



Chair's Address
Larry L. Braden, R.Ph., D.Sc.

Thank you, Craig, for that powerful introduction to the work of USP.

I would like to continue as the second speaker in this afternoon's series with my report on behalf of the USP Board of Trustees in my role as the current chair.

USP was founded in 1820, incorporated in 1900, and USP's first Board of Trustees was composed of an equally distinguished group of individuals. There have been 13 Boards since-the current one is the 14th. All of the Board members are with us today, and I would like to ask them now to stand as their names are called so that you can acknowledge their considerable efforts.

Alice Till accepted the challenge of serving as chair during the first year of this cycle and guided the board as we settled in and began the rather arduous process of learning about the complex and unique components of USP, and how we and staff could best work together. Dr. Till's broad experiences in the generic and research-based industries have contributed greatly to our discussions.

Mary Anne Koda-Kimble stepped into the tradition of a pharmacist serving as chair of the Board of Trustees for our second year and led a spirited process of review of the board-staff relationship while leading the board to the creation and adoption of a Strategic Plan for the organization.

Craig Brater's compassion and sense of purpose in life, as you heard from him moments ago, have served as a steady reminder of the reason we, and you, are all here, volunteering and hoping we are somehow making a difference in the world.

Jean Gagnon's career of academia and industry, his service as a member of the board in the previous cycle and his years of leadership in pharmacy organizations came into focus with a sharp pencil as Treasurer, and lent sharp focus to our discussions and debates over these five years.

USP Past-President Ted Bransome's institutional memory resulting from his 29 years of service to USP repeatedly led us away from brambles and briar patches where other boards had been, and kept us from repeating the work...and sometimes the mistakes...of prior boards.

Clem Bezold, a Trustee-At-Large with no formal medical or pharmaceutical background, has been the constant reminder of our responsibilities as trustees of an organization created solely for the public good. Dr. Bezold is a futurist, and his frequent "what if in the future.." scenarios always caused us to pause and ponder where our actions might lead in years to come.

Trish Byrns brought her deeply caring personal and professional attitude to the table. Combined with her research background and years of experience in the Medicaid policy arena, Dr. Byrns' contributions have greatly benefited the board and USP. Dr. Byrns has worked diligently as chair of the Governance Committee to develop a plan for a smooth transition from our Board to the next, another of our efforts to avoid some of the starts and stops experienced in the first months of this cycle.

Dr. Marvin Lipman is listed as the Public Trustee on the USP Board. Marv Lipman is a trustee of the public. His quiet, gentlemanly leadership style has constantly reminded each of us of the true meaning of trusteeship; of our responsibility as fiduciaries of the public interest.

Fred Telling, as a Trustee-at Large, armed with his Ph.D. in Economics, persistently drove our discussions towards reality checks: "Does this really make sense. Is this the best way for USP to spend its limited capital of volunteerism and money?" Fred's broad, corporate and international experience has frequently challenged assumptions among the rest of us.

Paul Schyve was elected by this board and joined us mid-cycle, after Dr. Ray Woosley's change of professional duties would not allow him adequate time to fully participate as a Trustee. Paul's keen attention to detail combined with his ability to synthesize complex issues into manageable bites quickly demonstrated his great value to us and USP.

I feel compelled to add that Dr. Schyve's training as a psychiatrist added a welcomed degree of stability to some of our more volatile debates. There were times that we were all glad that "the doctor was in."

These past five years have been a period of significant transition for USP.

In the prior cycle, the Board received the McKinsey report, which radically challenged the way USP was doing its work.

Those board members began working with a new Chief Operating Officer, Mr. John Fowler, who they hired about 18 months prior to the end of the cycle and to the election of us to the board. John and his staff colleagues have brought unprecedented management and financial stability to USP, and we on the board have had the pleasure of working with them in the establishment of that stability.

This period of transition was characterized not only by a new operating model for USP resulting from the McKinsey Report, a new board which had only two returning members, Drs. Gagnon and Bransome, but also by a new CEO, Dr. Williams, hired just three months prior to our arrival.

During our time, the Enron and other for-profit corporate scandals resulted in Congress adopting the Sarbanes-Oxley Act, and while not mandated for entities like USP, the board and staff moved assertively to adopt its standards of accountability to our thinking. There were certainly some challenging days and challenging meetings in the early years of our tenure, but an environment of commitment and mutual respect always prevailed. And I am pleased to tell you that while USP

may have encountered heavy seas along the course of these five years, the teamwork of the Board and staff rose purposefully to the numerous tasks at hand. I can assure you with the greatest confidence that we are in calmer waters and USP is sailing smoothly.

Let's look for a moment at some of the key tasks met during this past half-decade:

A Board of Trustees has many duties and obligations. It has a duty of loyalty and a duty of care.

Its obligations are to establish the strategic direction of the organization, monitor the performance of its CEO and staff, and assure the fiscal integrity of the organization

Review with me these three tasks:

1. The Board's Strategic Plan

In this cycle, as I mentioned in the introduction of Dr. Koda-Kimble, the Board gave much thought-and a lot of heart and soul-in developing a strategic plan. Our plan is termed the 2003-2005 Strategic Plan: Upholding Our Commitment and Securing the Core. It is a part of your Convention Member Notebook and I encourage you to read it.

The date and title are informative. It doesn't say 2000-2005 does it? The fact that it begins 2003 tells you that this task took a long time-more than two years of hard discussions, working with staff and consultants, to develop a document that is succinct, workable, and useful. The title speaks to the McKinsey report that says USP needs to remain true to its core purpose and activities. We're proud of this Board's Strategic Plan, and Dr. Williams and staff use it continuously to track their tactical programs.

The Plan speaks to both national and international challenges to assure good pharmaceutical care for all. We offer it as part of our legacy to the incoming Board that you will elect in the next several days.

2. Management of Staff

A second Board responsibility relates to staff oversight and the adoption of policies and positions consistent with the mission of the organization and its resources.

For this Board that meant monitoring the work of the CEO, Dr. Williams, and the COO, Mr. Fowler. I'll start by teasing Dr. Williams a bit-he, like us on the board as a collective body, initially had a steep learning curve! If I may say so, he may have come to USP from FDA with what is sometimes called the 'Commissioner's syndrome.' That syndrome arises because people hang on the Commissioner's every word when he leads FDA. But after he or she is no longer at FDA, no one pays much attention.

Dr. Williams says he had to suffer a bit with this syndrome in his first year or so with us volunteers in USP, even though he wasn't the Commissioner-but more importantly he soon recognized he had to learn a lot about working in the at-times unpredictable world of volunteer-based organizations.

But Roger rose to the need to gain new CEO and volunteer skills, has incorporated those new paradigms into his work with us volunteers, and I can assure you that Dr. Williams has proved himself to this Board, who believes him to be a highly talented and passionate chief executive officer.

We offer him also as a legacy to the new Board, tempered as he is now by the fiery furnace of the USP experience.

I can also speak to our oversight of USP's COO, Mr. John Fowler, who had a direct line of report to the Board when we came to our seats in 2000. Mr. Fowler's presence is a tribute to the wisdom of the prior Board, chaired by Dr. Jordan Cohen, who hired him to lead USP's operations during the difficult beginning of this time of transition. The financial numbers - the most important fiduciary responsibility of any board - that I am about to show you are a direct tribute to John's talent and commitment.

3. Fiduciary Responsibilities

So the third key area of a Board's responsibility is the fiduciary one. USP's Board played the strongest possible role in assuring the financial integrity of the organization in this cycle, working each year with staff to assure that budgets accorded with our Strategic Plan. Please note that the second key element of the Strategic Plan required us to manage USP's public health programs with fiscal responsibility to ensure efficiency and impact. You will hear about USP's financial status tomorrow in a presentation from Dr. Jean Gagnon, who served as USP's Treasurer for the last five years. I'm not going to steal Jean's thunder, so I will only show one slide here.

The red and orange bars speak to five year revenues and expenses respectively. And the blue bar speaks to the change in net assets.

Each year, like all well run corporations, whether for- or not-for profit, USP undergoes an intensive audit. These audits resulted in no major deficiencies in the management letters from the auditors; a tribute not only to our efforts but also to Dr. Williams, Mr. Fowler, and USP's fine staff.

Our legacy to the incoming Board is thus an organization with a rock solid financial statement.

There are two other topics that I would like to touch on in my remaining time with you this afternoon. First, I would like to give you a glimpse of how this Board worked and a bit more information on what they did.

Then I would like to speak to a core USP constituency in the audience today-the pharmacy community. I am a practicing pharmacist in Acworth Georgia, so this constituency is my constituency.

In this cycle, the Board met regularly four times a year for two or more days. The Rules of Business Practice adopted by the Board named four standing committees within the board: the

Executive, Audit, Compensation and Continuity, and Investment Committees. Recently, this Board added another - the Governance Committee.

During the cycle, we also established an additional eight ad hoc committees. The creation of those ad hoc committees arose out of necessity. There were so many complicated topics confronting us that we had to create forums to allow a subgroup of the Board to tackle them, develop a position and, if possible, a recommendation for the full Board to consider. Please allow me to move quickly through a series of slides and perhaps a few words about the various committees.

Executive

This committee provided financial oversight and advice to the Board on yearly budgets, extraordinary or unbudgeted expenditures, and collaborated on the evaluation of the CEO's performance.

Audit

The Audit Committee under the leadership of Jean Gagnon provided oversight of the audit of USP financial accounting statements and practices.

Compensation and Continuity

Clem Bezold and the C&C Committee conducted yearly reviews of staff compensation, benefits and Performance Award Plans and approved salary levels for direct reports to the CEO.

Investment

Jean and his committee on USP's investments oversaw investment policy and monitored the performance of the organization's investment portfolio.

Governance

Tish Byrns and her Governance Committee recommended standards/measurements for trustee performance, conducted three Board self-assessments in the cycle, and developed a new board member orientation for the incoming Board.

Compounding Activities

This committee, which I chaired, monitored USP's activities in the area of compounding, including the development of the *Pharmacists' Pharmacopeia*.

Convention

The Convention Committee was activated about a year ago to consider input from USP stakeholders and to recommend to the Constitution and Bylaws Committee proposed changes. Most appropriately, Craig Brater chaired this committee.

Food Chemical Codex

The Food Chemicals Codex Committee was established briefly during this cycle to explore the relationship between USP and the IOM Food and Nutrition Board, particularly as it related to USP and the Food Chemicals Codex project at IOM. Ted Bransome served as chairman of this committee.

Healthcare Information

Marv Lipman chaired the Healthcare Information Committee, which was asked by the board to carefully consider USP's relationship with Thomson regarding the USP DI, and recommend a prudent and appropriate approach to the existing agreement.

Patient Safety

Paul Schyve hit the ground running when he joined the board and took over the chair of this committee. It was charged with monitoring the strategic direction of USP's Patient Safety program to ensure optimum public health impact.

Process Analytical Technology

Clem Bezold, being the futurist he is, challenged the Board to monitor this technology and its implications on USP's core standards-setting activities.

Real Estate

Ted Bransome and his committee spent considerable time in reviewing USP's space needs and worked with staff to recommend appropriate options for Board consideration. You will see the fruits of their labors during the Convention.

Joint Task Force on Public Health Program #1

Ted Bransome also chaired this Committee and was joined by four members of the Council of Experts to consider the creation of a separate compendium, and to explore the drug substance/excipient verification program. We have recommended a continued presence for this committee in the next cycle.

As you consider these committees and their charges, please bear in mind that each required many additional hours beyond the regular Board meetings to read background material, understand some very complex issues, in some cases travel to conduct due diligence, and come to a recommendation or conclusion.

As a practicing community pharmacist in the midst of such an outstanding group of experienced leaders, I have been honored to serve as chair these past three years, in keeping with a USP tradition of a pharmacist holding that position.

As I close my report to you, I would like to offer a personal reflection on pharmacy's relationship to USP. As we look back into the past, we frequently see heroes from the pharmacy profession who helped USP be what it is today. There were many names who are still famous today such as Dr. Remington- caring practitioners of the art and science of pharmacy.

Dr. Williams asked that a treatise on the life and times of such a pharmacist, Charles Rice, be inserted in your Convention Notebook. Please find a few minutes to read that treatise and learn about a mysterious gentleman in New York who became a distinguished practitioner of pharmacy in that state, and who had an impact on USP that can be read on every page of *USP-NF*.

The legacy of Charles Rice brings to mind for me the intriguing book published a few years ago, "The Professor and the Madman," the story of the writing of the first edition Oxford English Dictionary.

In case there are descendants of Charles Rice present, I'm not implying he was a madman, but the parallels of contributions to such Herculean efforts of compilation are striking.

Early in this cycle we had a number of discussions within the board about the perceived relevance...or perceived lack of relevance...of USP to today's practicing physicians and pharmacists.

As we close this cycle the relevance to pharmacy, and the patients served by pharmacists, has risen somewhat like the Phoenix, from the ashes of the past, casting its shadow broadly across the profession.

The efforts of the Council of Experts in publishing the new sections on standards for sterility and the physical facilities for extemporaneous sterile preparations; the decision to proceed with the creation and publication of "The Pharmacists' Pharmacopeia;" the designation by Congress of USP to play a central role in the implementation of the Medicare Part D program; USP's role in the creation of the profession-wide Pharmacy Compounding Accreditation Board, all are tangible and relevant to today's practicing pharmacists.

A pharmacopeia directly relates to these arts and sciences, the practices of medicine and pharmacy. The term pharmacopeia means to make a drug. This work speaks to the first *Pharmacopeia of the United States of America* which provided recipes for early practitioners. And while most drugs are now made by talented pharmaceutical manufacturers, dependent themselves upon a wide range of USP standards, the practice of making drugs by recipe lives on in the dedicated work of physicians seeking solutions for their patients' unique needs, and compounding pharmacists meeting those needs.

At all times, USP wishes to work in a positive, supportive way with all components of pharmacy - as it does with all health care professions.

We work in service of you as you care for patients, and you are our primary constituents. I'm pleased to note that we have a special resolution that comes to this convention from the Joint Commission of Pharmacy Practitioners

The resolution requests that USP work more closely and effectively with the pharmacy profession in the years ahead. Dr. Williams tells me he is delighted by this resolution having been submitted, and will work at the direction of the Board to honor its intent.

We acknowledge many leaders of our time who continue to help USP, just as Charles Rice did so nobly more than 100 years ago.

While it's not possible to name them all, I would be remiss if I did not acknowledge the special efforts of Dr. John Gans of the American Pharmacists Association, Bruce Roberts of the National

Community Pharmacists Association, Dr. Henri Manasse of the American Society of Health-System Pharmacists, Dr. Lucinda Maine of the American Association of Colleges of Pharmacy, Carmen Catizone of the National Association of Boards of Pharmacy, and many others. Each in their way was a hero or heroine for USP in this cycle, and I thank them and their colleagues for this special support.

As specific evidence of our commitment to the pharmacy profession, we are working to launch a new publication termed the *USP Pharmacists' Pharmacopeia*

To help us in this work we will form an Advisory Panel of representatives from our member pharmacy organizations.

We also are working to support the fine efforts of the Pharmacy Compounding Accreditation Board, headed by Dr. Gans.

And I hope you notice that the slate of candidates for the Board of Trustees includes many distinguished pharmacists and pharmaceutical scientists, including my life-long colleague and recent Remington Medal Honoree, Lowell Anderson.

In closing . . . the two best words of anyone's speech. . . I would like to share a personal reflection.

We are called in life few times, or offered few opportunities, to exert a force for good, without thought of personal gain or recompense. USP provides one of those few times and opportunities. It does so for you, the members of this august Convention; it does so for the distinguished scientists of the Council of Experts; it does so for the many dedicated representatives from the world of pharmaceutical manufacturing and compounding professionals who are with us today; and it has done so for us, the USP Board of Trustees in this cycle.

We were privileged and honored to serve you, and I was privileged and honored to serve my colleagues as Chairman.

We thank you for your confidence.

In our way-perhaps not so small-we speak to this final slide from Urdang and to an impossible dream-good pharmaceutical care for all. Together we will continue to strive to make that dream, and those challenges presented to us by Dr. Brater, become reality.

Thank you.