Joe A. Callaway Award for Civic Courage

Ladies and gentlemen, thank you for being here tonight. I believe we are here to recognize not only Dr. Graham and myself, but all individuals who summon the faith and courage to challenge unethical and unlawful practices.

I want to share with you the story regarding my attempt to change the dysfunctional regulatory compliance culture of a pharmaceutical manufacturing plant in the years 2000-2002.

- I was hired in 2000 by Wyeth Pharmaceuticals to help in the introduction of Prevnar, a new vaccine designed to fight pneumoccocal pneumonia and meningitis in babies. The North Carolina facility where I worked is the sole production site for this pediatric vaccine which is taken in a four-dose regimen by every infant in the United States at 2, 4, 6, and 12 months. One of my key responsibilities was to assure compliant manufacturing through quality training and continuous improvement systems.
- Within weeks of hire, I was approached by numerous employees with regulatory compliance and safety concerns. My own investigation revealed chronic under-staffing at this 24x7 operation as well as shortcuts within basic quality control and training processes.
- As Wyeth attempted to meet the rapidly growing demand for Prevnar and to meet mandates of a FDA consent decree for quality control violations, large numbers of new employees with limited backgrounds in vaccine production were being hired. Because of the complex nature of biological vaccine manufacturing, basic training for front-line employees took 12 months.
- At the same time, repeated quality audits in 2000, 2001, and 2002 revealed noncompliance with corporate and FDA regulatory standards.
- In mid-2002, I wrote a letter to Wyeth management refusing to misrepresent the compliance status of the site in an upcoming consent-decree audit whose results were to be forward to the FDA.
- After being directed by management to not discuss or provide information regarding noncompliance, I filed complaints with ethics and compliance officers of the company, alleging gross noncompliance and release of product in violation of FDA regulations.
- Two months after my internal whistleblowing, I faced disciplinary action with a threat of termination for 10 alleged performance deficiencies, one of which included a "gag order" to not discuss compliance deficiencies with internal or external contacts (which I interpreted to mean the FDA).
- Two months after this retaliation, I was terminated for alleged "professional misconduct" by the same two company officials who delivered the gag order.

In reality, I was terminated for my efforts to address and rectify quality compliance failures leading to the adulterated release of vaccine in violation of both FDA consent decree mandates and SEC regulations regarding disclosure. With help from the Government Accountability Project, I brought suit against Wyeth in federal district court

for retaliatory discharge in violation of whistleblower protection provisions of the 2002 Sarbanes-Oxley Act.

Throughout my 21-year career as an organization development, human resource, training, and quality improvement professional, I have helped talented and progressive leaders learn how to change their organizational cultures to continuously improve workplace performance. I have spent a considerable amount of time and effort teaching and coaching people to use diagnostic tools to discover the root causes of problems and take action to prevent recurrence of systemic failures and breakdowns. As a result, I've developed expertise in redesigning and implementing operating and quality systems that engage workforces to deliver intended compliance and financial outcomes.

Organization or workplace culture is defined as the shared attitudes and perceptions within an organization. It is made up of the values and behaviors that formally and informally influence how employees think about themselves, their colleagues, their leadership, and their work. The "way we do things around here" gives people a common identity, builds commitment to achieve important objectives, and shapes human performance. Considerable research in the last ten years has verified the relationship between an organization's culture and its operating results and financial performance.

The valuable lessons I've learned from successful as well as failed efforts to change culture and improve performance include these:

1. Successful leaders proactively become aware of what's really taking place on the front-line of their organization.
2. Successful leaders quickly move through the typical responses of denial and resistance.
3. Successful leaders move past personal fear and confront unacceptable situations, including intimidating forces of resistance assembled against them.

In fighting the battle between greed, financial security, and personal integrity, successful and ethical leaders absolutely know the "right choice" to make and the "right thing" to do.

I've also learned that the most successful of leaders and work cultures are *not* afraid of bad news, they do *not* shoot messengers of bad news, nor do they seek to blame or ostracize people with dissenting points of view. They don't spend precious time and resources in complaining, whining, and looking for legalistic justifications to rationalize misconduct.

Within FDA regulated facilities, a work culture – whether high performing or dysfunctional - has a significant impact on the attitudes and performance of front-line employees. This is especially true when it comes to compliance with safety regulations that have an impact on product quality.

cGMPs – or current Good Manufacturing Practices - are the bedrock of regulatory requirements designed to assure the safety, integrity, sterility, quality, and purity of pharmaceutical or biological vaccine products. When you read about GMP issues at the Chiron flu vaccine facility or hear about FDA consent decrees at Wyeth and Schering-Plough for GMP manufacturing violations – think safety, integrity, sterility, quality, and purity – or simply, SISQP.

In the complex world of biological vaccine manufacturing, anything that has a direct impact on SISQP must come under documented and/or validated quality control protocols and procedures. These quality requirements are audited by the company and at times by third-party consultants, as well as by CBER, the FDA's Center for Biological Evaluation and Research. These inspection audits take place every two years to ensure compliance with GMP requirements.

Do not believe Wyeth or any pharmaceutical or biotechnology company if they tell you the Code of Federal Regulations and quality system procedures are *mere guidelines or expectations* with no legal or financial consequences. Or that effective dates which drive quality system operations are simply *internal moving targets.* Recent fines levied by the FDA for violation of GMPs destroy this wishful thinking. Reference the $30 million fine paid by Wyeth, the $100 million fine of Eli Lilly, the $229 million in fines of Abbott Labs, and the $500 million fine paid by Schering-Plough in four easy installments.

In fact, the FDA is atypically and unusually clear in this area. Quote: "There is a public health significance to cGMP noncompliance. A manufacturer who fails to comply with cGMP requirements is less likely to produce a product that performs as intended."

I'm sure you can appreciate the alignment created by the FDA and the SEC between noncompliance and the disclosure of production, sales, and financial information which securities analysts and shareholders use to make investment decisions.

Nor should you believe the pharmaceutical company or trade association spokesperson who claims there is *no connection* between operating, product safety, and compliance results in a regulated industry and the financial information disclosed to shareholders. In fact, they are "heads" and "tails" of the same coin

Finally, do not believe the Wyeth representative who claims there is *no significant impact* on the safety and health of newborn infants for violating regulatory requirements that drive product safety and manufacturing integrity.

As over 1 million doses of the pediatric vaccine Prevnar are distributed and administered each month in the United States alone, even odds of 1 million to 1 that anything significant could happen with a batch of vaccine means that 1 child each month could be harmed by this brew of chemicals – which is manufactured, by the way, with one of the most toxic substances known to human beings.

Changing the organizational culture at this North Carolina manufacturing facility was extremely difficult and painful, despite the presence of a consent decree and permanent injunction that prohibited Wyeth from releasing adulterated product into interstate commerce. Pharmaceutical drug or biological vaccine products are considered adulterated if they are manufactured in violation of current Good Manufacturing Practices.

Product adulteration – if willful and intentional – constitutes fraud. As the Associate Director of Training and Continuous Improvement at the site, I personally led two courses which covered basic ethical and compliance requirements. In addition, a comprehensive GMP curriculum was in place that specifically addressed adulteration and both the legal obligation and liability each manager and supervisor had for ensuring compliance.

So what happened? Why did it take over two years of internal struggle and conflict to achieve integration of core quality systems and put basic GMP compliance requirements into place? Why did the internal investigation, when finally conducted in August 2002, fail to meet standards established by both Wyeth and the FDA for just these noncompliant situations?

How did a $14 Billion multinational corporation – with plenty of smart people tripping over each other – manage to screw it up? And why was no one in the financial community or at the FDA told about or aware of these GMP compliance failures in 2002? We heard Wyeth executives provide contradictory and confusing disclosures about GMP manufacturing and Prevnar quality problems in November 2003. Why the silence in 2000, 2001, and 2002?

Was it the fear of monetary fines to the tune of $15,000 per day for missing FDA consent decree commitment dates? After all, Wyeth had already paid out $1.2 million in fines for missing deadlines in 2002.

Was it the fear of not being able to ship 200 batches of backlogged Prevnar, worth $200+ million in sales? After all, shipments of Prevnar were down 40% in mid-2002 and the 4th dose of this pediatric vaccine was yet again on curtailment.

Was it the fear of continuing a backlog of Prevnar orders and not being able to book and report revenue that commands a 95% gross profit margin?

Was it the fear of disclosing negative information about GMP non-compliance to the FDA or Centers for Disease Control? After all, the Vaccines for Children Program which purchased approximately $851 million dollars of Prevnar through taxpayer and Medicaid dollars in the years 2000-2002 required Wyeth to manufacture Prevnar in accordance with GMPs.

Was it the fear of having to disclose negative information to shareholders and consumers coming on the heels of publicity in July 2002 that Wyeth's hormone replacement

therapies weren't all they were marketed to be? After all, the stock price only crashed $20 dollars per share wiping out $24 billion in market value in a matter of weeks.

Or was it the fear that after manipulating a gullible and inattentive FDA about safety and compliance, investors, consumers, and government oversight committees would see that Wyeth had rushed Prevnar – or had been allowed to rush Prevnar - to market without adequate manufacturing capability and regulatory controls?

I'm afraid we may never know the answer to why Prevnar was introduced in February 2000 in a facility – supposedly inspected and approved by the FDA - that was not GMP compliant. Or why it took another 2 ½ years for basic quality systems and quality control processes to be enforced despite the FDA consent decree. Or why senior officials at CBER during a July 2003 meeting at FDA headquarters never responded to my concerns, allegations, or documentation.

In thinking about my experience at Wyeth and the legal battle to hold key decision makers accountable for their lack of courage in disclosing unlawful and improper compliance and business practices, I often ask myself: How could well-intentioned, intelligent people make such poor decisions related to a chemical-based product that is injected into innocent babies.

Is it greed? Is it fear? Is there an ethics gene that undergoes mutation in the heat of running large and complex organizations? What would possess a person or a group of decision makers with great influence to flunk such a basic test of ethics, business law, and social responsibility?

I wonder if the answer might lie in a simple, elegant question posed by a concerned manufacturing technician in October 2000 at this North Carolina facility.

In front of a group of some 40-50 employees, this technician asked me a question that I still remember to this day: "Mr. Livingston, are we here to make money or to save lives?" Without hesitation, I told her that we were here to save lives! I felt proud of my A+ response.

Then I blew it! The rational, left-side of my brain kicked into overdrive and I started to worry how the corporation or my boss would react to my answer. After all, we're a profit-making, free-enterprise, capitalistically-driven company that seeks to serve shareholders and recapture our R&D investment – right?

So I added, "But we also need to make money in order to continue making the product that saves lives." I did not feel proud of my new grade, a revised C-. Thank God the person was "North Carolina polite" and asked no more questions.

Upon reflection, I realized this technician was testing me and that I had failed to answer two important questions:

1. What is the real purpose and mission for our work?
2. How do I make a decision when it comes to safety vs. profit?

I would suggest that many of the recent problems in the pharmaceutical industry or at the FDA – indeed within our corporate and government institutions in general – have germinated and grown as a result of confusion and conflict over the answers to these two questions. Perhaps this is where we need to start in order to re-establish trust and credibility – that is, to revisit "mission" and "purpose."

Is it new drug approval or product safety? Is it treating the industry as a partner and client or is it enforcing regulations that protect consumers and patients? Is it having the courage to disclose bad news to shareholders or is it a desire to mislead investors and consumers with deceptive business and compliance practices?

In the stress of an ethical dilemma worth hundreds of millions of dollars, we must be absolutely clear on what is the correct answer. No hesitation, no waffling, no multiple-choice answers.

Courage has been defined as the state or quality of mind or spirit that enables one to face danger, fear, or the vicissitudes of life with self-possession, confidence, bravery, and resolve. Courage implies firmness of mind and will in the face of danger or extreme difficulty.

To this day, I continue to thank that manufacturing technician for teaching me – and us - a valuable lesson by asking the courageous question: are we here to make money or save lives?

I would like to thank the Shafeek Nader Trust for the Community Interest for this prestigious award. I sincerely appreciate the recognition – Ms. Nader – that you and directors of the Trust have provided.

Thank you…and thank you ladies and gentlemen.

For additional information, contact:

Mark Livingston
3905 Ketch Point Drive
Rocky Mount, NC 27803
252-451-0367; careerps@earthlink.net

Joanne Royce
Government Accountability Project
1612 K Street NW, Suite 1100
Washington, D.C. 20006
202-408-0034; joanner@whistleblower.org