# Whistleblower Protections for FDA and Private-Sector Employees

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# Whistleblower Protections for FDA and Private-Sector Employees

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Abstract

The goal of this paper is to provide an introduction to the whistleblower protection laws that impact the FDA as well as publicly traded pharmaceutical companies. The paper begins by discussing the recent developments surrounding Merck's voluntary recall of Vioxx. The discussion focuses on the fact that Merck allegedly knew of the drugs safety issues yet kept it on the market for several years, even seeking additional indications from the FDA. The paper looks at David Graham's involvement as a whistleblower and examines his best avenue for redress against retaliation, the Whistleblower Protection Act of 1989. Following the discussion of the Whistleblower Protection Act, the paper considers what the options would have been were a whistleblower to come from within a pharmaceutical company instead of from the FDA. That discussion revolves around the Sarbanes-Oxley Act. I outline how and why Sarbanes-Oxley applies to pharmaceutical companies and then move to an analysis of the Act's statutory language, outlining how one would bring a Sarbanes-Oxley whistleblower claim procedurally. Following this discussion, the paper gives a cursory analysis of other whistleblower retaliation statutes and issues, attempting to alert the reader that there are other avenues available and that additional considerations may be necessary, depending on the particular circumstances surrounding the retaliatory action. The paper concludes by looking at the current whistleblower climate

and suggesting that the FDA may need its own whistleblower statute, particularly if courts begin to reign in Sarbanes-Oxley's currently widening scope.

## I. What do Sarbanes-Oxley and Whistleblower Protections have to do with Vioxx, Merck, and I

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### The Merck Situation Overview

On September 30, 2004, Merck announced that it was pulling Vioxx from the

worldwide market. The decision was motivated by clinical trials that found an increased heart attack and stroke risk in patients who regularly ingested the drug. According to Merck, clinical data demonstrated that patients suffered an increased risk of heart attack and other cardiovascular complications as early as eighteen months after beginning a Vioxx regimen. Merck ended the clinical trial after researchers found a higher incidence of heart attack risk inpatients taking Vioxx than in patients taking a placebo.

Beginning in 2001, doctors at the Cleveland Clinic that reexamined the existing data and determined that Vioxx did in fact present a potential heart attack risk. In the face of mounting criticism and evidence suggesting a higher incidence of heart attack risk associated with Vioxx consumption, Merck launched a public relations campaign. Merck has apparently known for several years about Vioxx's public health concerns, yet it acted to keep Vioxx on the market, emphasizing the drug's effectiveness and safety. Merck ignored clinical criticisms and fought for, and won, the approval to expand Vioxx's applications, marketing the drug for juvenile arthritis and migraine headaches.

Merck's disclosures and voluntary recall of Vioxx caused the price of the company's common stock to fall on September 30 by 25%, roughly $12 per share. The market capitalization loss was around $26 billion. Following Merck's disclosures and the accompanying drop in stock price, several federal class action lawsuits were filed on behalf of individuals that purchased Merck securities in the time period between October 30, 2003 and September 29, 2004.

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Vioxx Background:

Merck, headquartered in Whitehouse Station, New Jersey, is a global pharmaceutical company that develops, manufactures and markets a range of human and animal health products. As of September 30, 2004, Merck has approximately 2.2 billion shares outstanding that traded on the New York Stock Exchange. Vioxx is a member of a class of drugs called COX-2 inhibitors, a compound that blocks an enzyme responsible for causing pain. COX-2 inhibitors allegedly do not interfere with COX-1, which protects the stomach's lining. The first COX-2 inhibitor was Pfizer's Celebrex, launched in 1998, which remains the largest selling COX-2 inhibitor. Vioxx, however, had nearly 2 million patients at the time of market withdrawal, and nearly 84 million patients have used the drug since its approval. Vioxx accounted for $2.5 billion of Merck's total sales in 2003.

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The Vioxx Issue

Throughout Vioxx's lifetime, Merck has touted the drug's success and the positive effect that the drug's strong sales and overall performance had on the company's financial condition. On October 22, 2003, however, Merck released its third quarter results and announced that it was cutting 4,400 jobs. An article published by Reuters, titled "Merck to Cut 4,400 Jobs, Posts Flat Earnings," noted that sales of Vioxx were hurt by findings that the drug was associated with an increased risk of heart attack coupled with the growing body of evidence that suggested that Vioxx was not any more effective than many other drugs on the market:

> Merck & Co., Inc. said on Wednesday that it would cut 4,400 jobs and reported disappointing earnings, hurt by falling sales of arthritis medicine Vioxx and a paucity of profitable new drugs... Sales of Vioxx fell 32 percent in the period to $510 million. The arthritis drug is suffering from clinical trial data suggesting that it might slightly raise the risks of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers.

Following this news on October 23, 2003, the price of Merck's stock declined, trading as low as $44.85 per share, or more than $2.05 lower than its previous trading day.

Given these disclosures and the resulting decline in Merck's stock price, a series of securities class actions were filed against the company, Raymond V. Gilmartin, Merck's Chairman, President and Chief Executive Officer, and other officers and directors of the company.[1]

[1] These cases were consolidated under the caption, *Pringle v. Merck & Co. et al.,* Case No. 03-3125. The consolidated class action asserts claims on behalf of Merck shareholders that bought Merck common stock between May 21, 1999 and October 22, 2003.

Following the October 2003 disclosures that served as the basis for the Pringle litigation, Merck and its management and officers embarked on a new strategy in hopes of saving the company's reputation and alleviate some of the concerns raised by the Reuter's article. Merck needed to keep Vioxx on the market and even expand the medical indications for which the drug could be prescribed. The pressure to push Vioxx was particularly strong in light of the fact that Zocor, Merck's blockbuster cholesterol reducing medication, is slated to lose patent protection in 2006, and should result in a drop in Merck's sales when faced with generic competition. These factors, coupled with Wall Street concerns that the company is moving too slowly in expanding its pipeline, caused Merck to feel substantial pressure to make Vioxx a blockbuster, and in the face of this pressure, Merck may have acted inappropriately, hiding the true nature of the drug's safety profile.

On October 30, 2003, The Wall Street Journal published an article entitled "Vioxx Study Sees Heart Attack Risk – Merck Funded Research After Concerns Were Raised About Its Painkilling Drug." The article states that a study, from Harvard University-affiliated Brigham & Women's Hospital in Boston and funded by Merck, found an increased risk of heart attack, or acute myocardial infarction, compared with patients' taking a competing painkiller, Celebrex, from Pfizer, Inc. The researchers also found Vioxx, which has annual sales of $2.5 billioin a year, was linked to an increased heart attack risk compared with patients not taking any painkillers. Researchers found that the apparent cardiac risk was greatest in the first 90 days in which a patient was taking Vioxx, which generically is known as rofecoxib. In the first 30 days, the researchers found the Vioxx was linked to a 39% increase in heart attack risk compared with Celebrex. Between 30 and 90 days, the increased relative risk was 37%. After 90 days there did not appear to be any increased risk. The company immediately moved to counter the data generated by the study and to

discount the study's conclusions. For example, in an article published in American Health Line on October 31, 2003, Alise Reicin, Merck's executive director of clinical research stated: "Randomized clinical trials are the gold standard and this isn't such a trial... In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo.

On November 13, 2003, Merck filed its second quarter 2003 report on Form 10-Q with the SEC. The report contained several false and misleading statements and material omissions. Merck continued to discredit past accusations concerning Vioxx. With regard to the previously filed litigation in Louisiana and other jurisdictions, Merck characterized the claims as "without merit," even though the company was in the process of conducting various trials and investigations concerning Vioxx's safety profile. Merck continued to hail Vioxx as the as the most widely prescribed and most frequently preferred coxib on managed care formularies, with more than 85 million prescriptions. The company made such statements despite the knowledge that Vioxx was potentially, if not probably, plagued with safety issues, and its preferential status would be lost once prescribers became aware that Vioxx was associated with serious cardiac problems.

On December 9, 2003, Merck issued a press release that, in part, stated that each of its current products ranks either No. 1 or No. 2 in sales across large therapeutic areas.[2] At the time of the press release Merck stated that Vioxx held the No. 2 position in the competitive U.S. coxib market and was the No. 1 coxib in the European market. Additionally, Merck has filed sNDAs with the FDA for an indication for migrane and juvenile rheumatoid authorities. These new uses are expected to enhance the efficacy profile of the product. Full-year 2003 sales totaled $2.5 billion, a 2% increase over 2002, and estimated wholesaler buy-in for Vioxx favorably impacted the revenues for the fourth quarter by some $40 million dollars. The press release emphasized the Vioxx was the most widely available coxib on managed care and the only one on the

[2] "Merck Strategy to Deliver Long-Term Shareholder Value," Dec. 9, 2003 Press Release.

U.S. market that offers 24 hour pain relief in a once-daily tablet for all indications.

On March 10, 2004, Bloomberg issued a report that Vioxx may carry a risk of heart attack and, more specifically, that the drug was linked to a higher risk of heart attack for patients with high blood pressure, according to a study funded by Pfizer, Inc. that examined possible risks associated with an array of painkillers.

So the trend was for studies to indicate that there was a potential for serious health risks, and Merck would respond by ignoring and/or attacking the studies while simultaneously launching marketing campaigns aimed at increasing Vioxx sales. Merck's voluntary recall on September 30, 2004 came as quite a surprise after several years spent denying that the drug posed a public health hazard. The FDA, which had just approved the drug for juvenile rheumatoid arthritis earlier that month, issued a Public Health Advisory that informed Vioxx users of Merck's recall and advising that users consult with their physician about alternative medication. Following the withdrawal, Merck retracted its third-quarter profit forecast and cut its full-year estimates by 50 cents to 60 cents per share. These announcements caused the company's stock to fall $12.07 to $33 per share, representing a 26% single day decline. Merck's market capitalization subsequently declined by nearly $26 billion.

On October 6, 2004 additional information was released pertaining to the study led by the FDA that was one of the contributing factors in Merck's recall decision. The study indicated that Vioxx may have been responsible for more than 27,000 heart attacks and sudden cardiac deaths. Specifically, the study, based

on an analysis of patient information, found that had patients been taking Celebrex, a Vioxx competitor, instead of Vioxx, 27,785 heart attacks and sudden cardiac deaths may have been avoided. Cardiologists have begun to call for a Congressional investigation into the approval process for the drug and have raised questions about similar adverse effects in similar medications.

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David Graham

On October 7, 2004, Dr. David Graham, an associate director in the FDA's Office of Drug Safety, disclosed that he was pressured by supervisors to suppress conclusions that Vioxx presented a public health hazard. Dr. Graham blames the FDA for allowing dangerous drugs to stay on the market and generally running a dysfunctional organization. Graham was quoted on CBS saying, "I know that FDA is responsible for 100,000 people being injured. And FDA wants to keep that swept under the rug."[3] The numbers he cited are based on his estimates of the number of Americans harmed by Vioxx and over the five years that the FDA allowed the drug to be on the market despite evidence that that it increased the risk of heart attack and stroke. Graham charged, before a Senate Committee, that the FDA had failed to act on Vioxx and was likely making or going to make the same mistake with other dangerous drugs due to what he characterizes as fatal flaw in the FDA's organization. The flaw is based on what Graham calls a "house divided," in which there are some scientists that study the long-term safety of already approved drugs but far more scientists involved with the process of reviewing and approving new drugs. Furthermore, Graham asserts the FDA has a system in place that "guarantees that unsafe drugs will remain on the market."[4]

[3] FDA: Harsh Criticism from Within, February 16, 2005. CBSnews.com.
[4] *Id.*

By August 2004, after a three-year FDA approved study on Vioxx, Graham told his supervisors that he thought that all high doses of the drug should be pulled from the market. He claims that the recommendation was met with resistance, retaliation, anger and hostility. The study, conducted with Kaiser Permanente of northern California, was initially submitted by Graham to the Lancet, but he retracted the findings after an alleged warning from his supervisor about publication. The FDA issued a statement after the Senate hearing claiming that Graham had not adhered to agency protocol when he submitted his data to the Lancet. When the British Medical Journal asked about the FDA's statement and publication of the study, Graham referred them to his attorney and legal director for the Government Accountability Project (GAP), Tom Devine. Devine commented that Graham feared for his job and sought his organization's help with the aftermath of the Vioxx study. Interestingly, GAP received an anonymous call from a party claiming to be a whistleblower inside the FDA and that he was being bullied by Graham and alleging that there was a possibility of scientific misconduct in Graham's study.[5] The "whistleblower" turned out to be FDA management, which, according to Devine, had full control over Graham.[6] Devine has asserted his belief that the FDA has attempted to discredit Graham instead of providing any scientific evidence contradicting the study's conclusions. Devine contends that these attacks lack credibility in the face of Graham's long career with the organization, and his history of correctly identifying dangerous drugs.[7] There is also some concern that Graham has been threatened with exile from his area of expertise within the division of drug safety and transfer to a bureaucratic position in the commissioner's office with little or no access to safety data.

[5] www.fda.gov/bbs/topics/news/2004/NEW01136.html.

[6] The determination that the anonymous caller was FDA management was made by Devine based on phone numbers and other identifying information.

[7] Throughout Graham's career 10 of 12 drugs that he has recommended to be removed from the market have been removed, including troglitazone (Rezulin), concomitant fenfluramine and phentermine (Phen-fen), and temafloxicin (Omniflox).

Grahams' situation serves as a springboard into the issue of whistleblower protections. What protections are available to Graham as a government employee? If Graham were a Merck employee, then he would be covered by the whistleblower protections of the SOX. However, since SOX applies only to publicly traded companies, Graham doesn't enjoy its protections. The best option for Graham is the Whistleblower Protection Act of 1989 (WPA). The situation, however involves a publicly traded company, and a whistleblower could have come from within Merck just as easily as from within the FDA, so it seems that it is appropriate, in light of the Vioxx scandal and recent general corporate accountability concerns, that the whistleblower discussion address options for both governmental and non-governmental whistleblowers. As the paper will discuss in the sections dealing with SOX, Merck, based on the information provided in quarterly reports and its alleged knowledge o Vioxx's threat to public health will likely be subject to the fraud and disclosure provisions of the act. Had the whistleblower come from inside Merck, SOX' whistleblower protections would apply. Therefore, this paper will examine both the WPA and SOX.

## II The Whistleblower Protection Act of 1989

The United States adopted whistleblower protection in the form of the Whistleblower Protection Act on July 9, 1989 and took further measures to strengthen the protections by enacting Public Law 103-424, which extended protections to employees of government corporations and to employees in the Veteran's Administration. The WPA is an anti-retaliation statute prohibiting the federal government from taking reprisals against employees that blow the whistle on public sector misconduct and providing a means of redress for employees. The Act provides for a secure internal mechanism for dealing with whistleblowers, and, in this way, employees can, in theory, make disclosures of wrongdoing without fear of retaliation.

The WPA model is based on a multilateral system in which whistleblowers are able to petition two governmental Executive branch agencies for protection against retaliation due to their reporting of wasteful or illegal activities or activities that pose a danger to public safety.[8] The two agencies charged with upholding the WPA are the Office of the special Counsel (OSC) and the Merit Systems Protection Board (MSPB).[9] The relationship of the Special Counsel to the Merit Systems Protection Board is that of a prosecutor to a judge, both of which serve as appellate organizations providing a mechanism by which U.S. public service employee's rights are upheld. The Civil Service reform Act (CSRA) of 1978 initially created the MSPB and the OSC, along with the Office of Personnel Management (OPM) and the Federal Labor Relations Authority. The OSC was, prior to 1994, a component of the MSPB, but it has since enjoyed full executive branch status.

To be a protected whistleblower in the United State federal government, one must make a disclosure to either the Special Counsel, Inspector General of an agency, or any other individual or organization, provided that the disclosure is not prohibited by law. A whistleblower may file complaint with the OSC with respect to most personnel actions allegedly based on whistleblowing ranging from appointments and reassignments to awards and training.

[8]WPA § 1213 Provisions relating to disclosures of violations of law, gross mismanagement, and certain other matters
(a) this section applies with respect to –
(1) any disclosure of information by an employee , former employee, or applicant for employment which the employee, former employee, or applicant reasonable believes evidences –
(A) a violation of any law, rule, or regulation; or
(B) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety

[9]WPA § 1212 Powers and functions of the Office of Special Counsel
(a) the Office of the Special Counsel shall –
(1) in accordance with section 1214(a) and other applicable provisions of this subchapter, protect employees, former employees, and applicants for employment from prohibited personnel practices;
(2) receive and investigate allegations of prohibited personnel practices...
The MSPB's powers can be found in Title 5 U.S.C. (12) (1) § 1204.

a. Office of the Special Counsel

The OSC, an independent federal investigative and prosecutorial agency, is the primary agency responsible for implementing the WPA. The OSC investigates complaints from people who allege to have suffered reprisals as a result of disclosing information about misconduct. Their primary mission is to safeguard the merit system by protecting federal employees and applicants from prohibited personnel practices, especially reprisal for whistleblowing. The OSC also serves as a safe and secure channel for federal workers who wish to disclose violations of laws, gross mismanagement or waste of funds, abuse of authority, and specific dangers to the public health and safety. Additionally, the OSC enforces and provides advisory opinions regarding the Hatch Act, and protects the rights of federal employee military veterans and reservists under the Uniformed Services Employment and Reemployment Rights Act of 1994.[10]

In a March 1999 statement before the Subcommittee on Oversight and Investigation Committee on Veteran's Affairs in the U.S. house of Representatives, Eline Kaplan, Special Counsel, provided an abbreviated summary of how the OSC prosecutes complaints:

[10]The *Hatch Act* regulates restrictions on political activity by government employees.

> [W]e have a Complaints Examining Unit known as "CEU," which serves as our intake unit. It is staffed by 14 examiners who conduct preliminary investigations into about 2000 complaints per year... Through a committee process, where other lawyers and investigators participate, they determine whether a prima facie case has been alleged and whether further investigation is warranted. In 1998 about 20 percent of the whistleblower retaliation complaints filed in the CEU were referred to our Investigation Division for further investigation. The remainder were closed. When a preliminary decision to close a matter has been made, the CEU sends out a preclosure letter to the complainant that spells out the reasons for the decision. The complainant may respond in writing to the preclosure letter and provide additional information within 16 days.

If after an investigation the Special Counsel determines that there are reasonable grounds to believe that a violation has occurred or may occur, the Special Counsel may bring a corrective action against the agency. Additionally, the Special counsel has the authority to bring disciplinary action against an employee alleged to have committed a violation. The procedures carried out by the OSC are taken from the OSC website and are as follows:

> [w]hen the Special Counsel sends the information to the agency, the agency head must conduct an investigation and submit a report to the Special Counsel. The Special Counsel sends the agency report, along with any comments provided by the whistleblower, and any comments or recommendations by the Special Counsel, to the President and the congressional committees with jurisdiction over the agency. If the OSC does not send the whistleblower's disclosures to an agency head, it returns the information and any accompanying documents to the whistleblower. The OSC sends the whistleblower a letter explaining why the Special Counsel did not refer the information. This letter will let the whistleblower know what other disclosure channels may be available.[11]

A 1997 report on whistleblowing by the Competition Bureau of Canada outlines the historically dysfunctional state of affairs of the OSC, stating that the Office of the Special Counsel was widely criticized throughout the 1980s and early 1990s for its ineffectiveness in encouraging whistleblowers to come forward, and protecting them from reprisals.[12] A 1993 report by the U.S. government's General Accounting Office found that most federal employees knew very little about their whistleblower rights. The Whistleblower Protection Act of 1989 was intended to improve the effectiveness of the OSC, and to increase protection for federal whistleblowers generally. For example, under the new provisions, employees can take their own cases to the federal government's Merit Systems protection Board if they are not effectively pursued by the OSC.[13]

Prior to the WPA, if a whistleblower filed a complaint with the OSC and the OSC did not seek corrective action from the Board, no further recourse was available, unless the action was directly appealable to the Board.[14] Now, under the WPA, a whistleblower may appeal directly to the Board if he first complains to the OSC and the OSC does not seek corrective action on his behalf.

*b.*

Merit Systems Protection Board

The responsibilities of the MSPB for whistleblower protections is outlined under

Title 4, Code of Federal Regulations Administrative Personnel, Chapter 11, Subchapter A, Part 1209. Specifically the MSPB deals with appeals or stay requests filed by an employee, former employee, or applicant for employment where the appellant alleges that a "prohibited personnel action" was threatened, proposed,

[12] http://strategis.ic.gc.ca/epic/internet/incb-bc.nsf/en/ct01111e.html.

[13] *Id.*

[14] Actions that are directly appealable to the Board include: adverse actions, performance based removals or reductions in grade, denials of within-grade salary increases, reduction-in-force actions, and denials of restoration or re-employment rights.

taken, or not taken because of the appellant's whistelblowing activities.[15] An employee who appeals a personnel action to the MSPB may raise the affirmative defense that the action resulted from a prohibited personnel practice. The CSRA authorized the MSPB to hear appeals of various agency actions including:

1. if a personnel action involves a prohibited personnel practice, regardless of whether the action is otherwise appealable to the Board, the employee may file a complaint with the Special Counsel, asking that the Special Counsel seek corrective action from the Board;

2. under the WPA, an individual who alleges that a personnel action was taken, not taken, or threatened because of whistleblowing may seek corrective action from the Board directly if the Special Counsel does not seek corrective action on his behalf;

3. additional jurisdiction issues arise when the employee is a member of a bargaining unit that has negotiated grievance p procedures covering any of the actions that may be appealed to the board.[16]

If an employee chooses to appeal to the board, the MSPB must have jurisdiction over both the action and the employee filing the appeal. It is also specified that the appellant must file with the appropriate MSPB regional office, therefore geography becomes an issue when filing an appeal. Within the specified jurisdiction, an administrative judge issues an initial decision. This decision stands final after 35 days if a petition for

[15] "Prohibited personnel action" is a term defined by law at §2302(b) of Title 5 of the United States Code to denote a list of twelve protected personnel practices, including those dealing with whistlebowing. It is prohibited to take, threaten to take, or fail to take personnel action because of an individual's legal disclosure of information evidencing wrongdoing ("whistelblowing").

review is not filed with the Board. Additionally, any party, OPM, or the Special Counsel may petition the full Board in Washington to review the initial decision. Special counsel corrective and disciplinary actions or actions against administrative law judges, after the initial decision is issued, may be petitioned to the Board to review the decision in question. In corrective action cases, the Board can order the agency to take necessary steps to correct the prohibited personnel practices or patterns of such practices. In disciplinary actions, the Board may order the employee's removal, reduction in grade, suspension, reprimand, debarment from Federal Employment of period not to exceed 5 years, and/or a fine up to a maximum of $1100.

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Two Types of Whistleblower Appeal under the WPA of 1989

The United States generally classifies whistleblower appeals as "otherwise appealable actions" and "individual right of action." The primary difference is procedural; the appeals reach the board in different ways. An "otherwise appealable action" is defined in an MSPB document as an "individual subject to a personnel action that is directly appealable to the Board and the individual claims that the action was taken because of the whistleblowing."[17] Just because the individual has the right appeal directly to the Board and chooses instead to first file a complaint with the OSC, does not mean that he forfeits the right to file a complaint with the Board after filing with the OSC if the OSC does not seek corrective action on his behalf. In going first to the OSC to seek protection, the whistleblower leaves himself a second chance if the OSC does not pursue an action on his behalf.

III.

How Does SOX Apply to Merck and Other Pharmaceutical Comp

[17] *Questions and Answers About Whistleblower Appeals*

The Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 stat. 745 ("SOX") was Congress' reaction to the recent corporate accounting scandals like those of Enron and WorldCom. While SOX's principle focus is on corporate accountability, the statute also contains significant protections for corporate whistleblowers. The question for our purposes is whether SOX's whistleblower protections encompass the type of activity that the FDA would likely be concerned with or if it only protects whistleblowing with respect to accounting practices. The short answer is that SOX definitely covers many corporations that are regulated by the FDA (think publicly traded pharmaceutical companies), and the provisions dealing with shareholder fraud and disclosure apply to Merck and will apply to other pharmaceutical companies in the future. Issues that the FDA is involved in such as drug safety and efficacy directly impact companies' financial outlooks and therefore involve SOX. However, SOX is a relatively new statute, and companies are scrambling for compliance as the courts struggle to interpret and apply the Act. There are relatively few cases on point, so I am operating more on logic and reasonable interpretations of the text and extensions of case law to argue that SOX should have real implications in the Merck Vioxx scandal, and that whistleblower protections could apply in the instant matter as well as to similar future situations. The whistleblower in this case is from the FDA, but it is possible if not likely that in the future a whistleblower could come from within a pharmaceutical company and alert the FDA to an unsafe drug, for example. So, in this section I will look first at how the Merck may be liable under SOX, and in the next section, I will outline SOX' whistleblower protections and discuss how one would procedurally bring a whistleblower retaliation claim under the act. The discussion is moot in the sense that it has no apparent bearing on the Vioxx situation, as there is no corporate whistleblower, but it is quite relevant for determining the rights of and laying out the appropriate steps for future in-house, publicly-traded pharmaceutical company whistleblowers. The next two sections of the paper will illustrate how SOX applies to Merck and, for that matter, any pharmaceutical company.

a. Fraud against shareholders

SOX forbids retaliation against an employee that violates "any provision of federal law relating to fraud against shareholders."[18] The question is whether Merck's activities around Vioxx and the resulting stock plunge qualifies as a fraud against shareholders that will subject Merck to liability under SOX. The determination has less practical application in the instant matter, seeing that the whistleblower came from outside of the company, but the implications for future cases involving in-house whistleblowers is important. The best answer at this point is "probably," as the courts are actively determining SOX' scope and limitations.

The courts recently dismissed a case where shareholders in a pharmaceutical company sought to allege securities fraud in a situation that appears similar to Merck's current predicament. In In re QLT Inc. Sec. Litig., a class of stock purchasers alleged that defendants issued false and misleading information to the public concerning sales projections for the corporation's product.[19] The court concluded that statements regarding the size of the existing market for the product and the corporation's progress in seeking Health Care Financing Administration approval concerned existing facts and were not forward-looking and were not subject to the statutory safe harbor or the bespeaks caution doctrine.[20] $Statementthatthecorporation'sresultsfromacertainquarterwerenotgoingtobeaone$ pursuant to 15 U.S.C.S. § 78u-5(c)(1)(A)(ii) and insufficient to support a claim of securities fraud. Further, the purchasers did not sufficiently plead that fourth quarter sales forecasts were false when made, and, as to

[18] 18 U.S.C. 1514(a)(1).

[19] *In re QLT Inc. Sec. Litig.*, 312 F. Supp. 2d 526.

[20] The Private Securities Litigation Reform Act of 1995, 15 U.S.C.S. § 78u-4, creates two categories of statutory safe harbors. First, there is no fraud liability under federal securities laws for making a forward-looking statement if such a statement is either (i) identified as forward-looking and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the statement; or (ii) immaterial. 15 U.S.C.S. § 78u-5(c)(1)(A). Secondly, the statutory safe harbor also insulates from fraud liability the making of a forward-looking statement unless a plaintiff can prove that such a statement was made with actual knowledge by that person that the statement was false or misleading. 15 U.S.C.S. § 78u-5(c)(1)(B)(i). The judicial bespeaks caution doctrine protects forward-looking statements accompanied by adequate cautionary language from being actionable. Specifically, under the bespeaks caution doctrine, alleged misrepresentations are immaterial as a matter of law if it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language.

alleged exaggeration of the market for the product, did not plead the element of loss causation, which linked damages they suffered to the exaggeration; the complaint contained no allegation that the exaggeration directly caused the sharp fall in stock price.

The plaintiffs in QLT failed to establish the necessary scienter on the part of the company. The court stated that scienter may be established in one of two ways: (1) "by alleging facts to show that defendants had both motive and opportunity to commit fraud," or (2) "by alleging facts that constitute strong circumstantial evidence of conscious behavior or recklessness."[21] As the United States Court of Appeals for the Second Circuit explained in Novak, motive denotes concrete benefits that misrepresentations could create and opportunity entails "the means and the likely prospect of achieving concrete benefits by the means alleged."[22] Reckless conduct, while "harder to identify with... precision and consistency," can involve "an egregious refusal to see the obvious, or to investigate the doubtful."[23] The difference between QLT and Merck's situation is that in QLT, the shareholders were suing over forward-looking statements in the form of sales forecasts that ultimately proved untrue and negatively impacted the company's stock value. The court found that plaintiffs could not prove that the sales forecasts were untrue when made simply because they proved to be erroneous. Finding liability here would mean holding the company liable for "fraud by hindsight," a concept that courts have long rejected.[24] To prevail plaintiffs need to show that QLT possessed information at the time the sales forecasts were made that rendered the forecasts misleading or fraudulent. It seems that this statement makes the difference in the Merck's case, as facts suggest that Merck knew for some time that Vioxx was dangerous, and the company made forecasts and statements that were misleading in light of this information. While Merck touted the virtues of Vioxx it allegedly knew of the heart complications associated

[21] *Globalstar*, 2003 U.S. Dist. LEXIS 22496 at *15 *(quoting Novak v. Kasaks*, 216 F.3d 300, 307*)*
[22] 216 F.3d at 307 (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1130, 2d Cir. 1994).
[23] *Id.* at 308 (quoting *Chill v. General Electric Co.*, 101 F.3d 263, 269 (2d Cir. 1996)).
[24] *See Stevelman v. Alias Research Inc.*, 174 F.3d 79, 85 (2d Cir. 1999); *Shields*, 25 F.3d at 1129.

with the drug, suggesting that it intended to mislead investors. If Merck's forward-looking statements are held to be fraudulent, then it will violate federal fraud provisions and will likely fall under SOX coverage. Once SOX is determined to apply, its whistleblower protections would come into play were the whistleblower to come from inside Merck.

Another recent case alleging fraud against shareholders under SOX is Livingston v. Wyeth Inc..[25] Wyeth is a pharmaceutical company that manufactures the pneumococcal meningitis vaccine Prenvar, one of the most lucrative vaccines ever developed. The vaccine, which takes a full year to produce, also provides some protection from pneumococcal infections of the ear and sinus. But thousands of infants and toddlers won't receive the full inoculation, consisting of four shots, at the recommended age, when they are at greatest risk of infection, because of the most recent shortage of Prevnar that began in February of 2004. The CDC advised pediatricians to postpone the fourth shot of Prevnar to conserve scarce vaccine stocks; later the CDC advised that patients be limited to two doses. Supplies are expected to remain tight through the summer and perhaps beyond, the CDC says. We're barely holding on to a two-dose schedule, reports Lance Rodewald, the CDC's director of immunization services.

Wyeth says the current shortfall of Prevnar is the result of too little capacity at its factory in Pearl River, N.Y., where sterile vials are filled with vaccine and packaged. The company says it expects to resolve the problems fully by the end of the first half of 2004. Meanwhile, a former Wyeth executive, Mark Livingston, has filed an unusual lawsuit alleging that in the haste to create more vaccine, Wyeth cut corners at another plant involved in Prevnar production, raising questions of quality control. The lawsuit, naming Wyeth and two employees, was filed in October in U.S. District Court in Greensboro, N.C., by former Wyeth

[25] *Livingston v. Wyeth Inc. et al,* No. 03-CV-919.

manufacturing manager, Livingston, who trained workers at a factory in Sanford, N.C.. Bulk vaccine is processed there before being shipped to a Pearl River facility for packaging. In the suit, Mr. Livingston alleges that Wyeth was so far behind in efforts to meet demand for Prevnar that it cut corners in training at the plant and failed to comply with standards set by the Food and Drug Administration. The suit alleges Wyeth at times kept lax records, raising quality-control questions and contributing to the problem of shortages. Mr. Livingston says he was dismissed in retaliation for complaining about these issues to higher-ups. What is novel about the suit is the plaintiff's claim that Wyeth's conduct amounted to fraud against shareholders in violation of SOX. In order to prevail, Livingston must prove that he reasonably believed company misconduct violated SEC rules and must have made those concerns known to relevant federal officials or company executives in a position to discover and terminate the misconduct. If those conditions are met, the plaintiff could be covered by SOX' protections against whistleblower retaliation and discharge. The case is currently pending, and the potential precedent is tremendous. If the court finds that a company's manufacturing and personnel training amount to noncompliance with FDA and other federal standards in such a way that constitutes fraud against shareholders and invokes SOX whistleblower protection, employees should have a much easier time establishing that they reasonably believed that their company has engaged in fraud against shareholders. If manufacture and compliance are in the sphere of shareholder fraud, it seems that most activities that an employee can report could be construed as fraud, and concealing potentially deadly side effects of a drug would almost certainly fall under SOX.

There are many cases where SOX whistleblower protections have been held to apply to matters that are seemingly unrelated to the accounting scandals surrounding its creation. For example, in Morefield v. Exelon Services, Inc., the complainant, the former vice president of finance for a corporate subsidiary, alleged that he

had been threatened, intimidated and, ultimately, terminated from his employment after he reported that top management of the subsidiary intentionally manipulated internal financial results, forecasts and accounting records to make the company's financial performance appear better than it actually was.[26] Though the complaint had been dismissed at the administrative level, the ALJ reinstated it. In seeking dismissal, the company contended, first, that no violation of any applicable securities rule or law had been stated because external reports were not affected by the alleged internal overstatement of revenues and, second, that since the overstatement of approximately $2 million amounted to less than 1/10,000 of 1 percent of the ultimate parent's revenues, there was no reasonable basis for believing that it was material. The ALJ rejected both arguments, contending as to the first that because SOX whistleblower protection extends to "any federal law broadly relating to fraud against shareholders," it encompassed alleged violations "of accounting rules and the adequacy of internal accounting controls" for covered companies. As to the second argument, the judge concluded that because SOX "places no minimum dollar value on the protected activity it covers" and is "largely a prophylactic" measure, SOX whistle-blowing protection applied even for "seemingly paltry sums" and irrespective of whether materiality was an element of the predicate SOX-required frauds.[27]

Additionally, in Hendrix v. American Airlines, Inc., the scope of SOX was extended even further to what most employers would view as "garden variety" employee theft.[28] There, the complainant alleged retaliation for participating in an investigation of a co-worker who had been accused of creating sculptures during his work time out of the company's spare parts for its aircraft. Because the sculpting machinist violated Federal Aviation Administration (FAA) and company procedures for tagging and disposing of scrap aircraft parts, the employee was protected by the federal aviation whistleblower statute. Rejecting (as in Morefield) the

[26] 2004-SOX-00002 (ALJ Jan. 28, 2004).
[27] *Id.*
[28] 2004-AIR-00010, 2004-SOX-00023 (ALJ Dec. 9, 2003).

administrator's dismissal of the complaint, the ALJ concluded that the whistleblower was also protected by SOX because he reasonably believed that the co-worker "was committing fraud against [the airline] and its shareholders by creating art objects for personal gain out of company material, on company time." While the conduct was undoubtedly dishonest and, perhaps, even deceptive, the ALJ never explained how it was fraudulent, let alone one of the predicate frauds required for SOX whistleblower protection except to say that the sculpting machinist "undoubtedly used the mail or wires as part of his sculpture business," and thus his fraudulent activity is of a kind proscribed by federal law.[29]

Another decision affording protection to matters seemingly far removed from the principal concerns of SOX was Platone v. Atlantic Coast Airlines Holdings, Inc..[30] There, the former manager of labor relations for the respondent airline reported her "suspicions" that members of management were allowing certain pilots to abuse payroll rules that, in effect, overcompensated them for absences from work for attending to union business and that, since the pilots were union officials responsible for collective bargaining, this was part of a scheme to "improperly channel money to senior members of [the pilots' union]... in order to convince these union officials to make contract concessions that would favorably affect [the airline's] bottom line."[31] The ALJ concluded that the complainant's reports of this "scheme" qualified as protected activity under SOX because "[s]uch a scheme, by its very nature, would involve the use of the mail and wires, and could constitute fraud of the [airline's] shareholders."[32]

To be protected by SOX, the whistleblower must reasonably believe that the reported conduct violated one of

[29] *Id.*
[30] 2003-SOX-00027 (ALJ April 30, 2004).
[31] *Id.*
[32] *Id.*

several specifically enumerated federal fraud statutes, an SEC rule or regulation or — and this is the catchall clause — a provision of federal law relating to fraud against shareholders. Payoffs to union leaders — which presumably were intended to produce more savings to the company's labor costs than the amount of the bribe — would undermine free collective bargaining. It could be conceived of as fraud by the union leaders against the union members, and clearly violates a federal law relating to labor-management relations, but it is rather hard to see how this could be a violation of a federal law relating to fraud against shareholders. And, if it were, then it would seem that reporting violations of virtually any federal law, from bribing foreign officials to criminal violations of federal environmental protection statutes, could be held protected activity under SOX.

*b.*

Section 409

In addition to cases involving fraud against shareholders, there are certain trigger

events under SOX that require an immediate filing of form 8-K. Under Section 409, SEC-regulated companies have four business days to report 8-K events that could have a material effect on their financial results.[33] Merck accordingly issued an 8-K to investors announcing the Vioxx withdrawal the day after the withdrawal took place in compliance with SOX rules. The filing requirements, as amended on August 23, 2004, include some new "triggers" that will certainly apply to pharmaceutical companies.[34] As in the case of fraud against

[33]Section 13 of the Securities Exchange Act of 1934, as amended by SOX, is amended by adding the following text to the end of Section 13:

"(l) Real Time Issuer Disclosures. Each issuer reporting under Section 13(d) or 15(d) shall disclose to the public on a rapid and current basis such additional information concerning material changes in the financial conditions or operations of the issuer, in plain English ,which may include trend and qualitative information and graphic presentations, as the Commission determines, by rule, is necessary or useful for the protection of investors and in the public interest."

[34]The new trigger events include: (1) An unexpected entry into a materially definitive agreement; (2) an unexpected exit from a materially definitive agreement; (3) creation of a material direct financial obligation, including long and short-term debt and capital-lease commitments, or an off-balance-sheet arrangement; (4) the acceleration or increase of a direct financial

shareholders, section 409 filing requirements bring companies under SOX for reasons other than accounting improprieties.

Section 409 has the potential to act as a catch-all, bringing companies under Sox for virtually any changes that will impact, positively or negatively, a company's financial outlook. SOX opens by stating that it's goal is to protect investors by improving the accuracy and reliability of corporate disclosures. If we consider that an investor chooses each day to either buy or not buy stock, or, alternatively, to sell or not sell stocks already in the investor's portfolio, then investors may be said to make investment decisions each day. Section 409 demands that a company provide the kind of information suited to an investment decision, so depending on one's vantage point (an investor vs. an issuer) section 409 can be characterized as either a "sweet spot" or a "smoking gun."

Specifically, 409 demands that each issuer disclose to the public on rapid and current basis such additional information concerning material changes in the financial condition or operations of the issuer. The key words in the above mandate are "rapid," "current," and "material." The term that is currently at the center of heated debate is "material," and the consensus for the moment is that a matter is material when it has the ability to impact an investor's decision to keep, buy or sell any of the company in question's stock. So, companies need to keep investors abreast of their financial outlook, and it is difficult to determine if and when there is a cutoff for an event being too small or insignificant in its impact on company finances to

obligation or a material obligation under an off-balance-sheet arrangement; (5) material costs incurred an exit from a business or disposal of an asset; (6) impairment of assets; notice of a de-listing or failure to satisfy a continued listing rule or standard, transfer of listing, or completed interim review; and (8) a decision that previously issued financial statements or audit reports can no longer be relied on.

warrant 8-K reporting. If Hendrix is any indication, then there may be no event too trivial to report, and companies are going to need to issue 8-Ks almost continuously in order to avoid sanctions under SOX. This particular issue will likely be more definitively decided within the year.

Section 409 additionally requires rapid disclosure of trend information. This provision may prove to be at the heart of the new disclosure regimen and require companies to file 8-Ks early and often. Companies will have to look at their financial records and determine first how things have gone over the last year or 10 years and determine first whether any general trend exists. For example a trend may be that revenue or profits have increased by a certain number of percentage points over a period of time. Then a company needs to determine whether or not the trend will continue in the future. If the answer is "no," then investors need to be advised as to why and when things are going to change, and if the answer is "yes," then investors need to know how long the trend is expected to continue and whether there are any qualifications to the prediction.

What is understood about rule 409 at this point is that all events which could affect a company's finances, stock price or intellectual property, among other things, must be captured, documented with a process that can be audited, and reported in a rapid fashion. The threshold question in determining whether an event must be reported is deciding if it has a material impact on a company's financial status. That means, for example, a security breach at a credit card company where personal information is lost or stolen will need to be disclosed, whereas a breach where no sensitive data was compromised most likely is not. On the other hand, even a relatively minor security breach (like defacement of a page on a Website) at a major IT security company may qualify as reportable because it directly impacts that company's core business in terms of

perceived expertise and reputation in their market. In terms of a pharmaceutical companies, events ranging from negative test results from a clinical trial to corporate espionage could warrant reporting under 409.

## IV. An Overview of the Relevant Statutory Language of the Sarbanes-Oxley Whisleblower Provisions

### *a.* Whistleblower Protections Statutory Overview

SOX's whistleblower protections are contained in Section 806, codified as 18 U.S.C. §1514A ("Civil action to protect against retaliation in fraud cases"):[35]

(a) Whistleblower Protection for Employees of Publicly Traded Companies-

[35] Instead of providing a small section of statute followed by an explanation, I think it is more useful to present all of the pertinent language dealing with whistleblower protections and then interpret the language in the following sections.

No Company with a class of securities under section 12 of the Securities and Exchange Act of 1934 (15 U.S.C. 781), or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 780(d)), or any officer, employee, contractor, subcontractor, or agent o such company, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against any employee in the terms and conditions of employment because of any lawful act done by the employee-

(1) to provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of section 1341 [frauds and swindles], section 1343 [fraud by wire], section 1344 [bank fraud], or section 1348 [securities fraud], any rule or regulation of the Securities and Exchange Commission, or any provision of federal law relating to fraud against shareholders, when the information or assistance is provided to or the investigation is conducted by-

(A) a Federal regulatory or law enforcement agency;

(B) any Member of congress or committee of Congress; or

(C)

a person with the supervisory authority over the employee (or such person working for the employer who has the authority to investigate, discover or terminate misconduct); or

(2) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed or about to be filed (with any knowledge of the employer) relating to an alleged violation of section 1341, 1343, 1344, 1348, or any provision of Federal law relating to fraud against shareholders.

(b)

Enforcement Action-

(1) A person who alleges discriminatory discharge or other discrimination by any person in violation of subsection (a) may seek further relief under subsection (C), by-

(A)

filing a complaint with the Secretary of Labor; or

(B)

if the Secretary has not issued a final decision within days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, bringing an action at law or equity for a de novo review in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy.

(2) Proceedure-

(A)

An action under paragraph (1)(A) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, U.S.C.

(B) Notification made under section 42121(b)(1) of title 49, U.S.C., shall be made to the person named in the complaint and to the employer.

(C) An action brought under pararaph (1)(B) shall be governed by the legal burdens of proof set forth in section 42121(b) of title 49, U.S.C.

(D)

An action under paragraph 1 shall be commenced no later than 90 days after the date on which the violation occurs.

Section 42121(b) of title 49, U.S.C. provides:

(b) Department of Labor Complaint Procedure-

(1) Filing and notification-

A person who believes that he or she has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, no later than 90 days after the date on which such violation occurs, file (or have any person file on his or her behalf) a complaint with the Secretary of Labor alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary of Labor shall notify, in writing, the person named in the complaint and the Administrator of the Federal Aviation Commission of the filing of the complaint, of the allegations contained in the complaint, of the substance of evidence supporting the complaint, and of the opportunities that will be afforded to such person under paragraph (2).

(2) Investigation; preliminary order-

(A)

In general-

No later than 60 days after the date of receipt of a complaint filed under paragraph (1) and after affording the person named in the complaint an opportunity to submit to the secretary of labor a written response to the complaint and an opportunity to meet with a representative of the Secretary to present statements from witnesses, the Secretary of Labor shall conduct an investigation and determine whether there is reasonable cause to believe that the complaint has merit and notify, in writing, the complainant and the person alleged to have committed a violation of subsection (a) of the Secretary's findings. If the Secretary of Labor concludes that there is reasonable cause to believe that a violation of subsection (a) has occurred, the Secretary shall accompany the Secretary's findings with a preliminary order providing the relief prescribed by paragraph (3)(B). Not later than 30 days after the date of notification of findings under this paragraph, either the person alleged to have committed the violation or the complainant may file objections to the findings or preliminary order. Such hearings shall be conducted expeditiously. If a hearing is not requested in such 30-day period, the preliminary order shall be deemed a final order that is not subject to judicial review.

(B)

Requirements-

(i) Required showing by complainant -

The Secretary of Labor shall dismiss a complaint filed under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor to the unfavorable personnel action alleged in the complaint.

(ii) Showing by the employer -

Notwithstanding a finding by the Secretary that the complainant has made the showing required under clause (i), no investigation otherwise required under subparagraph (A) shall be conducted if the employer demonstrates, by clear and convincing evidence, that the employer would have taken the same unfavorable personnel action in absence of that behavior.

(iii) Criteria for determination by Secretary -

The Secretary may determine that a violation of subsection

(a) has occurred only if the complainant demonstrates that

any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

(iv) Prohibition -

Relief may not be ordered under subparagraph (A) if the employer demonstrates by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

(3) Final order -

(A)

Deadline for issuance; settlement agreements –

Not later than 120 days after the date of the conclusion of a hearing under paragraph (2), the Secretary of Labor shall issue a

final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary of Labor, the complainant, and the person alleged to have committed the violation.

(B)

Remedy –

If, in response to a complaint filed under paragraph (1), the

Secretary of Labor determines that a violation of subsection (a) has occurred, the Secretary of Labor shall order the person who committed such violation to –

(i) take affirmative action to abate the violation;

(ii) reinstate the complainant to his or her former position together with the compensation (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and

(iii) provide compensatory damages to the complainant.

If such an order is issued under this paragraph, the Secretary of Labor, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's and expert witness fees) reasonably incurred, as determined by the Secretary of Labor, by the complainant for, or in connection wit, the bringing the complaint upon which the order was issued.

(C)

Frivolous complaints –

If the Secretary of Labor finds tat a complaint under paragraph (1)

is frivolous or has been brought in bad faith, the Secretary of Labor may award to the prevailing employer a reasonable attorney's fee not exceeding $1,000.

(4) Review -

(A)

Appeal to court of appeals –

Any person adversely affected or aggrieved by an order issued under paragraph (3) may obtain review of the order in the United States Court of appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred or the circuit in which the complaint resided on the date of such violation. The petition for review must be filed not later than 60 days after the date of the issuance of the final order of the Secretary of Labor. Review shall conform to chapter 7 of title 5, United States Code. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

(B)

Limitation on collateral attack –

An order of the Secretary of Labor with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

(5) Enforcement of order by Secretary of Labor -

Whenever any person has failed to comply with an order issued

under paragraph (3), the Secretary of Labor may file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

(6) Enforcement of order by parties -

(A)

Commencement of action –

A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such an order was issued to require compliance with such order. The appropriate United states district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

(B)

attorneys fees –

The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such award is appropriate.

*b.*

Parties under SOX

The threshold question one should ask is whether the person or entity that

allegedly retaliated against an employee in violation of SOX is either (1) a company with "a class of securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 781), or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 780(d))" or (2) any "officer, employee contractor, subcontractor, or agent of such company."[36] The former is defined by the DOL regulations as a "company," and the latter as a "company representative."[37]

Since the DOL is tasked with power to adjudicate whistleblower claims, it is the DOL, and not the SEC, that must interpret securities law to determine whether a respondent is a "company" for the purposes of the statute.[38] Where an entity is covered, it is likely that subsidiaries of the entity will also be considered "companies" for purposes of he statute. In Morefield, the ALJ held that non-public subsidiaries of publicly traded companies are liable for their retaliation against their own employee whistleblowers, stating that

[36] 18 U.S.C. § 1514A.

[37] 29 C.F.R. § 1980.101.

[38] *See Flake v. New World Pasta*, 20303-SOX-18 (ALJ July 7, 2003) (DOL administrative Law Judge granted respondent's motion for summary judgment after concluding that the respondent, the complainant's employer, was not a respondent that was required to file reports under section 15(d) because its securities were held by fewer than 30 persons at the start of the fiscal year and it never registered a class of securities under section 12. The complainant's employer was held not a "company" for the purpose of SOX proceedings).

"nothing in the Act persuades me that Congress intended to wall of from whistleblower [sic] Sarbanes-Oxley vast segments of corporate America that reside under the umbrella of publicly traded companies."[39] However, in Powers, a non-public subsidiary was found not to be a covered entity for SOX purposes where the complainant only named the subsidiary, and not the public parent company, as the respondent.[40]

A complainant could alternatively argue that a subsidiary constitutes a "company representative," as SOX, unlike most federal whistleblowing statutes, provides for individual liability. Section 806 prohibits retaliation by a "company representative," defined as an officer, employee, contractor, subcontractor, or an agent of the company. However, to date no company has been held liable under this interpretation of the statute.

While section 806 does not define the term "employee," the DOL regulations define an "employee" as "an individual presently or formerly working for a company or company representative, an individual applying to work or a company or company representative, or an individual whose employment could be affected by a company or company representative."[41] This broad definition widens the category of potential claimants to include individuals not traditionally thought of as employees. For example, the DOL has taken the position that an individual who works for an entity that is not considered a "company" for purposes of the statute but which is a contractor of a covered company (i.e. an accounting firm) would have a claim against the covered entity if he were retaliated against for reporting financial irregularities of the covered entity.[42]

[39] *Morefield v. Exelon Services, Inc.*, 2004-SOX-00002, at 4 (ALJ Jan. 28, 2004); *See also Platone v. Atlantic Coast Airlines*, 203-SOX-27 at 18 (ALJ April 30, 2004) (finding non-public subsidiary to be covered entity where its holding company was public, the two entities did not maintain clearly separate identities with respect to existing employee benefits and other terms of employment and there was significant commonality in the senior management of the two entities.).

[40] *Powers v. Pinnacle Airlines, Inc.*, 2003-AIR-12 (ALJ Mar. 5, 2003).

[41] 29 C.F.R. § 1980.101.

[42] DOL Whistleblowers Investigation Manual at 14-1 (note, however, that the DOL regulations do not purport to substantively

c. Protected activity

Two categories of whistleblowing are protected: (1) an employee's report of conduct that the employee reasonable believes is federal fraud, and (2) an employee's participation in proceedings relating to federal fraud.

To be a protected report of federal criminal fraud, the employee must "reasonably believe" that the reported conduct is a violation of some Securities Exchange Commission ("SEC") rule or regulation, or a violation of 18 U.S.C. § 1341 (frauds and swindles), 18 U.S.C. § 1343 (fraud by wire, radio or television), 18 U.S.C. § 1344 (bank fraud), 18 U.S.C. §1348 (securities fraud), or any federal law relating to fraud against shareholders (collectively, "federal fraud laws").[43] A whistleblower need not demonstrate that the reported conduct actually violates any such federal law or regulation, only that he reasonably believed that such a violation occurred. The belief can be "reasonable" even where a subsequent investigation establishes that the employee was "entirely wrong."[44] In determining "reasonableness," the ALJ or court will apply an objective standard.[45]

interpret section 806. 68 Fed. Reg. 31,860; 31,863 (May 28, 2003). So, the broad definition of "employee" in the DOL regulations, which is not supported by the language of section 806, will be open for challenge.).

[43] 18 U.S.C. § 1514A(1); 29 C.F.R. § 1980.102(b)(1).

[44] *Halloum v. Intel. Corp.*, 2003-SOX-7 at 10 (ALJ March 4, 2004).

[45] *Welch v. Cardinal Berkshires Corp.*, 2003-SOX-15 at 37 (ALJ Jan. 28, 2004).

To be considered protected participation, the employee must "file, cause to be filed, testify, participate in, or otherwise assist in a proceeding" relating to federal fraud law.[46]

Some of the initial DOL cases applying SOX have resulted in broad definitions of "protected activity." In Getman, for example, the ALJ determined that the complainant had engaged in protected activity where her supervisors questioned a stock rating that she had issued but did not advise her to change that rating.[47] Respondent terminated complainant citing performance reasons, but complainant contended that it was a result of her recommendations with respect to the stock rating. The ALJ found that this internal disagreement with complainant's supervisor in the context of a discussion meeting could constitute "protected activity" because if the respondent had issued an incorrect rating, this would have constituted fraud on the company's shareholders who bought stock based on the rating.

d. Unfavorable Personnel Action

A private cause of action lies only if the employee is discharged, demoted, suspended, threatened, harassed, or discriminated against in any other manner (collectively, "unfavorable personnel actions") in the terms and conditions of employment.[48] The DOL regulations state that no such actions may be taken "with respect to the employee's compensation, terms, conditions, or privileges of employment."[49] The DOL regulations

[46] 18 U.S.C. § 1514(a)(2); 29 C.F.R. § 1980.102(b)(2).
[47] *Getman v. Southwest Securities, Inc.* 2003-SOX-8 (ALJ Feb. 2, 2004).
[48] 18 U.S.C. § 1514A(a).
[49] 29 C.F.R. § 1980.102(a).

further provide that a violation exists where a company or company representative "intimidates, threatens, restrains, coerces, [or] blacklists or in any other manner discriminates against an employee in the terms and conditions of employment."[50] Thus the statute, in addition to the DOL regulations, casts a wide net on the kinds of adverse actions that are cognizable.[51]

e. Procedure

Filing with the DOL:

Section 806 provides that a "person who alleges discharge or other discrimination by any person in violation of [SOX] may seek relief. . . by. . . filing a complaint with the Secretary of Labor."[52] SOX expressly incorporates a subsection of the Aviation Investment and Reform Act ("AIR") that establishes the procedure that the DOL must follow to adjudicate the complaint.[53] The DOL has also issued interpretive regulations to guide the processing of SOX complaints. These are codified as 29 C.F.R. part 1980.

An aggrieved employee must file a complaint with the DOL no later than 90 days after the violation occurs.[54]

[50] 29 C.F.R. § 1980.102(b).

[51] *See Halloum*, 2003-SOX-7 at 10 ("[a]n employment action is unfavorable if it is reasonable likely to deter employees from making protected disclosures"). *But See Dolan v. EMC Corp.* 2004-SOX-1 (ALJ March 24, 2004) ("[u]unfavorable performance evaluations, absent tangible job consequences, do not constitute an adverse employment action").

[52] 18 U.S.C. § 1980.102(b).

[53] AIR contains a provision that protects airline employees from retaliation by their employers where the employee provided information to the employer or the federal government relating to an alleged violation of any order, regulation, or standard of the Federal Aviation Administration or any law relating to air carrier safety. 49 U.S.C. § 42121(a)(1). Airline employees who participate in proceedings relating to any such provisions on the burden of proof, statute of limitations, and filing procedures were the model for SOX's whistleblower protections, and thus the statutes are procedurally similar. DOL provisions implementing the provisions of AIR can be found at 29 C.F.R. part 1979.

[54] 18 U.S.C. § 1614A(b)(2); 29 U.S.C. § 1980.103(d).

The regulations require that a complaint be written, and "should include a full statement of the acts and omissions, with pertinent dates."[55] A complainant may not file a complaint by telephone.[56]

Statute of Limitations:

The 90 day filing period runs from the date on which the discriminatory decision has been both made and communicated to the employee.[57] Many of the published ALJ decisions to date concern the statute of limitations, and whether such limitations period is subject to equitable tolling or equitable estoppel. A number of cases have been dismissed on statute of limitation grounds, but a complaint survived a statute of limitations defense where the plaintiff claimed to have sent complaint by Federal Express to the DOL, even though the DOL never acted on the complaint.[58]

Several administrative decisions have considered whether the doctrines of equitable estoppel tolling may

[55] 29 C.F.R. 1980.103(b).

[56] *See Foss v. Celestica*, 2004-SOX-4 at 3, (ALJ Jan. 8, 2004) (dismissing claim as time barred where complainant's written complaint, filed eight days after his phone call to DOL, fell outside of the limitation period); *Cf. Walker v. Aramark Corp.*, 2003-SOX-22 at 3, (ALJ Aug. 26, 2003) (counting from complainant's termination date until his "first contact" with DOL, which was by phone, in determining that the claim was time barred).

[57] 29 C.F.R. § 1980.103(d); *See also* 68 Fed. Reg. 31,861 (*citing Delaware State College v. Ricks*, 449 US 250, 258 (1980) for the proposition that the statute of limitations begins to run when the employee either knows or reasonably should be aware of the adverse action); *See Foss*, 2004-SOX-4 at 2 (violation date is the date that the employee received written notice of termination by employer, giving the complainant the benefit of the doubt that he did knot know he was being terminated on an earlier date when he refused the respondent's attempt to give him termination paperwork).

[58] *Murray v TXU Corp.*, 279 F. Supp. 2d 799, 802 (N.D. Tex. 2003) (Evidence included the plaintiff's counsel's own sworn affidavit that he sent the complaint to the proper address, an airbill indicating that the mailing concerned the plaintiff, and documents showing that someone signed for the mailing. That the Secretary did not issuer the statutorily-required notice, investigative, or issue written findings did not cause the court to infer nonreceipt. The fact that the plaintiff failed to file his complaint with the appropriate DOL area director as required by the DOL regulations, and failed to contact the DOL after not receiving the DOL report required by statute after 60 days, was not itself a bad faith delay on the part of the plaintiff.).

be applied to allow an otherwise time-barred action to proceed. In one case, equitable tolling did not apply where (1) the complainant, represented by counsel, claimed his and his counsel's ignorance of SOX's protections; and (2) contacted both the SEC and his state's department of fair employment and housing within the limitations period but did not prove that he alleged to these agencies facts that would amount to a SOX violation.[59] Nor did equitable estoppel apply where no evidence existed that the respondent prevented the complainant from pursuing his rights as a whistleblower. An ALJ also refused to toll the statute of limitations where the complainant asserted that his travel outside of the country delayed his ability to file a complaint with the DOL because his trip was not at the respondent's request.[60]

SOX's whistleblower protections do not have retroactive effect. ALJs have uniformly held that SOX does not protect whistleblowers where the activities and the unfavorable personnel action occurred before SOX's enactment date, July 30, 2002.[61]

DOL Investigation:

After receiving a complaint, the DOL must notify the "named person(s)" of the complaint, its allegations, and the evidence supporting the complaint.[62] The regulations contemplate that the information relating to

[59] *See Moldauer v. Canandaigua Wine Co.*, 2003-SOX-00026 at 2-3 (ALJ Nov. 14, 2003) (dismissing claim as time barred).

[60] *Flood v. Cedant Corp.*, 2004-SOX-16 at 2 (ALJ Feb 23, 2004).

[61] *Gilmore v. Parametric Tech. Corp.*, 2003-SOX-00001 at 5 (ALJ Feb. 6, 2003); *McIntyre v. Merrill, Lynch, Pierce, Fenner & Smith, Inc.*, 2003 SOX-23 at 7 (ALJ Jan. 16, 2004) (finding continuing violation theory inapplicable where alleged discrimination occurring within the limitations period comprised discrete acts of alleged discrimination).

[62] 49 U.S.C. § 42121(b)(2)(A); 29 C.F.R. § 1980.104(a). the regulations defined "named person" to include "the employer and /or the company representative named in the complaint who is alleged to have violated the Act." 29 C.F.R. § 1980.101. "Person"

the identity of confidential informants will be redacted.[63] The statute requires that both the "person named in the complaint" and the employer receive such notice.[64] The notice must also disclose the standards for determining (1) whether an investigation is warranted; and (2) whether reasonable cause exists to believe that the SOX violation has occurred.[65] It must also notify the named person that, if the Administrative Review Board (the "Board") ultimately determines that a complaint was frivolous or made in bad faith, the named person may be entitled to a reasonable attorney's fee not exceeding $1000.[66] Further, a copy of this notice must be sent by DOL to the SEC.[67]

Within 20 days of filing the complaint, the named person has the right to submit a written position statement and any supporting materials, and request a meeting with the DOL officer in charge of investigating.[68] DOL will investigate only if complainant makes a prima facie showing that Section 806 has been violated.[69] If this showing is not made, the DOL will dismiss the complaint.

If the named person demonstrates by "clear and convincing evidence that it would have taken the same unfavorable personnel action in the absence of the complainant's protected behavior or conduct, the DOL will not investigate.[70] This may be demonstrated by the position statement(s), supporting affidavits, and, if

is defined to mean "one or more individuals, partnerships, associations, corporations, business trusts, legal representatives or any group of persons." 29 C.F.R. § 1980.101.

[63] 29 C.F.R. § 1980.104(a).

[64] 18 U.S.C. §1514A(b)(2)(B).

[65] 29 C.F.R. § 1980.104(a).

[66] *Id.*; 29 C.F.R. § 1980.110(e).

[67] 29 C.F.R. § 1980.104(a). According to the DOL Whistleblower Investigation Manual, copies of the investigation report and any orders associated with the hearing or appeal must also be provided to the SEC. The SEC must certify that the documents will not be disseminated outside the SEC without DOL approval. Manual 14-2, 14-5.

[68] 29 C.F.R. § 1980.104(c).

[69] 29 C.F.R. § 1980.104(b)(2).

[70] 29 C.F.R. § 1980.104(c); *See* 49 U.S.C. § 42121(b)(2)(B)(ii).

so requested, witness statements in meeting with the DOL.[71] If the named person fails to convince the DOL that it would have made the same unfavorable employment decision absent the protected activity, the DOL will conduct an investigation. Procedures to protect the confidentiality of the information provided may be followed.

No later than 60 days after the receipt of the complaint, the DOL should issue written findings stating whether or not there is reasonable cause to believe that a violation of Section 806 has occurred.[72] If such reasonable cause exists, the DOL shall issue findings and a preliminary order providing relief.[73] The findings and preliminary order will inform the parties of their right to file objections and request a hearing, and it is effective 39 days after receipt by the named person.[74]

Hearing Before an Administrative Law Judge:

The DOL's decision to investigate or refrain from investigating a complaint is not reviewable by the ALJ and a complaint may not be remanded for a completion of an investigation or for additional findings.[75]

[71] 29 C.F.R. § 1980.104(c).

[72] If the DOL officer investigating the complaint finds reasonable cause to believe that discrimination has occurred, the employee may be entitled to reinstatement pending the outcome of the case. 29 C.F.R. §§ 1980.104(e), 1980.105(a). Any such preliminary order requiring reinstatement is effective immediately, and may not be stayed by virtue of respondent filing an appeal. 29 C.F.R. § 1980.105(c); 49 U.S.C. §42121(b)(2)(A). However, where the named person establishes that the complainant is a security risk (whether or not the information is obtained after the complainant's discharge), a preliminary order [by a DOL investigating officer] of reinstatement would not be appropriate. C.F.R. § 1980.105(a)(1). AIR is silent as to whether the filing of objections automatically stays any other relief, but the regulations provide that all other provisions of the preliminary order will be stayed upon timely objection. 29 C.F.R. § 1980.106(B)(1).

[73] 49 U.S.C. § 42121(b)(2)(A); 29 C.F.R. § 1980.105(a)(1).

[74] 29 C.F.R. §§ 1980.105(b), 1980.105(c).

[75] *Id.*

A party that desires review, including judicial review, of the findings and preliminary order, or of an award for attorney's fees, must file objections and request a hearing on the record within 30 days of receipt of the findings and preliminary order.[76] Upon a timely objection, all provisions of the preliminary order will be stayed except for any reinstatement remedy contained in that order.[77] If no hearing is requested or if no objections are received within 30 days after the date of notification of the findings and preliminary order such order is the final order, not subject to judicial review. The regulations provide that the objections and request for a hearing must be in writing and state whether the objection is to the findings, the preliminary order, and/or the award for attorney's fees. The date of the postmark, facsimile transmittal, or e-mail communication will be considered to be the date of the filing, and if the objections is filed by hand deliver or other means, the objections are filed upon receipt.[78] Objections should be filed with the Chief Administrative Law Judge of the U.S. Department of Labor in Washington, D.C. and copies of the objections must be mailed at the same time to the other parties of record, the DOL designee who issued the findings and order, and the Associate Solicitor, Division of Fair Labor Standards of the U.S. Department of Labor[79]

The Chief ALJ will assign the case to an ALJ who will notify the parties of the hearing, date, time, and loccation that the hearing will take place.[80] While no formal evidentiary rules are applicable, the ALJ's must employ rules designed to "assure production of the most probative evidence" and may exclude "immaterial, irrelevant, or unduly repetitious" evidence.[81] After the hearing, the ALJ will issue a decision, and any

[76] 49 U.S.C. § 42121(b)(2)(A); 29 C.F.R. § 1980.106(a).
[77] 29 C.F.R. § 1980.106(a).
[78] *Id.*
[79] *Id.*
[80] 29 C.F.R. § 1980.107(b); 49 U.S.C. § 42121(b)(2)(A).
[81] 29 C.F.R. § 1980.107(d); *Welch v. Cardinal Bankshares Corp.*, 2003-SOX-15 at 6 (ALJ Aug. 15, 2003).

decision requiring reinstatement issued by the DOL may not be stayed. Although, all other portions of the judge's order can be stayed if a timely petition for review is filed with the Administrative Review Board.[82] The decision of the ALJ becomes the final order of the DOL unless a petition for review is timely filed with the Administrative Review Board, which has been delegated authority to act for the DOL and issue final decisions under SOX.[83] The petition must be received within 10 days of the date of the decision of the ALJ in order to be considered "timely."[84] The petition must be served on all parties, the Chief ALJ, the Assistant Secretary of OSHA, and the Associate Solicitor of the Division of Fair Labor Standards of the Department of Labor.[85] The Board's review is discretionary, and is conducted under the "substantial evidence standard."[86]

A final board decision will be issued within 120 days from the close of the hearing.[87] A final order is appealable to the United States Court of Appeals for the circuit In which the violation allegedly occurred or the circuit in which the complaint resided on the date of the violation by filing within 60 days after the issuance of certain final orders, however such an appeal will not stay the operation of the final order.[88] The court of appeals may only overturn the Board decision if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.[89] The court may set aside the Board's factual determinations if they are unsupported by substantial evidence.

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[82] 29 C.F.R. § 1980.1009(c).
[83] 29 C.F.R. § 1980.110(a).
[84] *Id.*
[85] *Id.*
[86] *See Walker v. Aramark Corp.*, 2003-SOX-15 at 3 (ARB Nov. 13, 2003) (declining to accept the case for review, without explanation).
[87] 29 C.F.R. § 1980.110(c).
[88] 29 C.F.R. § 1980.112; 49 U.S.C. § 42121(b)(4)(A).
[89] 5 U.S.C. § 706(2)(A).

Enforcement of Settlement Agreements or Administrative Order:

The parties may end the proceedings at any time by entering into a settlement agreement that is approved by the DOL. An approved settlement becomes the final order of the DOL investigator, the ALJ, or the Board, depending on which entity approves the settlement, and may be enforced by the DOL.[90] If a party fails to adhere to the DOL order or the terms of the settlement, the DOL may file an enforcement action in federal district court.[91]

Filing in Federal District court:

If the Secretary has not issued a final decision within the final 180 days of the filing of the complaint and there is no showing that such delay is due to he bad faith of the claimant, the claimant may bring his own action at law or equity for de novo review on the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy.[92] The employee must file notice with the ALJ or the Board, depending on where the case is pending, of his or her intent to file a complaint with the District court and serve notice on all parties and on the Assistant Secretary of OSHA and the Associate Solicitor of the Division of Fail Labor and Standards.[93]

[90] 29 C.F.R. §§ 1980.111(d)(e), 1980.113.
[91] 23 C.F.R. § 1980.113.
[92] 18 U.S.C. § 1514A(b)(1)(B); *See* 29 C.F.R. § 1980.114.
[93] 29 C.F.R. § 1980.114(b).

One issue that has not been definitively resolved is whether an employee who exercises the qualified right to file in federal court after 180 days automatically divests the DOL of jurisdiction by doing so. In Stone, the ALJ did not agree that his office was divested of jurisdiction after the complaint was filed in federal district court until the district court granted to complainant a stay of the DOL proceedings.[94] In Stone, the ALJ issued a ruling stating that he would retain jurisdiction over the case, and the pending summary judgment motion filed by respondent until such time as the motion was decided or until a Judge in the Federal District court agrees with the claimant and asserts that he or she has jurisdiction.[95] Other ALJs, however, have granted motions to dismiss upon a complainant's showing that he or she filed in the district court after 180 days have elapsed, absent any showing that the delay was due to complainant's bad faith.[96]

Burden of Proof:

The DOL must conduct an investigation if the employee makes a prima facie showing that his or her whistle-blowing was a contributing factor in the unfavorable personnel action.[97] The complainant must establish that:

(1)

[94] *Stone v. Duke Energy Corp.*, 3:03-CV-256 (W.D.N.C. June 10, 2003).
[95] *Id.*
[96] *Willy v. American Properties*, 2003-SOX-9 (ALJ June 19, 2003); *Williams v. Bordon Chemical, Inc.*, 2003-SOX-10 (ALJ Oct. 14, 2003); *Carnero v. Boston Scientific Corp.*, 2004-SOX-22 (Jan. 22, 2004).
[97] 49 U.S.C. 42121(b)(2)(B)(i).

He engaged in protected activity.

(2) His employer was aware of the protected activity. Some case law indicates that the ultimate decisionmaker does not have to have actual knowledge of the protected activity where an individual with the knowledge contributes the information that forms the basis of the decision.[98] In Platone, the complainant's supervisor had knowledge of her protected activity, and he suggested that she should be terminated for a separate reason. In discussions regarding the complainant's termination, the supervisor did not reference the protected activity. Nevertheless, the ALJ determined that the supervisor had terminated the employee based on the protected activity and that his knowledge could therefore be imputed to the decisionmakers.[99]

(3) He suffered an unfavorable personnel action; and

(4) circumstances exist which are sufficient to raise an inference that the protected activity was likely a contributing factor in the unfavorable personnel action.[100] The term "contributing factor" can mean any factor, which lone or in connection with other factors, tends to affect in any way the outcome of the decision.[101] Not that the temporal proximity may in itself be enough to raise the inference of causation.[102]

Once the complainant establishes these requirements, an inference of unlawful retaliation is created. The respondent may avoid liability by establishing by clear and convincing evidence that it would have taken the unfavorable personnel action in question in the absence of the protected activity.[103] The respondent is required to meet a relatively high evidentiary standard in putting forth a legitimate, non-retaliatory reason

[103] 49 U.S.C. § 42121(b)(2)(B)(iv).

for its actions, and the burden never shifts back to the complainant to establish pretext. Not many Section 806 cases have been decided on the merits, but several of them, when viewed together, seem to indicate that the DOL's interpretation of the statute and the employee-favorable burden of proof are creating negative precedents for employers.

In Welch, the aggrieved employee, the company's CFO, claimed that he was terminated because he reported a number of financial problems to the CEO, including accounting errors in the company's past financial statements and the company's noncompliance with SOX with respect to required certifications and disclosures. Additionally, the CFO told the CEO that he would not sign the company's certification required by SOX that the company's third quarter report does not contain any untrue statement of material fact, or omit to state a material fact, and is not misleading.[104] The respondent asserted that employee was actually terminated because he refused to meet with the company's attorney and independent auditors, who had been asked by the respondent's audit committee to investigate employee's claims, unless employee could have his personal attorney present.

The ALJ held that the complainant proved that his whistleblowing activities were a contributing factor in the company's decision to terminate him. The unfavorable personnel action occurred only six to seven weeks after he reported his concerns to the company's external auditors and to the CEO. The ALJ concluded that respondent's alleged reason for employee's termination – his refusal to meet with the company's attorney and independent auditor without his personal attorney – was not legitimate. The ALJ determined that the

[104] *Welch*, 2003-SOX-15 at 5-11.

company took steps to terminate the employee before he refused to attend the investigatory meeting without his attorney. For example, upon first learning of employee's allegations, the company audit committee held a meeting in which the committee focused on the complainant's alleged poor performance before requesting an investigation of his allegations. Additionally, the resulting investigation report to the board was replete with criticisms of employee's performance. The committee never adopted a formal resolution prohibiting the employee from having his personal attorney present at the meeting. The ALJ, therefore, concluded that the complainant's refusal to meet with the investigation team without his attorney present was not the real reason for termination.

Respondent viewed employee as an unhappy employee whose allegations of wrongdoing were part of his plan to leave his employer and exact a severance package on the way out the door. The respondent argued that employee was terminated solely on the basis of his refusal to attend the investigatory meeting without his attorney. The employer maintained that the presence of the employee's personal attorney would have interfered with the attorney-client privilege and transformed a fact finding investigation into an adversarial process. The ALJ rejected employer's arguments, finding that the investigation's purpose was to manufacture a situation in which the employee would not attend the meeting and they could use employee's act as grounds for termination.

Other negative precedents for employers can be found in the Platone and Getman cases that are previously discussed in the paper.

The ALJ has found in favor of the employer in some cases, the most notable of which is Halloum. There, an employee had a series of documented performance problems for which he had been poorly reviewed and had been placed on a corrective action plan by his employer. The employee made several fraud allegations to the SEC and the CEO, stating that an internal investigation determination was completely unfounded. When evidence of further improper behavior on the part of the employee came to light, including pressuring subordinates to provide favorable performance reviews and taping conversations with company employees, the employer placed the employee on a modified corrective action plan. The ALJ determined that employer would have placed employee on the corrective action plan absent the allegations employee made to the SEC and CEO; the decision was based on the fact of the heavily documented performance problems that predated the fraud allegations.

Remedies:

SOX provides that employee should be entitled to all relief necessary to make the employee whole, including reinstatement, back pay and attorney's fees and costs.[105] Equitable remedies such as writs of mandamus and stays of DOL proceedings may be available in addition to reinstatement with the same seniority status. Additionally, reasonable attorney's fees not in excess of $1000 may be awarded to respondent in the case of frivolous or bad faith complaints. A named person who believes that the complaint is frivolous or made in bad faith may seek this award by filing such requests in receipt of the DOL's findings and preliminary award.[106] There is no punitive damages provision in SOX.

[105] 18 U.S.C. § 1514A(c), (d); *See also* 29 C.F.R. § 1980.105(a)(1).
[106] 29 C.F.R. § 1980.106(a).

There is, in addition to civil penalties, the possibility of criminal liability under SOX. Specifically, Section 1107 of SOX makes it a criminal violation to retaliate against a whistleblower.[107] The provision seems to cover disclosures for any violation of federal law, not just those dealing with securities or other corporate fraud – "Whoever knowingly, with the intent to retaliate, takes any action harmful to any person, including interference with the lawful employment or livelihood of any person, for providing a law enforcement officer any truthful information relating to the commission of any Federal offense."[108] This language focuses on information conveyed to a law enforcement officer, so internal whistleblowing may not be covered.

f. Extraterritorial Application of the Whistleblower Protections

One concern that companies with international offices may face is the extraterritorial application of SOX, both for citizens working for U.S. companies abroad and for foreign nationals working abroad for U.S. companies. Suppose a U.S. citizen working exclusively in China for a U.S. pharmaceutical company blows the whistle in China. Does SOX apply? What if a Chinese citizen working for a U.S. company in China blows the whistle in China about violations what only occurred in China?

The statute provides little guidance as to whether it could apply extraterritorially. Several provisions of the act suggest some extraterritorial effect such as those provisions that address foreign accounting firms and foreign attorneys.[109] In an employment case relating to another federal statute that was silent on the

[107] 18 U.S.C. § 1513(e).
[108] *Id.*
[109] 15 U.S.C. § 7216; 15 U.S.C. § 7214.

issue of extraterritorial effect, Title VII of the Civil Rights Act of 1964, the U.S. Supreme Court found that it did not apply extraterritorially to regulate the employment practices of U.S. firms that employ citizens abroad.[110]

In Arabian, a U.S. citizen working in Saudi Arabia for a Delaware corporation brought a suit against his employer alleging that he was terminated in violation of Title VII. The district court dismissed his case, ruling that it lacked jurisdiction, and the court of appeals affirmed. The employee appealed the case to the Supreme court, and the court noted at the outset that Congress has the authority to enforce its laws beyond the territorial boundaries of the united States.[111] However, whether Congress has actually exercised that authority is a matter of statutory construction.

The court reiterated the long-established principle that legislation of Congress, unless contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States. The principle is so strong that the court noted a presumption against extraterritoriality. So, unless the contrary intention of Congress is clearly expressed, the Court stated that it would presume that a statute is primarily concerned with domestic relations such that it would not apply extraterritorially.[112] Some factors that the Court listed in its Title VII analysis include: (1) whether the statute as a whole indicates a concern what it not duly interfere with the sovereignty and laws of the States; (2) whether the statute mentions foreign nations or foreign proceedings; (3) whether the statute provides any mechanism for overseas enforcement; (4) whether the statute addresses conflicts with foreign laws and procedures; and (5) whether the administrative agency charged with enforcement of the law contends that it applies extraterritorially.[113]

[110] EEOC v. *Arabian Am. Oil Co.*, 499 US 224 (1991).
[111] *Id.*
[112] *Id.*
[113] 18 U.S.C. § 1514A(d).

In examining the factors discussed in Arabian in conjunction with SOX, it is unclear whether a court would conclude that the Act applies extraterritorially. With regard to the first factor, the whistleblower provision of the Act demonstrates an intent that it not preempt the laws of the States.[114] The Act does not address conflicts with foreign laws or procedures, and the DOL has not issued any regulations or other guidance regarding the applicability of the act overseas.

The second and third factors discussed in Arabian may indicate that the Act should apply extraterritorially. Section 106 pertains to foreign accounting firms and provides that "any foreign accounting firm that prepares or furnishes an audit report with respect to any issuer shall be subject to this Act and the rules of the Board. . . in the same manner and to the same extent as a public accounting firm that is organized under the laws of the United States or any state. . . ."[115] The Act also provides a mechanism and procedure for obtaining audit work papers prepared by foreign accounting firms and states that, by issuing opinions or performing material services upon which a registered public accounting firm relies, a foreign accounting firm is deemed to have subjected itself and consented to the jurisdiction of the courts of the United States.[116] Another provision of the Act, Section 302, pertains to a corporate requirement for a company to file periodic SEC reports.[117] This section expressly states that these requirements remain in force and are not affected by a company's foreign reincorporation or the company having engaged in any action that results in the transfer of the corporate domicile offices of the issuer from inside the United States to somewhere outside

[114] *Id.*
[115] 15 U.S.C. § 7216(a)(1).
[116] 15 U.S.C. § 7216(b).
[117] 15 U.S.C. § 1741.

the United States.[118] These provisions of SOX could be used to asset that the Act was intended to apply extraterritorially, but until Congress clarifies the scope of the Act, the DOL issues regulations on the subject, or case law develops regarding the extraterritorial application of the law, employers should proceed cautiously and obtain legal advice before taking any employment action against an overseas employee that reports corporate misconduct overseas.

V. Other Federal Whistleblower Statutes of Interest.

a. False Claims Act ("Qui Tam") ("FCA")

The FCA and the qui tam doctrine permit an individual to bring a cause of action on behalf of the federal government against one who has staked a false claim against the federal government.[119] The protections apply to employees who report their employers to the federal government for knowingly presenting or causing to be presented to an officer or employee of the United States Government or a member of the Armed Forces of the United States, a false or fraudulent claim for payment or approval.

The statute operates in substantially the same manner as those previously discussed, the only caveat being the burden of proof. Some courts have held that to establish causation, an employee must show that the employer knew that the employee was engaged in a protected activity and that the retaliation was motivated at lest in part by the employee's engaging in the protected activity.[120] Under this scheme, once causation is proved, the burden of proof shifts to the employer to affirmatively prove that the same decision would have

[118] 15 U.S.C. § 1741(b)
[119] 31 U.S.C. §§ 3729-3733.
[120] *Yesudian v. Howard Univ.*, 153 F.3d 731, 736 (D.C. Cir 1998).

been made even if the employee had not engaged in the protected activity.[121] Other courts, however, have gravitated towards the more employer-friendly McDonnel Douglass three-step method of proof.[122]

b. Environmental and Health Statutes

Several environmental and health statutes also protect individuals who report violations of federal law, including (1) the Surface Transportation Assistance Act, (2) the Asbestos Hazard Emergency Response Act, (3) the Clean Air Act, (4) the Safe Drinking Water Act, (5) the Federal Water Pollution Control Act, (6) the Toxic Substances Control Act, (7) the Solid Waste Disposal Act ,and (8) the Comprehensive Environmental Response Compensation and Liability Act. The retaliation provisions of these, and additional environmental and health services acts, are administered by OSHA. This paper will not discuss these acts in any more detail, but one should be aware that they are out there, and future SOX decisions, particularly with respect to unresolved SOX issues, may mirror the decisions made with respect to these environmental and health whistleblower statutes.

VI. Discussion of Burden of Proof Issues

a. Mixed Motive Cases

In the case where the plaintiff has direct evidence of discrimination and can demonstrate that an illegitimate

[121] *Id.* at 736.

[122] *Mann v. Olsten Certified Healthcare Corp.*, 49 F. Supp. 2d 1307, 1317 (M.D. Ala. 1999). (The McDonnel Douglass method of proof will be discussed in the section of this paper dealing with burden of proof issues.).

factor played a substantial role in a particular employment decision, the court will apply a mixed motive analysis.[123] Under the mixed-motive framework, the plaintiff must initially prove by a preponderance of the evidence that retaliatory animus played a motivating part in the alleged adverse action. The burden of persuasion then shifts to the employer who may avoid a finding of liability only by proving that it would have made the same employment decision in the absence of the protected conduct. The burden of proof in a mixed-motive case is similar to that of a SOX whistleblower case, except that SOX requires the employer to meet a clear and convincing evidence burden, as opposed to a lesser preponderance of the evidence standard required in a mixed-motive case.

b. McDonnell Douglas Burden Shifting Method

To succeed on a retaliation claim where there is no direct evidence of retaliatory animus, a plaintiff must both establish a prima facie case and prove that the defendant's stated business reasons for terminating the plaintiff are a pretext for the unlawful retaliation. So, unlike SOX claims or mixed-motive cases, the burden of proof resides with the plaintiff most of the time.

To prove a prima facie case of discrimination, a plaintiff must show: (1) protected activity of which the employer was aware, (2) an adverse employment action, and (3) a causal relationship between the protected activity and the adverse employment action.[124]

[123] *Fernandes v. Costa Bros. Msonry, Inc.*, 199 F.3d 572, 680 (1$^{st}$ Cir. 1999).
[124] *Hernandez-Torres v. Intercontinental Trading, Inc.*, 158 F.3d 43 (1$^{st}$ Cir. 1998); *MacCormack v. Boston Edison Co.*, 423

Plaintiffs often attempt to show causation by pointing to the temporal proximity between their protected activity and the adverse employment action taken against them. The Supreme Court has noted, however, that the cases that accept mere temporal proximity between and employer's knowledge of the protected activity and an adverse employment action as sufficient evidence of causality to establish a prima facie case uniformly hold that temporal proximity must be "very close."[125] However, even "very close" temporal proximity may not be enough to establish causation in some cases, particularly where the decision to take an adverse action was made before the employer knew of the protected activity. In such a case where the adverse action predates knowledge of the protected activity even very close proximity will not establish causation.

Other factors that might give rise to an inference of causation include: (1) evidence of differential treatment in the workplace, (2) statistical evidence showing disparate treatment, and (3) comments by the decision maker which intimate a retaliatory mindset. Additionally, to establish causation an employee will need to show that an employer had knowledge of employee's protected activity. Where a fellow employee has knowledge of the protected activity but someone else within the organization actually makes the decision to take the adverse employment action, the plaintiff may not be able to demonstrate causation if the other employee did not have any input into the decision to take the adverse action.

If the employee has established a prima facie case of retaliation, then the burden shifts to the employer to

Mass. 652, 662-63 (1996).

[125] *Clark County School Dist. v. Breeden*, 532 US 268, 273-74 (2001).

proffer a legitimate, nonretaliatory reason for its actions. Common defenses to retaliation include citing an employee's poor performance record, violation(s) of workplace rules, or insubordination as grounds for the adverse employment action in question. Additionally the employer can sometimes argue that its decision was compelled by a collective bargaining agreement or a change in the law.

If the employer meets its burden, showing that the employment action was taken for reasons other than retaliation, then the burden of production shifts back the plaintiff/employee to establish by a preponderance of the evidence that the employer's proffered reason is really a pretext and that the employer's desire to retaliate against the plaintiff was a determining factor in the decision to take the adverse employment action against the plaintiff. As compared to a SOX whistleblower claim, the plaintiff that raises a retaliation claim under an anti-discrimination statute that employs the McDonnell Douglass burden shifting scheme faces a much higher standard in order to successfully prove his claim.

## VII. Policies and Procedures for Addressing Internal Complaints

Employers can facilitate the opportunity for senior management to respond to possible whistleblower claims before any retaliatory action can occur by adopting policies that encourage employers and other persons to report illegal corporate financial practices ad by thorough and prompt investigation of such reports.

Section 301 of SOX requires that the audit committees of all covered public companies establish procedures

for: (1) the receipt, retention, and treatment of complaints by the company regarding accounting, internal accounting controls, or auditing matters; and (2) the confidential, anonymous submission by employees of the company of concerns regarding questionable accounting or auditing matters.[126] Section 406 of SOX requires that the SEC adopt regulations requiring companies to disclose whether or not, and, if not, the reason therefore, such company has adopted a code of ethics for senior financial officers, applicable to its principle financial officer and comptroller or principle accounting officer, or persons performing similar functions.[127] SOX does not require that companies adopt a code of ethics, or that such code of ethics be applicable to all employees. Section 406 defines "code of ethics" as:

> [T]he term "code of ethics" means such standards as are reasonably necessary to promote-
>
> > (1) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
> >
> > (2) full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by the issuer; and
> >
> > (3) compliance with applicable governmental rules and regulations.

In addition to SOX, the SEC, NASDAQ, NYSE, and AMEX all have rules and regulations (sometimes mandatory requirements) concerning audit committees' responsibilities for and appropriate procedures for handling complaints regarding company accounting practices.

[126] 15 U.S.C. § 78f(m)(4).
[127] 15 U.S.C. § 7264.

## VIII. Conclusion

We are well into the era of the whistleblower, where corporate fraud, abuse, and mismanagement is going to be reported by insiders at an ever-increasing rate. The Sarbanes-Oxley Act, in conjunction with existing acts such as the Whistleblower Protection Act of 1989, provides a deterrent to companies that would retaliate against whistleblowers and gives whistleblowers a means of redress when retaliation does occur. As the law stands today, whistleblowers that come from inside pharmaceutical companies such as Merck enjoy protection under SOX and those that work in government seek protection under the WPA. There are proposals on in the house and senate that would establish whistleblower protections that apply specifically to the FDA.

The proposed Consumer Food Safety Act of 2003 H.R. is such a bill. It seeks to establish a comprehensive program to ensure the safety of food products that are intended for human consumption and regulated by the FDA. The act contains a whistleblower provision that reads much like that of SOX, differing primarily in the procedure surrounding complaints and hearings, and would extend to the entire Food, Drug, and Cosmetic Act. Section 418 of the Act, introduced by Rep. Frank Pallone (D-NJ), states in part: "No employee or other person may be harassed, prosecuted, held liable or discriminated against in any way because that person (1) has commenced, caused to be commenced or is about to commence a proceeding, testified or is about to testify at a proceeding, or assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes, functions or responsibilities of the Consumer Food Safety Act of 2003, the Federal Food, Drug and Cosmetic Act, the Meat Inspection Act or the Poultry Products Inspection Act; or (2) is refusing to violate or assist in violation of law, rule or

regulation." The bill has recently been referred to the Subcommittee on Health of the House Committee on Energy and Commerce for further review. While it seems that SOX and the WPA provide adequate protection in many cases, this proposed legislation would erase any doubt felt by a potential whistleblower concerning coverage and protection.

One could look at existing law and conclude that additional protections are unnecessary, but such a conclusion may prove to be premature, as SOX litigation is still in its infancy. The courts and the American economy are still stinging from the accounting scandals associated with companies such as Enron and WorldCom. Judges are quick to expand SOX coverage, moving in a direction that suggests that nothing is too small or routine to be considered fraud or to fit the "material" requirement. It is entirely possible that after the initial period of expansion the courts could move into a phase of cutting back what counts as fraud against shareholders or setting a minimum actual or forecasted dollar impact necessary for an event to meet the "material" standard. So, while there seems to be no immediate danger of pharmaceutical workers and FDA employees facing whistleblower retaliation without any means of redress, it is possible that in the future some employees may not enjoy adequate protections. I think that an FDA-specific provision, such as that proposed by congressman Pallone, is necessary to ensure that both employees and management that work with the FDA or are covered by the Food, Drug, and Cosmetic Act are clear about their rights and are able to look to one place for whistleblower protection.