemeanor conviction of John Park, the CEO of a national food chain, who had been charged with allowing warehoused food to be exposed to rodent contamination. The Court held that to convict Park, the jury did not have to find that he was aware of the unsanitary conditions, only that he was in a position of authority to prevent them.

Prosecutors employed the doctrine sparingly over the next few decades, concerned that overuse would invite unwanted judicial scrutiny.

"Sooner or later a court might change its mind and say this is ridiculous, this is unconstitutional," said Paul Hyman, a former attorney in the Chief Counsel's Office of the U.S. Food and Drug Administration and now a director at the law firm of Hyman, Phelps & McNamara.

But earlier this year, following a government report critical of the FDA's oversight of its criminal investigations, the agency revised its policies and procedures regarding misdemeanor prosecutions.

The Purdue Pharma case, which is before the U.S. Court of Appeals in Washington, D.C., could be an important test for the newly-invigorated application of the doctrine, as the government attempts to find out how tough it can get on executives even in the absence of evidence that the executives knew of any wrongdoing.

'EFFECTIVELY ENDED THEIR CAREERS'

In court papers, Carter Phillips, a well-known Supreme Court litigator who leads the Purdue Pharma defense team, argued that the 12-year ban -- which he said "effectively ended appellants' careers" -- is unreasonable and unsupported by the evidence. The defense cited *Morissette v. United States*, a Supreme Court ruling that acknowledged the validity of strict-liability convictions involving penalties that "are relatively small, and conviction does no grave damage to an offender's reputation."

By that standard, Phillips argued, the Purdue executives' punishment does not fit their crime.

"By employing this extraordinary species of criminal liability, the government avoided the substantial burden of proving any fraudulent conduct by appellants," Phillips wrote in a brief to the appeals court. "It did so for good

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reason: There was no evidence that appellants were aware of any misbranding of OxyContin, the drug their company manufactured."

But last December, in a 30-page decision upholding the ban, U.S. District Judge Ellen Segal Huvelle in Washington, D.C., noted that the consequences of the penalty "are not nearly as dire as plaintiffs contend, as plaintiffs remain free to seek private employment at a company that does not rely on federal or state funds."

The future of the responsible corporate officer doctrine could depend on whether, in fact, executives who plead guilty under it are able to find other employment.

Cory Andrews, a lawyer with the Washington Legal Foundation, which filed an amicus brief on behalf of the Purdue defendants, said that as the severity of penalties increase for misdemeanors, so do the odds of a constitutional challenge.

"Arguably, where the deprivation is very small, the due process violations are not as significant," Andrews said. "But where the deprivation goes to someone's ability to earn a living -- I think that raises the constitutional temperature."

(Reporting by Andrew Longstreth)

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