G.P. Migliaccio comments to FDA Pharmaceutical Sciences Advisory Committee on October 22, 2002.

Introduction (if necessary): My name is Gerry Migliaccio. I am the Vice President of Global Quality Operations for Pfizer Inc and the Chair of the PhRMA GMP Task Force.

I would like to thank FDA for inviting me to discuss the proposed Manufacturing Subcommittee to the Pharmaceutical Sciences Advisory Committee on behalf of PhRMA.

The recently announced FDA initiative to develop science and risk-based GMP standards has created an opportunity for industry and FDA to refocus GMP compliance on areas that truly impact fitness for use of pharmaceutical products. That is, to focus on the patient. Innovative technologies that enable us to gain a greater scientific knowledge of our products and processes can significantly enhance the assurance of quality and compliance in pharmaceutical manufacturing. When combined with properly developed science and risk-based GMP standards, we have revolutionary potential. This potential must be harnessed to achieve our objective of GMP standards that are firmly rooted in science and to ensure that our collective efforts are expended on GMP and CMC review issues that are most critical to fitness for use.

The proposed Manufacturing Subcommittee can and should play a key role in the FDA's GMP initiative. Specifically, there are four areas where the Subcommittee could provide leadership and guidance:

1. First, it should serve as the principal forum for identifying the topics that would benefit from science-based GMP standards and for prioritizing work on these standards. In essence, the proposed Subcommittee should serve as the Steering Committee for implementation of the elements of the FDA's initiative related to science-based GMPs.
2. Secondly, the Subcommittee should provide the Pharmaceutical Sciences Advisory Committee with manufacturing and quality assurance perspectives on the concepts of risk-based GMP compliance and risk-based CMC review. These are complex subjects that can be distilled down to a common denominator: fitness for use of the product.
3. The third key area for Subcommittee involvement should be as a key player in the proposed technical issues resolution process. Not as a participant of the process as issues are addressed between FDA and firms, but to evaluate issues after they have been resolved to look for opportunities to clarify GMP standards on an industry-wide basis.
4. Finally, following the model established by the PAT Subcommittee to the Pharmaceutical Sciences Advisory Committee, the Manufacturing Subcommittee should focus on new technologies and ensure that process are in place to enable their introduction.

To ensure that this Subcommittee has the appropriate expertise to fulfill these responsibilities, it is essential that a broad section of the pharmaceutical manufacturing industry be represented. Manufacturing and/or quality professionals from innovator firms in both the traditional active pharmaceutical ingredient and drug product sector and the biotechnology sector are essential to the subcommittee.

PhRMA endorses the proposal to establish a Manufacturing Subcommittee to the Pharmaceutical Sciences Advisory Committee and PhRMA Members stand ready to serve on and support the Subcommittee.

Thank you.