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Part I
Memorandum
On behalf of the Council of the Convention, I am pleased to present the Final Resolutions Report of the Council of the Convention. Adopted Resolutions are considered important guidance for the United States Pharmacopeial Convention (USP). They are considered by USP’s Board of Trustees and Council of Experts (CoE) and reflected in the organization’s policy and operational agendas. Thus, wide participation in the Resolutions process, careful review of Resolution submissions, and well-crafted development of final language and background is a critical process for the organization.

In prior cycles, responsibility for the development of Resolutions resided with the Resolutions Committee, one of several USP Convention Committees. At the April 2010 Convention Meeting, the Membership adopted amended and restated Bylaws that, among other things, consolidated USP’s Convention Committees. The new Bylaws give the Council of the Convention (CoC), a committee composed of representatives from each of the Convention member categories, responsibility for developing Resolution proposals for consideration by Convention Members. (Bylaws provisions related to the CoC and its work are available in Appendix A of this report.)

In August 2010, USP Convention President Timothy R. Franson, B.S.Pharm., M.D., appointed 12 of the possible 25 USP member organizations to serve on the 2010–2015 Council of the Convention. The remainder of the Members would be appointed as the cycle progressed. The first meeting of the CoC was held in October 2010. At this meeting, the CoC discussed the process by which it would review Resolutions (see Appendix B) and the timing for delivering Proposed Resolutions to the Members. While the Bylaws require only that the Report be provided 30 days prior to the Convention Meeting, the CoC decided that it would be preferable for Members to have additional time to consider Proposed Resolutions. At the same time, the CoC did not want to curtail Members’ opportunity to provide submissions for Resolutions closer to the Meeting. Thus, the CoC decided that it would provide a preliminary Report 90 days prior to the Meeting, followed by a final Report 30 days prior to the Meeting.

During its initial and several subsequent meetings, the CoC also discussed how to keep the Convention Membership informed of and engaged in USP activities and Resolutions between Convention Meetings. Throughout the 2010–2015 cycle, the CoC has overseen activities intended to encourage Member awareness of and engagement in the Resolutions process. On an annual basis, the CoC has released an update on the Resolutions adopted by the Membership in 2010. The first few of these updates were in the form of a downloadable document provided to Members. In 2013, CoC Chair and Convention President, Dr. Franson, hosted a series of webinars presenting these updates in a more interactive format. During these webinars, a status update on each of the 2010 Resolutions was provided by the senior staff members overseeing the related programs. Each webinar included time for questions from stakeholders and all were recorded and posted on the USP website.

In 2012, the CoC hosted several “Listening Tour” sessions around the country and invited Member Delegates to provide feedback on the issues that were important to them, as a way of beginning to inform potential future Resolutions. Themes that emerged from these events were further considered by USP through a series of meetings involving appropriate subject matter experts.

On April 25, 2014, the CoC held the first ever face-to-face Member Meeting on Resolutions at USP Headquarters. During this meeting, the CoC and USP’s CEO, Ronald T. Piercingenzi, Ph.D., hosted a lively discussion with more than 60 participants regarding the progress made to advance the 2010 Resolutions and possible ideas for the 2015 Resolutions. This meeting also served as a platform for the CoC to deliver the formal Call for Resolutions to USP Convention Members and Observers. This included a quick overview and introduction of the new online Resolutions portal. This portal was created to serve as the central mechanism for stakeholders to submit proposals and for the CoC to collaborate, evaluate submissions, and develop the Resolutions.

In its subsequent meetings, the CoC finalized the rubric for evaluating Resolution proposals, which mirrored the Resolution submission form and was intended to create an objective approach to evaluating each proposal. Each Resolution submission received by the CoC was assessed based on the evaluation rubric.
In October 2014, the CoC held a meeting to consider the Resolution submissions received before the October 2, 2014, initial deadline. The CoC also received an update from senior staff regarding a comprehensive strategic planning process under way at USP. By the end of this meeting, the CoC had voted on a series of topics for an initial set of Resolution proposals for the preliminary Report, which was provided to the Convention Membership on January 21, 2015. In addition, CoC members volunteered to serve in working groups on the various Resolution proposal topics that had been approved for further development. (Appendix C lists the CoC working group for each Resolution proposal.) The CoC elected to defer a number of submissions that related to USP’s standards-setting areas, in order to allow staff to complete evaluation of these areas through the strategic planning process.

On February 6, 2015, the final deadline for Resolution submissions occurred. All remaining submissions from stakeholders were evaluated by staff and sent to the CoC in preparation for its final face-to-face meeting of the cycle. The previously assigned topical working groups all met to develop language for their respective proposals to be reviewed at the meeting.

At the CoC’s meeting on February 20, 2015, Dr. Piervincenzi provided a comprehensive briefing on the strategic plan approved by the Board of Trustees on February 9, 2015. All remaining Resolution submissions received after the preliminary deadline and reviewed by their respective working groups were discussed and voted on by the entirety of the CoC, taking into consideration USP’s new strategic plan.

The CoC is pleased to present, for Convention Delegates’ consideration, the 11 Resolution proposals for the April 2015 Convention Meeting. Each proposed Resolution, contained in Part II of this Report, includes a resource assessment conducted by the Board of Trustees and the Council of Experts in order to evaluate the impact that proposal might have on both financial and scientific resources available to USP. The CoC encourages Convention Member Organizations and Delegates to review each proposed Resolution, including its accompanying resource assessment and background information, in order to enrich the discussion at the Convention Meeting and to ensure that the Resolutions adopted are aligned with the strategic direction of USP.

This Report provides space to note any questions or comments Delegates may wish to bring forward during the Open Hearing on Resolutions on Thursday, April 23, 2015. Following the Open Hearing, the CoC will convene, consider comments, and prepare to deliver its Final Report to Delegates on Friday, April 24, 2015. Convention Delegates will vote on the final language of Resolutions on Saturday, April 25, 2015.

The CoC wishes to acknowledge the contributions of the following organizations and individuals that submitted Resolution proposals:

- Phil Ayers, B.S.Pharm., Pharm.D., American Society for Parenteral and Enteral Nutrition;
- Christopher Burgess, M.Sc., Ph.D., interested stakeholder;
- Diane Dorman, National Organization for Rare Disorders;
- Monica Eimunjeze, National Agency for Food & Drug Administration and Control;
- Barbara J. Ferguson, New Jersey Pharmaceutical Quality Control Association;
- Mary G. Foster, Ph.D., USP Convention Governance Committee;
- Vinayak Godbole, interested stakeholder;
- Muhammad Imran, interested stakeholder;
- Jingyee Kou, Ph.D., U.S. Food and Drug Administration;
- Raimar Löbenberg, Ph.D., Association of Faculties of Pharmacy of Canada;
- Gina Marsee, Pharmaceutical Research and Manufacturers of America;
- Peter J. Rice, Pharm.D., Ph.D., University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences;
- Donald C. Singer, M.S., American Society for Quality; and
- Shelly Spiro, Pharmacy HIT Collaborative.
Where the CoC deemed appropriate, it has incorporated these concepts into the proposed Resolutions presented herein. In other cases, submissions will be referred to the 2015–2020 Council of Experts or USP staff for further consideration and potential action. The CoC expresses its appreciation to all of the submitting organizations for their participation in the Resolutions process.

Respectfully submitted,

Timothy R. Franson, B.S.Pharm., M.D.
President, USP Convention
Chair, 2010–2015 Council of the Convention
Members of the Council of the Convention

Chair
Timothy R. Franson, B.S.Pharm., M.D., President, USP Convention

Members
Leon H. Bruner, D.V.M., Ph.D., Grocery Manufacturers Association
John E. Courtney, Ph.D., American Society for Nutrition
Barry D. Dickinson, Ph.D., American Medical Association
Diane E. Dorman, National Organization for Rare Disorders
Glen Fine, M.S., M.B.A., C.A.E., Clinical and Laboratory Standards Institute
Rita Munley Gallagher, Ph.D., R.N., American Nurses Association
David R. Gaugh, R.Ph., Generic Pharmaceutical Association
Ronette Gehring, B.V.Sc., M.Med.Vet. (Pharm), MRCVS, DACVCP, Association of American Veterinary Medical Colleges
Adam Gibson, Health Canada Natural Health Products Directorate
Stephen B. Greenberg, M.D., Baylor College of Medicine
John Lisack, Jr., C.A.E., American Association of Pharmaceutical Scientists
Charles W. Maas, M.D., M.P.H., California Medical Association
Thomas E. Menighan, R.Ph., M.B.A., F.A.Ph.A., American Pharmacists Association
Michael A. Moné, J.D., R.Ph., F.A.Ph.A., Florida State Pharmacy Association
Pallavi Nithyanandan, Ph.D., U.S. Food and Drug Administration
John S. Punzi, Ph.D., Consumer Healthcare Products Association
N. Lee Rucker, M.S.P.H., National Council on Patient Information and Education
Elizabeth Scott Russell, R.Ph., National Association of Boards of Pharmacy
Donald C. Sawyer, D.V.M., Ph.D., American Veterinary Medical Association
Hanan J. Sboul, M.B.A., C.A.E., Jordan Association of Manufacturers of Pharmaceuticals and Medical Appliances
Monica da Luz Carvalho Soares, Pharm.D., Ph.D., Brazilian Pharmacopoeia
Bhojraj Suresh, M.Pharm., Ph.D., D.Sc., Pharmacy Council of India
David R. Taft, Ph.D., Long Island University Arnold and Marie Schwartz College of Pharmacy
Part II
Proposed Resolutions
PROPOSED RESOLUTION 1
COLLABORATION WITH THE U.S. FOOD AND DRUG ADMINISTRATION

USP will increase communication and collaboration with the U.S. Food and Drug Administration (FDA) to promote alignment with FDA’s regulatory and scientific policies from the inception of the standards planning and development process. USP will work with FDA and industry to increase understanding of the regulatory impact of such proposals prior to the establishment of implementation timelines.

Background

Since 1906, when both the United States Pharmacopeia (USP) and the National Formulary (NF) were first recognized as official compendia under federal law, USP has had a special relationship in law with FDA. Through this unique partnership, FDA and USP have worked together for more than 100 years to help ensure the quality of drugs used in the United States. That partnership has expanded into the foods arena as USP’s standards-setting activities have grown to include dietary supplements and food ingredients.

Today’s globalized marketplace has made it increasingly challenging for FDA and USP to protect the quality and safety of the U.S. food and drug supply. At the same time, resources of both organizations are constrained, requiring both FDA and USP to work as efficiently as possible and maximize use of available resources. Thus, it is more important than ever that FDA and USP work closely together.

This Resolution would continue and expand on a 2010–2015 Resolution that encouraged USP to strengthen its relationship with FDA, emphasizing in particular the need for communication and collaboration earlier in the standards development process. Today, FDA has numerous liaisons participating on USP’s Expert Committees to provide input as standards are developed, and FDA also formally comments on proposals appearing in Pharmacopeial Forum. However, increased dialogue and interaction between USP and FDA at the policy and scientific levels at the time Expert Committees are developing their direction and work plans would help ensure better alignment from the outset, and allow both organizations’ resources to be deployed as efficiently and effectively as possible.

This Resolution also urges USP to work proactively both with FDA and industry on high-impact standards, such as broadly applicable general chapters, so that regulatory expectations and impact effects can be understood as implementation timelines are developed. These actions will help eliminate confusion for industry and other stakeholders, foster the efficient use of USP resources and expert volunteer time and effort, and facilitate both FDA and USP achieving their public health missions.

Resource Assessment

Although USP currently devotes significant resources to its relationship with FDA, a recently conducted strategic initiative focusing specifically on this topic recommended that USP add a senior-level staff member dedicated solely to coordinating and overseeing USP’s many interactions with FDA. This recommendation has been endorsed by senior management and the Board of Trustees. USP believes this position will help USP and FDA work more efficiently and effectively together, ultimately enabling both parties to better use their limited resources for maximum public health benefit.
PROPOSED RESOLUTION 1 WORKSHEET
COLLABORATION WITH THE U.S. FOOD AND DRUG ADMINISTRATION

Comments on Text of Resolution

NOTES:
PROPOSED RESOLUTION 2

USP–NF MONOGRAPH MODERNIZATION

USP will meet the needs of U.S. Food and Drug Administration (FDA), industry, and other stakeholders for modern monographs within USP–NF. USP will eliminate the existing backlog of monographs in need of modernization and proactively evaluate and update monographs to maintain their relevance given scientific advances and evolving manufacturing and regulatory approaches. USP will work with industry and FDA to explore new strategies for sharing analytical methods and specifications needed to modernize monographs.

Background

Public standards contained in USP–NF monographs can play a key role in helping to ensure the quality, security, and safety of pharmaceutical products and reduce the risk of adulterated, counterfeit, and substandard products. In today’s global pharmaceutical market, drug manufacturers increasingly source drug components from remote locations through complex supply routes, and rely on USP–NF standards to ensure the quality and integrity of incoming components. USP–NF monograph standards also help ensure patients that the medicines they are getting are what they purport to be, and are of consistently high quality.

USP recognizes that for monographs to effectively play this role, they must contain modern, up-to-date analytical methods and testing requirements. Over the past five years, USP has made monograph modernization an increasing priority. USP is now devoting a significant portion of its own laboratory resources to develop the methods needed to update monographs, rather than rely solely on donations from manufacturers. It has worked with FDA to identify and prioritize high-priority monographs, and has also collaborated with FDA on the development of new methods through a Cooperative Research and Development Agreement with FDA’s Office of Regulatory Affairs.

While much progress has been made, there is still significant work to be done. Many monographs still require updating to include more specific identification and other tests. In some cases, old and outdated monographs for products that are no longer in use should be omitted from the USP–NF altogether, as these are no longer of value and materials cannot even be procured for the modernization work. There is a particular need to modernize as well as develop monographs for over-the-counter (OTC) drug products that are marketed under the FDA OTC monograph system, rather than under an NDA or ANDA, and therefore do not undergo FDA pre-market review and approval.

This Resolution encourages USP to continue its focus on modernization in order to eliminate the backlog of monographs in need of modernization and move to more proactive approaches for evaluating and updating its monographs on an ongoing basis. Importantly, this Resolution also urges USP to work with FDA and industry to explore new approaches for facilitating the sharing of information needed to update monographs. USP’s modernization efforts have been hampered in the past by the fact that manufacturers may not be willing to donate methods and specifications, and FDA faces legal constraints on providing such information. While USP increasingly has relied on its own labs to develop the necessary methods, this is time-consuming and resource-intensive. Finding new ways to allow USP to obtain the necessary information from manufacturers or the FDA would greatly accelerate USP’s modernization efforts and help ensure that USP–NF standards can effectively serve to protect the quality of drugs and their ingredients.
Resource Assessment

Fulfillment of this Resolution will require a substantial and sustained investment of resources by USP. Because modernization of USP–NF is a fundamental tenet of USP’s emerging five-year strategic plan, USP is prepared to commit the resources necessary to accomplish this goal. However, accomplishing this goal will require that USP’s own resource-intensive laboratory development efforts continue to be supported by donations of information and material from sponsors. In addition, attainment of this goal can be expedited and fewer USP resources will be required to achieve it if FDA, industry, and USP are able to identify new ways of sharing the information necessary to continuously update USP monographs.
PROPOSED RESOLUTION 2 WORKSHEET

USP–NF MONOGRAPH MODERNIZATION

Comments on Text of Resolution

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USP will expand its commitment to harmonization of compendial standards by working with pharmacopoeias, the World Health Organization, and other stakeholders to determine optimal ways to advance and sustain globally harmonized standards.

Background

USP historically has collaborated with other pharmacopoeias, industry, and regulators to move toward greater consistency among the world’s quality standards for medicines. This has been pursued in different ways—some formal, some informal—and through multilateral, bilateral, and global efforts. The global nature of the food and drug industries has added urgency to the need for a more uniform set of standards by which the quality of these products can be established.

For 25 years, USP has participated with the European Pharmacopoeia and the Japanese Pharmacopoeia (with the World Health Organization as an observer) in the Pharmacopoeial Discussion Group (PDG), which has made limited but steady progress in harmonizing excipient monographs and key general test methods (general chapters). PDG is now reviewing and improving its processes so that it can be more productive in the future. In addition, FDA now attends PDG meetings with USP, which is important in ensuring regulatory alignment as USP works to harmonize standards within PDG.

In addition, multilateral collaborations among sponsors and pharmacopoeias result in a single test requirement in multiple markets for individual products. Bilaterally, USP and the European Pharmacopoeia are now concluding a Prospective Harmonization pilot, in which harmonized monographs are established at the outset across the pharmacopoeias in exchange for earlier submission from the innovator manufacturer. Additional Prospective Harmonization efforts are occurring with the British Pharmacopoeia, Korean Pharmacopoeia, and Japanese Pharmacopoeia on drug product and excipient monographs. Other bilateral collaborations and arrangements, such as “adopt-adapt” agreements that allow other pharmacopoeias to freely use or adapt USP standards, also facilitate harmonized standards.

Two global approaches to harmonization that draw in all national and regional pharmacopoeias began in 2011 and 2012, respectively (the Global Summit of the Pharmacopoeias and the World Health Organization’s International Meeting of World Pharmacopoeias). These two efforts have now combined into the WHO’s World Meeting of Pharmacopoeias, and its initial focus is developing Good Pharmacopoeial Practices.

USP envisions a future of global harmonization and partnering that could include the following:

1. Developing more globally harmonized standards worldwide due to increased collaboration across all pharmacopoeias.

2. Creating standards for drugs for which no adequate standard exists in any pharmacopoeia.

3. Increasing support by and possibly funding from the global industry or other interested parties to advance harmonization.

5. Evolving the WHO International Meeting of World Pharmacopoeias to become the forum by which all pharmacopoeias can come together on a regular basis. These meetings also could have science and stakeholder outreach components, and could minimize the number of individual pharmacopoeial meetings per year.

Working in collaboration with other pharmacopoeias, WHO, and other stakeholders, USP will continue to explore these and other ideas for advancing harmonization.

Resource Assessment

USP believes strongly in the importance of globally harmonized standards and remains committed to pursuing harmonization. However, there are challenges with the existing harmonization processes. To date, USP has expended a considerable amount of resources on its various harmonization-related activities, with limited success in producing harmonized standards. The PDG process in particular is time-consuming and resource-intensive both for USP staff and for the Expert Committees of USP’s Council of Experts who are responsible for these harmonized standards. To be successful, it will be important for industry (the primary beneficiary of harmonization) as well as FDA and other regulators to support these efforts, and to work with USP to identify and advance more efficient mechanisms and approaches for achieving globally harmonized standards.
PROPOSED RESOLUTION 3 WORKSHEET
GLOBALLY HARMONIZED STANDARDS

Comments on Text of Resolution

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USP will continue strengthening its quality systems to ensure the timely and accurate delivery of public standards. USP will maintain its commitment to implementing a fully integrated, global approach to quality and will monitor its progress against specified metrics and objectives to achieve continuous improvement as measured by USP performance.

Background

Over the past three years, there has been significant improvement in the integration of quality systems and practices into USP’s standards-setting processes. The significant quality accomplishments can be divided into two areas: organizational and systems. The Quality Assurance (QA) department has been organized according to the workflow for reference standard development and realization, as well as documentary standard content development and delivery. This has provided for the appropriate integration of quality throughout USP work processes via auditing, reviews, tracking and trending of workflow, and product documentation. In addition, QA now operates globally, meaning there is an enterprise-wide philosophy striving for consistency in quality work processes and reporting across the USP sites.

QA also has implemented a paperless, online global quality management system that enables QA to document issues (deviations, investigations, Corrective and Preventive Actions), identify trends, and monitor progress. Other electronic quality systems that intersect with this system include the newly instituted Quality Training Program—replete with quality course content in various media formats—and the Company Wide Incident Management System (CWIMS). CWIMS is a custom-made software that tracks and trends reference and documentary standard complaints and queries. This system enables USP to respond more consistently and timely to customers in order to meet and exceed their expectations.

Given that the concept of quality is based on continuous improvement, in the next cycle USP is committed to further strengthening quality by building it into the USP work processes in a cross-cutting fashion. To this end, “Passion for Quality” is one of the new Core Values that USP will hold as an essential guiding principle for all staff. In order to build quality into USP processes in a way that provides the most value to the organization and our customers, QA is introducing and institutionalizing Business Process Management as a method to clearly visualize processes in order to simplify them and to identify opportunities for improvement. USP is also focusing on improvements to its document management system and to the content and availability of its training programs. These improvements are being implemented as single-source global systems, thus ensuring unified processes. USP will also expand its Quality System footprint by adding the Center for Pharmaceutical Advancement and Training (CePAT) facility located in Accra, Ghana to our global ISO 9001 certification.

This process focused strategy and globalization effort will allow USP to continue on the path it has established in the 2010–2015 cycle while setting the stage for expanded growth and improvement of its quality systems.
Resource Assessment

USP has increased its investment in quality systems over the last cycle, bringing in new leadership for the QA function and steadily growing the department in order to better integrate QA into USP’s standards-setting and other processes. USP is prepared to continue these investments as it seeks to continuously improve the quality of its products and services and build a culture committed to quality.
PROPOSED RESOLUTION 4 WORKSHEET

USP’S QUALITY SYSTEMS

Comments on Text of Resolution

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USP will cultivate a robust research and innovation culture and operationalize a function that will allow USP to continuously assess new technologies and capabilities relevant to its standards-setting activities, and to identify, prioritize, evaluate and develop new opportunities that respond to the needs of USP’s stakeholders and further its mission.

Background:

Over its nearly 200 year history, USP has evolved as an organization to help ensure the quality and safety of medicines and foods in a changing national and global environment. Throughout this time, there have been periods of significant transformation and adaptation for the organization in its standards-setting work and allied compendial activities; and this transformation continues to this day. In order to continue to evolve to meet public health needs in today’s rapidly changing healthcare environment, USP must have the ability to continuously assess new and emerging technologies as well as potential new standards-setting opportunities. Examples of the kinds of issues that have arisen in this regard include the role of spectral libraries in the broader quality landscape, the implication of changing manufacturing practices on USP quality standards, and the potential role for USP in developing standards for companion diagnostics or other devices.

This resolution encourages USP to establish a formal research and innovation function within the organization that can operate in two ways:

- To create a scientific, technical support function that can be leveraged across the organization in order to achieve more effective execution of standards-setting activities.
  - Assessing new/alternative technology and capabilities
  - Supporting components that need technology support for future technology evaluation and adoption

- To systematically investigate new scientific and standards-setting opportunities.
  - Identifying, evaluating and developing new opportunities with an objective to addressing unmet public health needs and increasing USP’s long-term impact and sustainability
  - Proactively evaluating disruptive technologies to determine implications for USP

Beyond establishing this function within USP, the resolution encourages USP to more broadly cultivate an organizational culture which recognizes that innovation and ideas can come from all USP staff and stakeholders, and encourages the contribution of these ideas. Finally, USP is encouraged to set clear goals in these areas that are transparent and measurable.

Resource Assessment

While establishing this new function will require some additional resources, USP believes it can leverage its existing scientific and laboratory staff and equipment, and also utilize Expert Panels and other volunteer resources, to assist in this effort. Prioritization of new opportunities will be important to ensure effective use and allocation of resources.
PROPOSED RESOLUTION 5 WORKSHEET
RESEARCH AND INNOVATION WITHIN USP

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PROPOSED RESOLUTION 6
STANDARDS FOR BIOLOGICAL MEDICINES

USP will work with stakeholders to develop quality standards for biological medicines, ensuring that innovation and availability are facilitated and complemented.

Background

USP has been setting standards for biological medicines since early in the 20th century, even predating licensure of these medicines through any of the current approval pathways. The broad impact of modern biotechnology and the reality of global supply chains have since significantly changed the landscape in this part of the pharmaceutical industry. Since the early 1980s and in keeping with these developments, USP has incrementally increased its involvement in standards for biologics, including the early and timely development of standards for advanced therapies (e.g., cell, gene, and tissue therapies). This increasing commitment has been reflected in both a growth in the number of relevant Expert Committees and a diversification of expertise therein. In parallel, USP has been able to build staff expertise, a supporting laboratory network, and key enabling partnerships with other standards-setting organizations globally.

As USP enters its bicentennial cycle, the biologics arena is at the cusp of another inflection point, as key first- and second-generation biotechnology products are coming off patent and fueling rapid growth in the global biosimilars market. At the same time, manufacturing and analytical technologies for key product classes including monoclonal antibodies have matured and become accessible to platform approaches that are amenable to the application of broadly relevant analytical measurement standards. While these broader standards are growing in importance, USP also has a long history of developing product-specific standards (monographs), and continues to see value in an appropriate evolution of monographs, especially in an increasingly complex global manufacturing space. FDA as well as some manufacturers dispute the value of monographs, and have voiced concerns that monographs may constrain regulatory flexibility or inhibit innovation. Many manufacturers, however, support USP monographs and voluntarily donate information and materials to enable development of these standards. USP understands that development of biologic standards, particularly monographs, calls for a proactive dialog with regulators and industry stakeholders to clearly delineate the role and use of these standards within the quality and regulatory environments and ensure that they facilitate, rather than hinder, product innovation. Consideration should be given to impact, relevance, approach, and implementation pathways. USP remains convinced that a portfolio of general and more specific public standards, developed with stakeholder input, can serve as a reliable repository of trusted information that can support manufacturers’ quality systems, complement regulatory approaches, and help foster ongoing development of lifesaving medicines.

Over the past year, USP has engaged in an extensive strategic planning exercise related to biologics, intended to identify future focus areas for USP. Based on the 2015–2020 Strategic Plan, priority will be given to standards that can broadly support the quality of these medicines throughout their life cycle, including measurement standards and standards for ancillary and process materials used in biologics manufacturing while continuing the commitment to develop and maintain modern product-relevant standards. This will require a strong commitment to continuing to build broad expertise, in terms of both volunteers and scientific staff, to maintain an increasingly complex—but vitally important—portfolio of standards. This Resolution encourages USP to continue its efforts in the biologics arena, in accordance with its strategic plan, while recognizing the importance of ongoing interactions with key stakeholders to promote alignment and ensure that USP’s standards best serve public health.
Resource Assessment

USP intends to increase its investment in this area given its growing importance, and this investment is reflected in the 2015–2020 Strategic Plan. USP is also working to ensure that it has the appropriate expertise on its biologics Expert Committees to support USP's evolving activities in this area. However, these resources will need to be supplemented through collaborative work with industry and other stakeholders, including the use of Expert Panels to help develop and test new analytical methods, and this collaboration will be critical for USP to be successful in expanding its biologics standards.
PROPOSED RESOLUTION 6 WORKSHEET
STANDARDS FOR BIOLOGICAL MEDICINES

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PROPOSED RESOLUTION 7
QUALITY STANDARDS FOR COMPOUNDED MEDICINES

USP will continue working with stakeholders to develop and maintain practice and quality standards for sterile and non-sterile compounding. USP will increase the availability of its compounding standards, expand stakeholder outreach and education, and promote adoption of these standards by compounding professionals and regulatory authorities.

Background

The first United States Pharmacopeia (USP) published in 1820 contained 217 compounding “recipes” to promote uniformity in drugs. Although the USP today primarily contains standards for manufactured medicines, compounding remains an integral practice in healthcare in providing much-needed therapies to patients for whom there is no suitable commercial product and in the event of drug shortages.

USP’s general chapters on nonsterile and sterile compounding provide important quality and practice standards to promote quality preparation of medications and prevent harm to patients. Compounding monographs provide standardized formulas and concentrations and the majority of the monographs contain beyond-use dating supported by stability studies.

USP’s general chapters on compounding are recognized in federal law, initially in the Food and Drug Administration Modernization Act of 1997 and reinforced in the Drug Quality and Security Act of 2013. According to the most recent National Association of Boards of Pharmacy Survey of Pharmacy Law, 36 jurisdictions report that they currently recognize General Chapter <797> Pharmaceutical Compounding – Sterile Preparations in state law or regulations, another 5 report that they have adopted statutes or rules that parallel USP with only a few deviations, and another 3 report that they consider USP the standard of care, for a total of 44 jurisdictions that enforce this standard for pharmacies compounding sterile preparations. One additional state has regulations pending to require USP.

USP makes its compounding standards available through the USP Compounding Compendium, which offers compounding practitioners access to all compounding-related general chapters and monographs from the United States Pharmacopeia and the National Formulary (USP–NF). It is delivered as an electronic publication in PDF format that is updated with the release of each new USP–NF edition and supplement.

This Resolution continues and expands on a 2010–2015 Resolution that called on USP to develop and revise compounding standards as well as to conduct outreach to educate practitioners, regulators and other policymakers, and the public on compounding of quality preparations. It also reflects USP’s newly adopted 2015–2020 Strategic Plan, which reaffirms USP’s commitment to compounding. This Resolution urges USP to continue its development of compounding standards and to encourage adoption of these standards by professional associations, accreditation organizations, and regulatory bodies.
Resource Assessment

This Resolution will require continued investment of resources by USP, including funding stability studies necessary to support the development of compounding preparation monographs. USP will need to find effective ways of identifying and prioritizing monographs to be developed, to ensure the best use of these funds. USP will also need to invest in additional communications, education, and training programs to increase awareness and use of its compounding standards. Collaboration with key stakeholders including practitioners, professional associations, accrediting organizations, and schools of pharmacy and medicine, as well as FDA and state pharmacy and medical boards, will be critical.
PROPOSED RESOLUTION 7 WORKSHEET
QUALITY STANDARDS FOR COMPOUNDED MEDICINES

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PROPOSED RESOLUTION 8
HEALTHCARE QUALITY STANDARDS

USP will collaborate with stakeholders to develop, strengthen, revise, and promote adoption of healthcare quality standards that address quality and safety related to the use of medications and that are of value to patients and practitioners.

Background

USP has a long history of developing healthcare-oriented standards, beginning in the mid-1800s with the US Dispensatory, which was published by the two primary authors of the USP, Franklin Bache and George Wood. In the current USP–NF, practice-oriented standards are published as general chapters, and many have been recognized in state and federal regulations. In the 2010–2015 Convention cycle, Resolution 9 encouraged USP to pursue additional practice-oriented standards. General Chapter <17> Prescription Container Labeling (official May 2012) was developed in response to a request from the Institute of Medicine and has already been adopted in pharmacy regulations in several states and in national chain pharmacies. General Chapter <1066> Physical Environments that Promote Safe Medication Use (official 2010) has been adapted and incorporated in the Agency for Healthcare Research and Quality Safety Risk Assessment Tool. In addition, the core concept of <1066> medication safety zones has been voluntarily adapted in many U.S. healthcare facilities.

USP also continues to revise and update the USP Medicare Model Guidelines (USP MMG), fulfilling its statutory role in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (42 U.S.C. §1395w–104(b)(3)(C)(ii)). This non-compendial standard has provided a formulary classification model for Medicare Part D health plans for the past 10 years, and subsequently has been utilized in other federal legislation and regulations, including the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. §355(u)(3)(A)) and in the Affordable Care Act rule-making related to the Essential Health Benefit of Prescription Drugs.

The 2015–2020 Strategic Plan adopted by USP’s Board of Trustees calls for USP’s Healthcare Quality Expert Committee to continue to undertake standards-setting activities that leverage USP’s unique capabilities and respond to the needs of USP’s constituencies, prioritizing activities that are expected to have a strong public health impact. The current healthcare reform in the United States also presents some opportunities for practitioner-oriented standards. Discussions with stakeholders during the 2010–2015 Convention cycle have identified several key areas for potential standards development, including:

- Creation and revision of standards to foster patient-centered approaches to safe and effective use of medicines, building upon the concepts of health literacy, reduction of health disparities, and enhanced patient engagement.
- Creation of standards that support safe medication use to accompany technological advancements in healthcare, including the digitization of healthcare (e.g., electronic health records) and innovation in drug development (e.g., biosimilars, precision medicine, medical foods, parenteral nutrition).
- Creation of standards that address quality and safety issues related to the use of medications arising from implementation of national healthcare reform initiatives, such as creating a national formulary model for all outpatient drugs and developing drug allergy/intolerance classes to assist in electronic health records.
This Resolution encourages USP to continue to explore these and other areas of possibility, working carefully with healthcare practitioners and their respective organizations, and other stakeholders to ensure that needs are met rather than burdens added. Careful work with regulatory authorities and other conformity assessment bodies that might adopt USP-generated standards also will be critical.

**Resource Assessment**

This Resolution may require additional resources at both the staff and volunteer expert levels, depending on the standards developed in this area. Research and careful review and evaluation of standards-setting opportunities will be needed, taking into account the perspectives of healthcare practitioners and other stakeholders, to ensure that resources are invested in activities that fulfill stakeholder needs and have significant public health impact.
PROPOSED RESOLUTION 8 WORKSHEET
HEALTHCARE QUALITY STANDARDS

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PROPOSED RESOLUTION 9
QUALITY STANDARDS FOR DIETARY SUPPLEMENTS

USP will expand development of standards for dietary supplements, focusing on new and high-impact areas, and engage with stakeholders to promote the adoption of such standards.

Background

In 1995, following the enactment of Dietary Supplement Health and Education Act (DSHEA), the USP Convention adopted Resolution 12, which "encouraged the USP to explore the feasibility and advisability of establishing standards and developing information concerning dietary supplements." This Resolution resulted in a distinct section of USP for dietary supplement monographs, with allied USP Reference Standards. In 2010, the USP Convention adopted Resolution 7 to "Promote the Availability, Use and Recognition of Quality Standards for Dietary Supplements". Pursuant to this Resolution, USP has continued its efforts to develop new standards for dietary supplements in collaboration with stakeholders, and utilized workshops and other outreach opportunities to promote use and recognition of compendial standards. To further these efforts, in 2009 USP introduced the USP Dietary Supplements Compendium (DSC), with a second edition published in 2012 and the third edition to be released in 2015.

The market for dietary supplements is estimated to be $100 billion worldwide, and is rapidly growing as consumers of all ages are focusing on preventive health. An aging consumer population worldwide increasingly sees dietary supplements as one of the tools necessary to maintain a healthy and active lifestyle. Novel dosage forms like “gummies” and “chews” that satisfy consumer preferences, and new dietary ingredients that deliver promises of improved nutrition and health benefits, are continuously being introduced. At the same time, adulteration of dietary supplements has increased dramatically in recent years, and concerns about the quality and consistency of these products continues to grow, highlighting the need for public standards that can provide assurance to consumers and practitioners.

To meet this important public health need, USP’s new 2015–2020 Strategic Plan calls for increased development of quality standards for dietary supplements, focusing especially on high-impact areas, such as new dosage forms and dietary ingredients, and analytical methodologies that can help address the challenges of adulteration. Over the next cycle, USP intends to significantly ramp up development of these standards.

At the same time, USP must work proactively in concert with manufacturers, regulatory agencies, practitioners, and other stakeholders to promote the use of its standards. Given the current voluntary nature of USP’s dietary supplement standards, USP must partner with manufacturers and regulators to encourage adoption and recognition. USP’s Verification Program can also play a key role for manufacturers who want to provide assurance to consumers that their products meet USP’s quality standards, and USP should help grow consumer awareness of and demand for USP-verified and USP-compliant products. Through these efforts, USP can increase the availability of high-quality dietary supplements, and protect the public against the risks associated with substandard and adulterated supplement products.
Resource Assessment

USP's 2015–2020 Strategic Plan calls for increased resources to support the expanded development of dietary supplement standards. USP will also need to ensure that it has sufficient expertise and capacity within its Expert Committees and Expert Panels to address key topics such as novel dosage forms and adulteration. Prioritization of standards based on impact will also be important. USP will need to invest resources in expanded outreach to manufacturers, FDA and other regulators, practitioners, and consumers to increase awareness and encourage use of its standards.
PROPOSED RESOLUTION 9 WORKSHEET
QUALITY STANDARDS FOR DIETARY SUPPLEMENTS

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PROPOSED RESOLUTION 10
FOOD QUALITY AND SAFETY

USP will continue developing standards to improve the quality and safety of foods, including foods for vulnerable populations, and identify new products and services to meet the needs of stakeholders and increase USP’s public health impact.

Background

From its inception in the early 1960s, the Food Chemicals Codex (FCC) has been the authoritative source for quality standards for food ingredients. Since acquiring the FCC in 2006, USP has worked to expand and strengthen these standards, and encourage their adoption by industry and regulators.

The global food industry innovates at a rapid pace to meet consumer demands. Demand for packaged foods in particular continues to grow as more people move to cities and rely on the availability of packaged food, the growing global middle class increasingly desires the convenience of packaged food, and an aging population increasingly relies on specially adapted foods to serve their dietary needs. The need for high-quality food ingredients to manufacture those packaged foods will only increase in the years to come. In today’s global marketplace, food ingredients are shipped over ever longer and more complex supply chains, adding to the need for quality standards to verify the purity and authenticity of food ingredients at any point in the supply chain. An FCC that is kept up-to-date, where new and novel ingredients are continuously added as needed, is critical to help ensure the quality and safety of the foods we consume.

The development of standards for ingredients specific to medical foods warrants particular attention, to help protect the sensitive but currently underserved community whose daily lives and well-being depend on such specially formulated foods. Medical foods are a very special category crossing the areas of medicine, dietary supplements, and foods. USP is uniquely positioned, as it can draw on expertise from all these industry segments to investigate how best to develop standards that will help maintain and increase the quality, safety, and efficacy of medical foods to better serve the segment of our population that relies on these products for their health and survival.

Beyond the development of standards, the rapidly changing foods landscape will require USP to consider the development of new products and services to meet the needs of USP’s stakeholders. Under its 2015–2020 Strategic Plan, USP intends to pursue new activities that aim to establish USP as a recognized thought leader in food safety; a convener of scientific experts from industry, regulators, academia, and other segments to explore food safety issues; and a provider of information and tools that help stakeholders address the risks of contamination and adulteration and other threats to food safety.

Resource Assessment

USP does not believe that additional resources will be required for its standards-setting activities in this area, and intends to refocus existing resources on high-impact areas. Resources will be required to develop new products and services as called for by this Resolution, but as USP pursues these opportunities it will carefully monitor the progress of these initiatives against established milestones to evaluate their impact and sustainability and determine whether ongoing investment is warranted.
PROPOSED RESOLUTION 10 WORKSHEET
FOOD QUALITY AND SAFETY

Comments on Text of Resolution

NOTES:
USP will increase its commitment to global public health by advocating for the use of quality standards around the world, enabling access to relevant standards, and working through global partnerships to strengthen systems that ensure access to quality foods and medicines.

**Background**

In accordance with its mission to “improve global health,” USP has for many years been increasing its engagement with public health concerns outside of the United States. USP’s Global Health Impact Programs and related initiatives have helped pave the way for the effective use of public standards around the world, by strengthening regulatory systems in developing countries to facilitate quality control activities, working with emerging manufacturers to increase the world’s supply of quality medicines, and making reference materials available to partners who couldn’t otherwise afford them.

Current programs include USP training and capacity-building programs, including those offered through the USP-maintained Network of Official Medicines Control Laboratories (NOMCoL), and at the Center for Pharmaceutical Advancement and Training (CePAT) in Accra, Ghana. These programs help ensure that representatives of regulatory agencies and manufacturers are proficient in Good Manufacturing Practices, dossier evaluation, drug quality control, and other essential topics. Similarly, the Promoting the Quality of Medicines (PQM) program funded by USAID helps build capacity and strengthens quality control systems around the world, even while increasing the supply of quality-assured medicines by supporting new manufacturers to improve the quality of their processes and product. USP’s Technical Assistance Program (TAP) continues to provide USP Reference Standards to national quality control laboratories in developing countries at a reduced cost or free of charge.

In alignment with the 2015–2020 Strategic Plan, USP also is exploring ways to address global public health needs through its standards-setting activities and through new partnerships that focus on larger system issues and global supply chain challenges. USP is developing a targeted and collaborative approach to creating public standards for the world’s most essential medicines where such standards are not available elsewhere. The provision of specialized testing services on behalf of foreign regulatory agencies is being considered as another approach to boost global capacity for medicines surveillance and quality assurance. Through the Quality Medicines Alliance initiative and other efforts, USP seeks to generate greater visibility for the role standards play in ensuring quality medicines, and to mobilize new partners and resources to tackle the growing challenge of counterfeit and substandard drugs.

This Resolution would build on the 2010–2015 Resolution to assess the feasibility and advisability of advancing global public health initiatives, and expand USP’s resources for these initiatives. To fulfill its global mission, and realize the full potential of the organization’s standards-setting role, USP will build new partnerships and embrace a broader range of related and supporting activities around the world.
Resource Assessment

USP has steadily invested in its global public health programs over the last cycle. It intends to continue to invest in this area, while also pursuing new funding sources for these activities and developing new partnerships and collaborations that can support and magnify USP’s public health impact.
PROPOSED RESOLUTION 11 WORKSHEET
USP’S GLOBAL PUBLIC HEALTH IMPACT

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Part III
Appendices
APPENDIX A. EXCERPTS FROM THE USP BYLAWS PERTAINING TO THE COUNCIL OF THE CONVENTION

BYLAWS

Adopted by the USP Convention membership on April 24, 2010.

ARTICLE IX. COUNCIL OF THE CONVENTION

Section 1. Duties.

There shall be a Council of the Convention which shall have the following general duties:

a. Developing rules and procedures for inviting Voting Organizational Members, including criteria for membership and procedures for removing Voting Organizational Members for cause as defined in Article III, Section 7;

b. Recommending the invitation of additional Voting Organizational Members or the removal of Voting Organizational Members to the Board of Trustees in accordance with the established rules and procedures;

c. Establishing criteria for organizations to be invited as Observers to the Convention, inviting organizations to become Observers pursuant to such criteria, and developing rules and procedures for Observer participation;

d. Developing resolutions that advance the purposes of the Convention set forth in Article II for the Voting Members to approve based on input from the Membership, the Board and, where appropriate, the Council of Experts. The proposed resolutions shall be submitted to the Board and Council of Experts for a resource assessment and provided to the Membership along with the findings of the Board and Council of Experts by electronic mail or by a link to the USP website not later than thirty (30) days prior to the Regular Membership Meeting; and

e. Developing approaches and mechanisms for engaging and communicating with the Membership in the periods between Regular Membership Meetings.

Section 2. Number, Term and Qualifications.

The Council of the Convention shall be composed of not more than twenty-five (25) persons who are (i) Delegates or other representatives of Voting Organizational Members, or (ii) Voting At Large Members. The Council shall include at least one Voting Organizational Member representative from each category of Voting Organizational Member specified in Article III, Section 1a(i) above. The Council of the Convention members shall be appointed by the President in consultation with the EVP–CEO and subject to the approval of the Board of Trustees. The President of the Convention shall be the Chair of the Council of the Convention. The Council of the Convention shall be organized not later than six months after the Regular Membership Meeting and its members shall continue in office until adjournment of the next Regular Membership Meeting or until their successors are appointed.
Section 3. Rules.

The Council of the Convention shall adopt rules and procedures for its own governance and to carry out its duties as described above. Prior to adoption, the proposed rules and procedures shall be submitted to the Governance Committee of the Convention for review and to the Board for approval as set forth in Article X, Section 1c.
APPENDIX B. RESOLUTIONS REVIEW PROCESS

The Resolutions review process is as follows:

• Each submission will be acknowledged and evaluated for completeness by USP staff. Staff will consult with the submitter to obtain additional information/rationale, if needed.

• Depending on volume and at reasonable intervals, complete submissions will be forwarded to the Council of the Convention (CoC) within the Resolutions portal with a completed staff evaluation and recommendation.

• After reviewing the submissions and staff recommendations, CoC members will indicate whether they agree or disagree with the assessment. They may also combine concepts of several proposals into one Resolution proposal. The CoC will vote on each submission.

• The CoC will determine the working group for each approved proposal to help develop the final language for the CoC’s Reports.

• Staff will develop background and rationale statements for any proposals that are approved by the CoC for consideration at the Convention.

• Staff will inform submitters of the final disposition of their submission.

• The CoC will receive resource assessments from the Board of Trustees as well as the Council of Experts regarding the impact any Resolution would have on USP’s financial or scientific resources. The CoC will include this assessment in their reports.

• The CoC as a whole approves the Resolutions as crafted by the working groups and the Resolution Reports before they are published for public review.

In order to complete a thorough evaluation of each Resolution, a core group of relevant staff will be assembled to make an informed judgment about the submissions. The Secretary to the Convention and the Member and Professional Relations department will serve as staff liaisons to the CoC.
APPENDIX C. COUNCIL OF THE CONVENTION
WORKING GROUPS

The following is a list of the working groups for each Resolution proposal.

Resolution Proposal 1 — Collaboration with the U.S. Food and Drug Administration

Working Group:
John S. Punzi, Ph.D., Consumer Healthcare Products Association
Adam Gibson, Health Canada Natural Health Products Directorate
Pallavi Nithyanandan, Ph.D., U.S. Food and Drug Administration

Resolution Proposal 2 — USP–NF Monograph Modernization

Working Group:
John S. Punzi, Ph.D., Consumer Healthcare Products Association
David R. Taft, Ph.D., Long Island University Arnold and Marie Schwartz College of Pharmacy

Resolution Proposal 3 — Globally Harmonized Standards

Working Group:
Rita Munley Gallagher, Ph.D., R.N., American Nurses Association
Hanan J. Sboul, M.B.A., C.A.E., Jordan Assn of Manufacturers of Pharmaceuticals and Medical Appliances

Resolution Proposal 4 — USP’s Quality Systems

Working Group:
Thomas E. Menighan, R.Ph., M.B.A., F.A.Ph.A., American Pharmacists Association
Timothy R. Franson, B.S.Pharm., M.D., USP Convention President
Resolution Proposal 5 — Research and Innovation within USP

Working Group:

Rita Munley Gallagher, Ph.D., R.N., American Nurses Association
Hanan J. Sboul, M.B.A., C.A.E., Jordan Assn of Manufacturers of Pharmaceuticals and Medical Appliances

Resolution Proposal 6 — Standards for Biological Medicines

Working Group:

Rita Munley Gallagher, Ph.D., R.N., American Nurses Association
Thomas E. Menighan, R.Ph., M.B.A., F.A.Ph.A., American Pharmacists Association
Elizabeth Scott Russell, R.Ph., National Association of Boards of Pharmacy

Resolution Proposal 7 — Quality Standards for Compounded Medicines

Working Group:

Michael A. Moné, J.D., R.Ph., F.A.Ph.A., Florida State Pharmacy Association
Elizabeth Scott Russell, R.Ph., National Association of Boards of Pharmacy
Donald C. Sawyer, D.V.M., Ph.D., American Veterinary Medical Association

Resolution Proposal 8 — Healthcare Quality Standards

Working Group:

Elizabeth Scott Russell, R.Ph., National Association of Boards of Pharmacy
David R. Taft, Ph.D., Long Island University Arnold and Marie Schwartz College of Pharmacy
Resolution Proposal 9 — Quality Standards for Dietary Supplements

Working Group:
Charles W. Maas, M.D., M.P.H., California Medical Association
John S. Punzi, Ph.D., Consumer Healthcare Products Association

Resolution Proposal 10 — Food Quality and Safety

Working Group:
Charles W. Maas, M.D., M.P.H., California Medical Association
John S. Punzi, Ph.D., Consumer Healthcare Products Association

Resolution Proposal 11 — USP’s Global Public Health Impact

Working Group:
Council of the Convention as a whole