LJN LAW JOURNAL NEWSLETTERS

Business Crimes Bulletin ®

An ALM Publication

Volume 20, Number 8 • April 2013

Italy Adopts New Anti-Corruption Law

By Sean Hecker, Gregory P. Copeland, and Michael A. Janson

On Nov. 8, 2012, Italy enacted new anti-corruption legislation, joining other countries, including China, Russia and the United Kingdom, that have recently implemented strong anti-corruption measures. Disposizioni per la prevenzione e la repressione della corruzione e dell'illegalità nella pubblica amministrazione ("Provisions for the prevention and combating of corruption and illegality in public administration") (C. 4434-B), www.camera.it/_dati/leg16/lavori/stampati/pdf/16PDL0064270.pdf [Italian].

Development of New Law

Approved by overwhelming majorities in the Italian Parliament, the new anti-corruption law provides for the creation of an agency, the National Anti-Corruption Authority (NACA), to coordinate anti-corruption efforts, as well as numerous other measures, including increased penalties for corruption and whistleblower protections. C. 4434-B, note 1, *supra* at Art. 1(2), 3, 12, 19(1).The strength and scope of

continued on page 5

WE HAVE A NEW LOOK!

Our website has a new look and new features! If you are not already online, go to www.ljnonline.com/ljn_ buscrimes and register!

Reducing Adverse Legal Consequences Through FCPA Remediation

Part Two of a Two-Part Article

By Jonny Frank and Rex Homme

In last month's issue, we observed that both the Department of Justice (DOJ) and the Securities Exchange Commission (SEC) have placed what they term a "high premium" on remediation efforts made by companies that discover or are accused of violations of the Foreign Corrupt Practices Act (FCPA). In many cases, the punishments meted out for such violations will be diminished if a company is proactive in working to limit an FCPA violation's effects and ensure that future breaches will not occur. We continue our discussion herein.

Other Misconduct

Imagine the embarrassment and severe legal consequences if, subsequent to learning of and dealing with a bribery or fraud situation, the company, or worse, the government, discovers that the perpetrators engaged in other wrongdoing or that the misconduct the company claimed was isolated actually pervades across the organization. With this in mind, companies must make every effort to flush out other misconduct by the perpetrators of fraud or bribery, or similar misconduct by others in the organization.

The remediation team gains comfort through an auditing process called "negative assurance," which means conducting audit procedures to search for risk indicators or "red flags."

- *Perpetrator Misconduct* — Do not be fooled by tears, apologies or expressions of regret; perpetrators rarely come completely clean. Use COSO risk assessment procedures to identify other ways that the perpetrators may have engaged in misconduct. (COSO is an acronym for the Committee of Sponsoring Organizations of the Treadway Commission.) Develop key risk indicators, and conduct audit procedures, including data analytics, transaction testing and interviews, to gain negative assurance.

continued on page 2

In This Issue

FCPA Remediation ... 1

Italy's New Anti-Corruption Law... 1

Asset Forfeiture 3

In the Courts 7

Business Crimes Hotline 8

PERIODICALS

FCPA Remediation

continued from page 1

- *Misconduct by Others* — Use the root cause analysis to frame procedures to gain assurance that similar misconduct has not occurred elsewhere in the organization. If the misconduct arose from poor operating effectiveness, test whether control activities are operating effectively in a sample of other locations. If, however, the problem was one of design effectiveness, the team might need to conduct substantive forensic audit procedures to search for red flags of similar misconduct.

Corruption Risk & Controls Register

The DOJ and SEC specifically evaluate an organization's corruption risk assessment process when assessing a company's compliance program. FCPA deferred prosecution agreements usually include a requirement that the company identify and assess risks of potential foreign bribery.

Corruption risk assessments generally involve: 1) identifying interactions between the organization and public officials; and 2) potential methods to pay bribes. Begin by developing a framework that the company can use day-to-day. Suggested fields include: 1) Description of bribe scheme or scenario; 2) Source for including scheme in inventory; 3) impacted business units or functions; 4) inherent likelihood and significance (this refers to assessing risk without regard to existing controls); 5) preventive and detective controls; 6) residual likelihood and significance; and 7) residual risk response, including forensic data analytics.

Once the corruption risk assessment process is formulated, the next step is to develop an inventory of potential bribe schemes. Remediation advisers can jumpstart the process, if they have prepared industry risk inventories. Perform interviews and hold focus groups among relevant business unit and function leaders. Consider past allegations at the company, as well as the results of internal audits and business reviews of foreign business units and functions.

The team then assesses the likelihood and significance of a scheme occurring on an "inherent" basis; that is, without regard to existing controls. The next step is to link and evaluate controls relied upon by the organization to mitigate risks assessed as likely or significant. If existing controls do not lower the risk to an acceptable level, the team must devise a residual risk response, typically combining preventive and detective controls and forensic data analytics.

Keep the register up-to-date. This critical, but often overlooked, step is simple and not time-consuming, if the organization assigns responsibility for updating the register based on new whistleblower allegations, internal audits, business reviews and media reports.

Control Environment and Entity-Level Controls

The DOJ and SEC, as well as U.S. Sentencing Guidelines (USSG) criteria of an effective ethics and compliance program, require companies to take steps to enhance the control environment. DOJ Deferred Prosecution Agreements typically require that the organization:

- Promote an organizational culture that encourages ethical conduct and a culture of compliance;
- Use reasonable efforts not to include within the substantial-authority-personnel of the organization any individual whom the company knew, or should have known, engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program;

continued on page 6

Jonny Frank, a partner in the New York office of the StoneTurn Group, served for 12 years as a federal prosecutor and 14 years as a partner from PwC, where he founded and led the Investigations and Fraud Risks & Controls Groups. **Rex Homme**, a partner in StoneTurn's Chicago office, has over 20 years' experience supporting law firms and companies to prevent, detect, and investigate fraud and corruption worldwide.

Business Crimes
Bulletin ®

CHAIRMAN OF THE BOARD . . . . Laurence A. Urgenson, Kirkland & Ellis LLP, Washington, DC
EDITOR-IN-CHIEF . . . . Janice G. Inman
EDITORIAL DIRECTOR . . . . Wendy Kaplan Stavinoha
ASSOCIATE EDITORS . . . . Matthew J. Alexander, Jamie Schafer
MARKETING DIRECTOR. . . . . . . Jeannine Kennedy
GRAPHIC DESIGNER . . . . Amy Martin

BOARD OF EDITORS
DANIEL R. ALONSO . . . . NY County District Attorney's Office, New York
STANLEY S. ARKIN . . . . Arkin Kaplan LLP, New York
LAURA GROSSFIELD BIRGER . . . . Cooley LLP, New York
TOBY J.F. BISHOP . . . . Deloitte Financial Advisory Services LLP, Chicago
JONATHAN S. FELD . . . . Katten Muchin Rosenman LLP, Chicago
HOWARD W. GOLDSTEIN . . Fried, Frank, Harris, Shriver & Jacobson LLP, New York
JEFFERSON M. GRAY. . . . . . . U.S. Attorney's Office, Baltimore
JEFFREY T. GREEN. . . . . Sidley Austin LLP, Washington, DC
DAVID S. KRAKOFF. . . . . BuckleySander LLP, Washington, DC
DAVID J. LAING. . . . . Baker & McKenzie LLP, Washington, DC
RONALD H. LEVINE . . . . Post & Schell, P.C., Philadelphia
JONATHAN B. NEW. . . . . Baker Hostetler, New York
MARJORIE J. PEERCE . . . . . . Stillman Friedman & Shechtman, New York
JODI MISHER PEIKIN. . . . . . Morvillo, Abramowitz, Grand, Iason Anello & Bohrer, P.C., New York
ROBERT PLOTKIN. . . . . McGuireWoods LLP, Washington, DC
JOSEPH F. SAVAGE, JR. . . . . Goodwin Procter LLP, Boston
JUSTIN A. THORNTON . . . . . Law Offices of Justin Thornton, Washington, DC
GARY STEIN . . . . Schulte Roth & Zabel LLP, New York
STANLEY A. TWARDY, JR. . . . Day Pitney LLP, Stamford, CT
JIM WALDEN . . . . Gibson, Dunn & Crutcher, New York
JACQUELINE C. WOLFF . . . . Manatt Phelps & Phillips, LLP, New York

Business Crimes Bulletin® (ISSN 1090-8447) is published by Law Journal Newsletters, a division of ALM.
© 2013 ALM Media, LLC. All rights reserved. No reproduction of any portion of this issue is allowed without written permission from the publisher.
Telephone: (877) 256-2472
Editorial e-mail: wampolsk@alm.com
Circulation e-mail: customercare@alm.com
Reprints: www.almreprints.com

Business Crimes Bulletin P0000-245
Periodicals Postage Pending at Philadelphia, PA
POSTMASTER: Send address changes to :
ALM
120 Broadway, New York, NY 10271

Published Monthly by:
Law Journal Newsletters
1617 JFK Boulevard, Suite 1750, Philadelphia, PA 19103
www.ljnonline.com

Asset Forfeiture

Part Two of a Two-Part Article

By Jonathan B. New and Christy Nixon

Last month, we began discussion of the Department of Justice's (DOJ's) increased use of asset forfeiture and pursuit of higher-value forfeitures when it is prosecuting economic crimes. Sometimes when the alleged "ill-gotten gains" are restrained or seized prior to the criminal trial, the accused is left without sufficient funds to pay counsel. In other cases, assets rightfully belonging to third parties are affected. In such cases, although the laws are written to favor the government's interests, those whose assets are (or may be) seized have some options.

A *Monsanto* Hearing

As discussed in Part One of this article, the Fifth and Sixth Amendments to the Constitution give criminal defendants, including those that are the subject of parallel criminal and civil actions, the right to a pretrial probable cause hearing — commonly referred to as a "*Monsanto* hearing" after *United States v. Monsanto*, 491 U.S. 600 (1989) — to challenge a pretrial asset restraint or seizure if the defendant lacks sufficient funds to pay counsel. *United States v. Kam*, 2010 U.S. Dist. LEXIS 143458 (E.D.N.Y. 2011), a recent case involving a challenge to the seizure of commingled accounts, is instructive as to what counsel should be prepared to show to obtain a *Monsanto* hearing.

In *Kam*, the government seized three bank accounts, which it alleged were funded by fraudulent Medicare reimbursements. In addition, the government obtained defense counsel's agreement not to release funds in an attorney escrow account because Medicare reimbursements were deposited into it. The defendant sought the release of funds from the seized accounts or for court authorization to spend funds in the escrow account to pay his legal expenses.

To establish his need for the funds, the defendant's submissions included a declaration from himself and his wife, along with sworn financial statements, which provided detailed information concerning the couple's income, liquid and non-liquid assets, living expenditures, and outstanding liabilities. In addition, defendant's counsel proffered that, given the complexity of the criminal prosecution, pretrial expenses might total more than $100,000, not including legal fees and document duplication expenses already incurred. The court found that the evidence submitted established that the defendant had a legitimate need to access the seized funds to pay for his defense. In particular, the court noted that the defendant's sworn financial statements showed that his family's income, though substantial, roughly equaled the family's reasonable living expenses and debt payments. The court further observed that the defendant had access to minimal liquid assets; however, the other assets belonging to him and his family were encumbered and were thus unavailable. In addition, the court acknowledged that, given the complexity of the case, defense counsel's representation of the estimated pretrial legal expenses was appropriate.

To refute the government's allegation that the seized funds were not traceable to the underlying offense, the defendant argued that the subject accounts contained untainted funds which he could identify if the government was required to disclose the specific deposits it alleged were proceeds from fraudulent transactions. In comparison, the non-Medicare funds deposited in the escrow account were readily distinguishable from the deposited Medicare reimbursement payments.

In determining that the defendant did not satisfy the second prehearing factor with respect to the seized accounts, the court noted that the government has a low burden to establish probable cause as to forfeitability where an account is funded by both tainted and untainted funds. The court found that defendant had not made any factual showing to rebut the probable cause inference that the seized accounts were funded largely through tainted assets. In contrast, the court held that the government could not restrain the entire escrow account, finding that the proceeds of clearly identifiable non-Medicare payments were not traceable to the fraud. The court noted that, unlike the seized accounts, the escrow account lacked fungibility problems allowing for its restraint, since no withdrawals were made from the escrow account.

The Lessons of *Kam*

Kam illustrates several important considerations for counsel defending against pretrial restraints. For one, *Kam* identifies certain evidence a court will find persuasive in evaluating a defendant's claim that he lacks sufficient assets to pay counsel. It is essential for defense counsel to submit detailed and specific financial statements for the court to make a finding that the defendant has established that he needs the funds to pay for his defense. *Compare with United States v. Emor*, 794 F.Supp.2d 143, 149 (D.C.C. 2011) (finding that defendant failed to make a showing that he lacked funds to hire his counsel of choice where defendant filed a "bare-bones form in which he claims that he lack any income or investments, that his spouse is not employed, that he has six dependents, and that he has 'only between $22,000 and $50,000 in cash on hand or money in savings or checking accounts.'"). However, counsel must ensure that any such financial disclosures are complete and fully accurate or the client could face more serious consequences. In addition, clients may not want to expose their personal finances, and those of their close family, to additional government scrutiny.

Furthermore, *Kam* highlights the fact that the probable cause standard presents a significant obstacle that must be considered when determining the likelihood of success in challenging the government's pretrial

continued on page 4

Jonathan B. New, a member of this newsletter's Board of Editors, is a partner in the New York office of Baker Hostetler, where he focuses his practice on white collar criminal and regulatory matters, internal corporate investigations and complex commercial litigation. **Christy Nixon** is a litigation associate, also in New York office of the firm.

Asset Forfeitures

continued from page 3

seizure or restraint of a commingled account. Because the government is not required to trace the funds to the illegal activity on a dollar-for-dollar basis, it can seize or restrain all of the money in an account containing commingled funds where it can establish that the criminal proceeds deposited into the account exceed its current balance. Stefan D. Cassella, Criminal Forfeiture Procedure in 2012: An Annual Survey of Developments in the Case Law, 48 *Crim. L. Bull*. 863, 872-73 (2012).

Third Parties

White-collar practitioners should also be cognizant of the risk to innocent corporate clients whose assets may get tied up by restraint orders or asset seizures during the course of an investigation and prosecution. Due to the fundamental difference between criminal and civil forfeiture — the relevancy of the property's owner's culpability — each proceeding has different procedures for third parties to assert interests in forfeited property. Civil forfeiture proceedings are procedurally similar to a typical lawsuit. Stefan D. Cassella, Overview of Asset Forfeiture in the United States, 55 *United States Attorneys' Bulletin* 8, 16 (Nov. 2007). The government files a verified complaint alleging that the property in question is subject to forfeiture pursuant to the applicable forfeiture statute, and any third party asserting an interest in the property must file a claim to the property and answer the forfeiture complaint. *Id*. Thereafter, the case moves forward through civil discovery, motion practice, and trial. *Id*.

In contrast, a third party seeking to assert an interest in assets subject to a criminal proceeding must wait until the resolution of the criminal case to commence an ancillary proceeding to establish an interest in the forfeited property. *Id*.

One recent example of this problem is *United States v. Egan*. In this case, Robert Egan, the principal and owner of Mount Vernon Money Center (MVMC), a company engaged in various cash management businesses such as check cashing, ATM replenishment, armored transportation, and payroll services, was arrested on Jan. 29, 2010 (and later indicted), for allegedly misappropriating tens of millions of dollars of customer money to fund operating losses in MVMC's businesses, and to enrich himself. *Egan*, No. 10-CR-191 (JFK), 2010 WL 3258085, at *1 (S.D.N.Y. Aug. 16, 2010). On Feb. 11, 2010, Egan, MVMC and the government agreed to a consent order that authorized the seizure of all of the cash, currency, and other monetary instruments stored in MVMC cash vaults located at two of the company's offices, pending resolution of the criminal case.

MVMC customers had to wait almost one year to commence an ancillary proceeding to seek the return of their seized property. While certain customers sought relief from the court prior to the conclusion of the criminal action, none were successful. Specifically, on April 16, 2010, Clothing Emporium Inc., a former customer of MVMC, moved for the release of $106,320 of its alleged funds seized pursuant to the seizure order. Shortly thereafter, Granite Check Cashing, another former MVMC customer, filed a similar motion seeking the return of $392,000 from the seized funds. In denying these former customers' motions to release the seized funds to which they purportedly held an interest, the court stated that "the exclusive avenue available to third parties wishing to assert their interest in property charged to be forfeitable is an 'ancillary proceeding.'" *Id*. at *2.

MVMC's many corporate clients, including, but not limited to, Clothing Emporium Inc., Granite Check Cashing, Capital One Bank, Bank of America, Amalgamated Life Insurance Company, and Golden Krust Caribbean Bakery & Grill, were forced to wait until Sept.15, 2010, when Egan forfeited his interest in $19,288,702 seized from MVMC's assets in connection with his guilty plea. *See* Memorandum & Order, *United States v. Egan*, No. 10-CR-191 (JKF) (S.D.N.Y. Feb. 4, 2010), ECF 359. As of the summer of 2012, certain MVMC customers were still litigating their interests in seized property.

For third parties, the practical implication of criminal forfeiture, as demonstrated by *Egan*, is that innocent corporate clients and individuals whose assets are the subject of a criminal forfeiture proceeding may be forced to wait months or even years before they can pursue the return of their seized or restrained property. Even if ultimately successful, the property may have materially depreciated as a result of the delay, or financial conditions may have changed so as to decrease the value of the property. Thus, while one of the laudable goals of asset forfeiture may be to compensate victims of economic crimes, in practice seizures may also harm innocent victims and third parties. The only recourse in such situations is for experienced defense counsel to engage in discussions with prosecutors and convince them to exercise their discretion to release the property in the interests of justice.

Conclusion

In light of the DOJ's increased focus on seeking asset forfeiture in corporate fraud and other financial crime investigations, defense counsel must be prepared to navigate through the complex maze of asset forfeiture law. Defending and securing the property of business and individual clients, at an early stage, may be essential for providing effective representation over the course of an investigation or prosecution. In addition, innocent corporate clients who have an interest in property that could be subject to seizure should seek counsel on steps that may be taken preemptively, so as to avoid the procedural pitfalls of criminal forfeiture actions.

Forfeiture of attorneys' fees and third-party forfeiture are only two of the many issues that are likely to arise when individual and company assets are on the government's radar. To battle against the government's increased use of asset forfeiture — a trend that is likely to continue over the next few years — counsel and clients alike must take measures to inform themselves concerning this thorny area of law.

Italy

continued from page 1

the new anti-corruption law's provisions may initiate a more active era of anti-corruption enforcement in both the public and private sectors in Italy, a country previously not viewed as a leader in such efforts.

The new law was initially proposed by former Prime Minister Silvio Berlusconi in May 2010. *See* Directorate General of Human Rights and Legal Affairs Directorate of Monitoring, Council of Europe Group of States Against Corruption, "Compliance/Report on Italy" at 4 (May 27, 2011), www.coe.int/t/dghl/monitoring/greco/evaluations/round2/GrecoRC1&2(2011)1_Italy_EN.pdf. Current Prime Minister Mario Monti submitted the law to a confidence vote to speed its passage through both houses of Italy's parliament. Prime Minister Monti indicated that the reforms were required to encourage foreign investment and to enhance the country's reputation following the Berlusconi-related scandals that have engulfed Italy during the past year, most notably the Oct. 26, 2012 conviction of Berlusconi for tax fraud. *See* Sarah Delaney, "Italy Lawmakers Approve Anti-Corruption Legislation," *Los Angeles Times* (Oct. 31, 2012), http://articles.latimes.com/2012/oct/31/world/la-fg-italy-corruption-20121101.

The law incorporates changes recommended by the Organization for Economic Cooperation and Development (OECD) Working Group on Bribery and the Council of Europe Group of States Against Corruption. *See* Transparency International Italia, "Corruption Is Not an Inevitable Fate but a Cultural Dress" (Oct. 31, 2012), http://blog.transparency.org/wp-content/uploads/2012/10/CS_approvazione_ING.pdf. It builds on Italy's prior anti-corruption measures, both by augmenting existing provisions and by enacting new measures. (Italy is a party to the OECD's Anti-Bribery Convention (ratified Sept. 29, 2000), the UN's Convention Against Transnational Organized Crime (ratified Aug. 2, 2006), the UN's Convention Against Corruption (ratified Oct. 5, 2009), and the EU's Anti-Corruption Convention (ratified Sept. 29, 2000). Italy previously enacted its commitments under these international agreements in its domestic laws. Under Italian law, bribery of public officials is outlawed under Articles 318-322 of the Italian Criminal Code. Article 322-bis criminalizes bribery of foreign officials. Under these provisions, bribery of an official for acts in breach of official duties can be penalized with up to five years of imprisonment.)

Sean Hecker is a partner and **Gregory P. Copeland** is an associate in the New York office of Debevoise & Plimpton LLP. They are members of the Litigation Department and the White Collar Litigation Practice Group. **Michael A. Janson** is an Attorney Advisor at the Federal Communications Commission in Washington, DC. The opinions expressed herein are those of the authors alone and do not necessarily represent the views of the Federal Communications Commission, its Commissioners or its staff.

What It Means

The newly created NACA is provided with greater investigatory and supervisory powers than those of the existing anti-corruption agency, the Commission for the Evaluation, Transparency and Integrity of the Administration. 4434-B, note 1, *supra* at Art. 1(2), (3). Under the new law, NACA is authorized to implement a National Anti Corruption Plan developed by the Department of Public Service. *Id.* at Art. 1(2)(b), (g). NACA is required to provide an annual report to Parliament concerning anti-corruption initiatives. *Id.*

Regional and local government administrations are also required to develop plans to fight corruption that conform to the National Anti-Corruption Plan. *Id.* at Art. 1(5), (6). Public institutions must also name anti-corruption managers responsible for creating annual anti-corruption plans. *Id.* at Art. 1(7). The plans must identify areas prone to corruption, provide training to staff, and ensure adequate compliance monitoring. *Id.* at Art. 1(9). The anti-corruption managers of public institutions can be liable for failures that result in losses due to corruption unless an appropriate anti-corruption plan has been implemented and monitored. *Id.* at Art. 1(12). The new law also requires greater transparency of public institutions: budgets, details of public works project costs, and salaries of senior officers must be made publicly available on the Internet. *Id.* at Art. 3(1), (2).

Under the new scheme, an extra category of crimes has been added to the Criminal Code for corruption in the private sector. *Id* at Art. 19(1), Art. 20(1). The current anti-corruption law proscribes only conduct between private citizens when dealing with public bodies. *See* Delaney, *supra*. Under the new law, private corruption causing harm (regardless of whether there is any involvement of a public body) is punishable by one to three years in prison, with sentences doubled for corruption involving publicly listed companies. 4434-B, note 1, *supra* at Art. 20(1). It also limits influence peddling, requiring greater disclosure from lobbyists, and adding a crime for the "illegal traffic of influence." *Id.* at Art. 19(1)(r).

Prison sentences under the new law are increased for convictions for corruption, bribe demands, embezzlement, and abuse of office. *Id.* at Art. 19(1). In addition, anyone who has been convicted of a corruption-related crime is ineligible to run for public office. *Id.* at Art. 17. Finally, the new law also adds protections for public sector whistleblowers: Whistleblowers are guaranteed anonymity and protection from retaliation. *Id.* at Art. 12.

Turning Opinions Around

The new law comes at a time when Italy has increased its anti-corruption enforcement efforts, yet struggles to shake the perception that its efforts are less than adequate. Anti-bribery enforcement has increased in Italy in recent years, with 32 cases brought in 2011 as compared with 18 cases brought in 2010. *See* Transparency International, "Exporting Corruption? Country Enforcement of the OECD Anti-Bribery Convention, Progress Report 2012" at 9 (Sept. 6, 2012) www.transparency.org/whatwedo/pub/exporting_corruption_country_enforcement_of_the_oecd_anti_bribery_convention; *see also* OECD

continued on page 6

Italy

continued from page 5

Working Group on Bribery, "Phase 3 Report on Implementing the OECD Anti-Bribery Convention in Italy" at 7 (Dec. 16 2011), www.oecd.org/dataoecd/59/47/49377261.pdf.

Despite these efforts, Italy continues to be perceived as lagging behind many of its peers in anti-corruption efforts and in the perceived acceptance of corruption in the country's culture. According to Transparency International's 2011 Corruption Perceptions Index, Italy ranks 69th out of 183 countries surveyed. Transparency International, "Corruptions Perceptions Index 2011" at 4 (2011) http://cpi.transparency.org/cpi2011/results. This perception is derived, in part, from the lack of fines and penalties imposed in the majority of cases initiated. Of the 60 cases brought through December 2011, punishments were imposed against only three legal persons and nine individuals, all through settlements ("patteggiamento"). International Bar Association, "Italy Country Brief 2012" at 3 (2012), www.ibanet.org/Document/Default.aspx?DocumentUid=DDE48C04-E58B-46CC-8139-B82ED8F3F965. According to the OECD's Working Group on Bribery Phase 3 Report, issued in December 2011, numerous cases are dismissed because of statute of limitations problems, owing to the length of the investigations, and the difficulty in countering the frequently-asserted defense of extortion ("concussione"). Phase 3 Report on Implementing the OECD Anti-Bribery Convention in Italy, note 11, *supra* at 10-13.

Nevertheless, the law may mark the beginning of a new era of Italian anti-corruption enforcement. The OECD Working Group on Bribery Phase 3 Report called on Italy to provide increased enforcement resources, enact laws mandating greater transparency, and implement whistleblower protections. *Id.* at 50-53. All of these initiatives are embodied in Italy's new anti-corruption law.

Conclusion

It is too soon to tell how these measures will be implemented in practice, but the law is a step forward for Italian anti-corruption enforcement efforts and suggests that Italy may be entering a more aggressive phase of enforcement. As such, companies operating in Italy, as well as companies subject to the FCPA and UK Bribery Act, should pay particular attention to the new law's compliance requirements and ensure that they are following best compliance practices.

FCPA Remediation

continued from page 2

- Develop "clearly articulated" FCPA policies;
- Assign a corporate executive with responsibility for the implementation and oversight of compliance standards and procedures; authority to report matters directly to the Board; and appoint heads of compliance for each of its business units;
- Develop mechanisms to communicate policies, standards and procedures to all directors, officers, employees, agents and business partners, to include periodic training and annual certification; and
- Develop a system for: 1) providing guidance and advice; 2) reporting information on a confidential basis; and 3) responding to reports of misconduct or requests for advice.

Transaction-Level Controls

Transaction-level controls refer to procedures to ensure compliance and prevent and detect non-compliance with specific company policies. Organizations need to guard against weaknesses in both design and operating effectiveness. Design flaws involve inadequate protection against collusion, management override, unauthorized access and other forms of controls circumvention. Operating effectiveness refers to whether the controls are functioning as designed.

The remediation program must develop or enhance transaction-level controls to prevent recurrence of misconduct identified during the FCPA investigation, as well as to prevent significant risks identified during the corruption risk assessment. Common DOJ and SEC mandated transaction-level controls enhancements require that the organization:

- Promulgate controls governing gifts, hospitality, customer travel, political contributions, charitable donations, facilitation payments, solicitation and extortion;
- Modify internal controls so that they are reasonably designed to ensure accurate books, records, and accounts to ensure that they cannot be used for the purpose of foreign bribery or concealing misconduct;
- Institute diligence and compliance requirements related to all agents and business partners, to include: 1) documented risk-based diligence; and 2) informing agents of the company's commitment to abiding by the law; and
- Include standard provisions in agreements, contracts and renewals for all agents and business partners pertaining to anti-corruption, concerning anticorruption representations and undertakings, rights to conduct audits, and rights to terminate as a result of any breach of anticorruption laws and regulations or representations and undertakings.

Collusion and Management Override

Even the best anticorruption entity and transaction-level controls might be vulnerable to potential collusion, management override or other circumvention. To mitigate this risk, the remediation analyses should also assess whether management in the targeted areas have "bought into" an effective anti-corruption program. Interviews of these individuals, and their direct reports, are often useful in assessing future risks. Compliance should be built into the compensation, goals and evaluation process of country and regional managers. The

continued on page 8

IN THE COURTS

Second Circuit Vacates Conviction of Pharmaceutical Sales Rep

On Dec. 3, 2012, the U.S. Court of Appeals for the Second Circuit, in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), vacated the criminal conviction of former pharmaceutical sales representative Alfred Caronia, whose conviction stemmed from off-label promotion of a Food and Drug Administration (FDA)-approved drug. Notably, the court based its decision on First Amendment grounds, and held that the government cannot prosecute pharmaceutical manufacturers and their representatives "for speech promoting the lawful, off-label use of an FDA-approved drug." *Id*. at 169.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA must approve of a drug's specific uses prior to distribution to the general public. 21 U.S.C. § 355(a). Although doctors may freely prescribe a drug for purposes not approved by the FDA, the FDCA expressly prohibits the "introduction or delivery for introduction into interstate commerce of any … drug … that is … misbranded." 21 U.S.C. § 331(a). A drug is "misbranded" when labeling fails to bear "adequate directions for use." 21 U.S.C § 352(f). Directions are "adequate" when a person "can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5. Promotional statements by a pharmaceutical company or its representatives can serve as proof of a drug's intended use. *Id*. And if the FDA has not approved the intended use, then these promotional statements could be used as evidence of misbranding. Importantly, however, such statements do not constitute a crime in and of themselves under the FDCA and related regulations. *See Caronia*, 703 F.3d at 155 (citing 21 C.F.R. § 201.5).

In the Courts and Business Crimes Hotline were written by **Christian Izaguirre** and Associate Editor **Matthew J. Alexander**, respectively. Both are Associates at Kirkland & Ellis LLP, Washington, DC.

In 2009, a jury convicted Caronia of conspiracy to introduce a misbranded drug into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). The facts underlying Caronia's conviction relate to his promotion of the drug Xyrem when he was a sales representative for Orphan Medical Inc. (Orphan) (now known as Jazz Pharmaceuticals). *Caronia*, 703 F.3d at 155-56. As part of a federal investigation into the off-label promotion of Xyrem, Caronia was recorded promoting the drug for purposes not approved by the FDA at the time. *Id*. at 156. Before trial, Caronia moved to dismiss, arguing "that the application of the FDCA's misbranding provisions to his off-label promotional statements unconstitutionally restricted his right to free speech under the First Amendment and that the provisions were unconstitutionally vague and broad." *Id*. at 158. Caronia's motion was denied, and he was subsequently convicted and sentenced to one year of probation and community service.

On appeal, Caronia re-raised his First Amendment basis for dismissal below, and argued "that he was convicted for his speech — for promoting an FDA-approved drug for off-label use — in violation of his right to free speech under the First Amendment." *Id*. at 152. The government countered, arguing that Caronia's off-label promotion was used as evidence of his intent to misbrand, not as the sole basis of his prosecution. *See Id*. at 160-61.

The court rejected this argument. In addition to the trial court's jury instruction, which "left the jury to understand that Caronia's speech was itself the proscribed conduct," the court noted several examples in the record that belied the government's argument, including that the government never argued in summation or rebuttal that the promotion was evidence of intent; the government never suggested that Caronia engaged in any form of misbranding other than the promotion of the off-label use of an FDA-approved drug; and the government never suggested, for example, that Caronia conspired to place false labeling on a drug. *Id*. at 162.

In light of these examples (and others within the record), the court concluded that Caronia was prosecuted only for his off-label promotion of an FDA-approved drug. *Id*. The court then turned to whether the prosecution was constitutionally permissible under the First Amendment.

In *Sorrell v. IMS Health, Inc*., 131 S. Ct. 2653 (2011), the Supreme Court held that a Vermont law prohibiting pharmaceutical companies from using prescriber-identifying information for marketing purposes unconstitutionally restricted speech. In reaching that decision, the court engaged in a two-part inquiry: 1) whether the restriction was content-and-speaker-based; and 2) whether the government had shown that the restriction on speech was consistent with the First Amendment.

Here, the court applied the same two-part inquiry. First, the court found that the government's theory of prosecution was content-and-speaker-based because it disfavored speech with a particular content (off-label promotion) when expressed by certain disfavored speakers (pharmaceutical manufacturers), while allowing others to speak without restriction. *Id*. at 164-165.

Second, in deciding whether the government could justify a criminal prohibition of off-label promotion, the court applied the four-part intermediate standard of heightened scrutiny: 1) the speech must not be misleading and concern lawful activity; 2) the asserted government interest must be substantial; 3) the regulation must directly advance that interest; and 4) the regulation must be narrowly drawn to serve the government's interest. *Id*. at 164 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980)). The court found that the first two prongs were "easily satisfied here." *Id*. at 165. As for the third and fourth prongs, the court held that the prohibition of off-label promotion did not directly

continued on page 8

BUSINESS CRIMES HOTLINE

LOUISIANA

Dow Chemical Company Loses $1 Billion Tax Shelter Case

On Feb. 25, Chief Judge Brian A. Jackson of the United States District Court for the Middle District of Louisiana in Baton Rouge ruled against Dow Chemical Company (Dow) in a case addressing the validity of two tax-shelter transactions created for the company. The transactions, which included approximately $1 billion in deductions, involved the creation of a partnership via Dow's European headquarters in Switzerland, and were designed for the company by Goldman Sachs and King & Spalding, the international law firm. In ruling for the Government, Judge Jackson stated that the "tax law deals in economic realties, not legal abstractions." In addition to affirming the denial of the deduction, Judge Jackson also levied a penalty against Dow and he further remarked that "Dow viewed its tax department as a profit center."

According to published reports, a spokesperson for Dow noted that it had already paid all taxes at issue in the litigation, along with corresponding interest. Dow also noted at the time of the decision that it was considering all options, including a possible appeal. *Chemtech Royalty Associates v. United States*, No. 05-cv- 00944 (M.D. LA Feb. 26, 2013).

In the Courts

continued from page 7

advance the government's interests in drug safety and public health because off-label use itself is not prohibited, and the court noted that "[n]umerous, less speech-restrictive alternatives are available, as are noncriminal penalties." *Id*. at 167-68.

Accordingly, the court concluded: "[E]ven if speech can be used as evidence of a drug's intended use, we decline to adopt the government's construction of the FDCA's misbranding provision to prohibit manufacturer promotion alone as it would unconstitutionally restrict free speech." *Id*. at 168. Caronia's conviction was vacated and his case remanded to the lower court.

FCPA Remediation

continued from page 6

remediation team should also assess the design of the controls, including compensation controls to guard against collusion and override, and should validate operating effectiveness to ensure that employees and third parties are complying with enhanced policies and controls.

Discipline

Companies must take consistent and appropriate action. Discipline of primary actors is a given — but beware of business leaders trying to protect otherwise high-producing personnel.

Secondary actors pose the greater challenge. These include business leaders exerting undue pressure and poor supervision, as well as bystanders failing to report observed misconduct. Employees involved in financial reporting pose special challenges, as external auditors will be reluctant to place reliance on, or accept representations from individuals suspected of having engaged in misconduct.

Periodic Third-Party Review

Remediation programs require periodic review to ensure the effectiveness of remedial efforts. Prompt and proactive action is essential, if the company is to avoid a government-imposed compliance monitor or independent consultant. A company can beat the government to the punch by voluntarily installing its own monitor. This strategy works, however, only if company's monitor is highly credible and completely independent.

Incident Response and Remediation

Finally, an effective FCPA remediation must include a response plan for if and when future allegations of corruption arise. FCPA settlement agreements typically require companies to:

- Develop a process for responding to allegations of violations of anti-corruption laws; and
- Maintain mechanisms for making and handling reports and complaints related to potential violations of anti-corruption compliance issues, including a process for investigating and ensuring that appropriate remedial measures are undertaken.

Conclusion

FCPA allegations are akin to angina attacks. Respond appropriately and life continues as normal (or close to it). Fail to remediate to the satisfaction of the DOJ or SEC and the organization faces the corporate equivalent of a heart attack. Organizations can satisfy these agencies' expectations by following the recommendations we have discussed.

The publisher of this newsletter is not engaged in rendering legal, accounting, financial, investment advisory or other professional services, and this publication is not meant to constitute legal, accounting, financial, investment advisory or other professional advice. If legal, financial, investment advisory or other professional assistance is required, the services of a competent professional person should be sought.

To order this newsletter, call:
1-877-256-2472

On the Web at:
www.ljnonline.com