Ensuring Drug Safety: Where Do We Go From Here?
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Witness:
Mr. Keith L. Carson
The Williamsburg BioProcessing Foundation, Virginia Beach, VA
Chairman
Testimony

I am a chemical engineer with over 25 years experience in the biopharmaceutical industry. My training is as a process engineer, and my focus has been on the large-scale production of biological products including viral vaccines, antibodies, recombinant proteins, viral gene vectors, and cellular therapies.

I also received an MBA in marketing from George Washington University in Washington, DC, and lived on Capitol Hill from 1981 to 1993.

I helped found the Virginia Biotechnology Association and have served as a board member for seven years, plus one term as the association's president. I currently serve as an advisor to the board, and provide advice on biotech business development for the state and Hampton Road area.

In 1994, I founded the Williamsburg BioProcessing Foundation, or "WilBio," in Virginia Beach, Virginia. WilBio is a biotech information company that publishes the BioProcessing JournalTM, and organizes 12 international conferences on the development and production of biological products for human health care.

Our mission is to help develop safe and effective biological products, and our objectives are to make product development less costly, provide a trained workforce for the biotech industry, and improve communication between FDA and industry, and the academic processing centers.

Since 2000, WilBio has signed several FDA Co-Sponsorship Agreements for the development of viral reference materials. Our role has been to serve as a facilitator and coordinator for Working Groups, which manage the development of these materials and are made up of representatives from FDA, industry, and academia. In 2002, the first project resulted in the production of a well-characterized adenovirus, which is now used by product sponsors throughout the world to validate assays and internal reference materials.

Also through a Co-Sponsorship agreement, this is the third year that WilBio has helped organize and manage the Annual FDA Science Forum, which is held at the DC Convention Center in May. With approximately 2,000 attendees from government, industry, and academia; this unique meeting offers the best opportunity to learn about the scientific interests and activities at FDA, and how science is used to help formulate policy and regulate products.

I have just completed a lengthy analysis of FDA's Critical Path Initiative, and have written a review article for our publication. A copy of this article has been submitted to the committee, and additional copies are available upon request. As you will note, key concepts for this initiative include: well-characterized reference materials, standardized analytical methods, shared characterization and clinical data, and improved regulatory guidelines. I have proposed that working groups be formed to tackle these issues in a fashion similar to the one taken for the highly successful adenoviral reference material project.

Today, I am here to testify about Drug Safety, and specifically the impact that new technologies could have on drug discovery, development, and approval. While these technologies appear to offer tremendous potential, their use and implementation are still in a very early stage; and a number of technical, logistical, and ethical issues must be resolved.

Technological advances in sensors, analytical methods, instrumentation, and computing power are happening so quickly that it is very difficult to know how they can best be applied, or understand what the information they generate actually means. Some breakthroughs are occurring, but many years will be required to devise the correlations needed to make the data useful.

To keep up with these technological advances and use them in the regulatory process, FDA must be properly funded to staff and equip their labs, plus train their personnel. Product reviewers must be familiar with these technologies and how to apply them, as well as comprehend the sponsor data that is submitted.

The Agency also needs a permanent Commissioner who can provide consistent leadership, policy, and direction.