



**Remarks from the Chair, Council of Experts
Roger L. Williams, M.D.
As Delivered to the USP Convention**

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

I speak to you now in my role as Chair of the United States Pharmacopoeial Convention's Council of Experts in the 2005-2010 revision cycle. And I'm honored to follow Dr. Rene Bravo, President of the United States Pharmacopoeial Convention 2010. Speaking on behalf of the Council of Experts, my topics will cover the WHO, WHAT, HOW, SCIENCE, and WAY FORWARD. These topics speak to the work of the Council of Experts in the 2005-2010 revision, closing with a glimpse of activities as we advance into the 2010-15 cycle.

Who We Were

When we speak to each other at USP, we are surrounded by history, going back now 190 years. In the beginning, USP's framework was based on the idea of a Convention that charges a committee, first the Committee of Revision and now the Council of Experts, with maintaining a continuously revised *Pharmacopoeia*.

USP CONVENTION 2010 Chairs of the Committee of Revision/Council of Experts	
1. Lyman Spalding (1818–1820)	7. Joseph Carson (1870–1876)
2. Jacob Bigelow (1820–1822)	8. Charles Rice (1880–1901)
3. Samuel L. Mitchill (1828–1831)	9. Joseph P. Remington (1901–1918)
4. Thomas T. Hewson (1831–1840)	10. Charles H. LaWall (1918–1920)
5. George B. Wood (1840–1860)	11. E. Fullerton Cook (1920–1950)
6. Franklin Bache (1860–1864)	
Also Chief Staff Officer After 1954	
12. Lloyd C. Miller (1950–1970)	
13. William M. Heller (1970–1990)	
14. Jerome A. Halperin (1990–2000)	
15. Roger L. Williams (2000–)	

The first Chair of this Committee was Dr. Lyman Spalding, a practicing physician from New Hampshire, and the first publication of the *United States Pharmacopoeia (USP)*, which we term *USP 0*, came about in 1820. *USP 0* is now in its 33rd revision. Since Dr. Lyman's time there have been 14 further Chairs, so I am fifteenth in his line.



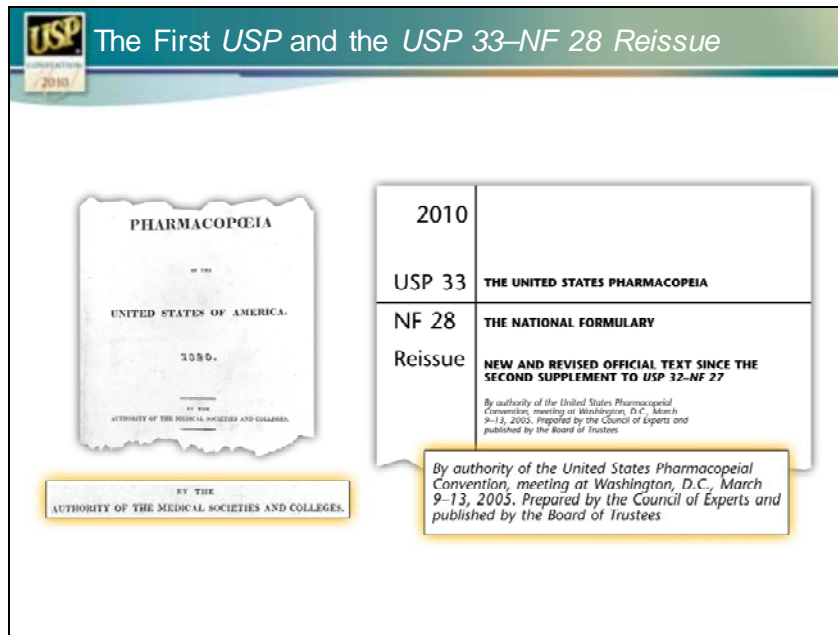
Who 'We' Were/Who We Are

- ▶ **The Convention and 'The Pharmacop(o)eia'**
- ▶ **10- to 5-year Cycles** (Transition in 1942 for *USP*; 1975 for Convention); *USP* to Annual Edition in 2001; Convention Remains at 5-year Cycle
- ▶ **Committee of Revision to Council of Experts** (2000—Bergen Report)
- ▶ **'The Pharmacop(o)eia'**
 - *United States Pharmacopeia* (1820)
 - *National Formulary* (1975)
 - Dietary Supplements (1990s NLEA/DSHEA)
 - *USP Pharmacists' Pharmacopeia* (2005)
 - *USP Dietary Supplements Compendium* (2009)
 - Pending Monographs (2007)
 - Non-U.S. Monographs (2007)
- ▶ **Board of Trustees (1900)**

USP is still in its first edition of 1820 with continuous revision occurring to keep up with new drugs, new tests, new procedures and new acceptance criteria. And the term *Pharmacopoeia*, which means *to make a drug*, has evolved in many ways. One key transition was occasioned by the 8th Chair in Dr. Spalding's line, Dr. Charles Rice, who transitioned *USP* from a book of recipes to a book of tests with procedures and acceptance criteria. This transition arose because of the rise in pharmaceutical manufacturing away from compounding in the late 19th century. Dr. Rice also created the *National Formulary* as a book of standards for articles sold and/or prepared by the pharmacist, and this compendium came to *USP* in 1975 where it evolved into a book of product standards for excipients, with tests, procedures and acceptance criteria. The cycle of Convention meetings and revisions to *USP* were initially aligned, occurring every 10 years. They became "non-aligned" first in 1942, where the Convention met at 10 year intervals but *USP* was published at five year intervals. This occurred again in 2002, when publications of *USP* occurred annually, with Convention delegates still meeting at five year intervals. The Convention's *pharmacopeia* is now more than the *USP* and the *NF*. The new publications—which may include print, CD and web-based publications—that have advanced in this cycle include:

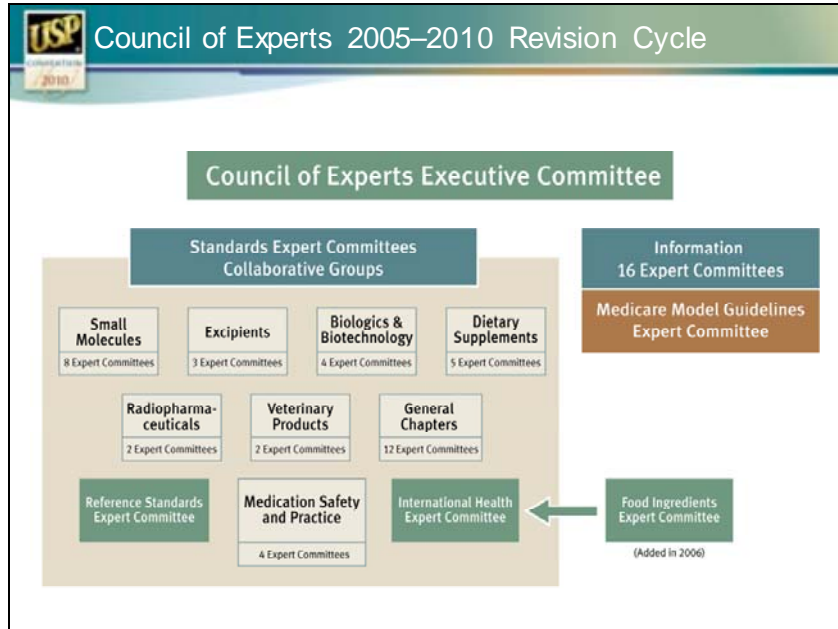
- *The USP Dietary Supplement Compendium (Foods)*
- *The Food Chemicals Codex (Food Ingredients)*
- *The USP Pharmacists' Pharmacopeia (Compounded Preparations)*
- *USP's Pending Standards* (web-based)
- *USP's Non-US Standards* (web-based)

You will hear more from Dr. Kirking, Chair of the USP Board of Trustees, about how our simple relationship—between the Convention—you—and the Council of Experts—which I chair—was made more interesting with the decision in 2010 for the USP Convention to incorporate and have a Board of Trustees.



The USP Convention plays an important role in USP’s standards. This has been a tradition since the beginning, when authority was drawn from medical societies and colleges—USP’s first Convention. As you can see in this slide, the Convention authorizes creation of a *pharmacopoeia*, which is prepared by the Council of Experts, and is published by the USP Board of Trustees.

Who We Are



The USP Council of Experts in the 2005–2010 revision cycle is comprised of the Chairs of 41 Standards Expert Committees and the Chairs of 16 Information Expert Committees. One additional Expert Committee, the Model Guidelines Expert Committee, is comprised of the 16 Information Expert Committee Chairs with either the Chair of the Council of Experts or the Chief Science Officer serving as chair.

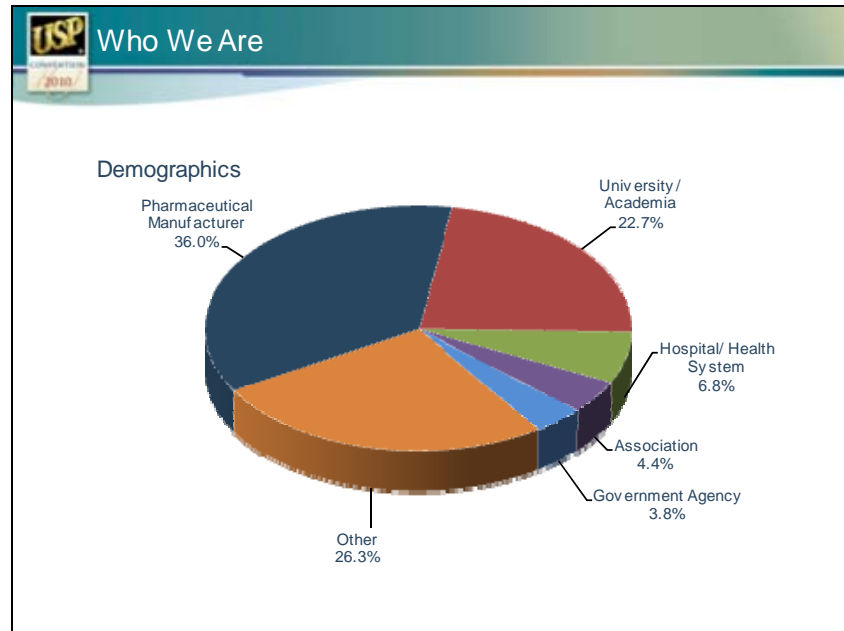
USP Who We Are
CONSTRUCTION
2010

- ▶ **58** Expert Committees
- ▶ **473** Expert Committee Members
 (includes 57 Expert Committee Chairs)

- ▶ **61** Advisory Panels
- ▶ **363** Advisory Panelists

- ▶ **57** FDA Liaisons

In addition, 61 Advisory Panels and one Advisory Group were formed during the 2005–2010 revision cycle to support the Council of Experts’ standards-setting initiatives. These Advisory Panels offer recommendations rather than decisions, each reporting to and receiving direction and oversight from a supervising Expert Committee.



The Council of Experts comprises a diverse group of individuals from the pharmaceutical industry, academia, healthcare practitioners, associations, and government. A large number of consultants, many of whom come from and consult with from the pharmaceutical industry also participate in USP’s standards-setting activities.

USP 2010		135 Volunteers Are from 30 Other Countries	
▶ Argentina	1	▶ Italy	4
▶ Austria	1	▶ Jordan	2
▶ Australia	1	▶ Mexico	2
▶ Belgium	3	▶ The Netherlands	1
▶ Brazil	2	▶ New Zealand	1
▶ Canada	23	▶ Norway	1
▶ China	17	▶ Panama	1
▶ Colombia	2	▶ Peru	2
▶ Denmark	3	▶ Russian Federation	6
▶ France	3	▶ South Africa	1
▶ Germany	4	▶ South Korea	2
▶ Hungary	1	▶ Sweden	1
▶ India	21	▶ Switzerland	4
▶ Ireland	1	▶ United Kingdom	22
▶ Israel	1	▶ Venezuela	1

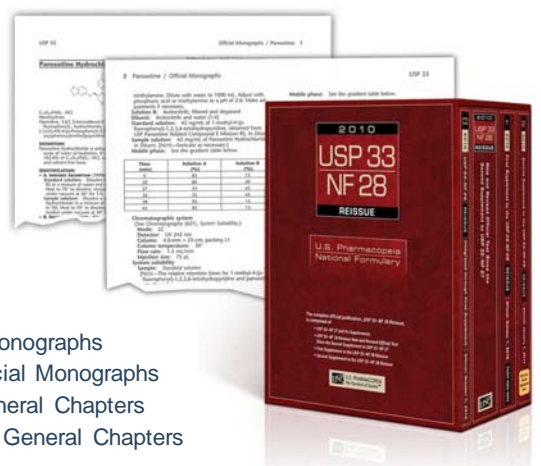
Due to USP's unique nongovernment status, USP can open its doors to experts from all over the globe. At this time, the number of non-US experts is about 15%, and this percentage is expected to grow in coming years.

In the 2005–2010 revision cycle, the Expert Committees addressed key strategic areas relevant to USP's mission to improve the public health through standards-setting and information development activities for drugs (medicines and their ingredients), dietary supplements, and food ingredients. Standards also were established for compounded preparations and the practice of compounding. These standards underwent a public review and comment period, and following review of comments received were balloted to official or authorized status by the appropriate Expert Committee.

What We Have Done

The *United States Pharmacopeia* and *National Formulary (USP-NF)* remain USP's core compendia, and much of the Council of Experts attention is devoted to their continuous revision. The two compendia provide public standards for drugs (medicines and their ingredients) legally marketed in the United States. But the standards contained therein may also be used for registration, market surveillance, and other purposes in many countries throughout the world.

USP 2010 The 'Pharmacopeia': 1) *USP* and 2) *NF*

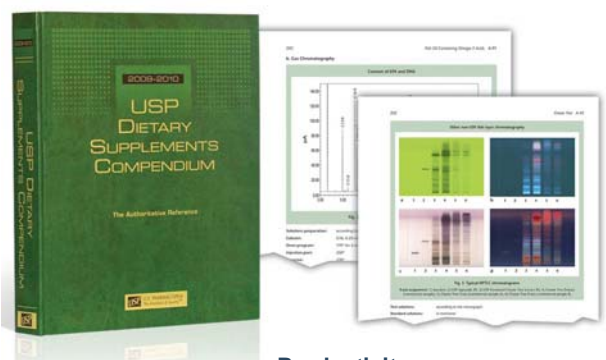


Productivity:

- ▶ 370 New Official Monographs
- ▶ 1,201 Revised Official Monographs
- ▶ 43 New Official General Chapters
- ▶ 89 Revised Official General Chapters

In this cycle the Council advanced a sweeping change to all the monographs in *USP-NF*. This would have been a crowning achievement in the 2005-2010 revision cycle, but the combined publication contained too many errors, with the result that *USP 33–NF 28* had to be reissued. The reissue does not detract in any way from the standards-setting achievements of the Council of Experts.

USP 2010 3) *USP Dietary Supplements Compendium*



Productivity:

- ▶ 51 New Official Monographs
- ▶ 60 Revised Official Monographs

In this cycle, the Council created a *USP Dietary Supplement Compendium*, which we term a 'line extension' containing full or abridged information from *USP-NF* as well authorized information from other sources. The *Dietary Supplement Compendium* is a mixture of official and authorized text.

USP
2010

4) Food Chemicals Codex

Fumaric Acid
(E)-Butenedioic Acid
Item 1,2-Ethylendicarboxylic Acid

O=C/C=C/C(=O)O

Chemical structure of Fumaric Acid.

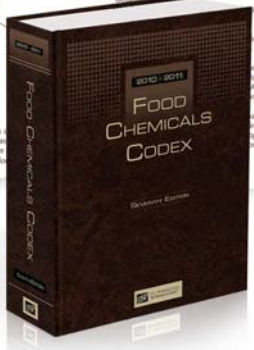
Chemical formula: $C_4H_4O_4$
INS: 297
FEMA: 2488

DESCRIPTION
Fumaric acid occurs as white granules or powder. A 1:1:30 aqueous solution has pH 2.5. It is soluble in alcohol, slightly soluble in ether, and very slightly soluble in chloroform.

Function Acidifier; flavoring agent

Packaging and Storage Store in airtight containers.

Sample: 5 g
Acceptance criteria: NMT 2 mg/kg
Organic Impurities
• Malonic Acid
Mobile phase: 0.001 M sulfuric acid, filtered and degassed
Detector: Acid RS in Absorbance
Injection volume: 100 µL
Mobile phase: Acid RS
Fumaric Acid RS
Mobile phase: Acid RS
Photography
Fumaric acid is included with a variety of sulfonated polymers in the Food Chemicals Codex.



Productivity:

- ▶ 39 New Monographs
- ▶ 228 Revised Monographs
- ▶ 10 New General Tests and Assays
- ▶ 11 Revised General Tests and Assays

We also took on a food ingredients compendium, the *Food Chemicals Codex*, from the U.S. National Academies Press, where it had been produced by the Committee of the Food Chemicals Codex with oversight from the Food and Nutrition Board in the Institute of Medicine. The logic of this decision was and remains strong, recalling that food ingredients are to dietary supplements as excipients are to drug products.

USP
2010

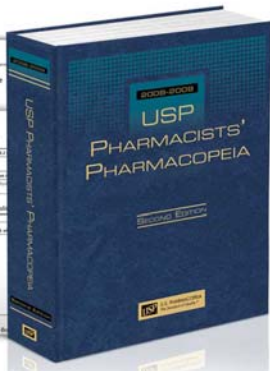
5) USP Pharmacists' Pharmacopeia

Cupric Sulfate
Cupric Sulfate
Cupric Sulfate Pentahydrate

Cyanoacrylates
Cyanoacrylates

Buffers and Buffer Solutions
Phosphate Buffer
Phosphate Buffer Solution

USP Pharmacists' Pharmacopeia
Second Edition



Productivity:

- ▶ 31 New Official Compounding Monographs

And finally we created the *USP Pharmacists' Pharmacopeia*, designed to assist the compounding practitioner with official and authorized text to help assure the quality of compounded preparations. While this compendium is highly modern and relevant, it harkens back to the first *United States Pharmacopoeia*, which contained recipes for physicians and pharmacists, a time when all medicines were compounded.

USP Reference Standards

- ▶ USP Offers More Than 2,500 Reference Standards for Use in the Full Range of *USP–NF* Tests and Procedures
- ▶ USP Reference Standards Have Been Rigorously Tested by USP, Industry, and Government Scientists

Productivity:

- ▶ **728** New Reference Standards
- ▶ **931** Replacement/Continuing Reference Standards



USP expends ~60% of its resources, mostly in our world-wide laboratories, to bring official USP Reference Standards to the United States and to the world. After intensive work in our laboratories to assess candidate material and determine content, resulting data are considered carefully by the Council of Experts' Reference Standards Expert Committee. We recently crossed a high water mark—2500 reference materials in commerce throughout the world. And many, many more are needed to undergird all the many public procedures needed to support test procedures for food and drugs moving in national and international commerce.


Top 20 High-impact Initiatives: 2005–2010 Cycle

1. Adulteration (Heparin, Glycerin, Melamine)
2. Residual Solvents
3. Elemental Impurities
4. Biologic Potency Tests
5. Standards for Tissue-based Products
6. 'Horizontal' Standards (Monographs Are 'Vertical')
7. Dosage Form Taxonomy
8. Shipping and Storage Practices
9. Dietary Supplements Disintegration and Dissolution
10. Safety Review of Dietary Supplements

 Top 20 High-impact Initiatives: 2005–2010 Cycle

11. Compounding Standards (<795> and <797>)
12. Patient Safety Standards (<1066>, Labeling on Ferrules and Cap Overseals, Strength in Total Volume)
13. Monograph Naming Policy (Based on Active Moiety)
14. Model Guidelines
15. Pending Monographs/Non-U.S. Monographs
16. Monograph Redesign
17. General Chapter Redesign
18. General Notices Revisions
19. Monograph Modernization
20. Workshops for High-impact Standards


I'd like to acknowledge that the Council at times takes on extremely difficult standards setting-activities, ones that we term 'high impact.' A list of these appears in the following slides. And in offering this list, I acknowledge also the importance of stakeholders who are impacted by standards. The two examples I focus on now relate to compounding professionals who make sterile compounded preparations and to manufacturers who control inorganic impurities in ingredients and products.

 Value and Cost: Sterile Compounding

- ▶ **Facilities**
 - Engineering Controls (\$10,000–\$1,500,000 per Facility)
 - > One-time Cost
 - \$100–\$1,000 per sq. ft. (ISO Class 5, 7, and 8)
 - > 30-year Depreciation (\$27–\$128/Monthly)
 - Cost Highly Dependent on Existing Conditions and Quality of Construction
- ▶ **Personnel Costs**
 - Garb—\$2 per Person per Day More for Sterile Gloves and Sterile Alcohol
 - > \$4 per Person per Day to Garbing According to USP 32–NF 27
 - Aseptic Technique Testing—\$18 per Employee Annually
- ▶ **Environmental Testing and Sampling (3 Hoods, 10 Samples)**
 - \$565 for Semi-annual Certification of Hoods and Rooms
 - \$5 per Sample Location Annually (In-house)
 - \$80–\$120 per Sample Location Annually When Outsourced

Modern standards affect people, processes and products—and all can add substantial costs to the manufacturers and/or compounding of food and drug articles. An example is The Sterile Compounding Expert Committee's General Chapter <797> *Sterile Compounding*. This General Chapter had the flavor of 'good compounding practices'—similar to good manufacturing practices,

and is a reminder that GMPs or any GxPs can add to the cost of manufacture and compounding. At the same time the added consumer protection can be substantial and even life-saving.




Elemental Impurities/Metal Impurities

- ▶ **International Conference on Harmonization**
 - Clarified Impurities in Medicines and Medicinal Ingredients (Organic, Inorganic, Residual Solvents) for Well-Characterized Small Molecules
- ▶ **USP Extended to All Articles in USP–NF via General Chapter <467>**
- ▶ **Next Revision Cycle:** Extend to All Articles in USP–NF for Inorganic (Elemental) Impurities

And USP's advances to better control inorganic impurities (elementals) For this reason, USP worked increasingly in the 2005-2010 revision cycle to assure a) sound justification for high impact standards; and c) thoughtful implementation strategies.

How We Do It



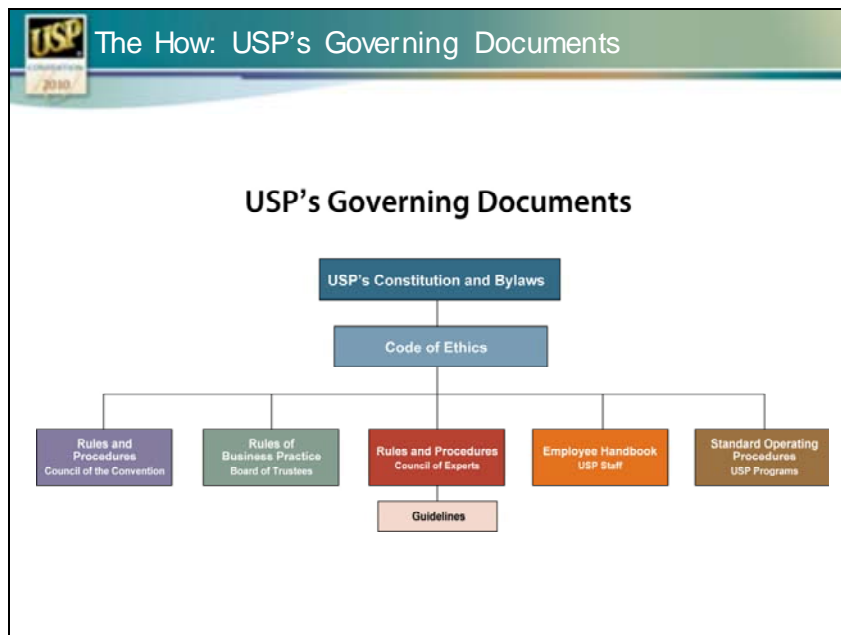
The How: USP's 'Spirit of Voluntarism'

- ▶ **Hourly Volunteer Time Spent:**
 - 3.5 Hours per Week on Average
- ▶ **Totalling Approximately 127,000 Hours**
- ▶ **Valued at \$10 Million per Year**
- ▶ **Totals for the 2005–2010 cycle:**
 - 635,000 Hours of Volunteer Service
 - Value of \$50 Million to USP

The extraordinary productivity of the Council of Experts, in the 2005-2010 revision cycle came about as a result of highly motivated volunteers and staff. For the Council, success came through extraordinary donations of time and energy. As the Council has internationalized, many volunteers are coming long distances, and to these volunteers I offer special thanks. I remind Convention delegates that all USP volunteers in the Council—and you as well—typically have busy professional and personal lives, so the commitment to advance the will of the Convention through creation of a *pharmacopoeia* is nothing short of remarkable. In fact, it's priceless.



I acknowledge impressive USP staff contributions. USP had on board at the close of the 2005-2010 revision cycle nearly 600 staff on five continents, and all of these staff directly or indirectly support the Convention's will to elaborate a *pharmacopoeia* through the work of the Council of Experts. Comparisons between the staff support for the Council of Experts in the 1995-2000 and 2005-2010 revision cycle are difficult because the changes are so great. Meetings in the current revision cycle have well defined agendas with excellent background material. Rules and procedures and requirements are clearly delineated at the beginning and followed strictly. Records are maintained and archived according to SOPs. Expectations for volunteers and staff are far more established and adhered to. And all of these changes occurred with a markedly increased number of volunteer groups, an increased number of compendia, and an increasingly complex balloting and publication schedule.



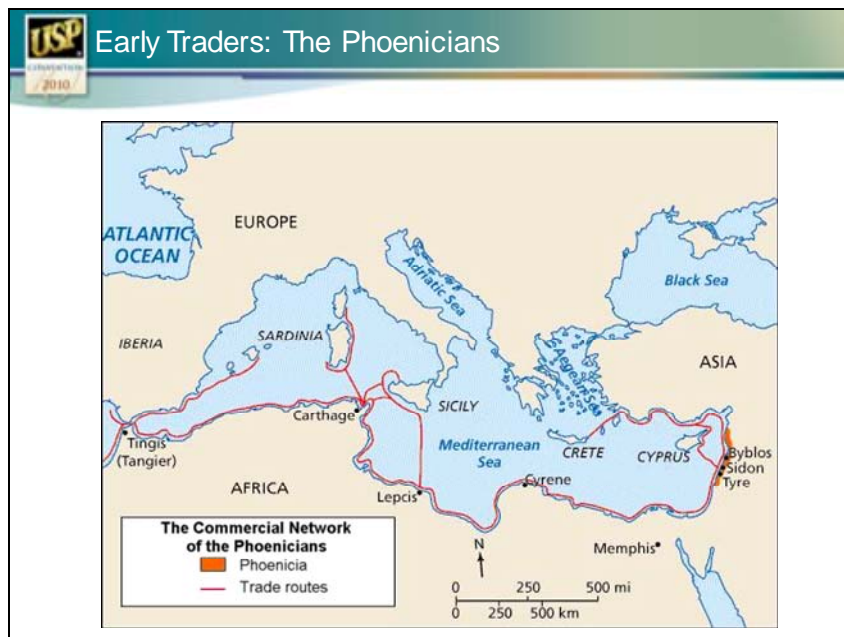
I also note that USP has a strong set of rules and procedures that guide all our activities, including those of the Council of Experts and allied groups such as Advisory Groups and Stakeholder Forums. We have also prepared Guidelines to assist sponsors of requests for revision and also provide additional information about USP's at times complex processes.

A key theme in the advance of science in any field, and perhaps particularly so in the science of standards-setting, is agreement on common terms. To a large extent, activities in Council of Experts brought USP to a better understanding of the nomenclature of standards-setting and conformity assessments. And this is not easy because different fields—metrology, analytical chemistry, statistics, and others as well—use different terms for the same concept. Coming to better harmony on terms is a common goal in any field of scientific endeavor, and this is true of USP.

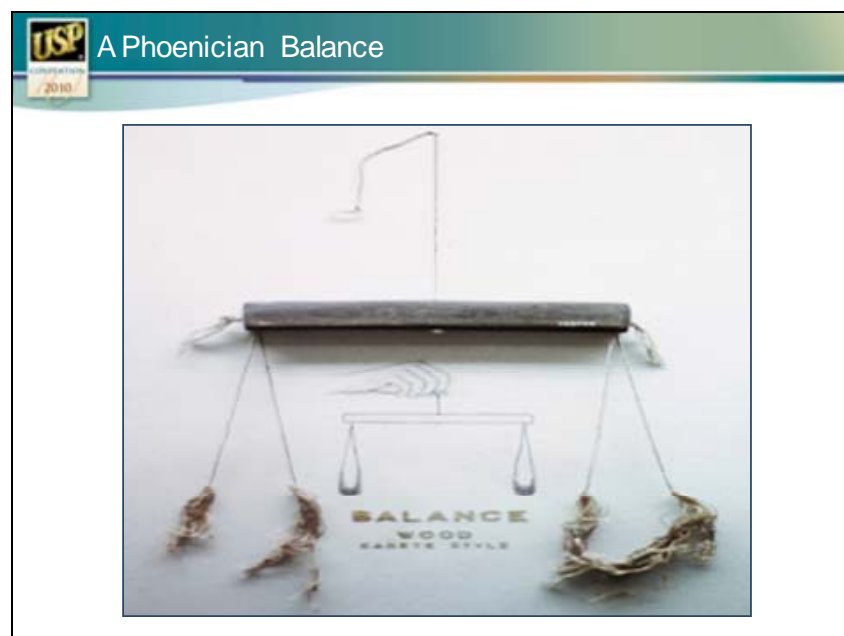
What Our Science Is: The Good, The Complex, And The Ugly

Measurement Science

Measurement science from a time long ago that speaks to principles of metrology that are directly relevant to the Council's standards setting activities.



Several thousand years ago, the Phoenicians were highly successful traders in the Mediterranean Sea. They traded goods based on their weight, with the idea that an independent weight would promote good trading practices



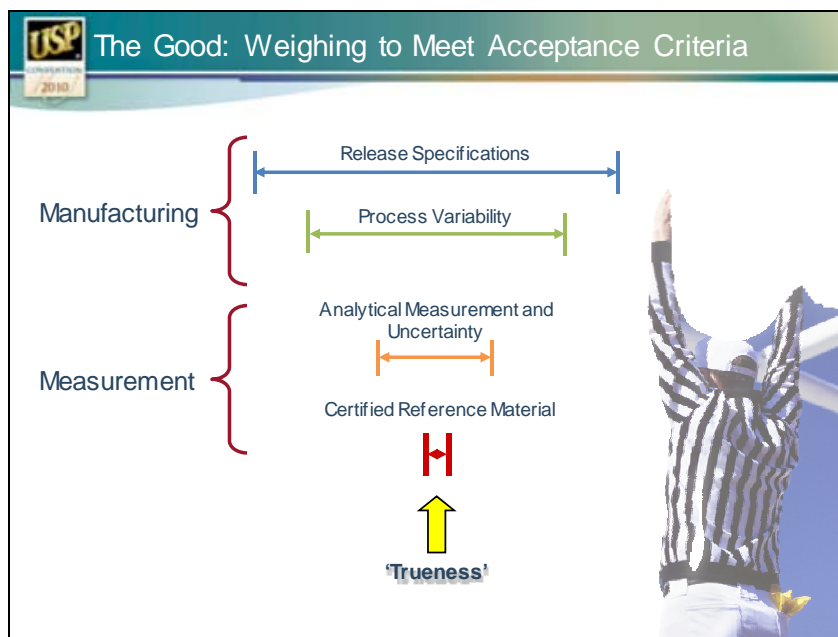
The general principles of good weighing practices exist today, and we all encounter them in our daily lives, e.g., at the food market, where scales at scanners provide a measurement of weight which is then adjusted into cost depending on type of goods sold. These scales are independently calibrated to assure that they weight correctly. Would it surprise you to know that this is more or less what USP does for all its monographs and their procedures?

USP
Compendium
2010

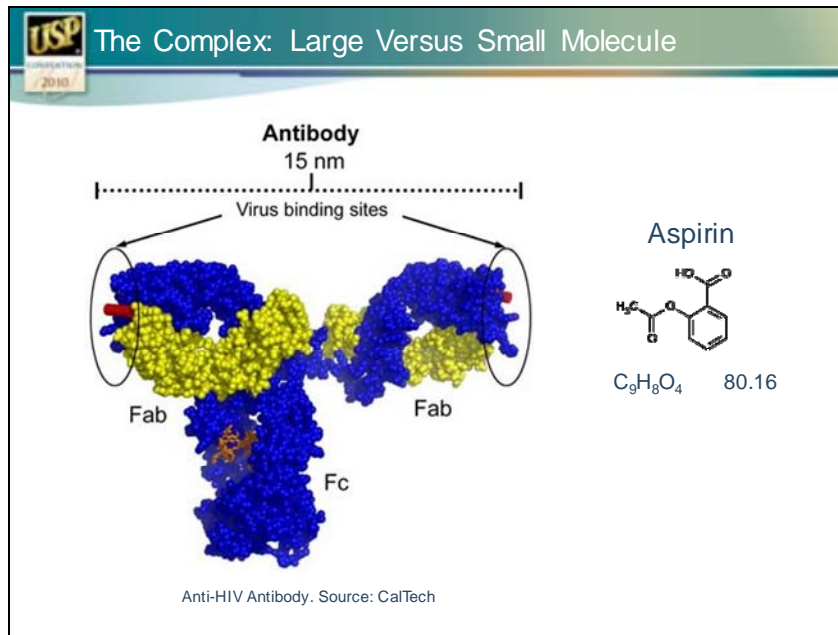
From Long Ago...to the Present

A False Balance Is an Abomination..., But a Just Weight is [a] Delight.

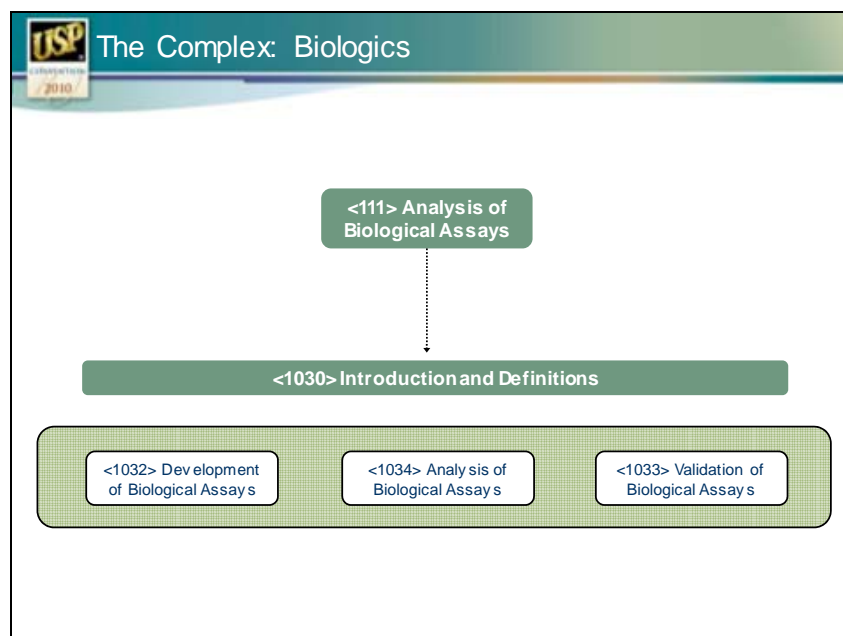
This quotation sums it up.



A typical monograph contains an Assay test that determines the amount of the drug substance and excipients in a medicine. And this amount must fall within acceptance criteria during the time the medicine is in the market place, so that practitioners and patients can rely a label that expresses the amount of the drug substance in the medicine, e.g., 200 mg ibuprofen in a capsule. And for those of you are chemists or have had some chemistry training, you know that the weight of a well-characterized drug substance can also be translated into the number of molecules in a specified mass, using Avogadro's number.



Historically, for about ~100 years (1880 to 1980), USP's focused on developing public standards for medicines that moved away from crude mixtures (e.g., chinchona bark) to pure moieties (quinine). This transition reversed with medicines arising as a result of the molecular biology revolution, first with rDNA insulin in 1980. Now almost half of the new medicines entering or soon to enter the market may be biologics drawn either from nature or from biotechnology-based approaches. Over the last several cycles, through Convention resolutions and in other ways as well, the Council of Experts has increased its standards-setting activities for biologic and biotechnology based medicines and their ingredients. And USP's standards apply to all medicines, including those registered under the Public Health Service Act as well as the Federal Food, Drug and Cosmetic Act. Because USP at times, and perhaps increasingly so, will have difficulty gaining the needed information and candidate materials for public monographs for biologics, the Council's efforts in this cycle turned to horizontal standards.



These provide general tests, procedures, and acceptance criteria that can be referenced in many monographs (both public and private) as opposed to the standards of a monograph for a specific article, which is a type of vertical standard. Over the last decade the Council of Experts has labored intensively to advance horizontal standards for the biologic potency test, which is a key test for biologics where full characterization is not possible, and thus dose is expressed in units rather than weight. This effort updated an older general chapter (<111>) to a suite of modern, relevant general chapters that includes General Chapter <1032> *Design and Development of Biological Assays* General Chapter <1033> *Validation of Biological Assays*; General Chapter <1034> *Analysis of Biological Assays*, revision of General Chapter <111> *Design and Analysis of Bioassays*, and a planned roadmap general chapter (<1030>). The suite will shortly be available to assist manufacturers of biologics where the ‘sine qua non’ procedure either in the public or private monograph is the potency test. Interestingly, the multiyear public dialogue for the suite of general chapters exposed an error in the determination of parallelism, where the proper hypothesis is one of equivalence and not difference, emphasizing the value of public, science-based standards-setting dialogues.

 The Ugly: Needles in Haystacks

How Did You Find It?


How Will You Find Another One?



How Will You Prevent It from Happening Again?


Adulteration and Contamination

The heparin story continues to evolve as part of the general challenge of detecting and deterring dangerous adulterants/contaminants in foods and drugs. This is a much larger and challenging task compared to the characterization and control studies needed to assure that what is allowed in a food and drug article is present in appropriate amounts. It is like finding a needle in a haystack.

 **The Ugly: Heparin Example**

Monograph Requirement	Old USP	Old EP	New USP
Identification	<ul style="list-style-type: none"> ▶ Flame test for sodium 	<ul style="list-style-type: none"> ▶ Sheep plasma clotting ▶ Optical rotation ▶ Zone electrophoresis ▶ Residue on ignition 	<ul style="list-style-type: none"> ▶ Proton NMR ▶ Anion Exchange Chromatography ▶ Anti-factor Xa to Anti-factor IIa Ratio ▶ Flame Test for Sodium
Assay	<ul style="list-style-type: none"> ▶ Sheep plasma clotting 	<ul style="list-style-type: none"> ▶ Sheep plasma clotting 	<ul style="list-style-type: none"> ▶ Chromogenic Anti-factor IIa

Working with FDA and many other stakeholders, USP advanced approaches to detect adulterants in heparin drug substances, e.g., oversulfated chondroitin sulfate...

 **The Ugly: Glycerin and Other High-risk Excipients**

- ▶ **Glycerin Revision** (Official May 1, 2009) Includes a Limit Test for Both Diethylene Glycol (DEG) and Ethylene Glycol (EG) at NMT 0.10% Each in the Identification Test
- ▶ **Revisions to Other High-risk Excipients** (Posting October 1, 2009; Official February 1, 2010)
 - Propylene Glycol
 - Sorbitol Solution
 - Noncrystallizing Sorbitol Solution
 - Sorbitol Sorbitan Solution
- ▶ **Includes Limit Tests** for Both DEG and EG at NMT 0.10% in the Identification Test

...and at-risk excipients, e.g., diethylene glycol and ethylene glycol, as well as contaminants in foods (melamine).

USP 2010 **A Hope: Spectral Libraries**

Every Pharmaceutical Ingredient or Formulated Product, Together with Its Packaging Materials, Has Unique Characteristics or 'Fingerprints' That Can Be Probed Using Various Regions of the Electromagnetic Spectrum.

The diagram illustrates the electromagnetic spectrum with a color gradient bar at the top. Below it, the spectrum is divided into regions: Radio, Microwaves, Infrared, Visible, Ultraviolet, X-ray, and Gamma Ray. A horizontal axis below the spectrum shows frequency increasing from left to right (Low Frequency to High Frequency) and wavelength decreasing from left to right (Long Wavelength to Short Wavelength). A sine wave is shown below the frequency axis, with its wavelength increasing as frequency decreases.

A key solution was to put tests for these dangerous materials in the Identity test of the public monograph. This placement calls on drug product manufacturers to test for the material prior to its use under US GMPs. It's a novel solution but it also adds the burden of routine testing for a rare event.

Where We Are Going

Convention delegates, observers, and guests will observe a major change in the Council of Experts in the coming revision cycle of 2010-15.

USP 2010 **2010-2015 Expert Committees**

The organizational chart for the 2010-2015 Expert Committees is structured as follows:

- International Health Advisory Group** (top left)
- Council of Experts/ Executive Committee** (top center)
- Scientific Advisory Group** (top right)
- U.S. Pharmacopeia** (center)
- A. Long** (Nomenclature, Safety and Labeling)
- Small Molecules: K. Russo** (Small Molecules Monographs 1, 2, 3, 4)
- Large Molecules: T. Morris** (B&B Monographs 1, 2)
- B. Jones** (Reference Standards)
- General Chapters: A. DeStefano** (Chemical Analysis, Physical Analysis, Biological Analysis, Dosage Forms, Microbiology, Packaging, Statistics, Toxicology)
- National Formulary: J. Griffiths** (Excipients)
- Dietary Supplements Compendium: J. Griffiths** (Dietary Supplements)
- Food Chemicals Codex: J. Griffiths** (Food Ingredients)
- Pharmacists' Pharmacopeia: A. Long** (Compounding)

The number of Committees is reduced to 20 from the current 57. There are several reasons for this. One is that USP's focus on production of drug information is now over, so that 16 expert committees are not needed. USP regrets this and hopes to strengthen its provision of drug


information and drug information standards if practitioner support and suitable business models can be found. And USP remains committed to its work on the Model Guidelines, drawing on knowledgeable experts from the prior and current cycles to evolve the categories and classes needed to assure beneficiary access, as required of USP in the Medicare Modernization Act Part D benefit provisions. Another reason relates to a model of standards-setting that allows each of the 20 Expert Committees to form one or more Expert Panels to accomplish a specific task over a time delimited period. This is an experiment that advances the type of flexibility envisioned in the Bergen Report created in the 1995-2000 cycle. The Council of Experts is excited about this experiment, but also will monitor execution carefully. And the Chair of the Council in the 2010-15 revision cycle will no doubt wish to report to Convention delegates in 2015 on how the experiment turned out.



Where We Are Going

- ▶ **April 23, 2010:** Chairs Elected
- ▶ **June 2010:** Chair Orientation/Expert Committee Members Elected
- ▶ **July 1, 2010:** 2010–2015 Cycle Begins, Work Plans Initiated
- ▶ **Thereafter:** Expert Panels Formed

Tomorrow at this Convention, delegates will vote to elect the Chairs of the Council of Experts in the 2010-2015 revision cycle. I thank you for this effort, and as soon as the election is concluded, we will begin immediately to advance the complex series of steps that will bring the Council to a high state of readiness to begin their important work when they take their seats on July 1, 2010.



Many Thanks

- ▶ Expert Volunteers Serving on Expert Committees, Subcommittees, Advisory Panels, and Advisory Groups
- ▶ Stakeholders and Project Team Members
- ▶ Donors of Monographs and Reference Materials
- ▶ Individuals Who Comment through *Pharmacopeial Forum* and *Food Chemicals Codex Forum*
- ▶ Food and Drug Administration Staff
- ▶ Practitioners, Patients, and Consumers

Just as it is difficult to comprehend in its entirety the standards-setting achievements of the Council of Experts in the 2005-2010 revision cycle, so too is it difficult to thank adequately the Council's volunteer and staff who support the revision of the 'Pharmacopoeia' that you, the delegates of the 2005 USP Convention called the Council to make. But I will try. My appreciation goes first to the volunteers themselves who served on Expert Committees, Subcommittees, and Advisory Panels, as well as to USP's talented liaison and other staff who assisted these volunteers. Sincere thanks go as well to a) donors who provide needed information and candidate materials in support of USP's standards-setting activities;; b) those who commented on proposed standards in the *Pharmacopeial Forum* and *Food Chemicals Forum*; and c) stakeholders around the world who give greatly of their time, understanding, and energy to help USP advance standards in thoughtful and useful ways. USP also thanks FDA staff who—in the midst of many other obligations—found time to comment on USP's proposed standards. USP's standards are at times 'downstream' from FDA's decision-making for private specifications, and the continuous cycle of cooperation between FDA and USP to come to the best possible public standards is an asset to the nation and the world. As we continue into the 21st century, this asset may be appreciated only with difficulty by practitioners, patients, consumers, and the public at large.

But it quietly works to the good of the public health and, when failure occurs, as it sometimes does in the U.S. and elsewhere—and as it did in the current revision cycle for heparin, with at times great pain and suffering, the main conclusion might be that it all works as well as it does, not that we might wish that it could work better.