

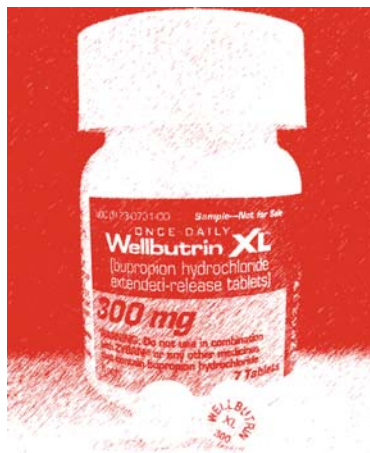
## INDUSTRY NEWS AND CASE UPDATES FROM BROWN RUDNICK'S WHITE COLLAR DEFENSE & GOVERNMENT INVESTIGATIONS GROUP

### FORMER IN-HOUSE COUNSEL ACQUITTED OF CHARGES RELATED TO FDA DOCUMENT PRODUCTION

Following a two-week trial, Judge Roger Titus of the District of Maryland granted the motion for judgment of acquittal made by former GlaxoSmithKline (“GSK”) in-house counsel Lauren Stevens. Stevens was charged with obstruction and false statements in connection with her role in GSK’s response to an FDA inquiry concerning GSK’s alleged off-label promotion of the anti-depressant Wellbutrin.

The Food, Drug and Cosmetic Act forbids promotion of a drug for so-called “off-label” uses — i.e., uses for which the FDA has not approved the drug. In 2002, FDA wrote GSK, asking that GSK provide it with materials related to the promotion of Wellbutrin, in connection with an inquiry into possible promotion of Wellbutrin for weight loss (an off-label use). GSK sponsored promotional programs for Wellbutrin, inviting physicians to speak at

them. In communications with FDA, Stevens noted that GSK would attempt to obtain “materials and documents presented at GSK-sponsored promotional programs, even if not created by, or under the custody or control of GSK.” Stevens agreed that GSK would “keep [FDA] informed” if physicians refused to provide their materials.



Taking advice from outside counsel, Stevens wrote to 550 speakers who had given promotional talks on Wellbutrin, advising them of the FDA inquiry, stating that GSK was cooperating with FDA, and asking for the slides and presentations used in their talks. Approximately 40 of the speakers responded, and Stevens wrote to 28 of them, stating that their materials contained information about unapproved uses of Wellbutrin, in contravention of “FDA’s requirements, GSK policy, and [each speaker’s] contract with GSK.” Stevens

produced to the FDA slide decks used by two of these doctors (the indictment charges that she did so only after learning that a GSK employee had already produced them). And in a letter to the FDA, Stevens stated that although there were “isolated deficiencies,” GSK “ha[d] not developed, devised, established or maintained any program or activity to promote” Wellbutrin for unapproved uses.

Stevens was charged with obstruction for “conceal[ing]” 38 of the unproduced slide decks that contained information regarding off-label uses. Another count charged obstruction in connection with the deletion of information concerning “entertainment” from a spreadsheet containing information regarding Wellbutrin

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promotional speakers. The defense argued that there was no concealment in either case. *First*, although only two slide decks were produced, the FDA knew that “hundreds” of other doctors had given promotional talks on Wellbutrin. The defense argued that it was reasonable for Stevens to believe that FDA knew it had not received every slide deck. *Second*, the spreadsheet had been created by GSK in response to FDA’s request for the date, location, speaker and number of attendees for Wellbutrin promotional events. Because the FDA had not requested the entertainment information, and because Stevens made no representation regarding that information, the defense argued, no such information was “concealed.”

The court dismissed these counts on a broader ground, holding that the obstruction statute’s “safe harbor” provision — which bars prosecution for *bona fide* legal advice, protected Stevens. The court held that the safe harbor provision protects an attorney who “zealously represent[s] his or her client and place[s] their position in the most favorable possible light.” Because GSK “did not come to Ms. Stevens and say, assist us in committing a crime or fraud,” the court found the safe harbor “an absolute bar” to the obstruction counts.

Stevens also was charged with several false statements. Most notably, prosecutors argued that her statement to the FDA that despite “isolated deficiencies,” GSK “ha[d] not developed, devised, established or maintained any program or activity to promote” Wellbutrin for unapproved uses. The government argued that this statement conveyed that GSK “did not engage in off-label marketing activities,” when in fact, there was a “*de facto* corporate program” of such activity. The defense argued that in light of other portions of Stevens’ communications, in which she disclosed off-label promotional activities, rather than denied outright *any* off-label promotion, a more reasonable interpretation of the statement was that GSK “did not have a *plan* to promote off-label, even

though certain off-label promotional activities did take place.” The court agreed, and found this statement — and the other allegedly untrue statements — not to be false.

Stevens also argued that the government had failed to prove the corrupt intent required for a conviction under each count, because in each case, Stevens had relied on the advice of outside counsel. The court agreed, finding that Stevens sought and obtained the advice of counsel, to whom she made full disclosure. Therefore, the court found, “even if some of these statements were not literally true, it is clear that they were made in good faith.”

Decrying the “enormous potential for abuse in allowing prosecution of an attorney for the giving of legal advice,” Judge Titus concluded that the order allowing prosecutors discovery of attorney-client privileged documents on which the prosecution was based — which had been premised on the crime-fraud exception — was “an unfortunate one,” and that Stevens “should never have been prosecuted.” The court wrote that “a lawyer should never fear prosecution because of advice that he or she has given to a client who consults him or her, and a client should never fear that its confidences will be divulged unless its purpose in consulting the lawyer was for the purpose of committing a crime or fraud.”

Although the result appears to be a ringing victory for the defense, the Stevens case raises new concerns for in-house counsel responding to government investigations. First, and most obviously, is the possibility of individual — as opposed to corporate — liability for missteps in the response. This is consistent with DOJ’s avowed intent to pursue individual liability in other areas, including, for example, the FCPA. Moreover, although the Stevens decision makes clear that the obstruction statute’s “safe harbor” provision protects counsel, and draws a distinction between advocacy and false statements, the mere fact that Stevens was indicted in this case is likely to have a chilling effect on in-house counsel in responding to investigatory requests.

## UK MINISTRY OF JUSTICE ISSUES BRIBERY ACT GUIDANCE; ACT TO TAKE EFFECT JULY 1, 2011

Originally scheduled to take effect in April of this year, the UK's new Bribery Act is now slated to take effect July 1, 2011. The British Ministry of Justice used the delay to rewrite Guidance for implementing the Act, responding to fears expressed by many businesses and commentators that the new law was too draconian. The new Guidance was issued in late March. The Guidance is not meant to be a "one-size-fits-all" prescriptive document. Instead, it focuses on the more general concept that all companies, no matter their size, should have in place procedures to prevent bribery that are commensurate with the risks that company personnel may engage in bribery.

The Bribery Act casts a wide net, applying to acts occurring in the UK and acts undertaken elsewhere by persons with a "close association" to the UK, including UK citizens and nationals, any individual "ordinarily resident" in the UK and any entity incorporated under UK law. The Bribery Act also applies to any entity that "carries on a business, or part of a business" within the UK. Thus, UK prosecutors are likely to take the position that the Bribery Act applies to a great many multinational corporations.

Like its counterpart, the US Foreign Corrupt Practices Act ("FCPA"), the Bribery Act forbids payments to foreign officials. However, the Bribery Act expands liability, making it a crime for companies to *fail to prevent* bribery in the workplace — businesses, and their senior executives, may be liable for Bribery Act violations unless the employers had implemented effective compliance programs. In addition, unlike the FCPA, which addresses only bribery of government officials, the Bribery Act also covers such payments between commercial entities.



In contrast to the FCPA, the Bribery Act does not criminalize bona fide hospitality and promotional expenses, as long as they are "reasonable" and "proportionate," and the payments are not made with improper intent. In fact, the foreword to the Guidance states, "no one wants to stop firms getting to know their clients by taking them to events like Wimbledon or the Grand Prix," and Section 6 of the Guidance states that "it is not the intention of the Act to criminalize such behavior."

The Bribery Act does not provide for the exception included in the FCPA for facilitation or "grease" payments, which are commonly made in certain countries to expedite routine, non-discretionary processes. The Bribery Act does appear to allow for prosecutorial discretion in cases where companies face difficult problems conducting business in certain areas of the world, however, and the Guidance notes that the common law defense of duress is available in situations where a facilitation payment was made to protect life, limb, or liberty.

To its broader set of liabilities, the Bribery Act offers businesses only one defense — having in place "adequate procedures" to prevent bribery. The Guidance and its accompanying commentary set out six core principles to aid companies in devising and implementing such procedures:

1. Proportionate procedures: policies and procedures must be clear, practical and proportionate to the scale, complexity, and nature of the business and potential bribery risk;
2. Top-level commitment: top-level management must be committed to preventing bribery by associated persons and must foster a culture in which bribery is condemned;

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3. Risk assessment: organizations should assess potential exposure to internal and external risks of bribery;
4. Due diligence: due diligence procedures should be applied to mitigate bribery risks;
5. Communication (and training): organizations should ensure that policies and programs are "embedded and understood" throughout the company through internal and external communication; and
6. Monitoring and review: monitoring and reviews should be designed to prevent bribery and to make improvements where appropriate.

In sum, the Guidance suggests that "adequate procedures" require a robust compliance program, proportional in scope to the risk of bribery, that is actively supported by top management and deeply embedded in the company's culture. A comprehensive risk assessment and a thorough evaluation of the risks associated with current operations (such as how and where in the world business is being conducted) will assist in ensuring compliance with the Bribery Act. For example, companies operating in countries with a high Corruption Perception Index<sup>1</sup> or companies utilizing significant numbers of agents, third parties, distributors, or other intermediaries, face a greater potential for risk of violating the Act, and will likely be held to higher standards in designing "adequate procedures." Companies should assess their individual challenges and obtain legal guidance where necessary on the best method of implementing proper policies and oversight.

<sup>1</sup>Transparency International's Corruption Perception Index measures levels of perceived public sector corruption in 178 countries worldwide on a scale from 10 (highly clean) to 0 (highly corrupt). Denmark, New Zealand, and Singapore are currently tied at the top of the list with a score of 9.3. Somalia has the lowest score of 1.1, Myanmar and Afghanistan have a score of 1.4, and Iraq has a score of 1.5.

## INSPECTOR GENERAL PREDICTS WAVE OF TARP-RELATED FRAUD CASES

On April 28, 2011, the Office of the Special Inspector General for the Troubled Asset Relief Program ("SIGTARP") presented its Quarterly Report to Congress. The Report notes that recent events — including the expiration of the Treasury Department's authority to initiate new TARP investments, the repayment of TARP funds by certain large banks, and the issuance of the final



TARP report by the Congressional Oversight Panel ("COP") — have led to the perception that TARP is "drawing to a close." That however, according to SIGTARP, is "simply not the case." The Report details several TARP-related frauds that have already led to criminal convictions and civil enforcement actions, and notes that although TARP investment authority expired last October, nearly \$60 billion in funds already obligated to existing programs remain to be spent under the program. In short, SIGTARP states that it is "more critical than ever that SIGTARP remain vigilant in protecting taxpayers."

The Report notes that the extraordinary size of TARP funds "inevitably attract[ed] criminal and other unlawful conduct." According to the Report, 61 individuals and 18 entities have been charged in criminal or civil actions related to SIGTARP investigations, and 22 individuals have been criminally convicted. The Report states that there are more than 150 ongoing

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SIGTARP investigations, and that charges will be filed “against more and more criminals.”

Among the “most common” frauds SIGTARP has investigated are schemes to steal money from TARP’s Capital Purchase Program. More than 3,000 banks and other financial institutions applied for TARP capital through CPP, and SIGTARP has found that many applications for such funding were fraudulent, based on multiple sets of books, roundtrip transactions and insider self-dealing. For example, Charles Antonucci, former president and CEO of The Park Avenue Bank, pled guilty to fraudulently obtaining CPP funds by claiming that he contributed \$6.5 million to the bank, when in fact he had borrowed the funds from the bank. Last month, the former chairman of Taylor, Bean & Whitaker Mortgage was convicted of bank, wire and securities fraud in connection with a scheme to obtain CPP funds by falsely claiming that TBW had raised \$300 million from private investors, when the money was actually diverted from a mortgage facility controlled by TBW.

The SIGTARP Report also details fraud investigations against individuals for inducing struggling homeowners to pay them thousands of dollars on false promises of TARP expertise. Several others have faced criminal or civil charges for falsely representing that securities are safe because they are connected to the TARP program.

The Report describes the SIGTARP Investigations Division as a “highly sophisticated white collar investigative agency” and promises that SIGTARP will “remain ‘on watch’ as long as TARP assets are outstanding.” With more than 150 ongoing investigations, there will undoubtedly be many more criminal and civil enforcement actions connected to TARP in the months ahead.

*“Among the ‘most common’ frauds SIGTARP has investigated are schemes to steal money from TARP’s Capital Purchase Program.”*

## PUSH TO TIGHTEN “DEEMED EXPORT” RULES

In a recent report, the General Accounting Office (“GAO”) found that improvements are needed to the controls governing “deemed exports,” in order to prevent the unauthorized release of technology to foreign nationals. One of GAO’s recommended improvements is already in place – new rules promulgated by the US Bureau of Citizenship and Immigration Services (“CIS”) now require employers seeking certain visas for foreign national employees to certify, in Part 6 of Form I-129, that they have reviewed the International Traffic in Arms Regulations (“ITAR”) and the Export Administration Regulations (“EAR”), and determined either (a) that no export license is required, because the affected employee will not have access to restricted information or technology; or (b) that if a license is required, (i) the employer has received the license, or (ii) the employer will prevent the employee from having access to the restricted information or technology until the license is obtained.

The ITAR (administered by the State Department) governs the export of “defense articles” and “defense services,” terms with broad definitions. The EAR (administered by the Commerce Department) govern the export of “dual use” items and technology — those with military and non-military uses. Generally, any person seeking to export any item covered by ITAR must first obtain authorization from the State Department. The EAR does not require authorization in all cases. Instead, it requires the would-be exporter to determine whether a license is required at all (certain uncontrolled items may be exported without any license) and, for controlled items, in



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what circumstances a license is required. The latter determination requires an analysis not only of what is being exported, but also where it is going, who will receive it, and its end use. For example, a license is required to export polygraphs to Honduras, but not to Iceland.

Both ITAR and EAR apply not only to physical shipments of products and technology to foreign countries, but also to “deemed exports” — *i.e.*, the transfer to foreign nationals within the United States of information or technology subject to the ITAR or EAR. If the physical shipment of information or technology to such an individual’s home country would require authorization under the ITAR or EAR, the transfer of that information or technology to the foreign national requires the same authorization. Although the export regulations have their most obvious application to companies that ship items overseas, the “deemed export” rules extend their reach to companies that ship nothing overseas, but that employ foreign nationals. The rules also extend to non-commercial entities, such as research universities.

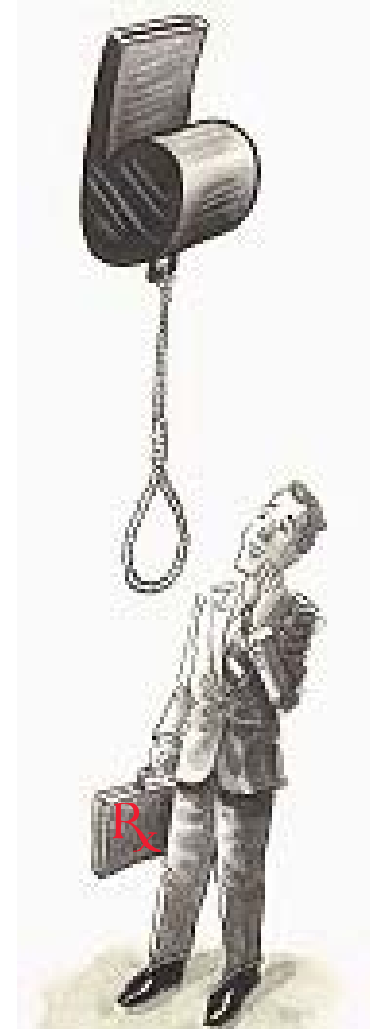
The knowing violation of ITAR or EAR restrictions can lead to civil and even criminal liability. In its report, GAO noted that in the past decade, screening of visa applications for compliance with the export control laws has fallen dramatically. As the new CIS regulations suggest, scrutiny in this area is likely to become much more focused in the future.

### NEW REPORT DOCUMENTS INCREASED FALSE CLAIMS ACT FOCUS ON PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRIES

Last year, DOJ announced that it would make the pharmaceutical and medical device industries a focus of its investigation and prosecution efforts under the Foreign Corrupt Practices Act. A new report indicates that these industries have received similar attention under the False Claims Act (“FCA”).

For its report, the consumer advocacy group Public Citizen attempted to compile a comprehensive database of all major criminal and civil settlements under the FCA between federal and state governments and pharmaceutical companies. Among the report’s conclusions:

- The pharmaceutical industry has overtaken the defense industry — and all others — with regard to the size of payments for FCA violations.
- The pace of these payments has increased. Of 165 settlements comprising \$19.8 billion in penalties during the 20-year interval studied, three-quarters occurred between 2006 and 2010.
- Four companies (GlaxoSmithKline, Pfizer, Eli Lilly, and Schering-Plough) accounted for more than half of all financial penalties imposed over the past two decades.
- The majority of the FCA payments came in cases of alleged off-label promotion of pharmaceuticals, which can also be prosecuted as a criminal offense.
- The most common charge in cases involving state governments — and the source of the largest amount of penalties in these cases — was overcharging state health programs, mainly Medicaid fraud.
- “Whistleblowers,” including former pharmaceutical company employees, were responsible for a growing number of cases. From 1991 through 2000, *qui tam* (whistleblower) cases made up only 9 percent of payouts to the government, but from 2001 through 2010, they comprised 67 percent of total payouts.



## ITALIAN COURT CLEARS BANKS IN PARMALAT SCANDAL

Last month in Milan, four international banks and six individuals were acquitted of criminal charges related to the collapse of the dairy empire Parmalat. A global empire with 36,000 employees in 30 countries, Parmalat collapsed in 2003, revealing a debt of some €14 billion, eight times higher than previously announced. As a result of Europe's biggest bankruptcy — dubbed “Europe's Enron” — more than 130,000 investors in the company's bonds were wiped out. After Parmalat's collapse, Italian prosecutors claimed to have uncovered a web of corruption involving international banks in what was said to be the biggest example of fraud in Italy in a century.

The four international banks — Citigroup, Morgan Stanley, Deutsche Bank and Bank of America — had been accused of lacking procedures necessary to prevent the alleged crimes that contributed to Parmalat's collapse. Earlier this year, the Italian prosecutor asked that they be fined, and that €120 million of their profits be impounded. The banks, which claimed they were defrauded by Parmalat, denied any wrongdoing. All four banks have now been cleared of criminal charges against them. In addition, the Milan court also cleared all the executives charged in the market-rigging trial.

Consumer groups representing retail investors damaged in the collapse, however, have continued to voice their objections. “A fraud of this kind never would have been possible without the collaboration of the banks that issued the bonds,” said Pietro Giordano of Adiconsum. Italian judges now have up to three months from the date of judgment to publish their reasoning behind the verdict and prosecutors may still decide to appeal. The end result is, thus, yet to be seen.



*“A fraud of this kind never would have been possible without the collaboration of the banks that issued the bonds...”*

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