

# **FDA Hearing on Risk Communication – December 7 & 8**

## **Testimony by John Wolleben**

### **Introduction**

Good morning. My name is Dr. John Wolleben. I am Senior Vice President for Safety and Risk Management at Pfizer.

Medicine safety is an obligation widely shared at Pfizer and we take our commitment to delivering safe and effective medicines very seriously. Safety issues are a collective responsibility at Pfizer. The global organization that I head is dedicated to collecting, assessing and reporting safety issues to facilitate the decisions surrounding pharmaceutical safety matters and assure compliance with the various reporting responsibilities. The Safety and Risk Management group at Pfizer reports directly to Pfizer's chief medical officer and has approximately 600 professionals in the central global organization who work with the thousands of staff in the country organizations who are the primary people within Pfizer who receive safety information. Our team collects, assesses and reports on about a quarter of a million adverse event reports annually that come from either clinical trials or commercial activities. Our team also proactively develops risk analyses, performs epidemiologic studies, creates risk management plans for our major products, and communicates in a number of ways the benefits and risks of our medicines.

By way of introduction, therefore, I am saying we have a strong organizational and cultural commitment to safety at Pfizer and a lot of experience and accountability in addressing safety issues for Pfizer, regulators, patients and other stakeholders.

Nonetheless – and because of that experience – we know that communication of the risks of medicines is far from perfect. This is something we all need to get better at doing: FDA, industry,

physicians and other health professionals, patient groups, and media. So, we commend FDA for its efforts in general to improve medicine safety and specifically for holding this public hearing on communicating risks. It demonstrates the agency's responsiveness to public input and commitment to improving its public interfaces. Promoting better health is a Pfizer priority, so we share FDA's desire to effectively communicate medicine risk, as well as benefits, in a way that advances patient well being. Thank you, too, for permitting me to speak before you today.

Today's focus is on nine FDA tools for communicating pharmaceutical risk. Since Pfizer does not have direct involvement in the production of these FDA vehicles we will avoid commenting on specific aspects of them. We would, however, like to offer FDA our perspective on a few principles for more effective drug risk communication. Some of our observations may seem obvious but they are so fundamental they bear repeating in the context of today's topic.

### **Maintaining A Benefit-Risk Perspective**

As FDA evaluates its risk communication tools, we urge to it to consider that any communication it provides on risks be in the context of benefits. The agency cannot effectively inform, educate or guide on safety issues without providing this broader perspective. Public communications that are one-sided, that focus only on risk, or for that matter only on benefit, are not in the public interest. We note that all the communication vehicles under examination today just focus on risks; we believe, therefore, that they may not be achieving what is in the true best interest of the public, namely an informed benefit/risk decision.

Medicine safety is not defined by potential or real risk. Medicine safety is best understood as the balance of risks within the context of benefits. This balance is at the core of what FDA does when

deciding whether to approve new drugs or indications. The benefit-risk balance is also the framework in which physicians decide to prescribe and patients decide whether to take a medication. Since the benefit-risk balance for a drug is different for different patients, it is very important that doctors and their patients are aware of at least the major possible tradeoffs. Therefore, a first guiding principle is that every communication to the public by FDA should contain a balance of benefit and risk information, reminding the reader of the benefits of the drug as well as what may be its known or potential risks.

We know, for example, that media tend to focus primarily on risks in their reports, often giving unbalanced views of therapies. If public communications only communicate risk, without a balanced presentation of benefits, those communications have the potential of unreasonably amplifying risk and creating unintended consequences – perhaps unnecessarily frightening many people away from taking much needed medicines that are safe for them, doing more harm than good.

So we strongly encourage FDA to minimize unnecessarily frightening people away from needed medicines and ensure that its risk communication vehicles take into account and present information on both benefits and risks. We believe that a well-designed communication system should allow for the distribution of safety and risk/benefit information in such a way that metered responses from the patient/physician community can be achieved depending on the nature of the specific risk/benefit information that is being communicated.

### **Empowering the Physician-Patient Relationship**

A second guiding principle for FDA to consider is ensuring that its risk communication vehicles respect, re-enforce and empower the doctor-patient relationship, and not substitute for it. Since there

are so many variables that affect whether an individual can tolerate and effectively use a modern medicine, an uninhibited dialogue between health care providers and patients who may decide to use medication to treat illness is essential.

It is important to remember that supplementary risk information that FDA provides on a medicine will be but one of many inputs a physician will rely on in treating patients. Other information likely used in prescribing decisions would be the medical history and situation of the individual patient, the information contained on the drug label, the physician's experience with a specific drug, alternative treatment options available, and the risk tolerance of the patient, among others. Consequently, it is critical that the FDA ensures that implementation of FDA tools respect physicians' prescribing discretion.

In order to maximize the effectiveness of FDA risk communications tools for physicians and other health care providers, it is essential that these tools provide clear, accurate, useful and actionable information that physicians, in discussions with patients, can use as an input in prescribing decisions. We encourage FDA to continue to work with physician groups on the usefulness of current tools directed at health care providers and how providers think they can be improved.

### **Enhancing Audience/Public Comprehension**

A third area for consideration is ensuring that FDA's tools communicate in a manner that the intended audience truly understands. FDA certainly recognizes that individuals have varying degrees of health literacy and perceive risks and benefits differently, so its communication tools should strive to reflect this diversity. Literature on communicating risk to the public indicates that many persons are innumerate and cannot understand some of the basic mathematics used in risk concepts. There is still

uncertainty about how individuals personally characterize risks, how best to communicate risks to the public, and whether and how persons understand risk concepts and communications. In fact, we do not yet know what people want to know and in what format they want it.

In May of 2004, Pfizer made a presentation to the FDA about its “Clear Health Communication Initiative.” The Clear Health Communication program aims to reach as broad a consumer audience as possible with information people can understand and act upon, in both print and web-based materials. We are reaching out to all consumers who can benefit from Pfizer products and services by promoting better health outcomes through improved medication compliance.

This program provides Pfizer personnel a step-by-step approach to shape materials that maximize understanding of the benefits and risks of our medicines. For print documents, for example, we have established principles for clear communication with a clearly defined process for achieving each principle. Those principles include focusing the content on the needs of the audience, explaining the purpose of the content to the audience, involving the reader in the document, making it easy to read, making it look easy to read, selecting visuals that clarify and motivate, and writing content at a 6<sup>th</sup> grade level of reading. Pfizer makes these principles available to the public through its health literacy web site at [www.pfizerhealthliteracy.com](http://www.pfizerhealthliteracy.com).

### **Willingness to Collaborate**

Given the importance of risk communications and the potential for giving confusing and possibly harmful information to the public, we urge FDA to empirically study the real impact of its tools on patients and physicians. FDA should seek the advice and counsel of experts in risk communication, including those in the

pharmaceutical industry, researchers in cognitive psychology and practicing physicians. We also recommend that FDA regularly monitor patient and physician behavior in response to risk communications, and then modify its communications tools accordingly.

You have heard (or will hear) from PhRMA about the industry's willingness to partner with FDA, academia, and others on risk communication. Pfizer has been and continues to be an active partner with others to improve risk communications globally, working with the International Conference on Harmonization, PhRMA, and the European Federation of Pharmaceutical Industries and Associations. We would like to reaffirm our willingness to partner with FDA to find solutions that enhance risk comprehension and patient safety.

Thank you.