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Senate Health Education Labor and Pensions Committee

"Restoring FDA's Ability to Keep America's Families Safe"

April 24, 2008

I would like to thank Chairman Kennedy and Ranking Member Enzi for inviting me to provide this written testimony and to participate in today's hearing, "Restoring FDA's Ability to Keep America's Families Safe." My name is Gerry Migliaccio; I am the head of Quality for Pfizer Inc, the world's largest research-based biomedical and pharmaceutical company. In this testimony, I would like to outline Pfizer's approach to ensuring a secure pharmaceutical supply chain.

Pfizer currently operates 57 manufacturing sites around the world. To complement our internal manufacturing, we currently outsource the manufacture of approximately 17% of our active ingredients and drug products. The drivers for outsourcing include: sourcing flexibility, competitiveness, need for special technology, cost control and site divestitures. Pfizer's reputation depends heavily on the quality and safety of the products it sells. Whether we produce internally or outsource, a secure supply chain is paramount in protecting the patients who use our products. Industry and FDA share the responsibility for assuring the security of the pharmaceutical supply chain. As companies in emerging countries enter and expand the global pharmaceutical supply chain, industry and FDA face significant challenges.

Traditionally, pharmaceutical companies in the US have sourced active ingredients and drug products from within the US, from Europe, Japan and other developed countries. Our suppliers and contractors in these countries operate within sophisticated regulatory environments with highly competent inspectorates. Most operate to internationally recognized standards established by the International Council on Harmonization (ICH). Therefore, they generally have effective quality systems that provide a high degree of confidence in the overall supply chain.

Companies in emerging markets are operating in a developing regulatory environment with a novice inspectorate. Many have rudimentary quality systems or none at all. Before a US pharmaceutical firm can consider sourcing from these suppliers, it is imperative that the firm works with the suppliers to upgrade their quality systems and standards. To accomplish this, Pfizer and other companies have taken steps to Educate, Evaluate and for lack of a better word, Enforce appropriate quality standards.

Educate

Industry and FDA share the responsibility to educate manufacturers and regulatory authorities in emerging countries. FDA's proposal to place resources in select foreign countries will certainly aid their ability to educate and train foreign regulatory authorities and manufacturing firms. Industry, working through public workshops and private meetings with potential suppliers, should establish clear expectations. Compliance with ICH quality guidelines, effective quality systems including management and oversight of the suppliers supply chain, and compliance with appropriate environment, health and safety standards are just some of these expectations.

Evaluate

The evaluation of an active ingredient or drug product supplier, whether in a developed or developing country, is an essential element of a pharmaceutical firm's quality system. For Pfizer, the evaluation consists of a number of clearly defined steps that are articulated in a written standard operating procedure. The most important point to make regarding Evaluation is that you cannot test quality into a product; quality must be designed in and assured by effective quality systems. No amount of inspection and testing by itself will assure quality. It is neither technically nor physically feasible to test for all potential adulterants in every active ingredient and drug product entering the United States. Therefore, although we do a fair amount of statistically based sampling and testing, the integrity of the supply chain must depend on the careful selection of a contract manufacturer or supplier, and reliance on the quality systems they have in place. The quality systems must include direct management and oversight of raw material suppliers (the actual manufacturers, not commercial brokers).

Pfizer has a dedicated quality assurance unit to evaluate and provide oversight to contract manufacturers. That unit, which is divided into three groups located in the United States, Europe and Asia, provides quality

professionals who speak the local language and understand local customs and closely follow the operating practices of our suppliers.

Pfizer initiates the process by providing the potential contract manufacturer a list of expectations and a self-assessment questionnaire. The response is reviewed and a decision made as to whether to proceed to the next step, a due diligence audit conducted by representatives from quality, manufacturing and other disciplines. This audit will examine the company's quality system including their sources of materials and control of their supply chain. (Frequently, Pfizer will insist that the contractor obtain materials only from Pfizer-approved sources.) At the end of the audit, the results are reviewed and a decision is made whether to continue with the evaluation. The decision to continue is based on a conclusion that either the firm is in compliance with Pfizer standards or the firm has committed to an action plan to close compliance gaps. If the latter, follow-up audits are conducted until a determination is made that the firm is in compliance. Only when compliance with Pfizer standards is established, will the evaluation of active ingredient and drug product begin. The evaluation includes testing of quality attributes as well as a review of the overall process validation. The evaluation process utilizes risk assessment models to assist in the approval or rejection of a potential contract manufacturer. Once approved, quality oversight includes ongoing evaluation of changes, deviations, and trends, as well as on-site reviews during production to ensure that standards are sustained.

Enforce

Contract manufacturers and suppliers are eager to enter the global supply chain. US pharmaceutical firms should grant access only to those who have demonstrated that they have achieved the standards required. This rigor will provide significant economic motivation for would-be contractors to upgrade and maintain their facilities and quality system and secure their supply chains. Pfizer admittedly is moving in a very cautious manner when evaluating potential sources from developing counties, but it is imperative that we enforce our corporate standards for suppliers in all countries.

Securing our supply chain through education, evaluation and enforcement requires a significant commitment of resources; this represents a necessary investment to fulfill our corporate responsibility to patients.