



**President's Address
D. Craig Brater, M.D.**

Welcome to USP Convention 2005. This is USP's 23rd Convention and its 185th Anniversary.

I am pleased to come before you today as your President. You or your predecessors elected me five years ago, and I have been privileged to serve you. The service has been intense. In this afternoon's section of the program, you will hear first from me, from the Chair of the Board of Trustees, Dr. Braden, and finally from Dr. Williams, USP's Chief Executive Officer. Afterwards, we have a roundtable discussion with members of USP's senior management team moderated by Dr. Paul Schyve, so that we can hear your questions and your voice.

Dr. Braden, Dr. Williams, and I each will tell you that this organization has gone through rapid change in the last five years. That pace of change will continue. Change is positive, it is helpful, it is necessary, and it is sometimes painful. For you, it must be relevant.

You are the shareholders of this organization who will, in the next several days, elect a new President to succeed me. You will also elect a new Board of Trustees who will collectively lead USP over the next five years. You will adopt new resolutions to focus the organization in important areas, and you will institute, as you wish, changes in USP's Constitution and Bylaws.

You also will elect the standards setting body of the organization—the chairs of the standards expert committees of the Council of Experts. These experts will continue to evolve the *Pharmacopeia of the United States of America* and the *National Formulary* to stay abreast of the times. And indeed we live in interesting times?

For healthcare workers such as we, the times are beyond interesting. They are a clarion call to take up arms against disease in ways that sometimes are beyond our comprehension, much less our capability. But the call and challenge are USP's heritage since its beginning in 1820. You are called here today to advance USP's activities into the future, based on that heritage. Please consider that there are other critical responsibilities that you must execute over the next several days.

- First, we are called in this meeting to a high purpose and a broad objective—an objective that supports good health care, and in particular, good pharmaceutical care for all. This objective is directly expressed in USP's mission statement. Based on my own personal experience, much of my talk will be devoted to international health. Drs. Braden and Williams, who follow me, will add more about national needs and perspectives.

- Second, I am accountable to you, the Members of the USP Convention, as are Dr. Braden and Dr. Williams. We need to hear your voice about how we did our job.
- And third, beyond these considerations, I have a very special request. I hope you will enjoy yourselves and get to know each other even better than you already do. USP is a unique organization and a family-and this is a time for joy, for sorrow, for remembrance, and for renewed commitment to our larger purpose.

INTRODUCTION TO KENYA

This morning, you heard three distinguished speakers. Dr. Lucian Leape spoke to issues and challenges of quality health care and patient safety. Uwe Reinhardt spoke to issues and challenges of healthcare in the United States. And Dr. Jack Chow spoke to even larger health care challenges in the world, with a focus on three dread diseases-HIV/AIDS, malaria and tuberculosis. These topics were brilliantly and poignantly framed for you by these speakers.

USP stands ready to serve the national and international communities in addressing these issues and challenges. Our resources are small, we may be ‘Davids’ in the face of many ‘Goliaths,’ but our commitment and determination are great. The empowerment to move forward will come from you. And with challenge comes opportunity. USP works in four key areas

National product quality, International product quality, healthcare information, and patient safety. I draw your attention to more detailed information about these four areas in the panels displayed in the break area behind this ballroom. Key programs and services to meet objectives in these areas will be considered by Drs. Braden and Williams.

KENYA

I would now like to turn to my personal experience in international healthcare that I spoke about. At Indiana University, where I serve as Dean of the School of Medicine, we've formed a partnership with Moi University in Eldoret, Kenya. This is Kenya's second medical school serving the catchment area of western Kenya-the so-called highlands from which all the famous Kenyan distance runners come. In a true partnership, we have established a clinical delivery system that's making a difference.

If you'll permit me the indulgence of using this office as a bully pulpit, I'd like to share a look at what we're doing in Kenya, and what's been accomplished. I do so to make the topic of international health and USP's role therein more visceral and more palpable to each of you.

It's difficult to fathom the devastation and suffering of this disease, which goes beyond the body...

Video segment - IMPACT OF AIDS

Beginning is always difficult and our beginning was no different. I'm pleased that my university, working with dedicated health care workers and patients in Kenya, has made a difference. You can see that difference in smiling faces and healthy bodies, in clean hospital rooms and bustling clinics.

And you can see it in the availability of good quality medicines to treat HIV and the terrible infections that accompany HIV.

One of the biggest problems in treating HIV/AIDS is that no one wants to talk about it. Because AIDS has been ignored for so long, it has been allowed to fester and grow to the current pandemic we face. Thus, an important element to combating the disease is support groups that educate the population and help to overcome the stigma associated with AIDS. With appropriate medical care, good medicines, and emotional support one can live positively.

Video segment - MAKING A DIFFERENCE

For the medicines, we can be thankful for brilliant investigators and manufacturers. And we acknowledge the services of many national and international partnering organizations, including the US Government and the World Health Organization, for advancing the cause of good health and good pharmaceutical care at this health care delivery system in Kenya.

The final clip is a call to action that I hope resonates with all of you.

Video Segment - CALL TO ACTION

Over the next five years, the scourge of HIV/AIDS will have the cumulative impact of 195 Indian Ocean tidal waves. As Greg Behrman wrote in *The Invisible People*, his 2004 study of the catastrophe (a book that I urge all of you to read), HIV/AIDS is “refashioning the social, economic and geopolitical dimensions of our world.”- not just Africa, but OUR world.

Twenty percent of South Africa's adults are infected. The life expectancy in Botswana has dropped from 71 to 39 years; in Zimbabwe, it has fallen from 70 to 38. By 2010, when we meet again, Africa will be home to 20 million of the world's 25 million AIDS orphans. Five years from now, according to the National Intelligence Council, China, India, Russia, Nigeria and Ethiopia will have between 50 to 75 million infections, possibly more. Fifteen years after that, the Council projects, those countries' economies could be crippled by the effects of the disease.

“The toll taken thus far,” concludes Behrman, “is merely a harbinger of what is still to come.”

Each of us must ask individually what we will say to our grandchildren when they ask us what we did in the face of this crisis. But just as each of us must search our souls, every organization that has anything to do with public health must also search theirs.

USP is committed to public health. Does the fact that we have the words United States in our name mean that we are obligated to focus only on public health in the US? Said in another way, does the US part of our label allow us to turn our backs on our brothers and sisters in other parts of the world?

WHAT IS USP DOING NOW INTERNATIONALLY?

USP's vision statement calls us to work both nationally and internationally. USP has a long history of supporting international objectives that promote good pharmaceutical care for all. There are many past and recent examples. Here are a few:

- Via modern monographs in *USP-NF* and official USP Reference Standards, USP can facilitate market access to good medicines to treat HIV/AIDs, malaria, tuberculosis in many countries throughout the world.
- Via these same monographs and official USP Reference Standards, USP can help eliminate counterfeit and substandard medicines from Africa and other regions. Counterfeit medicines pose a grave risk of increasing resistance to HIV/AIDs, malaria and tuberculosis, which substantially worsens prognosis.
- Through strong and continuing resources from the United States Agency for International Development, USP's Global Assistance Initiatives staff, directed by Nancy Blum, leads a significant effort to promote drug quality and good information in developing countries of the world, including many countries in Africa.
- USP is working on an international compendium that will amplify the availability of monographs for HIV/AIDs, malaria, tuberculosis, and other dread diseases, together with official USP Reference Standards.
- USP is also working to provide translations of *USP-NF* into Spanish and other major languages.
- USP is developing plans for sites throughout the world, starting with India. At its final full meeting this last January, the USP Board of Trustees approved the site in the India.

The panels that I mentioned earlier speak to USP's public health efforts. One of these is devoted to international health. I encourage you to spend some time looking at the display to get a larger sense of USP's strong and enduring commitment to international public health.

U.S. NEEDS

My focus on international health by no means suggests that USP should not consider its domestic purpose. Our challenges here are large and growing. While pharmaceutical and other technologic successes abound, the numbers are not always good. The U.S. spends more per capita on health care than any other country—approximately 15% of our GDP. Yet many in the U.S. lack health care coverage—approximately 45 million according to a recent estimate.

According to a recent RAND study, only about 55% of Americans receive care recommended for common conditions. Health disparities exist based on race, ethnicity, geography, and socioeconomic status.

As many as 98,000 patients die each year as a result of medical errors. The time for practitioners to adopt basic research findings is approximately 17 years. There is substantial underinvestment in information technology compared to other industries. And in a WHO report from the year 2000, the U.S.—compared to all other countries—ranked 37th in terms of the overall health system performance and 72nd in terms of level of health. I regret to say—on behalf of President Bush—that France ranked number 1.

WHAT WILL USP DO?

USP will not ignore these statistics and the challenges they bring. Our commitment is always to practitioners and patients of the United States, to which we owe our loyalty, wisdom, and strength. In our current strategic plan, we describe an “imagined future.” That is, one in which “all therapeutics meet clearly defined quality standards that ensure benefit to practitioners and patients. “The Board’s strategic plan states that (previous slide builds with following text) we’ll approach this imagined future with a sense of urgency and purpose, recognizing the critical need for good quality, safe, and effective therapeutic products and authoritative, unbiased health care information worldwide. We have promised we will focus our efforts both domestically and internationally.

Your voice on the topics I have been speaking about is needed in many ways. For example, the Constitution and Bylaws calls for a Council of the Convention that is intended to draw you into our hopes and dreams in a stronger way over a five year cycle. There is a resolution that calls for this Council to consider Convention membership, perhaps as a means of expanding USP’s international commitment. In addition, Resolution No. 6 specifically addresses our international presence and role for the coming five years. Please look at these Constitution and Bylaws changes and resolutions. We need to hear your voice, as you drive us, through your energy and wisdom, to our imagined future.

CLOSE

In closing, I’d like to speak about my own continuing service to USP. Like many of you, I have served USP joyfully, knowing that this service speaks to the most positive aspects of the human spirit. I hope that you share with me a dream of good health and good pharmaceutical care for all. You have in your hands now the power to drive USP’s energies and commitment both nationally and internationally to the public good. As part of good pharmaceutical care for all, USP promotes the availability and rational use of good quality, safe and effective therapeutic products. These products will be available to patients throughout the world—in Kenya and in Maryland, in Southeast Asia and in California, in Birmingham and Baltimore. They will be used wisely by patients, consumers and practitioners. Their use can be tracked by good reporting systems that promote continuous quality improvement.

USP can and will make a difference. Your voice in the next several days can and will make a difference. And at the end of the day, when our children and children’s children asked what we did during the health crises of the early part of this century, we can say, through the power of your commitment, that we met the challenges and did the right thing.

Greg Behrman concludes “The Invisible People” with a quotation from Michelangelo. “The greater danger for most of us is not that our aim is too high and we miss it, but that it is too low and we reach it.”

Thank you.