



**Remarks from USP Board Chair
Duane M. Kirking, Pharm.D., Ph.D.
(as prepared for delivery)**

**2010 Convention
Washington, D.C.
Friday, April 23, 2010**

Good afternoon. My name is Duane Kirking and I am honored to speak to you today as Chair of the Board. I'd like to start by emphasizing the three important responsibilities the Board has to the Convention Membership.

First, it is charged with setting the strategic direction for the organization in a way which enables and encourages USP to work towards fulfilling its important public health mission. In doing so, the Board must take into account the resolutions that you, the membership, adopt at this meeting.

Second, the Board has to make critical policy, financial and other decisions that will allow USP to further its mission and vision. That is an assignment that certainly is easier said than done. And it has taken our careful attention and concerted energies over the entire five-year cycle.

And third, while making these decisions Board members always must be mindful that we are fiduciaries responsible for protecting and preserving the assets of the organization. By assets I don't just mean financial assets – although certainly those are significant since they allow USP to continue its important work. USP's assets also include its staff, its volunteers, its reputation and its credibility as an impartial scientific standard-setting organization that is now nearly 200 years old.

Before I discuss these responsibilities, I want to acknowledge the current Board of Trustees, into whose hands you entrusted the organization back in 2005. These are some of the most talented, responsible, and committed volunteers that USP has ever seen.

SLIDE: USP BOARD

First, let me introduce the three members serving a second term, finishing a 10-year commitment on the Board: Drs Craig Brater Larry Braden, and Mary Anne Koda-Kimble. Their contributions have been remarkable with Craig serving as President and Past President and Larry as the current Treasurer. Larry and Mary Anne both served as Chairs of the Board during the last cycle and among Mary Anne's current responsibilities is chair of the very important International Activities Committee. Their institutional knowledge provided continuity that is critically important in an organization like USP where the entire Board is elected at five year intervals.

SLIDE: USP-NF REISSUE

In 2005 USP began discussions on a process to transform the *USP/NF* through a redesign of all of its monographs. The monographs had become text-laden and burdensome to use. The redesign would eliminate cross-references, simplify language, standardize the format, and generally create compendia that were streamlined and easier to use.

This initiative was supported by the Board as well as the Council of Experts. At the end of 2009, we learned that this initiative failed! The post-publication discovery of numerous errors prompted Dr. Williams to determine that *USP 33 – NF 28* had to be recalled from the market, a move the Board also supported. Since that decision, USP has worked diligently to obtain the return of as many copies of the recalled publication as possible, and to quickly reissue *USP 33 – NF 28* in a form that will allow it to continue to provide accurate information while efforts are underway to proceed with its redesign. The support USP received from customers during this difficult process was gratifying.

SLIDE: TASK FORCE

And now the Board has engaged in a vigorous set of activities to explore the causes of this major setback. We have formed a Task Force that is working with USP's senior management to look at the Monograph Redesign Project to determine how it can better advance in the future. And we have also sponsored an independent inquiry that is currently underway to review the root causes of the error in more depth. As you can see from this slide of the Task Force membership, we have turned again to our volunteer communities—the Convention, the Board itself, and the Council of Experts. Thank you Task Force members for agreeing to assist in this most important task. All of you can be assured that the Board views this matter very seriously and will persist in its evaluations to advance from failure to success.

SLIDE: USP LOCATIONS

Let me turn now to the second responsibility of the Board -- to advance the organization through decisions that will allow it to grow and evolve. This responsibility has been manifested during this cycle by Board decisions that allowed USP to establish four international sites in a five-year period – a remarkable accomplishment. We believe that when future Conventions look back on this Board's tenure, they will find that our most critical action has been to facilitate expansion of USP's physical infrastructure to other countries, -- and beyond infrastructure -- to endorse a larger globalization strategy of which the sites are one element, albeit an important one. This expansion was not a decision taken lightly by this Board, but was supported by the entire body. It also aligns with 2005 Convention Resolution 6, which urged USP to pursue globalization in pursuit of its public health mission.

Let me note that international activities are not a new venture for USP. In reading the history of the USP Board of Trustees prepared for the 2000 Convention, I learned that USP's international public health activities started as early as 1902, included publication of the first Spanish translation of the USP in 1908, and have continued in various forms through the years.

Given its singular importance I want to talk for a few moments about the rationale behind the current global expansion. Certainly one important factor is the globalization of the pharmaceutical, food and other industries. Manufacturing has continued to shift to countries like India, China, Brazil and others, creating a complex global supply chain that often lacks important "safety nets". Manufacturers in India and China alone are estimated to account for over 80% of the world's production of small molecule active



pharmaceutical ingredients (API). And the United States imports more pharmaceuticals than any other country – nearly \$60 billion worth a year.

Many manufacturers in these countries rely on USP standards, particularly when they are importing into the US. Indeed, today more than half of USP reference standards are sold to organizations outside of the U.S.

USP's international sites have given us a platform for partnering with pharmacopeias, regulators, and industry in other countries to help them develop and implement standards that will raise the quality not only of drugs and foods shipped to the U.S., -- but also those consumed locally and exported to other parts of the world. There is also an important potential synergy between these sites and USP's other international programs such as those operated through USPs grant from USAID that are intended to improve regulatory and testing capabilities in developing countries. Today, all four non-U.S. sites may be viewed as "hubs" that support outreach to key constituencies in critical countries and regions. They all help to better position USP to engage in crucial public health programs in areas most in need of the support and resources USP can provide.

Certainly, there also have been economic benefits to this organization. By establishing additional state-of-the-art laboratories in places like India and China, USP has been able to increase its reference standards testing capabilities and to reduce its reliance on contract labs. As USP's relationships in these countries have grown, their government laboratories have also shown increased interest in participating in reference standards testing. This further strengthens USP's partnerships with regulators around the globe and allows them to benefit from USP's experience and expertise. It also contributes to USP's ability to develop new standards.

SLIDE: NEW INDIA BUILDING

In January, the USP Board endorsed the opportunity to build a new, state-of-the-art building in Hyderabad, which will increase USP's capabilities in India about seven fold. The building is necessary because we have already outgrown the facility opened just four short years ago, a mark of the success of USPs international efforts. It will allow many activities that support USP's work throughout the globe, working particularly with India and its talented groups of regulatory, compendia and manufacturing scientists.

SLIDE: USP HEADQUARTERS – PAST AND PRESENT

Imagine for a minute that you were on USP's Board. In the midst of the recent worldwide financial crisis, the Chief Financial Officer comes to the Board and says "we think you should spend a few million dollars and buy some more land." Furthermore, this idea comes about one year after the dedication of our beautiful new headquarters with its state-of-the-art laboratories, excellent meeting and office spaces -- and substantial mortgage. Perhaps you would think like us: "Which of our drug reference materials has he been into?!"

We learned that the land he was talking about was the only undeveloped land in Rockville within close proximity of our headquarters. And it happened to be immediately adjacent to our current buildings. Furthermore, given the recession we were told that we think we can get it for a reasonable price. Now, as a farm boy from Wisconsin, any land price which includes six zeros in it just doesn't equate to "reasonable" to me. But it was clearly a unique opportunity. Through the impressive and substantial efforts of USP financial staff along with the diligence of Treasurer Braden and other Board members, we now own two acres of land adjacent to our headquarters to allow future expansion into a new building



SLIDE: FUTURE HEADQUARTERS EXPANSION

While the land is a reality, with a loan to remind us of the reality, a new building is now only a dream. But I can assure the incoming Board that there is no doubt we will need it someday. Information and materials needed to support our standards are burgeoning as the cornucopia of available food and drugs expands, and I can easily imagine that a new building linked to our current structures will become an imperative for subsequent trustees to take up and resolve.

To provide just one quick example of a not-too-distant future facilities need, I read last month that by the year 2014, fully half of the top 100 best-selling drugs will be biologicals. These complex molecules require an entire new set of technical capabilities to develop standards, for example aseptic packaging or the handling of materials that are considered biohazards, because they are derived from living organisms. Part of the new building could be designed to meet these needs.

Without a doubt, this Board has had an optimistic view of USP's growth potential – a potential that has borne much fruit and which we see as continuing into the next cycle.

I've talked about expansion in USP's facilities, and now I want to turn briefly to expansions in USP's programs, products and services.

SLIDE: FCC, DSC, P2

Certainly one of the most significant of these was USP's decision to acquire the *Food Chemicals Codex* from the Institute of Medicine in 2006, so that this compendium could be continued and supported. USP saw its expansion into food ingredients as a logical extension of its standards-setting activities in the areas of dietary supplements and excipients. Under USP's stewardship, the *FCC* has been reestablished as a primary source not just in the U.S. but internationally for quality public standards for food ingredients.

Following up on a 1995 Convention Resolution, USP created the 2009 *USP Dietary Supplements Compendium (DSC)*. This addition to the array of USP compendia is intended to become a resource focused exclusively on dietary supplements and their ingredients. The *DSC* contains relevant monographs and other materials from *USP-NF* and *FCC*. It also contains other information useful to regulatory officials, dietary supplement manufacturers, and to stakeholders at large, including reference tables, charts, and regulatory and guidance documents, as well as full-color photographs, chemical structures, and chromatographs.

At the prior Board's urging, USP introduced the *Pharmacists' Pharmacopeia* in 2005 as a resource for the pharmacy community. The publication contains official text from *USP-NF*—compounding preparation monographs and general chapters—as well as abridged material (e.g., drug substance monographs) and additional authorized information. Online supplements are produced to reflect revisions to *USP-NF*. The second edition of the *Pharmacists' Pharmacopeia* was released in 2008, and included a new section on veterinary compounding as well as more than 500 monographs for preservatives, flavorings, and colorings abridged from *FCC*.

Now that the publication has been available for several years, the Board, especially with Dr. Braden's urging, has asked USP to evaluate the *Pharmacists' Pharmacopeia* to determine how it can be redesigned to provide an optimal resource to compounding pharmacists—and perhaps to the larger practitioner community as well. That evaluation is now underway.



USP has also invested in expanding its allied compendial activities, which also are prominently featured in the Strategic Plan. These are programs that support and promote the adoption and use of USP standards throughout the world, and thus are directly aligned with USP's core compendial activities. While still relatively small, the Board is proud of these activities and their progress during this cycle. .

SLIDE: PHARMACOPEIAL EDUCATION

USP has strengthened its pharmacopeial education programs, which arose from a 2000 Convention resolution. And these programs have shown solid advances, put somewhat in abeyance in the last year from the financial and economic crisis. Here, too, USP's international sites have proven to be synergistic, providing a launching pad for conducting pharmacopeial education programs in regions and countries that are eager to learn about the role of public standards in ensuring drug and food quality. I took the opportunity to talk informally with some participants at one of these educational programs held in Toronto last fall concurrent with USP's annual science meeting. I can attest personally to the how valuable this program was to those with whom I talked.

SLIDE: VERIFICATION PROGRAM

USP's third party certification programs for dietary supplements have stood the test of time, with more than 300 million labels displaying our certification mark to guide consumers toward products of verified quality. In this cycle, USP extended these programs to dietary supplement ingredients and drug ingredients -- both drug substances as well as excipients. The uptake for the drug ingredient programs has been slow in the absence of regulatory recognition or other drivers. We continue to believe these programs can play an important role in filling regulatory gaps and helping to assure manufacturers and consumers that the products and ingredients they purchase meet high quality standards. And we could do more. For example, FDA has encouraged third party certification for foods, and USP's certification activities could be advanced to food ingredient articles that would rely in part on the standards of *Food Chemicals Codex*. The new Board will need to monitor closely the environment for both USP's existing programs and new, potential opportunities in this area

SLIDE: FINANCES

Let me turn finally -- and very briefly - to the third area of Board responsibility: serving as stewards and fiduciaries for the organization. This aspect of our job was not easy in the 2005-2010 cycle. There were many challenges. One of these was the financial meltdown that began in the fall of 2007 and occupied the Board's attention during much of the following year. It is no understatement to say that the roiling of national and international financial waters caused ripples--no really waves--ok, really, tsunamis--in the previously placid waters of USP's financial pond. As you will hear from Treasurer Braden, these events required us to make difficult decisions regarding USP's bond financing, its investment portfolio -- and most painfully, about USP's staff and programs. But as you will also hear, we have been fortunate to have quickly recovered from much of the damage caused by the financial downturn -- a testament to the fortitude of the organization and the strength of its basic financial model, which allows USP to fund its standards-setting activities entirely through the sale of its products and services.

We have had our challenges during the cycle -- both financial and technical. I can say with great confidence that despite these challenges -- and in some respects because of the way in which USP is responding to these challenges --, there is great reason for optimism as we look toward the future. The successors to this Board will lead a vibrant, thriving organization -- one that is emerging from the problems of this cycle stronger and more resilient than ever and ready to face the opportunities and challenges that the next cycle will bring.



In closing, I want to return to that prepared history of the USP Board of Trustees I referred to earlier where I found these remarks from USP President Horatio Wood's address delivered just shy of 110 years ago.

SLIDE: QUOTE

"We live but for the moment; one hundred years from now the greatest of us will remain only as fading memories. Let us see to it that preserving...that which has come to us, and adding to it in our day and generation as strength is given us, we may leave for the coming century good work and true, which shall remain as the abiding though unrecognized witness of our earnest living." (Horatio C. Wood, USP Presidential Address, May 2, 1900)

Let me tell you on behalf of the entire Board what an honor and privilege it has been to serve you, the Convention membership, over the past five years. Please accept our sincere thanks and appreciation for entrusting us with this important responsibility. We are confident we have "preserved that which has come to us" and we hope we have "added to it in our day" with the result being "good work and true." We join you in looking forward to the next cycle and to a bright and promising future for USP.





Report of the Chair Board of Trustees

Duane M. Kirking, Pharm.D., Ph.D.

ADVANCING HEALTH THROUGH PUBLIC STANDARDS



USP Board



Back row: Rene Bravo,
John Mauger, Duane Kirking,
Larry Braden, Craig Brater,
Roger Williams

Front row: Ellen Cosgrove,
Judith Outlon, Carolyn Asbury,
Mary Anne Koda-Kimble,
June Osborn



Above: Rita Colwell

USP CONVENTION 2010 2005–2010 Strategic Plan

**Enhance & Expand
Core Compendial Activities**

**Build & Strengthen
Allied Compendial Activities**


**Engage
in Other Health Programs**

**Operate
Nationally & Internationally**

USP CONVENTION 2010 USP–NF Reissue

The image displays a stack of three red books titled "2010 USP 33 NF 28 REISSUE" and "U.S. Pharmacopoeia National Formulary". In the background, several pages of official monographs are visible, including the title page for "Paroxetine Hydrochloride" (USP 33) and a detailed monograph page for "2. Paroxetine / Official Monograph" (USP 33). The monograph page includes a chemical structure, a table with columns for "Time", "Injection A", and "Injection B", and various test parameters like "Medium", "Solvent", "Column temperature", "Flow rate", and "Injection date".

Time	Injection A	Injection B
0	0.0	0.0
5	0.0	0.0
10	0.0	0.0
15	0.0	0.0
20	0.0	0.0
25	0.0	0.0
30	0.0	0.0
35	0.0	0.0
40	0.0	0.0
45	0.0	0.0

 **Task Force**

- ▶ **Convention Members**
 - ▶ Enrique Fefer, Ph.D., Honorary Delegate
 - ▶ Yana R. Mille, R.Ph., FDA Center for Drug Evaluation and Research
- ▶ **Board Members**
 - ▶ Carolyn H. Asbury, Sc.M.P.H., Ph.D., Public Trustee
 - ▶ John W. Mauger, Ph.D., Pharmaceutical Sciences Trustee
- ▶ **Council of Experts Members**
 - ▶ Andrew G. Ebert, Ph.D., Chair, Food Ingredients Expert Committee
 - ▶ Timothy J. Wozniak, Ph.D., Chair, Monograph Development- Cough, Cold and Analgesics

 **USP Locations**



The map displays five global locations with corresponding photographs of their facilities:

- USP Headquarters**: Located in North America, shown with a modern glass-fronted building.
- Europe/Middle East/Africa**: A regional office located in Europe, shown with a multi-story office building.
- USP-China**: Located in China, shown with a large industrial-style building.
- USP-Brazil**: Located in South America, shown with a white industrial building.
- USP-India**: Located in South Asia, shown with a large brick industrial building.



New India Building



USP Headquarters—Past and Present





USP
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2010

Pharmacopeial Education

- Classroom
- On-Demand Online
- Hot Topic Webinars
- Workshops

▶ Since 2006, slightly more than 50% of PE courses have been taught outside the U.S.



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2010

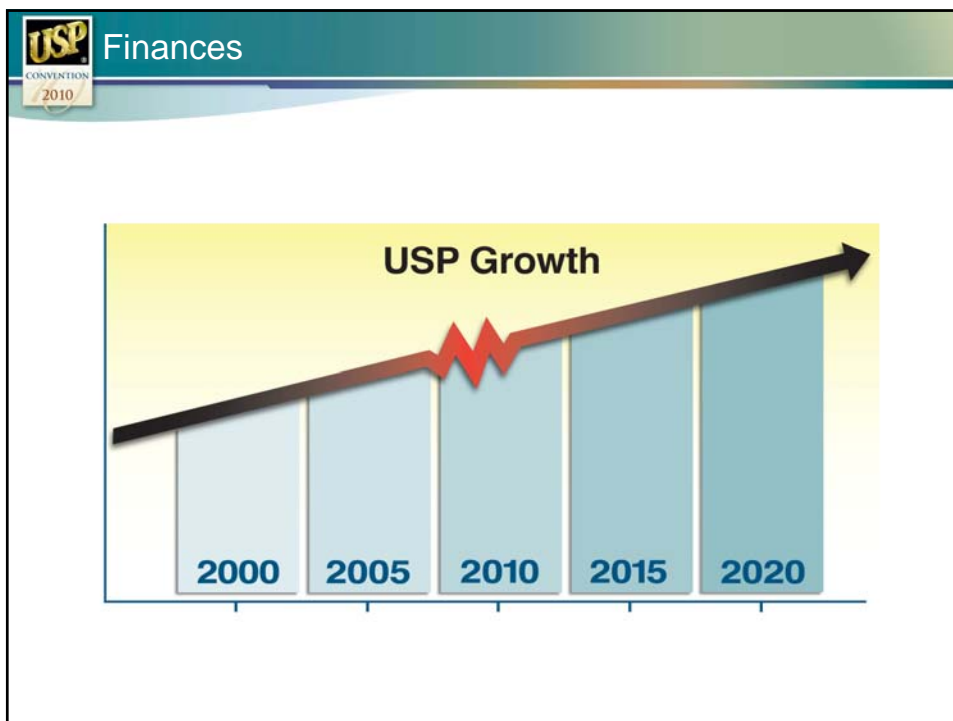
Verification Program

▶ In 2006, USP expanded its verification portfolio



- USP VERIFIED
- INGREDIENT USP VERIFIED
- PHARMACEUTICAL INGREDIENT USP VERIFIED





USP
CONVENTION
2010

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—Horatio C. Wood,
USP Presidential Address, May 2, 1900