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Compliance Developments

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A. Introduction

In 2010, the U.S. Government recouped billions of dollars in settlements and judgement from government contractors that were found to be non-compliant under their government contracts. Matters arising under the False Claims Act alone led to the Government receiving more than $3 billion in fines and penalties. We anticipate the scrutiny and vigilance on the part of the Government to continue for the foreseeable future due to declining federal budgets, further implementation of the Mandatory Disclosure Rule (Rule) and an otherwise focused effort by the Government to increase transparency in its acquisition activities.

This presentation highlights some of the notable financial recoveries by the Government in 2010 due to contractor non-compliance and discusses several approaches that contractors should consider to maximize their ability to satisfy their compliance obligations.

B. Recent Developments

The Government did not pursue a single industry or market sector in 2010; rather, it was an "equal opportunity enforcer." Specifically, the pharmaceutical, information technology, education, defense and security, and financial industries all felt (and continue to experience) the reach of the U.S. Government.

1. Pharmaceutical

Perhaps, big pharma was hardest hit of any industry in 2011, with settlements and judgments exceeding $1 billion. In October 2010, GlaxoSmithKline (GSK) agreed to pay $750 million to settle a Department of Justice (DoJ) investigation into allegations that GSK sold adulterated drugs used under Medicaid and other government programs. Novartis agreed to a $422.5 million settlement in late September to resolve both criminal and civil allegations relating to its off-label marketing of Trileptal and other allegations involving Diovan, Exforge, Sandostatin, Tekturna and Zelnorm. As part of the settlement, Novartis plead guilty to a criminal misdemeanor for the unlawful promotion of Trileptal, including paying kickbacks to doctors to prescribe the drug.

In September 2010, in yet another significant settlement, DoJ announced that Forest Pharmaceuticals, Inc., a subsidiary of Forest Laboratories, Inc., agreed to a $313 million settlement to resolve claims that the company unlawfully distributed an unapproved drug product, Levothroid; promoted off-label uses for Celexa; paid kickbacks to induce physicians to prescribe Celexa and Lexapro; and submitted false claims for payment under federal healthcare programs.

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That same month, Allergan similarly settled a Government investigation into whether the company marketed its product improperly and paid kickbacks to physicians. Allergan agreed to pay $375 million in fines and $225 million in civil penalties, totaling $600 million, for its off-label use of Botox for headaches, pain management and cerebral palsy. In the same week, AstraZeneca and Johnson & Johnson each settled cases with the federal Government. AstraZeneca paid $520 million to settle allegations that it unlawfully promoted its antipsychotic drug, Seroquel, and misled doctors and patients about the drug's safety. Johnson & Johnson paid an $81 fine for off-label marketing of its epilepsy drug, Topamax.

Irish drug maker, Elan, paid $203.5 million to settle allegations that it unlawfully marketed its own epilepsy drug, Zonegran. As part of the settlement, Elan's U.S. subsidiary agreed to plead guilty to a criminal misdemeanor and enter into a corporate integrity agreement with the Department of Health and Human Services Inspector General.

2. Information Technology

Information technology companies recently have been confronted with a number of eight figure settlements. For example, last month, Verizon paid the Government $93.5 million to settle charges for allegedly overcharging federal customers on their voice and data contracts. Verizon was accused of invoicing the Government for the company's own property taxes and other costs that were unallowable under Verizon's contracts. The Government argued that Verizon was responsible for paying such costs.

Hewlett Packard Co. (HP) agreed to pay $55 million to resolve allegations that it knowingly paid kickbacks, or "influencer fees," to systems integrators in exchange for recommendations that federal customer's purchase HP's products. The settlement also resolved concerns that HP's General Services Administration (GSA) contract was defectively priced because it provided incomplete information to GSA during contract negotiations. Cisco Systems and Westcon Group North America also agreed to pay $48 million to resolve allegations that they made misrepresentations and provided incomplete information to GSA and other federal agencies during contract negotiations.

EMC Corp. (EMC), paid $87.5 million to settle claims that the company misrepresented its commercial pricing practices causing GSA to enter into a contract at an inflated price. Following contract award, EMC failed to conduct the stated price comparisons that would have afforded the Government the opportunity to acquire the contract deliverables at the lowest price provided to the company's commercial customers making a comparable purchase. Several similar, but smaller settlements were negotiated with the Government involving IBM ($2.9 million), Computer Sciences Corporation ($1.3 million) and PricewaterhouseCoopers ($2.3 million).

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3. Education

As we look to 2011-12, we expect that the Government's scrutiny of educational companies participating under federal financial assistance programs will increase significantly. Currently, for-profit educational entities are subject to increased oversight from the Department of Education (DoEd) because of concerns about low graduation rates, poor career placement and overwhelmingly high student debt.

Earlier this month, Education Management Corporation (EDMC) disclosed that DoJ was joining a *qui tam* lawsuit against the company alleging that EDMC knowingly paid recruiters based on their success in enrolling students, a violation of the Higher Education Act and DoED regulations. Schools that participate in federal financial aid programs are prohibited from taking such incentive-based compensation. The Government does not want schools enrolling unqualified students in return for these incentive payments. EDMC has stated that it will defend itself vigorously against the allegations.

Unrelated directly to the EDMC lawsuit is the recent announcement on May 3, 2011, that the Attorneys General in ten states have initiated a joint investigation into potential violations of consumer protection laws by for-profit colleges. Kentucky Attorney General Jack Conway (D) is leading this multi-state effort. The investigation may have been accelerated by the University of Phoenix's $78.5 million settlement of allegations that the university also provided incentive payments to recruiters based on the number of students that they could recruit or enroll in university programs. This latest agreement in 2010 by the University followed a 2004 settlement, where the university agreed to pay $9.8 million to resolve similar accusations.

Finally, four other student aid lenders paid the Government a total of $57.7 million to settle claims that they improperly inflated their entitlement to certain interest rate subsidies from DoEd. Although DoJ did not intervene in this *qui tam* lawsuit (however, DoJ did assist with the settlement), Nelnet Inc. and Nelnet Educational Loan Funding Inc. agreed to pay $47 million, Southwest Student Services Corp. paid $5 million, Brazos Higher Education Authority and Brazos Higher Education Service Corp. paid $4 million, and Panhandle Plains Higher Education Authority and Panhandle Plains Management and Servicing Corp. paid $1.75 million.

4. Defense and Security

There have been a number of settlements between defense and security contractors and the federal government during 2010. These recoveries, while not the magnitude of the pharma settlements, still demonstrate the continued oversight by the Department of Defense (DoD) and related agencies over contractors' compliance with contracting requirements. For example, Bell Helicopter Textron, Inc. agreed to settle allegations raised by DoD concerning the company's overcharging of the Army and other agencies in connection with the sale, servicing and customization of helicopters. The company paid $16.5 million to resolve these allegations.

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Northrup Grumman agreed to pay $12.5 million to resolve the Government's allegations that the company failed to test electronic components intended for use in navigation systems. These systems were to be integrated into various military platforms, such as aircraft and submarines, as well as certain space-based equipment. Louis Berger Group, Inc., an engineering firm, paid $69 million to settle criminal and civil claims concerning its work under reconstruction contracts in Iraq and Afghanistan. The settlement stemmed from allegations that the company improperly calculated and billed its overhead costs under its government contracts. In another well-publicized settlement, U.S. Food Service, a major supplier to DoD and VA, agreed to pay $30 million to resolve allegations that the company overcharged the Government for food products supplied under various contracts, including domestic military base agreements.

Early in 2010, DoJ announced a $4 million settlement with Lincoln Fabrics Ltd., a Canadian company, over the manufacture of defective body armor containing Zylon fabric. The defective fabric was used in bulletproof vests purchased by federal, state and local law enforcement personnel. This was yet another settlement from a manufacturer of defective body armor containing Zylon fabric – to date, settlements have exceeded $50 million.

5. Financial

Small business lender Ciena Capital LLC paid $26.3 million to settle claims that it submitted misleading and false applications for loans backed by the Small Business Administration (SBA) in May 2010. SBA enforcement activity should increase further, as there have been a number of new regulations issued that amend the eligibility and performance requirements under several of SBA's widely-used government contracting programs.

Department of Housing and Urban Development (HUD) contracting also witnessed increased oversight in 2010-11. For example, DoJ acknowledged in March that the FBI was investigating over 2,800 mortgage fraud cases. More recently, in December 2010, the Government filed a lawsuit against 14 defendants – including sellers, lenders and appraisers – alleged to have engaged in a conspiracy to commit mortgage fraud in New York City.

C. The Current Environment Regarding the Mandatory Disclosure Rule and a Heightened Awareness on Compliance

The passage of the Mandatory Disclosure Rule in 2008 raised the bar significantly by shifting contractor compliance from longstanding voluntary disclosure to mandatory disclosure and full cooperation.

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1. Summary and Operational Impact of the Rule

The Rule imposed onerous requirements on government contractors, *e.g.:*

> The Contractor shall timely disclose, in writing, to the agency Office of the Inspector General (OIG), with a copy to the Contracting Officer, whenever, in connection with the award, performance, or closeout of this contract or any subcontract thereunder, the Contractor has credible evidence that a principal, employee, agent, or subcontractor of the Contractor has committed—
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> > (A) A violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code; or
> > (B) A violation of the civil False Claims Act (31 U.S.C. 3729 - 3733).

(FAR 52.204-13(b)(3)).

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> (2) Whether or not the clause at 52.203–13 is applicable, a contractor may be suspended and/or debarred for knowing failure by a principal to timely disclose to the Government, in connection with the award, performance, or closeout of a Government contract performed by the contractor or a subcontract awarded thereunder, credible evidence of a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code or a violation of the civil False Claims Act. Knowing failure to timely disclose credible evidence of any of the above violations remains a cause for suspension and/or debarment until 3 years after final payment on a contract (see 9.406–2(b)(1)(vi) and 9.407–2(a)(8)).
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> (3) The Payment clauses at FAR 52.212–4(i)(5), 52.232–25(d), 52.232–26(c), and 52.232–27(l) require that, if the contractor becomes aware that the Government has overpaid on a contract financing or invoice payment, the contractor shall remit the overpayment amount to the Government. A contractor may be suspended and/or debarred for knowing failure by a principal to timely disclose credible evidence of a significant overpayment, other than overpayments resulting from contract financing payments as defined in 32.001 (see 9.406–2(b)(1)(vi) and

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9.407–2(a)(8)).

(FAR 3.1003(a)(2)(3)).

Since the implementation of the Rule, most of the disclosures – 80 to 90 percent – have been made to DoD. These disclosures have been made by companies of all sizes, representing a number of different industries.

Toward the end of 2010, it was our understanding that more than 300 disclosures have been made to DoD. A majority of these disclosures seemingly have been made to preclude any future liability and the possibility of suspension or debarment, even though the contractor and DoD (after its review) believe that there has been no statutory/regulatory violation or significant overpayment. Other agencies have received fewer disclosures, *e.g.*, GSA – approximately 30-40 disclosures.

Many of the companies highlighted in Section B., above, likely (a) had ethics codes and compliance programs in place; (b) were required to develop a written Code of Business Ethics and Conduct (Code); and/or (c) were required to create a Business Ethics Awareness Program and Internal Control System (Internal Controls). *See* FAR 52.230-13 (discussing the requirements for a Code and Internal Controls). However, the mere presence of compliance procedures and protocols does not automatically insulate a contractor from liability.

As a practical matter, all contractors should institute internal controls mechanisms regardless of whether the new FAR clause at 52.203-13, Contractor Code of Business Ethics and Conduct, is included or incorporated in a company's government contract. This is the case because FAR Subpart 9.4 now includes as a basis for suspension and debarment a "knowing failure" by a principal to timely disclose a violation of federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations, a violation of the civil False Claims Act or significant overpayment(s) on the contract. To compound matters, the "knowing failure" occurs at any time during contract performance or closeout, and the "basis" extends until three years after final payment on the contract.

2. Mitigation Steps

A contractor should review its existing Code and confirm that it addresses the unique requirements when contracting with the government. If a contractor does not have a Code, one should be created. As noted previously, a contractor should evaluate and incorporate an internal control system into its Code.

The Code also cannot simply be "words on a page." Senior management must enforce the Code – a "Tone from the Top" – to ensure its effectiveness. As a whole, a contractor must foster a culture of compliance by conducting regular training and keeping records of such training sessions (date,

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agenda/scope, attendees). Especially in larger organizations, it is imperative that each of the contractor's business units (a) knows who within the company is conducting business with the Government; and (b) confirms that they understand the FAR and agency supplement requirements (*e.g.,* DFARS, DEAR and GSAR).

Moreover, we recommend that an internal review be completed to determine whether appropriate government contracting business practices are being complied with across the company. As part of the process, company "principals" should be identified and interviewed to assess whether there are any violations that are required to be disclosed in accordance with the Rule. One of the more successful methods to conduct this review is to perform a compliance audit.

These audits are an effective tool to ensure corporate policies and procedures are in compliance with applicable laws and regulations. The audit also should review employee compliance with a contractor's stated processes and practices. The audit team should consist of corporate personnel and/or external resources that have clearly defined the scope of the audit and its stated objectives. During the audit, such top-level activities may include:

- Surveying and/or interviewing personnel to better understand the company's formal and informal system of controls and contracting practices;
- Reviewing documents and other contractor materials;
- Assessing whether a contractor's controls and compliance activities that have been documented during the audit are (a) functioning as intended; and (b) effectively mitigating the risk of noncompliance;
- Evaluating selected company programs and/or contracts to determine compliance with the identified policies and procedures;
- Identifying compliance successes and deficiencies.

The audit deliverables should include a final report to senior management, which will include an in-depth assessment of the contractor's compliance system and an evaluation of company's compliance procedures. The report should further provide prioritized recommendations for improvement and detail any follow-on corrective action and training.

Jeff Newman's practice focuses extensively on all aspects of government contracts, federal and state procurement, and administrative law and litigation. Over the course of his career, he has represented government contractors and commercial vendors before the Department of Defense and virtually all other civilian agencies. Jeff regularly counsels contractors on a wide range of compliance matters from conducting internal investigations to implementing corporate compliance programs.

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