



CEO's Report
Roger L. Williams, M.D.

I'm honored to speak to you today, following our distinguished speakers this morning and as the third and final speaker this afternoon. It is impossible to summarize adequately the work of many hundreds of people over five years in a few minutes. For greater detail, I refer you to the written CEO report, which you received in your registration packet. I also draw your attention to some of the posters on display at the Convention and the written material that is distributed with them.

The events of the 1995-2000 cycle had a profound impact on USP. That impact led, in Mr. Braden's words, to a perfect storm. These events led to an in depth rethinking of the way this organization works, continuing the McKinsey work of the prior cycle.

As a consequence of this storm, USP is now in the midst of a vigorous renewal process, and my talk today will focus on the primary themes of that renewal. These themes number two: first, where we are; and second, where we need to go. Speaking as CEO of USP and on behalf of both the staff and the Council of Experts, we know where we need to go. Using words from management texts, we will move from good to great.

In our assessment, we speak of where we are by using the customer as the reference point. USP has many customers. Our primary customers are practitioners and patients. Our direct customers are manufacturers, compounding professionals, regulatory agencies, policy-makers, and others.

I'd like to use a metaphor to describe the journey we must take, again drawing from management texts. The metaphor is a vehicle - A BUS - which will move us through change. We use the BUS to understand where we are going. The bus takes us to objectives defined by USP's Board of Trustees.

Who is on the bus?

First, as Convention Members, you are on the bus. Your organizations appointed you to represent a particular constituency, but as a Convention Member you must also consider what is in the best interest of the USP. You come through the doors of this room with that responsibility.

Please take this seriously—we do. You are our shareholders, and we are accountable to you. If you don't care enough to make us accountable, we are in trouble! Your leader is Dr. Brater, who spoke to you earlier. He spoke to a transformative dream of good pharmaceutical care for all, focusing on the international arena.

Second, the Board of the Trustees is on the bus. You or your predecessors elected this remarkable group of men and women five years ago and on Saturday you will do it again. Dr. Braden spoke to you about the challenges this Board faced, engaged, and overcame.

Third, the Council of Experts is on the bus. It is the core standards setting body of the organization. You will hear a report Saturday about the work of this outstanding group of men and women, when I speak as the Chair with Dr. Sheinin, Mr. Zeruld, and Ms. Cousins.

We have added new volunteers in this cycle—representatives of stakeholder forums and project teams who serve in an advisory capacity to the Council of Experts. They too are on the bus in this new role.

Together, you, the Board, the Council of Experts, and the stakeholder forums and project teams fill the volunteer seats on the bus. After each Convention, the members of the Council of Experts elect members of Expert Committees. In this cycle, we have a total of 62 Expert Committees with about 650 members. This brings the number of volunteers on the bus to around 1000, counting those working in the stakeholder forums and project teams.

I thank and honor each and every one of these volunteer groups who have given so freely of your time. Your work helps USP bring world class standards and programs to people everywhere. Please take a moment in this busy week to think about the thousands of hours given so generously by passionate, skilled, wise people—including you—who come to USP and make this organization happen.

I also thank their organizations, their colleagues, their friends, and most of all their families. When you are here helping us, you aren't with them. In a sense, they are volunteers, too, and I thank them for allowing you to be here with us.

We have others on the bus. Here is an organization chart that speaks to USP staff. I am responsible for this staff and collectively we are responsible to the Board and to you.

Let me tell you a little bit about USP staff.

In this cycle, staff grew from 286 to 390. We have many experts at USP to help volunteers and to advance the products and services to serve USP's customers. More than 130 are scientists, and we also have many others—financial, marketing and sales, legal, information technology, and other types of experts. There are five key leaders in this chart—Dr. Sheinin, Mr. Fowler, Ms. De Mars, Mr. Hendrix, and Mr. Zeruld. These five senior managers will join us on the stage after my presentation. With Dr. Paul Schyve moderating, we hope to answer the questions you might have about USP. We'd like to hear your voice—please think now about your questions and challenge us. Think of this as a shareholders meeting, and we are pleased to answer your questions.

Now that I have talked about the volunteer and staff seats on the bus, the key becomes: where is the bus going? The answer to this question is found in our mission and vision statements that are in your notebooks. And it is reflected in the Board of Trustees 2003-2005 Strategic Plan, a remarkably concise document! Please review this document over the next several days and ask us questions about it.

The USP bus has to travel along a certain path. This path is set before us by our activities as a standards setting organization. That is what USP does—we are not a regulatory body nor are we an enforcing body. Those are the responsibilities of regulatory agencies such as the FDA. But we do help regulatory market access and enforcing activities through the excellence of our standards and information. In this sense, we work collaboratively with all of our customers, including especially manufacturers and compounding professionals, to get the right information to the right place at the right time.

Please note that our scope is limited—we cover drugs and biologics, some devices and dietary supplements. We do not create standards for food additives—that is done by Food Chemicals Codex, which is published by the National Academy of Sciences. And we do not create standards for foods—that is done by *Codex Alimentarius*, which is a joint publication by the World Health Organization in Geneva and the Food and Agriculture Organization in Rome.

USP executes the strategic plan of your Board of Trustees through tactical programs. Let me review them for you briefly. As I do so, consider how you will help us take them from good to great.

First: The United States Pharmacopeia and the National Formulary

First, significant changes have occurred in the two compendia over the last five years. They are now published annually with two Supplements rather than every five years with ten Supplements. They are available in all possible electronic media. We are developing publications in other languages in addition to English. The first will be Spanish. We have a very talented advisory body overseeing this work led by Dr. Enrique Fefer. Many of the members of the translation team are in this room. Subsequent languages might be Russian, Chinese, and Arabic. These are major world languages, as defined by the United Nations.

Your two compendia undergo continuous revision. The *USP* is still in its first edition of 1820—we call this *USP 0*. It is now in its 28th revision. *National Formulary* joined USP in 1975. It is now in its 23rd edition. Both are good now—but it will take a great deal of work to make them great. They are missing about 2000 monographs and an additional 1,000 or so need updating. We need many more compounding monographs, and the General Chapters continuously need updating to stay abreast of the rapid and accelerating pace of scientific change—profound change based on analytical capability and a modern understanding of the science of metrology, and of course, the cornucopia of sophisticated ingredient and products from talented innovators.

In this cycle, we created 95 dietary supplement monographs, both botanical and non-botanical, three new dietary supplement General Chapters and made major revisions to three others. We separated these dietary supplement documents into a distinct section of *USP*. And we moved dietary supplements out of the *National Formulary*, which now contains only excipient monographs.

These changes—and more to come—will move the two compendia from good to great.

Second: The Pharmacists' Pharmacopeia

Based on a Board of Trustees directive, USP will create another publication called the USP *Pharmacists' Pharmacopeia*. It is now in development with the expectation that it will be offered sometime over the summer.

The text of the *Pharmacists' Pharmacopeia* will contain two parts. The first part will contain excerpts from official *USP-NF* text. The second part will be authorized text. We hope to actively involve the pharmacy associations in this publication, working with the Joint Commission of Pharmacy Practitioners and other stakeholders. Please note Resolution 13 in your Convention Member notebooks. This resolution calls for USP to work more closely with the pharmacy profession to advance our mutual interests. I am delighted with this Resolution and—at your direction—will be pleased to honor it. With your support and encouragement, USP will continue to move from good to great with this publication in the service of the pharmacy professional.

Third: USP–International

With your support and encouragement, USP also is considering an international compendium that would contain monographs for articles legally marketed in countries outside the United States. In some ways, this compendium would support the excellent work of the World Health Organization in treating dread diseases that Dr. Jack Chow spoke about this morning. This is a challenging opportunity that can move USP from good to great. It is further discussed in material provided in the Background section of your Convention Member notebook. Please read this material and give us your opinion.

Fourth: Official USP Reference Standards

USP maintains an extensive and growing collection of official USP Reference Standards. The primary reason for these standards has been the growth of instrumental techniques—gas- and liquid chromatography—that rely on ratio comparisons in compendial procedures.

USP has done a tremendous amount of work in this cycle to improve this collection and the way it is generated. We have increased the number of official USP Reference Standards by about 500 and are adding many impurity standards. We have developed new ways to get these standards to the customer, and have worked on ways to assure the integrity of the collection. We are working on new ways to bring biologic standards to the biologics and biotechnology industry, which increasingly is turning out major therapeutic advances based on the molecular biology revolution.

USP business operations are now ISO 9001 certified. USP's laboratories are ISO 17025 certified. We are clearly moving from good to great in our laboratory activities and will continue to do so.

Fifth. Dietary Supplement Verification Program and Pharmacopeial Education

USP has two more core pharmacopeial programs. One is USP's Dietary Supplement Ingredient and Product Verification Program. The other is USP's Pharmacopeial Education Program.

The former program represents a new focus for USP. In standards-setting language, USP's Dietary Supplement Verification Program assesses conformity to product and process standards. Dietary supplement product standards are created by the standards setting work of the Council of Experts. Process standards for dietary supplements are exemplified by USP's General Chapter *Manufacturing Practices for Dietary Supplements* <2730>.

USP's Board of Trustees discussed verification programs in a highly positive way at its last meeting in January 2005. Verification programs offer a way to partner with manufacturers throughout the world who wish to provide the best quality drug substances, excipients and dosage forms as a means of assuring good pharmaceutical care. Working with them, USP and they advance the Dietary Supplement verification program from good to great.

Our Pharmacopeial Education Program is also a new program this cycle based on a resolution adopted by your predecessors at the 2000 Convention. It has become a robust activity that is being offered throughout North America and the world. In some ways now it could be seen as a pilot effort, based on your directives from the 2000 Convention and can grow substantially in the coming years.

The previous programs are summarized in a poster in the Convention meeting area. Please look at this poster and consider 1) the enormous amount of work that has gone into these efforts, both from volunteers and staff; and 2) how we can do even better in the next cycle. Your input, your voice, will help us go from good to great for all these programs.

I would like to summarize briefly the status of our information and patient safety programs. In this cycle, USP terminated many programs, including our Veterinary Reporting Program, our Drug Product Problem Reporting Program and, most importantly, our contribution of value added information to *USP-Drug Information Volumes I and II*.

For all three programs, the value, as evidenced by practitioner, patient, and other stakeholder interest, had declined. This does not mean they were unsuccessful or bad ideas. USP often serves as an incubator for ideas that are later taken on by others. Probably the most momentous of the three terminations was the decision to stop contributing content to *USP-DI Volumes I and II*. This decision was very carefully considered by staff with oversight both from a Board of Trustees Committee chaired by Dr. Marvin Lipman and by the Board itself. It was done with the full recognition of the extraordinary contributions of the Information Expert Committee volunteers and staff in this and previous cycles. But *USP-DI* was not competitive in the marketplace—and at the end of the day we could not guarantee to the Board, given the resources needed from USP staff, that it could be adequately maintained—much less advance to great. In this context, the Board wisely concluded the best course was to exit from the agreement.

And I would like to thank our partners at Thomson Healthcare for a fine working relationship over a six year period. We wish them every success as they advance their information programs for the benefit of the healthcare community. And I especially thank the remarkable work of the *USP-DI* staff and the Information Expert Committees that made *USP-DI* the excellent publication that it still is.

Despite the conclusion of *USP-DI*, USP remains highly engaged in the general area of drug information, subject to an exit agreement with Thomson. We are working diligently to fulfill requirements under the Medical Modernization Act to create and maintain the Model Guidelines and associated databases and documents. The Model Guidelines are an excellent opportunity for USP to advance healthcare information to the community—as we have done since 1820. We thank Congress, the Administration, and the Centers for Medicare and Medicaid Services for allowing USP to help in making this tremendous work benefit society.

USP's exit agreement with Thomson, in which we agree not to develop competing products, ends in January 2007, just short of two years from now. My hope is that thereafter USP—working with you—can provide a strong drug information service to all stakeholders and especially CMS in assuring that the Part D benefits works for the elderly and the needy in this country in the years to come.

Before I leave this topic, I must acknowledge and honor the extraordinary work of the Model Guidelines Expert Committee. This ad hoc committee met on 14 occasions over a brief period of about seven months—all are busy professional people like you, who were already members and chairs of other USP committees. Working with a very dedicated staff, they provided the deliverables requested by CMS under the law. You will hear more about this work on Saturday when Mr. Zeruld speaks.

I will close this brief overview of USP's tactical programs with a brief look at USP's patient safety activities. We have two reporting programs—one MEDMARX and one the USP Medication Error Reporting Program. While numbers don't always tell the story, sometimes they tell a large part of it. MEDMARX has been taken up in about 10 percent of the nation's hospitals. The cumulative number of spontaneous reports given anonymously via the web to the database is now about 900,000. Each year USP has produced a report drawing on the experience of the database. The latest summarizes the experience of five years of hard work.

And the third slide in this series shows that while the number of reports is increasing, the fraction of errors associated with harm is falling. This is surely a good sign and a cause for hope. This work isn't just good—it is great—and you heard from Dr. Leape this morning about the challenges and opportunities for patient safety in this new century. You will hear from Dr. Cousins on this topic on Saturday.

In speaking about this program, I not only acknowledge the remarkable work of USP staff and the Safe Medication Use Expert Committee, but also those hospital staff who were brave enough to report errors into the MEDMARX system. They offered their experience, always painful and sometimes devastating, in the hope of making things better for their patients. Do I have to tell you that they were great?

In closing, I would like to touch on three topics. The first is the private character of USP, the second is our new site in India, and the third is USP's new building. They are closely related.

USP is a very special organization that arose as part of the American experiment in democracy. If you look at the front material from an early *European Pharmacopeia*, you will see that they extol their patrons—in this case the Regno d'Italia—the king of Italy or Dukes and Princes. If you look at the front material for the first *British Pharmacopoeia*—an excellent pharmacopeia of today—you will see that it is published by the government—in cooperation with representatives from the healthcare profession.

Look at the front material of the first *Pharmacopeia of the United States of America*. USP is entirely independent of government. It was initially published by the medical colleges of the United States. USP is non-governmental—and perhaps the only fully non-governmental pharmacopeia in the world. As taxpayers, you will be glad to know that we do not depend on taxes from anyone. We derive our income through the excellence of our products and services that we make available to our customers. These are your products.

Through authorizing statements from your Board of Trustees, you publish the *United States Pharmacopeia* and *National Formulary*. These are documents from practitioners such as yourselves—physicians, pharmacists, and nurses, who come together to create the standards in the *USP* and *NF*. And it is the primary reason that so many Convention members are practitioners—you are with us today as pharmacists, physicians, nurses, emulating the spirit of the founders of USP 185 years ago.

Despite its name—that of the United States—the United States Pharmacopoeial Convention, Incorporated knows no boundaries. As you look about you, you will see Convention members from all over the world. They work in the interest of the practitioner and patient—our primary customers. It is in this spirit that the USP Board of Trustees concluded at its January 2005 meeting to establish a site in India

By itself, this site is small—and it will create no new tactical programs. It will bring USP's products and services closer to Indian manufacturers who want to meet the high standards of USP. USP looks forward to working with these manufacturers—many of whom already are bringing a substantial number of ingredients and dosage forms to the U.S. market. While small in initial staff, the India site is large in spirit. It speaks to a world community where manufacturers and compounding professionals work to provide the best drugs and the best quality drugs to patients and practitioners. Subject to Board approval, other sites will follow.

These sites reflect a USP commitment to work with all its international stakeholders—the World Medication Association, the Federation of International Pharmacy, the International Council of Nurses, the World Health Organization, and its regional offices such as the Pan American Health Organization.

Together with these and others, USP wishes to serve the 'invisible people' that Dr. Brater talked about—those patients throughout the world with few healthcare resources who dream of the kind of good health and hope that many in this country consider routine. For now, good pharmaceutical care for the peoples of the world is an impossible dream—but if we don't collectively dream these dreams, can they ever happen?

Let me close with a look at our new building. This is your building—collectively you are its owners and its heirs. It can be a clearing in the forest where we can dream the kind of dreams that now seem impossible. Let me focus on the most important part of the building. It is the conference center and associated meeting rooms. These rooms are yours, and I look forward to welcoming you, with great joy and purpose, to them in the early fall of 2007.

As we spoke to our talented architects, HOK, I reminded them of the Greek temples and amphitheatres where Athenian democracy flourished two thousand years ago. And I spoke of the medical and pharmacy circular lecture halls of 100 year ago that are embedded in the collective memory of nurses, pharmacists, and doctors.

Please think of your new building with these memories from ancient times. They speak to learned, committed free women and men coming together to dream impossible dreams—to move from good to great and to bring good pharmaceutical care to all.

Thank you.