"Livington says he was also concerned about the dangerous working conditions for employees. "I had many manufacturing technicians from 2000-2002 tell me," he said, "they did not want to work in the Prevnar manufacturing area for fear of the chemicals used in the production process, including cyanide."

"Sodium cyanide is a dangerous chemical," he says, "mix it with water and you get hydrogen cyanide, the gas of choice used in the Holocaust."

Sodium cyanide is used in the Prevnar manufacturing process, but trace amounts remain in the vaccine itself, according to Livingston.

There are in fact, he says, many toxic substances in vaccines. "Mercury, lead, aluminum, cyanide, it's not a pretty picture," Livingston warns, "for a child's immune system, for unsuspecting parents and caregivers, who are never told about the presence of these chemicals, and for employees who have to keep their mouths shut or face losing employment," he adds."

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Whistleblower Mark Livingston Battles Wyeth Pharmaceuticals
by Evelyn Pringle

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Washington DC Attorney, Jason Zuckerman, says a positive result of the recent corporate scandals is the recognition of the value of whistleblowers in exposing fraud, corruption, and other wrongdoing within a company.

As a result of a shift in the public's perception, he says, some whistleblowers are viewed as heroes for taking on powerful corporations like Enron and serving the public interest. "The recent trial of Kenneth Lay was a reminder that a whistleblower, in that case Sherron Watkins, had warned senior management that the company would implode in a wave of accounting scandals. Had management taken her concerns seriously and implemented appropriate corrective action," he notes, "Enron might not have collapsed."

"This enhanced public perception," Zuckerman says, "coupled with the substantial remedies available to whistleblowers, provides an incentive for employees who have suffered retaliation for exposing fraud to bring claims under the Sarbanes-Oxley Act, which contains a whistleblower protection provision."

Zuckerman admits that battles against drug companies are extremely difficult. "I can tell you that whistleblowers in the pharmaceutical industry really face an uphill battle, a David versus Goliath struggle," he says.

"Some pharmaceuticals are obsessed only with the bottom line," he notes, "and they are determined not to let a whistleblower get in the way."

"My clients who have tried to raise concerns to management about Medicate fraud, off-label marketing, and other improprieties" he says, "often come under attack and are either terminated or forced out."

"Sadly," Zuckerman says, "management often adopts a shoot-the-messenger mentality towards whistleblowers, and that is why we need to vigorous enforcement of whistleblower protection laws."

A SOX action against a drug giant, is currently underway in a North Carolina involving Mark Livingston, a former associate director of training at a Wyeth vaccine manufacturing plant in North Carolina, who says he was fired for raising concerns that vaccine production employees were not properly trained, in violation of FDA regulations, and a consent decree previously

imposed on Wyeth by the FDA.

Whatever the outcome of the case, attorneys say it will be an important decision due to the fact that it will be one of the first cases decided by a federal court under the Sarbanes-Oxley Act.

Sarbanes was signed into law on July 30, 2002, and provides a tool for the vigorous enforcement that Zuckerman says is needed. Coming on the heels of the WorldCom, Enron and Author Andersen scandals, the Act was intended to restore investor confidence in publicly traded companies by improving corporate accountability through changes in corporate governance and accounting practices and by providing whistleblower protection to employees who report fraud.

The Act's official title is the "Public Company Accounting Reform and Investor Protection Act of 2002," but is commonly called SOX. The law is named after its sponsors Senator Paul Sarbanes (D-MD) and Representative Michael G Oxley (R-OH).

The Act "mandated a number of reforms to enhance corporate responsibility, enhance financial disclosures and combat corporate and accounting fraud, and created the "Public Company Accounting Oversight Board," also known as the PCAOB, to oversee the activities of the auditing profession," according to the Security and Exchange Commission.

SOX applies to all companies that have obtained a listing in the US or have registered securities with the Security and Exchange Commission and as of this year, all publicly-traded companies are required to submit an annual report on the effectiveness of their internal accounting controls to the SEC.

To add teeth to the Act, the SEC adopted new rules that apply to top management officials including: (1) requiring Chief Executive Officers and Chief Financial Officers to certify information in company quarterly and annual reports; (2) requires management to return bonuses or profits from stock sales received within 12 months of a restatement resulting from

material non-compliance with financial reporting requirements as a result of misconduct; (3) prohibiting company officers from trading during pension fund blackout periods; (4) prohibits companies from making loans to insiders; (5) accelerated deadlines and mandated electronic filing of disclosures of insider transactions in company stock; (6) disclose whether they have a code of ethics for CEO, CFO and senior accounting personnel.

SOX is one of 14 whistleblower laws passed since 1974, however, most of the previous laws applied to specific areas such as nuclear materials; water and air pollution, airline, trucking and shipping safety; and abuse of migrant workers.

Another feature of SOX whistleblower protection is that it contains both civil and criminal provisions and creates a civil cause of action for whistleblowers who have been subject to retaliation.

It protects two types of conduct: (1) employees who provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct which the employee reasonably believes constitutes" securities fraud, bank fraud, wire fraud, or violation of "any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders;" and (2) employees who "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 the laws.

Under SOX, the assistance must involve: (A) a Federal regulatory or law enforcement agency; (B) a Member of Congress or committee of Congress; or (C) a person with supervisory authority over the employee (or other person working for the employer who has the authority to investigate, discover, or terminate misconduct).

Enforcement of the civil provision falls to the Secretary of Labor. However, if within 180 days of the filing of a complaint, the Secretary has not issued a final decision, and the delay was due to the bad faith of the claimant, the employee may bring a de novo action in federal district court.

The US Courts of Appeals have the authority to review the Secretary of Labor 's final decisions.

Employees who believe that they have been subject to adverse action in retaliation for a protected activity may file a complaint with the Secretary of Labor within 90 days of the retaliatory act. The Secretary of Labor has assigned responsibility for administering the Act to the Assistant Secretary for Occupational Safety and Health Administration.

Under SOX, companies may not "discharge, demote, suspend, threaten, harass or in any other manner discriminate against an employee in the terms and conditions of employment" because of any protected activity.

A broad range of whistleblower activities are protected, including providing information to Congress, federal agencies, or internally within a company, and also filing, causing to be filed, testifying, participating in, or assisting in proceedings.

Protected activity includes providing information that the employee "reasonably believes" constitutes a violation of federal mail, wire, bank or securities fraud, or a violation of any SEC rule or federal law relating to fraud against shareholders.

SOX's criminal provision, makes it a felony for anyone to retaliate against or take any action "harmful" to any person, including interfering with his employment, for providing truthful information to a law enforcement officer relating to the possible commission of a federal offense, and is enforced by the US Department of Justice. Criminal penalties can include fines and or imprisonment of up to 10 years.

In addition to the whistleblower provisions, SOX contains two other mechanisms to encourage the disclosure of corporate fraud. First, it requires companies to establish procedures for the receipt, handling, and retention of anonymous complaints from employees relating to accounting or auditing matters.

And second, to ensure the reliability of corporate disclosures, the SEC issued a rule requiring attorneys "appearing and practicing before the Commission" to report "evidence of a material violation" to their client's chief legal officer or chief executive officer and, absent an "appropriate response," to the company's audit committee or board of directors.

SOX whistleblower provisions also apply to "any officer, employee, contractor, subcontractor or agent" of a covered company and therefore, private companies, as well as other entities or individuals, that serve as "agents" or "contractors" of the publicly traded employer, are subject to the whistleblower provisions.

For instance, the 2003 OSHA, Whistleblower Investigations Manual, specifies that a small accounting firm acting as a contractor could be liable for retaliation against an employee who provides information regarding a violation of SEC rules to the SEC.

And there have been cases, where the Act's retaliation provisions have been applied to private subsidiaries of publicly traded companies. For example, in Platone v Atlantic Coast Airlines Holdings Inc., 2003-SOX-27 (April 30, 2004), an Administrative Law Judge held that an employee of a subsidiary was a covered "employee" where the subsidiary's parent company was publicly traded and the company was the alter ego of the subsidiary and had the ability to affect the employee's employment.

The ALJ in Gonzalez v Colonial Bank, 2004-SOX-39 (ALJ August 20, 2004), concluded that Congress intended to provide whistleblower protection to employees of subsidiaries and held that an employee of a subsidiary set forth a cause of action sufficient to withstand a motion for summary decision where the evidence reflected that the action affected the plaintiff 's employment and the company shared management and function with the subsidiary.

In the first reported federal district court decision, Collins v Beazer Homes USA, Inc, 334 F Supp 2d 1365 (ND Ga 2004), held that where the officers of a publicly traded parent company had the authority to affect the

employment of the employees of the subsidiary, an employee was a "covered employee" within the meaning of the SOX.

The remedies available to whistleblowers generally provide that an employee subject to retaliation is "entitled to all relief necessary to make the employee whole," and employees who proceed before the Department of Labor are entitled to "interim reinstatement."

Tom Devine is the Legal Director of the Government Accountability Project, the nation's leading whistleblower protection group, and describes the procedure for filing and processing claims under SOX as follows:

(1) Claims must be filed with the Department of Labor (DOL) within 90 day of the alleged retaliatory event.

(2) The DOL conducts an investigation, attempts to mediate a settlement, and, if necessary, order temporary relief and issue an initial decision.

(3) Either party may appeal the final results of a DOL investigation to an Administrative Law Judge. Relief from the initial ruling remains in effect.

(4) Either side may appeal to the Department of Labor's Administrative Review Board for a final agency decision.

(5) Either party may appeal to a US circuit court of appeals for review of the final Department of Labor ruling.

Although by statute the Department of Labor normally must complete this process in 120 days, Devine says, the actual range has extended to 14 years, with delays of two to three years common.

However, if an investigation is not completed in 180 days, the employee has the right to seek injunctive relief and have a jury trial in a District Court. "This opportunity long has been the promised land for whistleblowers to have a fair system protecting their legal rights," Devine notes.

Since the SOX legislation was enacted in 2002, about 750 cases have been filed with the DOL, by persons saying they were retaliated against for revealing wrongdoings within a company. "The number of cases has risen, with about 150 in the law's first year and nearly twice that in its third," according to the article, "Whistle-Stop Campaigns," by Kathleen Day, in the April 23, 2006 Washington Post.

Day reports that the majority of cases have been dismissed and that fewer than 100 cases have been settled.

"And only five whistle-blowers have won," she wrote, "though that number dwindled to four last summer when the agency's administrative review board overturned a case on appeal."

In addition, three of those four cases have been appealed to the board, "whose handful of judges so far have not decided an appeal in favor of a whistle-blower," according to Day.

The Washington Law Office of Jason M Zuckerman, PLLC, primarily represents clients in whistleblower cases, including retaliation claims under the Sarbanes-Oxley Act and qui tam actions under the False Claims Act. The firm's principal, Jason Zuckerman, has lectured and written extensively about whistleblower protection laws.

Whistleblower claims generally fall into two categories. One is retaliation claims, which Zuckerman explains, are essentially discrimination claims alleging that an adverse employment action was taken in retaliation for the employee's protected conduct (exposing wrongdoing), and the other are qui tam actions under the False Claims Act, civil fraud claims brought on behalf of the government against companies that have defrauded the government.

In a qui tam action, "A qui tam relator brings forward to a federal prosecutor information demonstrating that a government contractor is engaged in fraud, typically charging the government for a service that was not performed or a product that was not provided," Zuckerman explains.

Nowadays, he says, the consequences of retaliating against a whistleblower can result in more than a civil lawsuit. "In the post-Sarbanes Oxley regulatory climate," Zuckerman warns, "a whistleblower retaliation lawsuit can also result in an investigation by a regulatory agency such as the SEC, and in bad publicity."

Under the whistleblower protection provisions of SOX, the burden of proof is more favorable to employees than it is under employment discrimination laws such as Title VII of the Civil Rights Act of 1964. "A plaintiff in a SOX claim merely needs to demonstrate that his protected conduct was a contributing factor, not a motivating factor, in the employer's decision to take an adverse employment action," Zuckerman explains, "and once the employee has met his burden, the employer must demonstrate by clear and convincing evidence that it would have taken the same adverse employment action absent the employee's whistleblowing."

If an employer is forced to defend against a retaliation claim, "it will need strong evidence to demonstrate that it would have taken the same unfavorable action against an employee in the absence of the employee's whistleblowing," Zuckerman points out.

Employees who go up against big Pharma can find themselves subjected to a wide variety of retaliatory acts. "Their managers put them on pretextual performance improvement plans and do everything to make the work environment unbearable," Zuckerman reports.

"Whistleblowers also find themselves alienated," he explains, "their coworkers try not to associate with them for fear that management will view them as disloyal."

"My clients," he says, "whose only infraction was committing the truth have found themselves unemployed and suffer permanent damage to career and reputation."

Fortunately, he says, the False Claims Act provides a good remedy. "Damages under the anti-retaliation provision of the FCA include reinstatement, three

times lost wages, compensatory damages, and attorney's fees," Zuckerman notes. "In addition, a successful qui tam relator is entitled to between 15 to 25 percent of the amount that the government recovers."

Zuckerman, however, notes that when he obtains favorable settlements for his clients, he feels that the client is not truly getting "make whole relief" when the client has suffered permanent damage to career and reputation.

For instance, after a client recently accepted a substantial settlement in a whistleblower retaliation case, he asked the client why he was still so upset and the client told Zuckerman that he felt it was unfair that his whistleblowing had derailed his career and that what he really wanted back was the chance to continue his successful career at this company.

Mark Livingston is entangled in the same type of battle with pharmaceutical giant Wyeth.

Wyeth denies his allegations that employees were not properly trained, but says even if they are true, Livington's reporting of concerns that vaccine production employees were not properly trained, in violation of FDA regulations, is not a protected activity unless the rules relate to a direct fraud against shareholders.

The Government Accountability Project is handling the case, with General Counsel, Joanne Royce, Deputy General Counsel, Karen Gray, and former GAP chief trial lawyer, Thad Guyer, as lead counsel, and disagrees.

The GAP and Livingston argue that SEC rules require the disclosure of any violation of federal law, and all risks that could potently diminish stock value, and that a failure to adequately train employees could lead the FDA to halt the manufacturing process or result in infants being injected with defective vaccines, and that either event would damage profits.

Therefore, Livingston maintains, the compliance failures are a direct threat to stockholders.

Wyeth hired Livingston in 2000 to help in the introduction of Prevnar, a new vaccine designed to fight pneumoccocal pneumonia and meningitis in infants. The facility where he worked was the vaccine's only production site.

One of Livingston's responsibilities was to assure manufacturing compliance through quality training and he discovered serious deficiencies in training as soon as he arrived.

"When I got to the Wyeth vaccine plant in August 2000," he said, "they had a part-time nurse delivering safety training to new hires."

An occupational health and safety specialist was not hired until February 2001, a full year after Prevnar was approved by the FDA, he says. "And this occurred only after the October 2000 consent decree for ongoing manufacturing violations," he adds.

A consent decree results when a company repeatedly fails to comply with FDA standards.

The FDA announced a consent decree after inspectors determined that Wyeth plants were not meeting manufacturing standards in New York and Pennsylvania. As part of a settlement, Wyeth agreed to pay $30 million, and to hire experts to conduct an all-inclusive inspection of the plants and to certify overall quality efforts.

"This occurred," Livingston said, "after realization by Wyeth executives that they had a blockbuster pediatric vaccine on their hands and no one had bothered to do any planning for staff additions in the next several years."

Prevnar is definitely a blockbuster and its largest customer is the government. According to a 2003 Institute of Medicine report, "Financing Vaccines in the 21st Century," the US government spends more than $1 billion annually to purchase childhood vaccines to give to poor and uninsured children under the federal Vaccines for Children (VFC) program.

This represents about 55% of the total market for childhood vaccines. After

the CDC added the chicken pox and Prevnar vaccines to the program, the VFC budget rose from $500 million in 2000, to over $1 billion in 2002.

In 2004, it became the first vaccine to top $1 billion in yearly sales, mainly because it costs more than $220 per 4-shot regimen and the "federal government recommends Prevnar and pays a good price for it -- as do private purchasers," according to the November 9, 2005 Wall Street Journal.

And sales have continued to increase each year. According to Wyeth's first quarter earnings report for 2005, Prevnar achieved net revenues of $391 million, or more than double the first quarter earnings reported in 2004. And the company's first quarter earning report for 2006, show that Prevnar sales rose another 10% to $432 million so far this year.

According to Livingston, once Prevnar was added to the childhood vaccine schedule, Wyeth was caught totally unprepared, and as it attempted to meet the skyrocketing demand for Prevnar, "large numbers of new employees with limited backgrounds in vaccine production were being hired."

"Despite the presence of PhD's and MBA's out the wazoo," he said, "no one in the marketing or research departments at Wyeth ever bothered to call the supply chain folks up and ask if they could produce the vaccine in the amounts they wanted."

Which Livingston says amounted to 20 million plus does per year on a consistent basis.

In just 3 years, the plant's employment numbers went from 300 employees to over 1200, he says, and providing proper training to that number of new employees would be impossible. "Because of the complex nature of biological vaccine manufacturing," he explained, "basic training for front-line employees took 12 months."

According to Livingston, "repeated quality audits in 2000, 2001, and 2002 revealed noncompliance with corporate and FDA regulatory standards."

As it turns out, his prediction that vaccines production could be halted came true and was revealed in February 2004, when Wyeth came up short of Prevnar. In less than 4 months, the CDC, had to issue two advisories relating to the rationing of Prevnar.

Publicly, Wyeth claimed that the supply was hampered by unspecified production problems. However, many doctors were upset when they learned about the extent of the manufacturing problems that led the shortage and that Wyeth had been cited by the FDA for manufacturing violations again and again in the years before the shortage occurred.

For instance, Wyeth failed to reveal that in 2003, FDA inspectors found so many quality-control failings at the Prevnar packaging plant in Pearl River, NY, that production was shutdown at the site.

Among the many problems listed in FDA reports, inspectors described dirty work areas, sloppy operating procedures, contamination, improper environmental monitoring and insects in a hallway outside the room where vials were filled with the vaccine.

Wyeth's own internal investigations were also found to be inadequate. "Manufacturing investigation reports are not always completed in a timely manner," the FDA inspectors wrote in reviewing Wyeth's compliance in correcting previously cited problems. "Further," they said, "there is a lack of evidence that product impact is addressed in a timely manner and that all batches/processes are fully investigated."

In one FDA report alone, inspectors identified 59 problems.

In 2001 and 2002, Livingston says he repeatedly reported the violations to the managing director at the plant, an outside auditor, and a quality council of managers and nothing was done to correct the problems.

Livington says he was also concerned about the dangerous working conditions for employees. "I had many manufacturing technicians from 2000-2002 tell me," he said, "they did not want to work in the Prevnar manufacturing area

for fear of the chemicals used in the production process, including
cyanide."

"Sodium cyanide is a dangerous chemical," he says, "mix it with water and
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a child's immune system, for unsuspecting parents and caregivers, who are
never told about the presence of these chemicals, and for employees who have
to keep their mouths shut or face losing employment," he adds.

Attorney, Thad Guyer, now of T.M. Guyer, Ayers & Friends, PC, says the
Livingston case is still undecided, but that a favorable ruling on the same
issue was handed down on March 29, 2006, in the whistleblower case of Walton
vs Nova Information System and US Bancorp.

Guyer's private law firm handled the Bancorp action and Guyer describes the
ruling as a "major victory," because the "court held for the first time that
a SOX claim does not require the allegation of fraud, but merely of any
violation of any SEC law," he explained.

In Bancorp, the company had also denied that any security lapses had
occurred, but said that even if some did, Walton's voicing concerns about
them did not constitute activity protected by the Act.

Like in Livingston, Guyer disagreed and argued that SOX protects the
providing of information on a violation of any provision of Federal law
relating to fraud against shareholders, or the violation of a rule or
regulation of the SEC.

The Administrative Law Judge agreed and stated: "the argument that SOX does
not protect providing information of a violation of a rule or regulation of

the SEC unless the Complainant also shows that the rule or regulation is related to fraud against shareholder is rejected."

The ALJ pointed out that the Act contains the specific phrase, "any rule or regulation of the Security and Exchange Commission," and said if the activity was not protected, "there would be no reason to specify as protected activity a violation of SEC rule or regulation as such a violation is of course also a violation of Federal law."

"It is an elementary rule of statutory construction that every statute shall be construed, if possible," the court added, "to give effect to all its provision."

More information for whistleblowers can be found at Lawyers and Lettlements.com
http://www.lawyersandsettlements.com/articles/wyeth.html