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White Collar and Government Enforcement Practice

White Collar Watch

The Newsletter of the White Collar and Government Enforcement Practice

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Tools of the Trade: BP Case Shows Advantage of Pretrial Motions

By Christine M. Pickel

IN BRIEF

- **A recent defense victory related to the BP oil spill exemplifies the smart use of a pre-trial motion in limine.**
- **Trial counsel should use motions in limine to exclude irrelevant and inflammatory facts.**

Defense counsel in white collar cases often face a seeming uphill battle against prosecutors, whistleblowers and other colleagues-turned-government-witnesses. When fighting the war of a criminal prosecution, counsel should strive to win the motion in limine battle. Motions in limine provide an opportunity before trial to limit the government's ability to introduce irrelevant and unfairly prejudicial evidence. A successful motion also serves to focus the court on the essential elements of the crimes charged and no more. A well-timed strategic motion in limine may also generate positive momentum for the defense in advance of trial.

Defense counsel in the closely watched prosecution of *United States v. Kurt E. Mix* has employed this tactic to the defendant's clear advantage. Mix is the first BP engineer whom the government has charged with obstruction of justice in the wake of the infamous 2010 oil leak in the Gulf of Mexico. The allegations stem principally from Mix's deletion of information from his cell phone before his electronic files were to be turned over to BP's attorneys. Counsel for Mix has used a motion in limine to successfully bar the government from even mentioning during trial:

- the 11 deaths resulting from the explosion
- the size of the spill
- any potential pre-spill misconduct by BP
- BP's guilty plea to criminal charges

The District Court for the Eastern District of Louisiana also ordered that references to the 11 deaths and the size of the spill be stricken from the superseding indictment. *See U.S. v. Mix*, No. 2:12-cr-00171-SRD-SS, Docket No. 362, at p.2-3 (E.D. La., May 7, 2013).

According to the ruling, the District Court relied on Federal Rule of Evidence 401, which defines "relevant evidence," to support its conclusion that BP's pre-spill conduct and guilty plea were both irrelevant and "of no consequence in determining the criminal charges against Mr. Mix" where Mr. Mix's allegedly criminal conduct occurred "entirely after the explosion." Evidence Rule 403, which bars the admission of relevant evidence where unfair prejudice outweighs the probative value of the evidence, rendered references to the 11 deaths and the size of the oil spill inadmissible. In contrast, and applying the same Rule 403 balancing test, the District Court found that references to the flow-rate of the oil spill during the response process admissible. The District Court concluded in its ruling that evidence of flow-rate would provide "context for attempting to discern Mr. Mix's motive and intent" and that the prejudice did not outweigh the probative value of such evidence. Nonetheless, the District Court sided with the defense to the extent that it limited such references "to those made by individuals involved in the response effort who have sufficient expertise to discuss the rate. . ." where flow rate was a bone of contention, according to the ruling.

We should not underestimate the importance of this tactical victory for the defense. The successful motion in limine has left the government with a far more "plain vanilla" obstruction of justice case without troublesome details which would have appealed to the jury's emotions. Instead, the jury will hear evidence tailored to the elements of the crimes charged. White collar cases often encompass extraneous facts and consequences that cause the conduct at issue to feel inherently punishable to a jury. The *Mix* case exemplifies such a situation – the act of deleting text messages and emails from the defendant's cell phone did not cause the spill and the deaths that resulted from the explosion. The defendant's successful motion in limine will free Mr. Mix from the burden of defending the actions of BP that led to the massive spill and the deaths of 11 men. White collar defense attorneys should consider using the same pre-trial tactic when defending against discrete criminal allegations which are part of a larger web of prejudicial events.

Postscript: At the time of publication, the United States had filed a Second Superseding Indictment. No new counts are alleged, but the superseding indictment adds the allegation that Mr. Mix admitted to deleting some text messages and voicemails. The superseding indictment also reduced the number of text messages that Mr. Mix allegedly deleted.

Increased cGMP Enforcement has Gone International: South Korean Action Against Johnson & Johnson Serves as Warning

By Christopher Hall and Matthew Smith

IN BRIEF

- **In both the United States and abroad, food and drug regulatory and enforcement agencies are increasing current Good Manufacturing Practices enforcement, including criminal sanctions.**
- **Companies manufacturing and selling products outside the United States should take heed of the increased international trend in enforcement actions.**

The U.S. Department of Justice has pursued criminal sanctions for current Good Manufacturing Practices ("cGMP") violations with increasing frequency since roughly 2009. It now appears that our federal government is not alone. Other

countries, with their own regulatory agencies mirroring the U.S. Food and Drug Administration, are stepping up their enforcement game. South Korea's recent enforcement action initiated against Johnson & Johnson regarding Children's Tylenol provides a good example.

Last month, South Korea's food and drug regulator, the Ministry of Food and Drug Safety ("MFDS"), announced its intention to open an investigation and seek criminal charges following a recent recall of 1.7 million bottles of Children's Tylenol produced by Johnson & Johnson's South Korea subsidiary Janssen Korea Ltd. The recall occurred earlier this spring after an audit discovered that some bottles of Children's Tylenol produced at the South Korean over-the-counter plant contained unusually high levels of acetaminophen, which can cause liver damage. Fortunately, no adverse reactions due to the error have been reported. The production error allegedly occurred when some bottles were manually filled, rather than using the automated process, because the filling machinery was broken.

The criminal investigation involves allegations that the company violated the country's Pharmaceutical Affairs Law and cGMP regulations. The government decided to file its criminal complaint against Janssen Korea's CEO, Kim Oak-yeon, for manufacturing and selling dangerous medicine. If convicted, he faces up to three years in prison.

Prior to announcing the criminal investigation, South Korean officials had already ordered Johnson & Johnson to shut down manufacturing at the plant and suspend production of several products for varying periods of time ranging up to five months. According to Ministry spokesmen, production halts are a standard response to recalls in South Korea.

The MFDS has stated that its punitive measures are heavier than usual because of the company's multiple violations. With regard to the criminal investigation, the MFDS's focus seems to center on the fact that the company discovered the manufacturing anomalies in March and then sold approximately 38,000 bottles before notifying the agency. Pharmaceutical companies are obligated to immediately report any safety problems to the MFDS. The decision to bring charges may also stem, in part, from the risk involved to vulnerable customers — children.

South Korea's MFDS recently underwent a major organizational restructuring aimed at increasing its ability to protect consumers from unsafe products. Until just a few months ago, the agency was known as the Korea Food and Drug Administration. The South Korean administration's renaming and reorganization came just weeks after China's State Food and Drug Administration (now the China Food and Drug Administration ("CFDA")) underwent similar changes. Like China and its CFDA, South Korea restructured the MFDS as a ministry-level agency — primarily to address food safety concerns. The Korean agency's restructuring also involved decentralization. The MFDS now maintains one main office that oversees policymaking and development and numerous regional offices that handle enforcement, surveillance and monitoring. The changes will facilitate and promote monitoring, on-site inspections and enforcement.

These developments demonstrate a worldwide trend toward greater enforcement of cGMP standards. As pharmaceutical drug manufacturers develop emerging markets outside the United States, they would be wise to heed this trend and take a proactive approach to regulatory and cGMP compliance.

DoD Seeks Enhanced Authority to Withhold Funds from Contractors

By Patrick Hromisin

IN BRIEF

- **The U.S. Department of Defense wants to step up its efforts to fight fraud by lowering the threshold for it to withhold payments to contractors who are suspected of bribery.**
- **The proposed changes to federal law underscore the importance of a strong compliance and anti-fraud program for those contractors.**

Maintaining a robust compliance program to avoid accusations of bribery is as important as ever for defense contractors as Congress considers granting the U.S. Department of Defense ("DoD") greater authority to fight contract fraud.

The DoD has asked lawmakers to amend a law that governs its ability to withhold funds from contractors. The proposed changes to 10 U.S.C. § 2207 would give the DoD the authority to withhold contractual payments based on preliminary notice that a contractor improperly bribed or attempted to bribe a U.S. government official.

Current law may provide the DoD with an implied right to withhold funds upon preliminary notice of a bribe, but there is no federal court ruling explicitly confirming the existence of that right, the DoD contended. As such, the DoD pointed out, "the United States could be required to make contractual payments to a malfeasant contractor while the proceeding required by Section 2207 is underway, even if the United States knew that the contractor would immediately disburse all payments received on its government contract, potentially even to employees or owners personally responsible for an illegal gratuity." If that were the case, the DoD stated, once the procedures established the occurrence of the bribe, there would be no funds left for the DoD to recoup.

Under the DoD's proposal, contractors will be subject to withholding of funds due to possible bribes at an earlier stage than they currently are. And because the current system leaves open the possibility that the contractor could exhaust all funds before the DoD has the chance to recover them, the new system could result in greater recoveries from contractors.

The proposal also establishes that for the DoD to withhold funds based on the suspicion of a bribe, it must meet the standard of preponderance of the evidence. The DoD pointed out that it already applies this standard in such situations, and that incorporating it into the governing law will result in more consistent application of the law. Contractors also will gain "a clearer understanding of their rights" with this change, the DoD contended. In addition, the proposal establishes that the DoD must provide contractors notice before withholding funds on a contract.

Another change the DoD proposed is to establish a fraud-fighting fund within each military department. Under the proposal, all damages that the DoD collects under the provisions discussed above would be deposited in the fraud-fighting fund of each relevant department.

Currently, when the DoD collects those damages, they are deposited into the U.S. Treasury as "miscellaneous receipts" and are not then available for use by DoD departments until they are appropriated through the legislature.

Under the proposed system, the DoD would retain the funds and use them to strengthen and broaden its efforts to combat government fraud. The DoD proposal does not specify the concrete actions that it would take using the recovered funds, but any further anti-fraud efforts could impact the business of any government contractor.

The DoD made these proposals as part of a slate of requests to Congress in connection with Congress' consideration of the 2014 National Defense Authorization Act ("NDAA"). The yearly NDAA provides funding for all DoD programs, but is also often used to make changes to DoD's authority and procedures. The proposed NDAA was approved by the House Armed Services Committee on June 6 without the DoD's proposed changes regarding contractor fraud, but it must still be passed by the full House of Representatives, and the Senate must consider and approve it as well. That process is expected to take months, and the DoD's proposal may still be added to the legislation as lawmakers continue to work with it.

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