National Academy of Pharmacy

Statement

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I extend greetings to the National Academy of Pharmacy of Brazil from the United States Pharmacopeial Convention. I am honored to note that my guest at this distinguished conclave is Dr. René Bravo, President of the USP Convention. Accompanying Dr. Bravo is Dr. Flavio Vormittag, Vice President and director of USP's site in Sao Paulo, operational now for about one year, and other USP staff. Please note that all three of us are physicians. There are many examples of great and historic events that bring practitioners of the art and science of healing together, and the USP Convention is one of the finest of these. Throughout its 189 year history, the USP Convention has been an important collaboration between physicians and pharmacists, and even now delegates of the USP Convention come largely from colleges and schools of medicine. The Convention is not a national body reflective of one country's interests but draws in about 400 distinguished practitioner delegates from all over the world. In its almost 200 year history, the Convention met first every decade and now every five years. Its next meeting will be in the beautiful city of Washington, DC, in April 2010.

At USP I am the 15th chair of the Council of Experts and the fourth Chief Executive Officer. I am both honored and humbled by my distinguished and hard-working predecessors who were either pharmacists or physicians. I could say that USP is lucky to have me in both positions because I am trained as a physician but have spent my entire career as a pharmaceutical scientist and clinical pharmacologist. But I am the lucky one—and indeed it is mostly good fortune that brought me the opportunities that I now enjoy in my dual roles at USP.

I began my education at a small liberal arts college in Ohio, one that many generations of my family had attended, and in this I was indeed fortunate. This college was imbued with a strong sense of ethical behavior and social justice that has stayed with me throughout my life. Thereafter, I completed all medical training including internship and residency at the University of Chicago, after which I entered the United States Army. At the time, the US was engaged in a war that required many types of physicians and pharmacists, including those with my specialty of internal medicine. Because I was fortunate to have a fine son, John, later joined by a fine daughter, Catherine, the Army stationed me in Korea and not Viet Nam. And following my tour of duty there, I was fortunate to be sent to Walter Reed Army Institute of Research (WRAIR) where my love of pharmaceutical sciences began. At WRAIR, my colleagues and I studied an antimalarial drug called mefloquine. In its initial human studies, it proved powerless, and we subsequently discovered that the investigational preparation was poorly formulated so that the clinical trial tablets did not release the active ingredient to malarious volunteers. That was a fine example for

me of the challenges of bioavailabilty—and also fortunate for malaria patients because mefloquine when properly formulated turned out to be a good antimalarial drug first marketed as Lariam by the Swiss pharmaceutical giant Roche.

After completing my military service, I trained as a fellow in clinical pharmacology at the University of California, San Francisco, and stayed on there running a clinical investigation unit in the School of Pharmacy for 12 years. This was an excellent apprenticeship for me because much of our work was devoted to bioavailability and bioequivalence studies related to the newly burgeoning US generic industry. I spend a further year at a small biotech company in San Francisco studying a medicine for HIV infection, and then moved to FDA for ten years. At FDA I first headed the Office of Generic Drugs for three years, then advanced to a deputy in charge of about 500 staff in the Office of Pharmaceutical Sciences in the Center for Drug Evaluation and Research. FDA was and remains an amazing public health institution, and it was there that I began to appreciate the value of standards. At FDA, these are expressed in law, regulation, and guidance that undergird availability of safe, effective and good quality medicines. In 1999, my predecessor at USP departed his position, and USP opened up a search that resulted in my coming to my present two positions at USP. I will spare you the series of fortunes—and yes misfortunes—that moved me along my path, although I will note that it seems likely, and I have heard many others say, that a strong career inevitably has both challenges as well as opportunities, and that is surely the case with mine.

Perhaps I should tell you now that I did not choose my scientific career. Rather it chose me, and it chose me fairly late in life. And while I will firmly state that I enjoy science in all its myriad manifestations, I do not directly engage in the conduct of science either at the bench or at the bedside. Rather I engage in what I would call science-based standards-setting policy, which is at the core of what USP does. And further, my science focuses on how we determine whether things are the same or different, focusing on foods and drugs and their ingredients. The science of equivalence is fascinating and seems to reflect an inherent human capability. Watch the wise shopper in the supermarket choosing, for example, apples, and you will see a careful judge of equivalence using measures of color, weight, and texture. When the distinguished practitioners of the first USP Convention came together in 1820, they referred to equivalence as consistency, and consistency is a very good word that we still use today in therapeutics. Consistency in the quality and performance of a medicine day after day in a single patient is critical to a good therapeutic outcome, and, interestingly, we still have much to learn about how to achieve this consistency. Perhaps the emerging world of personalized medicine will advance us further down the path of consistency that our Convention forebears started us on so long ago.

Of course I could speak a good deal more about my career and the many individuals who guided me, sometimes with great difficulty on both our parts, to my present position. But I want to return to the word fortunate. I was and am fortunate to live in exciting times. What I have termed challenges could also be termed great moments of good fortune that allowed me to be where I am now, holding such exciting positions in the USP Convention. And I will be fortunate indeed to have a strong role at the April 2010 Convention. At this upcoming conclave, very similar to the one

tonight, distinguished pharmacy and other practitioners will meet to consider key healthcare challenges of our time insofar as they relate to medicines and foods. And these challenges are indeed exciting, relying as they inevitably do on science-based standards. I thank you for the honor you have bestowed on me this evening. I accept it in recognition of the many distinguished physicians, pharmacists and pharmaceutical scientists who have worked so hard to bring us to where we are now in the realm of medicinal therapeutics. And I stand in awe of the new generation of practitioner scientists who will carry us even beyond our current dreams of good health for all. My good fortune in being here with you tonight astonishes me, and I thank you sincerely and with all my heart for the honor you have bestowed upon me.