Renowned Experts in Global Health, Medicine, Pharmacy and Food Named to Board of Trustees

Robert L. Buchanan, Ph.D.
Michael D. Maves, M.D., M.B.A.
Thomas E. Menighan, B.S.Pharm., M.B.A., FAPhA, Sc.D.
Jeffrey L. Sturchio, Ph.D.

Adding to a distinguished roster of experts, USP recently named four new members to its Board of Trustees. These new appointments will help guide the organization in its work to advance the quality of medicines and foods in the United States and worldwide.

The USP Board makes decisions that guide the organization’s policies, finances and strategic direction. The newly appointed members are:

Robert L. Buchanan, Ph.D.: Professor & Director, Center for Food Safety and Security Systems, University of Maryland—Dr. Buchanan has 30 years of experience teaching, conducting research in food safety, and working at the interface between science and public health policy—first in academia, then in government service in both the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA), and most recently at the University of Maryland. He has published extensively on a range of subjects related to food safety, and is one of the co-developers of the widely used USDA Pathogen Modeling Program. Dr. Buchanan has served on numerous national and international advisory bodies including in his role as a permanent member of the International Commission on Microbiological Specification for Foods and as the U.S. Delegate to the Codex Alimentarius Committee on Food Hygiene for 10 years. Dr. Buchanan is an At-Large Trustee of the USP Board.

Michael D. Maves, M.D., M.B.A.: Former Executive Vice President-Chief Executive Officer, American Medical Association (AMA)—A board-certified otolaryngologist, Dr. Maves distinguished himself in academic circles as professor and chairman, Department of Otolaryngology–HNS at Saint Louis University College of Medicine. Prior to joining AMA, where he served as executive vice president-CEO from 2001 to 2011, he was executive vice president of the American Academy of Otolaryngology–HNS. He previously headed the Consumer Healthcare Products Association, a 120-year-old trade organization representing

Continued on back cover. See Board of Trustees ≥
For USP, Evolving a “Tried and True” Approach to Better Meet the Needs of Those Most in Need throughout the World

For this issue’s CEO Column, Dr. Roger L. Williams has invited USP Chief Operating Officer Brian Hendrix to discuss a new avenue of activity for USP.

Development. Philanthropy. Fundraising. Those are all familiar words in nonprofit and academic circles, but they are relatively recent additions to USP’s vocabulary. That may seem odd, but USP is unusual in how we do what we do. USP’s operating model depends not on donations or membership dues, but rather on selling products and services that serve a unique public health need. Through these sales, we achieve our mission to improve the health of people around the world through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods. Other nonprofit organizations talk about establishing “non-dues revenue streams” or “diversified funding models” are really trying to work toward our own operating model. In some ways, the decision to sell reference standards in the 1980s was many years ahead of its time, just as was creation of the first Pharmacopoeia of the United States of America in 1820.

USP’s operating model gives us distinct advantages—and was of great relief to me during the recession of 2009, when other nonprofit organizations experienced wrenching reductions of great relief to me during the recession of 2009, when other nonprofit organizations experienced wrenching reductions and layoffs from which many still have not recovered today. But a delivery model such as ours really works best in affluent, industrialized countries. What about the rest or the world? No one should ever argue that poor people deserve poor-quality medicines, yet our tried and true model may not adequately serve parts of the world that are most in need.

USP has tremendous freedom to operate since it is a non-governmental body. We can work throughout the world, with all who are interested, to improve processes, standards and technology that affect the quality of medicines that are delivered to patients. Technology alone is a special challenge since pirates and counterfeiters are often better equipped (and funded) than patients. Technology alone is a special challenge since pirates and counterfeiters are often better equipped (and funded) than patients. Technology alone is a special challenge since pirates and counterfeiters are often better equipped (and funded) than patients. Technology alone is a special challenge since pirates and counterfeiters are often better equipped (and funded) than patients. Technology alone is a special challenge since pirates and counterfeiters are often better equipped (and funded) than patients. 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So how might USP make our standards broadly available to all countries that have an interest in ensuring that their citizens receive the best medicines? Look back to the first three words in this column.

Over the years, USP has talked about philanthropy as a means to fund activities that either a) are not part of our core compendial activities or b) need start-up funding to build a case and demonstrate potential. Sometimes we chose between reinvesting in the core activities and funding other activities that could have positive global impact. As USP has grown, our non-compendial programs are largely self-funding and we increase our annual investments into the core activities—but global needs exist and increase every year. At this junction I note that core compendial activities increasingly demand major income support. The task of a nonprofit body in producing and maintaining these standards in USP’s compendia, without receipt of any tax dollars—unlike all other pharmacopeias of the world—grows yearly. Nearly all of USP’s income from sales of its standards must be thus returned to support those standards.

USP currently engages in modest philanthropic activities that it can fund out of current operations. Over the past decade, these include the Visiting Scientist Program, which connects us to the world and helps builds capacity in other countries to apply in their regulatory framework. We also offer fellowships and internships (see www.usp.org/aboutUSP/careers/ for more information). Perhaps the most significant recent philanthropic activity is the Technical Assistance Program (TAP), which allows countries’ official medicine control laboratories, typically part of or closely related to Ministries of Health and their regulatory agencies, to receive deeply discounted or free documentary and physical standards along with pharmacopeial education classes from USP. Discounts are based on income figures published by the World Bank—affluent countries pay full price and the poorest countries receive publications and materials for free, with a sliding scale between the two points. We have products on the ground in five sub-Saharan countries and Egypt with hopes of further expansion in fiscal year 2012. The educational component of this program is particularly popular, as a recent TAP educational seminar sponsored in Accra, Ghana, demonstrated (see article on page 13).

To date, our philanthropic efforts have been small but carry the potential for huge impact. Imagine the possibilities that external funding could provide! At its May 2011 meeting, the USP Board of Trustees did just that and approved the creation of a development function at USP. During fiscal year 2012, USP will hire a Vice President of Development to begin work in this area, reporting to me as COO. Initially, we will “mine” USP for impactful activities that might be amplified with outside funding. We will also contact large foundations and other donors to assess the interest in funding our activities. Reputation and relationships are the keys to a successful development function. The first exists and the second can be built. The goal for fiscal year 2012 will be to obtain outside philanthropic funding for at least two programs at USP and to set the stage for even larger philanthropic activities in future years.

Brian L. Hendrix, M.S.
Chief Operating Officer, USP

www.usp.org
In his essay, Dr. Williams writes, “Clearly, public health can no longer be seen as nation-specific. Borders are porous and cross-boundary threats have no respect for political boundaries. “As manufacturing of medicines and foods forges ahead on its globalized path, certain vulnerabilities will be difficult to avoid. This includes, but is not limited to, the threat posed by substandard and counterfeit products,” Dr. Roger L. Williams, chief executive officer of USP, warned in an essay appearing in the June 27, 2011, issue of Chemical & Engineering News (C&EN). Exploring the dynamics of the global pharmaceutical supply chain, its article, “Medicines Quality Faces Challenges: Access, Innovation and Globalization,” appears in the C&EN issue dedicated to the International Year of Chemistry—a year-long celebration focused on chemistry’s contributions to advancing human health and the environment and providing sustainable sources of energy, clean water and advanced materials.

USP “…is focused on the critical intersection where access and innovation meet on the global stage,” Dr. Williams notes. As a scientific, nonprofit public health organization, USP develops quality standards for medicines, enforceable by the U.S. Food and Drug Administration. These are also used by regulators, manufacturers and others involved in healthcare in more than 130 countries. C&EN is the weekly newsmagazine of the American Chemical Society (ACS). With more than 163,000 members, the ACS is the world’s largest scientific society and is the professional home for chemists, chemical engineers and related professionals around the globe.

To help ensure that medicines and their ingredients used around the world are of good quality, USP announced this summer the availability of a free, online collection of voluntary public standards to allow testing of a medicine and its ingredients. These standards appear in the new USP Medicines Compendium (MC). Dr. Roger L. Williams, chief executive officer of USP, wrote about the public health motivation for the MC in the Spring 2011 issue of The Standard.

The MC will support good quality medicines through tests, procedures and acceptance criteria for critical quality attributes. Available at www.usp-nc.org, the MC will include standards for medicines legally marketed in various countries. Initially, the MC will include 10 standards proposed for public comment, and another 11 standards proposed for development.

The first group of standards posted includes those for antimicrobial, antiretroviral (HIV) and contraceptive medicines, among others.

MC standards are voluntary, unless they are adopted by a regulatory authority or otherwise made official. They are intended to support the text and work of other pharmacopoeias, and not supplant it. MC standards may be especially useful for manufacturers who export to countries with scarce regulatory resources and no national pharmacopoeia.

“Public standards help ensure that all manufacturers of a given medicine or ingredient meet the same fundamental requirements, providing a ‘common ground’ that allows practitioners to have confidence in the medicines they prescribe, and patients in the medicines they take. These standards are critical—especially where resources are constrained or absent,” said Dr. Williams. “The USP Medicines Compendium will be offered freely to all, so that it can be used by anyone—not just manufacturers, but purchasers, regulatory agencies and other pharmacopoeias as well, as a means of helping to ensure high-quality medicines. As the only nongovernmental pharmacopoeia in the world, USP is in a special position to develop this compendium—a manifestation of the organization’s global public health mission.” Based on public comment, USP expects the standards to become authorized and final later in 2011, following approval by an Expert Committee of the USP Council of Experts. The written standards, or monographs, included in the MC utilize a novel scientific approach that differs from any other pharmacopoeia. MC standards are Performance Based Monographs (PBM). PBMs allow flexibility by permitting a manufacturer to use the Reference Procedure or other Acceptable Procedures in the monograph. MC standards may include a posting of validation data relied upon to set the standards; this type of disclosure is a special feature of the MC. USP will offer reference materials for monograph tests where needed.

MC standards are created in an open, transparent process similar to that utilized for USP’s other compendia. MC standards will be approved by the Council of Experts—USP’s volunteer, independent, elected body of experts. The initial Expert Committee focusing on the MC is based in the South Asia region, in India, which is a major exporter of medicines to the world. Additional Expert Committees in other regions may be added over time. Standards proposed for inclusion in the MC are available for public review by any interested party for a 90-day comment period before becoming authorized by the MC Expert Committee. At that time, regulators, purchasers, manufacturers, pharmacopoeial bodies or others will be free to utilize these standards. The MC will be updated monthly at www.usp-nc.org.

The standards proposed this summer were acyclovir, acyclovir topical cream, amloclonax, chloroquine oral solution, chloroquine phosphate, chloroquine sulfate, etoricoxib, nelalfivin mesylate, ormetoxilone hydrochloride and stibogluconate sodium. Standards proposed for future development are artesunate tablets, clathromycin, dipyridamylamine hydrochloride, efavirenz, eforsitine for injection, eforsitine hydrochloride, eforsitine topical cream, metofloquine hydrochloride, nelafivin tablets and nelafivin for oral suspension.

USP Standards for Biologics and Biotechnology Products Continue to Evolve
A Q&A with USP’s Vice President of Biologics & Biotechnology
Dr. Tina Morris on Standards and USP’s Upcoming Symposium

As the use of biologic drugs and biotechnology products expands in the therapeutic landscape, the role of public quality standards for these products continues to grow. Over the past several years, USP has developed a comprehensive set of information chapters on biologic development, analysis, and validation. Chapters <1032>, <1033>, <1034>, and <1035> are slated to become official with the First Supplement to USP 35–NF 35. At the Seattle meeting, we will cover implementation of these new chapters as well as example data sets that will be posted to our website before the conference. Industry software experts and bioassay users will have the opportunity to discuss the analysis of these data sets in an interactive session.

Q. How do USP standards for biologics differ from traditional USP standards?
A. Standards for biologics have to cover a much greater variety of molecules than in the chemical world. A “biologic medicine” can be anything from a small peptide to a living cell. This makes it much more challenging to define compendial standards in terms of identity, strength and purity. In this situation it helps to group biologics into product classes, based on the type of molecule or molecule mixture they represent. Within a molecule class, often the same or at least similar analytical approaches can be applied across different products. This is especially true for some of the more modern biologics, like monoclonal antibodies, where so-called “platform approaches” are applied to both manufacturing and analysis. We are trying to capture this thinking in our General Chapter development by creating product class chapters that speak more broadly to the quality attributes and testing expectations within a given product class. We have an expert panel currently working on General Chapter Therapeutic Monoclonal Antibodies <1260> and General Chapter Quality Attributes of Monoclonal Antibodies <129>.

Chapter <129> spells out a clearly defined set of quality expectations. Chapter <129> in turn links to other chapters under <1000> in USP–NF that cover analytical procedures as well as quality expectations for ancillary and process materials. At the product-specific level, there will always be the traditional monograph that spells out the specific quality attributes of a given drug in the market place, but for biologics—due to the complexity of the materials—it is more important than for chemical drugs to undergird the monograph with a broad foundation of general standards. Many of these topics, including data sets developed for potency measurement, will be discussed at our meeting. We are very excited that our monoclonal antibody panel will be reporting on the chapters’ development at this conference.

Q. What are some of the main challenges associated with the development of standards for biologics and biotechnology products?
A. Biologics cover a wide range of drug products, some derived from recombinant (or genetically manipulated) expression technologies, and others still involving the use of natural-sourced material. What they all have in common is that their development and manufacture are based on living material. A manufacturer needs to be concerned about the characterization of a biologic or biotechnology medicine based on tests, procedures and acceptance criteria, but also about the materials used in the earlier stages of manufacturing. These include ancillary materials (e.g., fetal bovine serum) that are often animal-derived and used as supplements for cell growth. While the goal is to remove completely the ancillary material from the drug substance, traces may remain, especially in products with limited downstream processing, such as cell therapies. A USP–NF chapter on <129> spells out a clearly defined set of quality expectations. Chapter <129> in turn links to other chapters under <1000> in USP–NF that cover analytical procedures as well as quality expectations for ancillary and process materials. At the product-specific level, there will always be the traditional monograph that spells out the specific quality attributes of a given drug in the market place, but for biologics—due to the complexity of the materials—it is more important than for chemical drugs to undergird the monograph with a broad foundation of general standards. Many of these topics, including data sets developed for potency measurement, will be discussed at our meeting. We are very excited that our monoclonal antibody panel will be reporting on the chapters’ development at this conference.

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New USP–NF Chapter on Quality Attributes, Functionality Tests Related to Fetal Bovine Serum Becomes Official

Bovine Serum—Quality Attributes and Functionality Tests <90>, became official in USP–NF.

FBS is an example of an “ancillary material”—a biologic component needed for the manufacture of vaccines, cell-, gene-, or tissue-engineered therapies; and several other biotechnology products. Ancillary materials generally are removed from final products once manufacturing is complete. Nevertheless, the quality of materials going into the manufacturing process can still have a direct impact on the quality of the final biologic drug.

FBS is derived from blood that is collected and allowed to clot before being centrifuged (spun in a tube around a central axis so that the more dense components move to the bottom of the tube). The serum is separated from the other blood components, including cells, fibrin and clotting factors. When serum is removed from the clot, it is transferred to labeled containers and frozen. Manufacturers employ sterile filtration before final packaging. Additionally, gamma irradiation is applied to reduce viral and other adventitious agents while still preserving cell growth performance. Screening FBS for viral contamination is accomplished by using all applicable testing described in the Code of Federal Regulations 9 CFR 113.53 (known as full 9 CFR testing). General Chapter <90> includes specific tests that determine the functionality of specific FBS lots and aid in optimizing growth conditions of mammalian cell cultures in the presence of FBS. The first of these tests is the growth-promotion curve, which reflects a measure of the ability of cells to grow when combined with FBS. Because FBS is a supplement for cell culture, cell growth is a straightforward indicator of its functionality. The other functionality test appearing in General Chapter <90> is a clonal assay, a very sensitive test that demonstrates functionality via cell growth and cell survival.

During the development of General Chapter <90>, USP received valuable input from the International Serum Industry Association (ISIA). USP and ISIA currently are working together to develop an associated reference material for FBS that will provide users with access to a highly qualified material for testing. According to Dr. Fouad Atouf, senior scientific director of ISIA, the ISIA reference material is fetal (no more than 500 mg/L of IgG indicates the material is fetal).

The complexity of FBS makes it challenging to characterize, and its complete composition is not defined. However, certain quality attributes are known to apply to all FBS samples. These include:

- Identification characteristics—use of a bovine immuno-globulin G (IgG) antibody to indicate that the material is bovine (no more than 500 mg/L of IgG indicates the material is fetal).
- Hemoglobin content—reflects a quality of processing.
- Osmolality—provides a range of values, indicating a particular balance of sodium and other electrolytes in the serum solution (falling out of this range would be indicative, for example, of the addition of water to dilute serum).

New Dissolution Testing Standard Proposed to Evaluate Liquid-Filled Capsules’ Performance

Liquid-filled capsules. They come in soft-shells. And in hard-shells. They appear with formulations similar to substances found in traditional solid oral dosage forms (perhaps as product line extensions). And as oily or waxy substances that are not as easily formulated as are solid delivery systems.

But what does a manufacturer or quality control specialist do when these capsules need to be tested for dissolution purposes? What are the best, most proper ways to do these tests? That is where the newly proposed USP General Chapter Liquid-Filled Capsules—Dissolution Testing and Quality Attributes <1094> comes in.

Liquid-filled capsules are a common dosage form for drug products as well as dietary supplements including multivitamins, vitamin E, vitamin D, fish oil and other oily products, among others. Dissolution testing is widely used by manufacturers for quality control purposes, to evaluate consistency batch to batch, as well as in product development. Dissolution testing is covered in General Chapter Dissolution <711>. When General Chapter <711> was developed, liquid-filled capsules were not as common a dosage form as they are today. As a result, there was only limited information regarding liquid-filled capsules in the General Chapter. Today, with several large manufacturers of the capsules and much broader acceptance and usage, it is appropriate for USP to provide more guidance in the dissolution testing of these materials. As a harmonized chapter under the Pharmacopeial Discussion Group—which comprises the European Pharmacopoeia, the Japanese Pharmacopoeia, and USP—changes to <711> are more complex than for non-harmonized chapters contained in the USP–NF. Hence, the need for a new chapter arose to cover this dosage form.

The chapter was developed under the guidance of the General Chapters—Dosage Forms Expert Committee. It will be published in an upcoming Pharmacopeial Forum (PF). The basis of the chapter was a Stimuli article published in PF 35(4): 1029–1041, 2009. Comments and suggestions should be sent to Dr. Marques at MRM@usp.org.

Chemical and physical properties of liquid-filled capsules pose unique challenges when manufacturers attempt to develop dissolution methods. This testing requires several special conditions that <711> does not encompass. The issues are complex. Dissolution behavior depends on many things, including the time it takes the capsule to rupture and whether the materials mix readily with the dissolution medium or don’t mix well and, for example, float on the surface. The new chapter also covers quality attributes for liquid-filled capsules that may affect the manufacturing and filling of capsules. These include stability (of both the product formulation and the capsule shell) and storage conditions, among others.

“The chapter is very helpful for parties developing dissolution methods for liquid-filled capsules, highlighting conditions you might not need to think about with other dosage forms,” said Dr. Margareth Marques, senior scientific liaison at USP. “It answers the question of how to develop a meaningful test. That is critical, and ultimately results in developing a better product.”

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Continued Evolution of Compounding Standards a Manifestation of USP’s Commitment to Pharmacists

Through its suite of compounding chapters, USP provides critical guidance to pharmacists who compound preparations designed for individual patients. These standards help ensure the quality of medicines for patients who require customized treatment because of special dosing needs, allergies or other factors. Many patients require compounded medicines in response to drug shortages, or to get access to a drug that is no longer manufactured. Additionally, compounding encompasses sterile preparations such as total parenteral nutrition, which supplies all daily nutritional requirements to patients who cannot eat, and consists of intravenous nutrition pumped through a major vein rather than taking food by mouth.

Over the past few years, USP has reviewed and enhanced several of its compounding chapters. In May 2011, two revised General Chapters became official: Pharmaceutical Compounding—Nonsterile Preparations (<795>) and Quality Assurance in Pharmaceutical Compounding (<1163>). Both contain significant updates designed to ensure the quality of compounded medicines.

General Chapter Pharmaceutical Compounding—Nonsterile Preparations (<795>) provides pharmacists with guidance on applying good compounding practices in the preparation of nonsterile compounded formulations that must be taken to ensure the safety and quality of medicines. The chapter includes new material such as categories of compounding (simple, moderate and complex), new definitions for terms including beyond-use date, hazardous drug and stability, and 15 criteria when compounding each drug preparation (e.g., suitable compounding environment, use of appropriate equipment).

General Chapter Quality Assurance in Pharmaceutical Compounding (<1163>) describes a quality assurance program as a system of steps and actions that must be taken to ensure the maintenance of proper standards in compounded preparations. The revision includes entirely new content with sections on training, physical testing of dosage units, weight and volume, and working with these preparations can put women of child-bearing age at risk of fertility or other reproductive problems.

While guidelines exist from the World Health Organization, other organizations such as American Society of Health-System Pharmacists (ASHP), the National Institute for Occupational Safety and Health (NIOSH), and the American Society of Health-System Pharmacists (ASHP)—as well as in USP General Chapter Pharmaceutical Compounding—Nonsterile Preparations (<795>)—USP is looking to create one comprehensive chapter. USP will also be reviewing information from the World Health Organization, other pharmacopeias and international regulatory agencies as it develops this important chapter. An important point regarding NIOSH and ASHP guidelines is that these are not legally enforceable.

While the context of the chapter is still being developed by USP’s Compounding Expert Committee, USP Scientific Liaison Dr. Rick Stoeckel explained some considerations at play. "Gloves are not enough when working with hazardous drugs. Hazardous drugs must be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal. Additionally, hazardous drugs must be prepared in an appropriate environment."

Beyond these chapters, USP is continuing to look at ways to further enhance its support of compounding pharmacists through quality standards. To do so, USP is considering development of two new General Chapters: Compounding with Hazardous Drugs and Compounding for Investigational Drug Studies. Both reflect realities of compounding pharmacists’ work.

The purpose of Compounding with Hazardous Drugs will be to provide guidelines and recommendations to reduce the potential harmful effects of hazardous drugs on the well-being of healthcare workers when compounding preparations for patient administration. Pharmacy staff working with hazardous drugs can experience adverse health effects when exposed to such drugs when appropriate precautions are not taken. For instance, those working with chemotherapy drugs may be at increased risk of developing cancer themselves if not protected properly. Biodisential hormone replacement therapy is another category of hazardous drugs and working with these preparations can put women of child-bearing age at risk of fertility or other reproductive problems.

While guidelines exist from the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH) and the American Society of Health-System Pharmacists (ASHP) as well as in USP General Chapter Pharmaceutical Compounding—Nonsterile Preparations (<795>), USP is looking to create one comprehensive chapter. USP will also be reviewing information from the World Health Organization, other pharmacopeias and international regulatory agencies as it develops this important chapter. An important point regarding OSHA, NIOSH and ASHP guidelines is that these are not legally enforceable.

The new agreement furthers annual collaborative testing between USP and FDA laboratories of roughly 40 chemical reference standards, primarily for controlled substances. It also promotes joint work to modernize tests and assays in USP’s written, or documentary, standards, and to further develop test methods for handheld instruments that law enforcement inspectors can use to screen drugs in the field for adulteration, contamination and authenticity.

According to Dr. Roger L. Williams, USP’s chief executive officer, “This agreement strengthens the long-standing public-private partnership between FDA and USP, which has its roots in the early years of the 20th century. Pharmaceutical science has advanced dramatically since then—as, unfortunately, have the ability and willingness of some to perpetrate fraud that can result in harmful or deadly medicines. It is vital that quality standards support development of USP written and physical reference standards for the quality, identity, purity and strength of medicines. Both chapters are in their early phases. Please look to future issues of The Standard for more information as these chapters progress.”

Expanded Joint Testing between FDA and USP Laboratories to Strengthen Medicines Quality Under New Agreement

Continuing and expanding a prior pact, USP and the U.S. Food and Drug Administration (FDA) signed a three-year Cooperative Research and Development agreement this spring that supports development of USP written and physical reference standards for the quality, identity, purity and strength of medicines. Both FDA and USP have expertise in this arena, and the collaboration should accelerate development of more accurate and specific technologies.

“This agreement with USP is a good expression of the collaborative history the two organizations have in the interest of protecting public health,” said Carl Sciacchitano, director of FDA’s Division of Field Science within the Office of Regulatory Affairs. “The two organizations’ strong scientific expertise and laboratory capabilities complement each other, and the USP Reference Standards program is an important component of the FDA lab-based regulatory programs and is essential to the pharmaceutical industry. We’re pleased to keep that relationship strong as part of our effort of advancing science and technology.”

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ISO Class 5 environment with protective engineering controls in place and follow aseptic practices specified for the appropriate contamination risk levels. This is just the tip of the iceberg. The chapter will be written for the practicing pharmacist, and is intended to take an A-to-Z approach to setting good standards to protect pharmacy staff as well as others in the pharmacy from often highly toxic drugs.

The purpose of Compounding for Investigational Drug Studies will be to provide guidelines and guidance to compounding pharmacists on preparing investigational new drugs for use in early clinical trials. Today, when pharmaceutical companies develop new products and begin initial testing on very small populations of patients, they may rely on compounding pharmacists to make the preparations they will be using in these early clinical trials. However, these pharmacists are not subject to the same Good Manufacturing Practices pharmaceutical companies are required to adhere to, and both pharmaceutical companies and compounding pharmacists could benefit from standards in this area that guide pharmacists in their environment. Topics in the chapter will likely include materials management, standard operating procedures as part of a quality assurance program, assigning beyond-use dates, packaging and labeling, etc.

Both chapters are in their early phases. Please look to future issues of The Standard for more information as these chapters progress.

Continued on page 12. See Compounding Chapters >
New Standards for Infant Formula/Functional Food Ingredients, Sweeteners and Synthetic Food Dyes to Help Ensure Quality, Purity of Ingredients

Building on a growing collection of quality standards for ingredients of interest and importance to the food industry—including infant formula ingredients, functional food ingredients, sweeteners and food colorings—new specifications were proposed in these categories in June 2011. These standards are available as a resource to manufacturers and suppliers to help ensure the identity, quality and purity of ingredients used in finished foods—both domestically and internationally.

The Food Chemicals Codex (FCC) includes standards for a full range of ingredients used in foods, including colorings, flavorings, nutrients, preservatives, emulsifiers and thickeners, among others. The FCC accommodates any food ingredient or additive that can be legally added to food in the United States or elsewhere, making it a truly international compendium. The FCC Forum is the free-access online vehicle through which USP accepts comments on proposed FCC standards. Food manufacturers and all other interested parties are invited to provide feedback on the latest proposed standards available on the FCC Forum during a 90-day comment period, which closes September 30, 2011. The FCC Forum is accessible at www.usp.org/fcc/fccForum.html.

Highlights from the latest FCC Forum include:

- **Sodium Molybdate**—A source of molybdenum (an essential trace element), this micronutrient source is used in formula designed for older infants and young children as a supplement to food when special dietary needs exist. These are the first known global specifications for this ingredient for use in food. The Institute of Medicine recommends a daily allowance of 45 μg/day. FCC contains standards for a variety of infant formula ingredients, many of which were recently added to the compendium.

- **Docosahexaenoic Acid (DHA)** from Algal (Ulkenia) Oil—An essential omega-3 fatty acid present in fish, this ingredient is added to a variety of functional foods for its purported health benefits. The FCC contains quality standards for DHA from other sources, as well as a standard for arachidonic acid (ARA) oil, a source of the omega-6 fatty acid. These ingredients are commonly used in traditional and functional foods, and some can be used in infant formulas.

- **Nenosperidin Dihydrochalcone (NHDC)**—A plant-based sweetener roughly 340 times sweeter than sugar, this flavor enhancer is used in food and beverages, including soft drinks, chewing gum, dairy products and desserts, among others. It is considered to be effective in masking the bitter tastes of compounds found in citrus. NHDC is approved as a sweetener by the European Union, and holds Generally Recognized as Safe (GRAS) status (through the Flavor and Extract Manufacturers Association) in the United States, though its use in the United States is not prevalent.

- **Three Synthetic Red Color Additives**—Standards for the food dyes Amaranth, Azorubine and Ponceau 4R join a host of synthetic and natural food colors with quality specifications in FCC. These three new color additives are approved for use internationally—including by some European and Asian countries—but are not among the seven synthetic food dyes approved for use in the United States.

“With inferior medicines threatening the lives of citizens every day in Africa, it is essential for governments to be equipped with the tools necessary to accurately gauge the quality of the medicines circulating in their markets. Having a team of scientists trained in essential analytical techniques is a fundamental aspect of a well-functioning regulatory system that protects the domestic drug supply,” said Dr. Patrick Lukulay, director of the Promoting the Quality of Medicines (PQM) Program, a USP-U.S. Agency for International Development program that works in more than 30 countries to help ensure the quality, safety and efficacy of medicines to treat diseases such as malaria and tuberculosis. TAP is a USP initiative that makes USP standards available to promote drug quality in developing countries by leveraging resources toward a common goal.

As Ghana makes strides to address the devastation caused by substandard or fake medications, we are very pleased to host a delegation of countries seeking to do the same,” said Dr. Stephen Opuni, chief executive officer of the Ghana Food and Drugs Board. “This training will enhance our ability to detect such ‘medicines,’ which can cause as much harm as a disease itself.”

The objectives of the training were to 1) improve the technical competence of the scientists; 2) familiarize participants with information contained in the USP–NF and how to utilize the information to effectively perform quality control analysis; and 3) improve capacity and effectiveness of participants to identify poor-quality and counterfeit medicines.

The training was driven by the needs of the attending countries, and having a team of scientists trained in essential analytical techniques is a fundamental aspect of a well-functioning regulatory system that protects the domestic drug supply.”

Scientists from the national laboratories of five African nations gathered in Accra, Ghana, in April 2011 to take part in technical training that provided them with improved capacity to detect substandard and counterfeit medicines. The training—which included participants from Ethiopia, Ghana, Kenya, Senegal and Sierra Leone—is part of a larger Technical Assistance Program (TAP) announced in February 2011 and funded by USP.

Dr. Lukulay with Dr. Opuni of the Ghana Food and Drugs Board at the TAP training.

Under TAP—which is currently a pilot program involving these five sub-Saharan African countries and Egypt but may be expanded in scope—USP is providing a comprehensive package of pharmaceutical reference standards, written documentary standards and technical training to assist these countries in improving the quality of their medicines. Constrained by limited resources, the national laboratories in these nations may resort to using unreliable or outdated standards, and/or may not be equipped to offer their analysts the scientific training required to appropriately analyze medicines. As such, these laboratories may not obtain accurate results when they test questionable samples—a serious gap in quality assurance that can lead to severe health outcomes for patients, including prolonged disease and death. The USP-sponsored training focused on three key topics necessary to appropriately test medicines quality—Fundamentals of High Performance Liquid Chromatography, Microbiology and Effectively Using USP–NF.

In all the participating nations, poor-quality medicines represent a significant public health challenge. In the host country of Ghana, for instance, a recent World Health Organization study found that 39 percent of tested antimarial medicines failed quality testing—for reasons that include insufficient amounts of the active pharmaceutical ingredient (a serious problem that can lead to the rise in drug-resistant disease parasites) and excess levels of problematic impurities.
USP Visiting Scientists Engaged in Broad Range of Compendial Activities

Early this summer, USP welcomed five scientists from Brazil, Ukraine, Egypt and Bolivia through its Visiting Scientists Program (VSP), with additional scientists joining in subsequent months. The goal of the VSP is to promote international harmonization of standards through the exchange of scientific staff and information with organizations committed to pharmacopeial advancement. Through an application and review process that matches VSP candidates to relevant USP projects and technical mentors, the visiting scientists are selected based on skills, experience and related job roles at their home organizations. For three months, each of the following visiting scientists is involved in activities that directly support USP’s ongoing compendial efforts.

Ms. Barbosa Antunes is a biochemical pharmacist with the faculty of pharmaceutical sciences at the University of São Paulo. Working with USP Senior Scientific Liaison for USP General Chapters, Dr. Kahakanab Zaidi, Ms. Barbosa Antunes is evaluating existing wet chemistry approaches associated with traditional metal limits tests. In addition, she is learning about new methods and is gaining knowledge about elemental impurities, which she plans to apply in her work at her laboratory in São Paulo. According to Ms. Barbosa Antunes, “In Brazil, the current demand from industry—especially among small- and medium-sized companies—for guidance on technology related to quality is high.” She looks forward to sharing her newly gained skills with her Brazilian colleagues and hopes to incorporate her USP experiences into future doctoral studies.

Bringing “the spirit of USP” back to the Ukrainian Scientific Pharmacopeial Centre for Quality of Medicines is what Dr. Maryna Dmitrieva plans to do once completing her tenure at USP and returning to her position as head of developmental and implementation of proficiency testing schemes for medicines control laboratories. Working with Mr. Antonio Hernandez-Cardoso, senior scientific liaison for USP General Chapters, Dr. Dmitrieva is engaged in efforts to help modernize documentary standards through literature research on identification tests, by evaluating tests using wet chemistry methods, and by making recommendations based on those evaluations. She also has had an opportunity to learn more about USP’s model for developing documentary standards and reference materials. When asked how she would define “the spirit of USP,” Dr. Dmitrieva describes it as “being excited about being part of a large team” while still being able to focus on individual contributions.

Dr. Emad Mohamed Hussien—a senior scientist in the analytical chemistry department of the National Organization for Drug Control and Research (NODCAR) in Cairo, Egypt—is currently working with Dr. Samir Wahab, director of USP’s separations science laboratory, in support of USP’s efforts to modernize small molecule standards. Dr. Hussien is evaluating a current method that uses open column chromatography to detect the limits of 4-epianhydrorotetraacycline for tetracycline and tetracycline hydrochloride in order to determine if a new procedure is required for generating more reliable and reproducible results. Eager to learn more about standard operating procedures for laboratory practices, document reporting on results and general USP processes, Dr. Hussien hopes to apply the experiences and knowledge he gains at USP in creating a more rigorous standards system at NODCAR.

Under the guidance of Dr. Radhakrishna Trumalai, principal scientific liaison in USP’s documentary standards division, Dr. Juliano Ferreira Silva is working on the identification of objectionable microorganisms in non-stere pharmaceutical dosage forms and the evaluation of appropriate risk-based approaches for eliminating microbial contaminants. A faculty member in pharmaceutical sciences, he works in research and development at the University of São Paulo in Brazil. According to Dr. Ferreira Silva, his experience at USP is the first opportunity he has had to work simultaneously with members of organizational management.

Continued on page 15. See Visiting Scientists →

U.S. and Chinese Standards Setters for Drug Quality Become Mutual Advisors

In an agreement that promises to further advance and harmonize standards for drug quality, leaders of USP and the Chinese Pharmacopoeia Commission (ChP) exchanged appointments in April to serve as special counselors on international affairs to each other’s organization. The unprecedented step builds upon strong relationships that the organizations have built over the past several years, and representatives from key producer and consumer economies, we recognize that improving the harmonization of our standards is vital, and this formal recognition is yet another step in that direction.” Mr. Wu reiterated China’s commitment to improve the quality of medicines domestically and abroad, and he pointed to ChP’s vigorous efforts to advance its standards. “Our organizations have worked together very well over the past several years in a collaborative, respectful fashion, and I value the efforts and expertise of USP as we develop and put in place additional and improved standards for medicines,” he said. “These mutual appointments will help to ensure even closer ties and better and more consistent standards.”

Continued on page 15. See U.S. and Chinese Standards Setters for Drug Quality Become Mutual Advisors →
Liberian Regulatory Authority Recalls Three Counterfeit Antimalarials, PQM Assistance Leads to First Enforcement Action

LMHRA collected 56 samples of antimalarial medicines for quality testing. Thirty-two failed visual inspection or testing by thin-layer chromatography (TLC). TLC tests showed that what appeared to be the three front-line antimalarial medicines—Artesunate 50 mg Tablet (Batch Number 07015FX), Colquine, quinine sulphate syrup 60 ml (Batch Number EQC-10001), and Colquine, quinine sulphate suspension 60 ml (Batch Number EQC-1001)—were counterfeit and contained no antimalarial ingredients. The same batch number was found on the two recalled medicines identified as Colquine, an indicator of product tampering since different dosage forms of the same drug cannot be assigned the same batch number.

In its recall notices, LHMRA directed that all pharmacies, medicines stores, hospitals, clinics and individuals that have purchased or hold stocks of the recalled medicines to return and/or report them to LHMRA’s office in Monrovia. LHMRA said that failure to adhere to the recall would lead to appropriate legal actions. LHMRA will be taking further regulatory actions on counterfeit and other substandard medicines found in the market in the course of implementing LHMRA regulatory policies.

According to Dr. Patrick Lukulay, director of PQM, “Assisting the government of Liberia in drafting medicines regulations for the LMHRA was an important part of helping to build national capacity to protect the Liberian public against counterfeit and substandard medicines. Employing fundamental screening tests like TLC and providing further training to LMHRA on this and other screening methods will augment Liberia’s capabilities to identify poor-quality medicines based on effective and consistent protocols.”

“Counterfeit and substandard medicines, such as the three recalled products, have the potential to create serious health threats to those counting on their medicinal properties to help combat diseases such as malaria,” according to Dr. Clavenda Bright Parker, chair of the board and acting managing director of LMHRA. “LMHRA is committed to working diligently with all our partners in carrying out our vision, which is to establish and operate a medicines and health products regulatory authority of excellence in Liberia that protects public health.”

A new office, managed and run by Ethiopians, will intensify efforts in the east African nation to reduce the burden of substandard and counterfeit medicines for malaria, tuberculosis and HIV/AIDS. The office was opened in late June 2011 and is part of the Promoting the Quality of Medicines (PQM) Program—a U.S. Agency for International Development (USAID) program implemented by USP—which works to help ensure the quality, safety and efficacy of medicines. Activities of the new office will complement the work of the Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA), the country’s regulatory body formed two years ago.

Poor-quality medicines—which may have no active ingredient, the wrong amount of an active ingredient or harmful levels of impurities, among other problems—can lead to prolonged illness and even death, and can contribute to the development of drug-resistant strains of diseases.

Ethiopian staffers will carry out activities in four major areas to help promote quality medicines: 1) post-market surveillance of pharmaceutical products; 2) development of registration guidelines for medicines; 3) Good Manufacturing Practices (GMP) inspection training and development of GMP guidelines; and 4) laboratory training and pursuit of International Organization for Standardization (ISO) laboratory accreditation. One of the major goals will be achieving ISO:17025 accreditation, which helps ensure testing and calibration laboratories are producing consistently valid results. This would make Ethiopia’s national laboratory among the first in sub-Saharan Africa to be ISO:17025 qualified.

With malaria, tuberculosis and other diseases continuing to take a tragic toll in Ethiopia, we are pleased to collaborate with PQM officials to help protect the health of our citizens,” said Mr. Denekew Yehuleu Alamneh, director-general of FMHACA. “This will be accomplished through a comprehensive program that will better secure the quality and safety of our drug supply.”

“PQM initiated work in Ethiopia roughly two years ago, and our activities in the country are critical for a number of reasons,” explained Dr. Patrick Lukulay, director of the PQM Program. “Africa’s second most populous nation, Ethiopia ranks seventh among the world’s 22 high-burden tuberculosis countries. Its location in the Horn of Africa, bordering other large countries such as Kenya, makes medicines quality issues particularly important as better controls can prevent the country from becoming a transit point for counterfeit medicines to other nations. Ethiopia also has a significant local pharmaceutical manufacturing presence, in contrast with many other African nations. This makes GMP and other training for manufacturers supplying medicines particularly vital.”
**PQM Expands Activities in Indonesia**

Indonesian Anti-TB Medicine Makers Pursue WHO Prequalification

Promoting the Quality of Medicines (PQM) Program Manager/Good Manufacturing Practices (GMP) Specialist Edwin Toledo traveled to Indonesia in early March 2011 to evaluate two manufacturers of first-line anti-tuberculosis (TB) medicines for compliance with GMPs. Both companies are pursuing endorsement by the World Health Organization (WHO) Prequalification Programme, an achievement that will demonstrate to procurement agencies that the medicines the companies produce meet unified standards of quality, safety and efficacy. PQM had inspected these firms in November 2010, this follow-up visit evaluated the progress in implementing corrective actions and identified new opportunities for improvement. As part of the technical assistance it provides to companies on the road to WHO prequalification, PQM also reviews the dossiers that manufacturers are required to submit to WHO during the prequalification process. While in Jakarta, Mr. Toledo also met with a third company to review its product dossier and provide suggestions to strengthen documentation in light of recent facility upgrades.

**Workshop Introduces More Manufacturers to Prequalification**

Fifty-five people participated in a workshop in Indonesia that presented information about the WHO Prequalification Programme and the availability of PQM technical assistance to manufacturers of seven anti-TB medicines. At the workshop, held jointly with WHO, the United Nations International Drug Purchase Facility for HIV/AIDS, TB and Malaria (UNITAID) and the Global TB Drug Facility (GDF), PQM staff led discussions to learn how more manufacturers in Southeast Asia could be encouraged to actively participate. Some 38 individuals, representing 17 manufacturers from seven countries in the region, attended the workshop to learn about the quality-assured anti-TB medicines to overcome the current limited availability and contribute to the global control of TB and TB resistance. After hearing about the assistance that PQM could provide to help manufacturers meet WHO GMPs and prepare the documentation required for submission, 16 manufacturers expressed interest in the WHO program and in receiving PQM technical assistance for anti-TB medicines on the GDF/WHO priority list. See the number of companies that stepped forward, UNITAID Supply Advisor Lorenzo Whithpoon expressed his optimism that “solutions to the supply of acceptable quality anti-TB medicines are on the horizon” and reaffirmed the agency’s commitment to its partnership with PQM in the war against tuberculosis.

PQM Trains Analysts for Study on Quality of Oxytocin

At the request of the Indonesian Ministry of Health, PQM taught 11 laboratory analysts how to evaluate the quality of oxytocin injection in ampoules using USP compendial analytical methods and procedures. The analysts will be conducting a study to assess the quality of existing oxytocin in selected regions of the country, following anecdotal evidence that the ampoules are not being stored properly in some remote health facilities. Oxytocin is an essential medicine used to prevent post-partum hemorrhage (PPH). The course provided refresher training on good laboratory practices and sampling methodology and expanded the analysts’ technical knowledge on the quality control of oxytocin injections. Dr. Souly Phanouvong, PQM manager-Asia programs, instructed them on the study design and methodology, providing detailed descriptions and explanations on the sampling protocol and procedures.

Dr. Phanouvong, Chemist Dr. Yangya Djibha and PQM Consultant Dr. Asawin Likhitsup first introduced participants to theoretical discussion, followed by two days of practical, hands-on learning of analytical methods. By day four, the analysts could perform the tests independently with a high level of reliability, accuracy and precision.

A visit to a district health center warehouse and some private midwife clinics in Jakarta in November 2010 revealed that there was no quality assurance or quality control in place for the acquisition, distribution and storage of oxytocin injections. That called into question whether the stocked products in these areas remained potent enough to prevent PPH. The study is a collaborative effort of the global health nonprofit PATH, PQM, the National Institute of Health Research and Development, and the National Quality Control Laboratory for Drugs and Food, supported by the USAID Maternal and Child Health Integrated Programme, which focuses on reducing maternal, neonatal and child mortality.

**PQM Convention News**

**Important Member Action—Appointing Delegates**

Voting Organizational Members of the USP Convention (Convention Members) represent the pharmaceutical care and food ingredient communities interested in USP’s standards-setting activities. A key responsibility of each Convention Member is to name a voting delegate. To date, 50 percent of USP’s members have named their delegates. Keeping a delegate in place is the best way to ensure continued membership, so USP encourages members to take this action now if they haven’t already. Reminder letters went out in June 2011 to the executive of any organization that does not yet have a delegate, citing a December 31, 2011, deadline. Additional information, including an appointment form, may be found on the Member Page at www.usp.org/audiences/volunteers/members/private. If you are not sure about the status of your delegate appointment, please contact membership@usp.org.

**2010–2015 Resolutions Status Report**

A Status Report on the resolutions that were adopted by the USP Convention at the 2010 Membership Meeting is available at www.usp.org/pdf/en/members/2010-2015-Resolutions.pdf. Resolutions are tied closely to USP’s strategic plan and focus the organization on key activities that effectively implement the plan.

**Council of the Convention**

USP Convention President and Council of Convention (CoC) Chair Dr. Timothy Frannon appointed three new CoC members to represent the perspectives of consumers, patients and food companies, respectively:

- N. Len Buckner, M.S.P.H., senior strategic policy advisor at AARP
- Diane E. Dorman, vice president of public policy at the National Organization for Rare Disorders
- Leon H. Bruner, D.V.M., Ph.D., senior vice president for scientific and regulatory affairs and chief science officer at the Grocery Manufacturers Association

**Governance Committee**

The Convention Governance Committee reviewed and the Board approved the Rules and Procedures of the Council of the Convention (CoC) and the Council of Experts (CoE). When the Amended and Restated Bylaws were drafted prior to the 2010 Membership Meeting, operational details and descriptions pertaining to the CoC and CoE were removed and the Bylaws called for these to be placed in separate Rules documents. The Convention membership determined that Rules documents can be more easily updated to reflect progress in governance and standards-setting practices. Rules and Procedures are posted to the USP website at www.usp.org/aboutusp/governance/policies.

Summaries of the meetings of the CoC and Governance Committee are now available at www.usp.org.

**USP Appoints V.P. of Brazil Site**

USP appointed Mr. Nelson dos Santos as vice president and general manager of its São Paulo, Brazil facility in June 2011.

In Brazil, the USP site is responsible for performing tests on candidate reference standards that are relied upon by regulators and manufacturers in the United States and elsewhere to help ensure quality of pharmaceuticals.

Mr. Santos joined USP–Brazil as director, quality assurance and regulatory affairs in January 2008. He has more than 25 years of experience in the industrial pharmaceutical field, working in quality control, quality assurance, manufacturing, marketing and sales.

He received a degree in pharmacy and biochemistry from Faculdade de Ciências Farmacêuticas, São Paulo University, in 1988. He completed a postgraduate course in industrial management at Fundação Getulio Vargas and an Executive M.B.A. for the pharmaceutical industry at Fundação Getulio Vargas.

**USP Learns from, Supports Patients and Consumers**

In April, USP brought together leaders of key patient and consumer groups, as well as FDA representatives, to better understand the health-related challenges facing consumers and patients and where USP standards for drugs and dietary supplements could help. Participants encouraged USP to broaden its interactions and collaborations with patient and consumer organizations and partner with them to educate their constituents. In response, USP will exhibit at AARP’s annual meeting, AARP 50+, in September, and planning is under way for a possible Patient and Consumer Forum on Dietary Supplement Labeling.

USP is also working with several other organizations on behalf of patients.

**National Council on Patient Information and Education (NCPIE):** USP is a founding member of this nonprofit coalition of over 125 organizations. NCPIE’s mission is to improve and communicate information about the appropriate use of medicines to consumers and healthcare professionals.
more than 200 U.S. manufacturers and distributors of nonprescription (over-the-counter) medicines. Dr. Maves has served as a specialty society representative and alternate delegate to the AMA House of Delegates as well as a governor of the American College of Surgeons. He has also held faculty appointments at the University of Iowa Hospitals and Clinics and Indiana University School of Medicine. Presently, he is adjunct professor at the Saint Louis University School of Medicine. Dr. Maves is a Medical Sciences Trustee of the USP Board.

Thomas E. Menighan, B.S.Pharm., M.B.A., FAPhA, Sc.D.: Executive Vice President-Chief Executive Officer, American Pharmacists Association (APhA)—Mr. Menighan assumed his current position at APhA in July 2009 (he previously was a senior staff member from 1987 to 1992). Prior to rejoining APhA, Mr. Menighan was president of SynTegra Solutions Inc., which provides supply chain and chargeback auditing and consulting in risk management, 340B Systems, anti-counterfeiting and the technology of medication information. Mr. Menighan founded SymRx, Inc., and developed CornerDrugstore.com®. Throughout his career, he has served volunteer roles within the profession of pharmacy, including president of APhA and a member of the APhA Board of Trustees. He is a fellow of APhA. Other professional experiences include management of the PharMark Corporation, creator of RationalMed®, and licensed systems for states to conduct Drug Utilization Review for millions of state Medicaid enrollees. Mr. Menighan also founded and was a 20-year Medicine Shoppe owner in Huntington, W.V., and is a partner in Pharmacy Associates, Inc., a multi-state specialty pharmacy. Mr. Menighan is an At-Large Trustee of the USP Board.

Jeffrey L. Sturchio, Ph.D.: Former President and Chief Executive Officer, Global Health Council—Dr. Sturchio served as president and CEO of the Global Health Council from May 2009 to August 2011. The Council is the world’s largest membership alliance dedicated to improving global health. He was previously vice president of corporate responsibility at Merck & Co. Inc., president of The Merck Company Foundation and chairman of the U.S. Corporate Council on Africa. His leadership and diplomacy at Merck focused on a range of partnerships, including programs treating more than 100,000 HIV-infected patients in Botswana as well as protecting tens of millions of people from river blindness in endemic regions in Africa, Latin America and the Middle East. Dr. Sturchio was centrally involved in Merck’s participation in the UN/Industry Accelerating Access Initiative to help improve HIV/AIDS care and treatment in the developing world. He previously was a Board member of the African Comprehensive HIV/AIDS Partnerships in Botswana and a member of the private sector delegation to the Board of the Global Fund to Fight AIDS, TB and Malaria. He is a visiting scholar at the Institute for Applied Economics and the Study of Business Enterprise at Johns Hopkins University, a member of the Health Industry Board of Trustees and a fellow of APhA. Other professional experiences include management of the PharMark Corporation, creator of RationalMed®, and licensed systems for states to conduct Drug Utilization Review for millions of state Medicaid enrollees. Mr. Menighan also founded and was a 20-year Medicine Shoppe owner in Huntington, W.V., and is a partner in Pharmacy Associates, Inc., a multi-state specialty pharmacy. Mr. Menighan is an At-Large Trustee of the USP Board.

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professionals, and its website, www.talkaboutrx.org/index.jsp, features links to pamphlets, books and other resources on topics such as avoiding medication misuse and preventing prescription drug abuse.

Script Your Future: USP is a committed partner in this multimedia medication adherence campaign sponsored by the National Consumers League and endorsed by Surgeon General Dr. Regina Benjamin. The website http://scriptyourfuture.org/ features resources designed to help patients take their medicines as directed to manage health conditions such as asthma, chronic obstructive pulmonary disease, diabetes, high blood pressure or high cholesterol.

Partnership for Patients: Better Care, Lower Costs: USP has pledged support of this public-private partnership to improve the quality of patient care (administered by the U.S. Department of Health and Human Services and funded by the Affordable Care Act). The core goals of the partnership are to improve the safety of patients in the healthcare system and help patients heal without complication by improving the transition of patients from acute-care hospitals to other care settings.