OIG seeks to exclude Forest’s chief executive officer

Forest Laboratories said last week that its Chief Executive, Howard Solomon, plans to challenge the HHS Office of Inspector General’s (OIG) attempt to exclude him from federal healthcare programs. The OIG notified Solomon of the potential action on April 12. According to Forest, the agency said the potential exclusion is connected to the company’s $313 million settlement in September 2010 to resolve criminal and civil charges that it marketed three drugs for off-label uses, distributed a drug that was not FDA-approved, and obstructed the government’s investigations.

Forest was quick to point out that the settlement included no finding of knowledge or wrongdoing by Solomon. “The only basis given in the letter notifying Mr. Solomon of the potential action is that he is ‘associated with’ Forest,” the company said in a statement.

The OIG does not comment on potential exclusions, but the agency is widely expected to use its permissive exclusion authority under Section 1128(b)(15) of Social Security Act to exclude Solomon. If so, it would represent a particularly significant development, because unlike the three senior executives of Purdue Pharma who were excluded under the Park Doctrine following misdemeanor pleas in 2007, and the recent exclusion of the CEO of K-V Pharmaceuticals, who later pled guilty to felony misbranding charges, Solomon would represent the first permissive exclusion by the OIG of a senior pharmaceutical executive who was not personally charged with any wrongdoing. There is no suggestion at this point that he will be.

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Former GSK associate general counsel indicted by DOJ – again

GSK’s former Associate General Counsel, Lauren Stevens, was re-indicted on charges of obstruction and making false statements, the Justice Department announced last week. The indictment returned late Wednesday in the District of Maryland contains essentially the same charges that were brought against Stevens in November 2010 – one count of obstructing an official proceeding, one count of concealing and falsifying documents to influence a federal agency, and four counts of making false statements to the FDA.

On March 23, the original indictment was dismissed by District Court Judge Roger Titus. Because the dismissal addressed jury instructions by the prosecutors rather than any intentional wrongdoing it was widely expected that DOJ would seek another indictment (see Rx Compliance Report, April 7, 2011). Titus set a tentative trial date of April 26.
OIG seeks to exclude Forest’s chief executive officer

“Numerous other major pharmaceutical companies have pled guilty to much more egregious offenses,” said Forest V.P. and General Counsel, Herschel Weinstein, “and none of them has faced the exclusion of a senior executive who has not himself been convicted of a crime or pleaded guilty to a crime.” Weinstein contends the OIG would be using a statute never used under these circumstances that would exceed the bounds of its authority.

This is where the alphabet soup of exclusion authorities, as detailed by Sidley Austin’s Paul Kalb in the article that follows, gets rather complicated. In fact, the OIG used its permissive exclusion authority under Section 1128(b)(15) of the Social Security Act to exclude Marc Hermelin, the former chairman of the board and CEO of K-V Pharmaceuticals. That marked the first time the OIG excluded a drug company executive without first bringing criminal charges, says former federal prosecutor, Christopher Hall. The OIG took that action after a subsidiary of K-V pleaded guilty to felony misbranding charges in March 2010.

There are differences between K-V’s Hermelin and Forest’s Solomon, however. Most notably, four months after the OIG excluded Hermelin, he pled guilty to two misdemeanor violations of the Food, Drug and Cosmetic Act (FDCA) pursuant to the Responsible Corporate Officer doctrine.

The respective size of the two companies also varies dramatically. Moreover, the position of the 82-year old Solomon at Forest should not be underestimated. One of the highest paid industry executives, Solomon has been CEO of Forest Laboratories since 1977. He is also Chairman of the Board. During a reorganization last year in November 2010, he also assumed the title of president.

For his part, Hermelin was sentenced to a month in jail and fined $900,000. While that may not send shockwaves in some quarters, any jail time under the Responsible Corporate Officer doctrine is significant, says Hall. “Section 333 of the FDCA relegates non-intentional violations of section 331 to misdemeanor status, for which a presumption of probation by custom exists,” he explains. “In this context, Hermelin’s sentencing to jail represents a milestone for the government.”

Permissive exclusion

It is important to note that much of the recent discussion about excluding pharmaceutical executives has revolved around use of the Responsible Corporate Officer doctrine, otherwise known as the Park Doctrine. However, if the OIG uses its permissive exclusion authority to exclude Solomon and he is never personally charged with any wrongdoing, the Park Doctrine would not apply in this instance.

The OIG has made clear in policy statements that it does not depend on convictions to exclude executives, notes Hall, a partner with Saul Ewing in Philadelphia. He points out that Section 1128(b)(15) of Social Security Act, 42 U.S.C. §1320a-7(b)(15) authorizes (but does not require) the Secretary to exclude individuals who control a sanctioned entity. “That’s how the OIG proceeded against Hermelin,” says Hall. “I presume that’s how they will proceed against Solomon.”

While there is no reason to believe that DOJ will charge Solomon, he was chief executive at Forest when it pleaded guilty to obstructing the FDA, distributing an unapproved new drug, and distributing a misbranded drug. According to Hall, this conduct makes Forest a “sanctioned entity” within the meaning of Section 1128(b)(15) of Social Security Act, 42, U.S.C. §1320a-7(b)(15), and subjects Solomon to exclusion under this provision.

Immediate litigation planned

The OIG’s letter gives Mr. Solomon 30 days to respond and explain why he should not be excluded. Should Solomon’s argument fall short, he would be required to step down from his present executive positions, unless the effectiveness of such exclusion is enjoined by a court. “Mr. Solomon plans to commence immediate litigation to prevent such exclusion from taking effect if HHS-OIG determines to proceed,” said the company.
Forest Board member and Chairman of the Audit Committee William Candee III, said it would be “completely unwarranted” to exclude a senior executive against whom there has never been any allegation of wrongdoing. He credits Solomon with setting “a tone of the highest integrity from the top” and says the company has significantly enhanced its sales force monitoring and compliance procedures under his direction.

Christopher Hall, Partner, Saul Ewing, Philadelphia, chall@saul.com

Former InterMune CEO gets probation; Judge rejects prison sentence sought by prosecution

Last week, W. Scott Harkonen, the former CEO of InterMune Inc., was sentenced to three years probation for wire fraud in connection with a 2002 press release about the results of a clinical trial of InterMune’s drug Actimmune. Harkonen’s sentencing is not the asterisk on this long-running case that it might appear to be at first glance.

At the sentencing last week, U.S. District Judge Marilyn Hall Patel rejected the government’s assertions that Harkonen’s actions caused any loss or harm to anyone. Pointing to this lack of harm, the Judge rejected the government’s request for 10 years of imprisonment and $1 million fine, and sentenced him to three years probation, 200 hours community service, a $20,000 fine, and six months home detention, the latter to be served only if the appeal is unsuccessful.

In addition to failing to prove any harm, says Harkonen’s attorney, Mark Haddad of Sidley and Austin in Los Angeles, the government has repeatedly conceded that the data that were reported in the press release were all accurate and that the prosecution is based on its conclusions.

According to Haddad, the argument the government made to the jury that the 2002 press release is “fraudulent” reflects “a profound confusion” over basic scientific principles and expresses a view that many mainstream biostatisticians and medical researchers reject – and that the government itself rejected in its recent Matrixx Initiatives brief. Harkonen and his legal team plan to appeal the lower court’s rulings.

This case will be examined in the next issue.

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OIG’s exclusion authority could face stiff test

Former Justice Department attorney, Laurence Freedman, says the OIG’s attempt to exclude Forest Laboratories CEO, Howard Solomon, will be an important test of the OIG’s “very aggressive” attempt to use its (b)(15) exclusion authority. “Hopefully, federal courts will restrain the OIG’s use of the (b)(15) authority to exclude individuals with no demonstrated culpability,” says Freedman, a partner with Patton Boggs in Washington, D.C.

In short, he says, the OIG’s attempt to make an example of certain senior pharmaceutical executives amounts to a “widespread application” of its exclusion authority that potentially extends to all executives of companies that have resolved federal investigations. “Of the OIG’s 10 factors for use of its (b)(15) authority,” he adds, “only two – at most – have anything to do with an individual’s actual conduct.”

The OIG has been telegraphing expanded use of exclusion against senior pharma executives for more than a year. In several high-profile statements, the OIG’s longtime Chief Counsel, Lew Morris, and other agency officials, have warned that the agency is considering exclusion of senior executives and mandatory divestiture of products as a means of dealing with pharma companies that have been subject to multiple fraud settlements.

OIG Chief Counsel makes case for exclusion

Last month, Morris outlined the case for exclusion before the House Ways and Means Subcommittee on Oversight. In imposing discretionary exclusions, he said, the OIG must weigh the fraud and abuse risks to the programs and beneficiaries against the impact on patient access to care if the provider or entity is excluded from the federal health care programs. “Some hospital systems, pharmaceutical manufacturers, and other providers play such a critical role in the care delivery system that they may believe that they are ‘too big to fire,’” he said in written testimony.

Morris said the OIG is concerned that providers engaged in health care fraud may consider civil penalties and criminal fines “a cost of doing business.” As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue, he said.
Morris singled out the pharmaceutical industry, pointing out that some major drug companies that have been convicted of crimes and paid hundreds of millions of dollars in False Claims Act settlements continue to participate in the federal health care programs, in part because of the potential patient harm that could result from exclusion.

“One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies,” said Morris. “By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.”

To illustrate his point, he pointed to the OIG’s exclusion of three former executives of Purdue Pharma in 2008, based on their convictions for misbranding of the painkiller OxyContin. Each of the executives was convicted based on his status as a responsible corporate officer, he noted.

Permissive exclusion highlighted
Morris then highlighted the OIG’s discretionary authority under section 1128(b)(15) of the Social Security Act to exclude certain owners, officers, and managing employees of a sanctioned entity even if the executive has not been convicted of a crime. The OIG has used this exclusion authority in over 30 cases since it was added to the statute in 1996. But until recently, he said, the agency typically applied this exclusion authority to individuals who controlled smaller companies, such as pharmacies, billing services, and DME companies, rather than executives of large complex organizations like a drug or device manufacturer.

The OIG intends to use its exclusion authority more broadly, he told the subcommittee. “We do not propose to exclude all officers and managing employees of a company that is convicted of a healthcare-related offense,” he said. “However, when there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization, OIG will operate with a presumption in favor of exclusion of that executive.”

Whistleblower secrecy remains safe... for now

In a split 2–1 decision on March 28, 2011, the 4th Circuit U.S. Court of Appeals upheld the automatic 60 day sealing provision of the False Claims Act. The suit, brought by the American Civil Liberties Union, the Government Accountability Project and OMB Watch, alleges the secrecy unlawfully blocks the public’s access to judicial proceedings and violates the whistleblower’s right to freedom of speech by forbidding them to discuss the misconduct. They also argue it violates the separation of powers doctrine by not allowing judges to decide on case by case basis whether the matter should be sealed.

The ACLU alleged specifically that the sealing of qui tam lawsuits was hiding Iraq war costs as well as the possibility of war profiteering. Judge James Dever, III states in the majority decision that the sealing provision protects the integrity of ongoing fraud investigations. In response to the plaintiffs’ claim that sealing qui tam complaints violates the separation of powers doctrine by not allowing judges to decide on case by case basis whether the matter should be sealed.

The majority opinion states that whistleblowers are not forbidden from discussing the underlying misconduct that caused them to bring the complaint, rather they are only prohibited from discussing the existence of the complaint. They also ruled the plaintiffs had no standing to make the argument, since they could not produce a whistleblower who wanted to talk about the fraud and abuse but was prohibited from doing so.

In a dissenting opinion, Judge Roger Gregory stated transparency was key to the fight against fraud and abuse. Additionally, he stated the seal provision should be decided by judges on a case by case basis, allowing for more public review.

Note: According to the ACLU’s Amanda Simon, no decision had been made on whether to appeal.

This was excerpted from Pietragallo Gordon Alfano Bosick & Raspanti’s April 2011 issue of Whistleblower Update.